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- VOLUME 1 -

IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

- - -

RECKITT BENCKISER	:	CIVIL ACTION
PHARMACEUTICALS INC., RB	:	
PHARMACEUTICALS LIMITED,	:	
and MONSOL RX, LLC,	:	
	:	
Plaintiffs,	:	
	:	
vs.	:	
	:	
TEVA PHARMACEUTICALS	:	
USA, INC.,	:	
	:	
Defendant.	:	NO. 14-1451 (RGA)

- - -

Wilmington, Delaware
Tuesday, November 3, 2015
8:30 o'clock, a.m.

- - -

BEFORE: HONORABLE RICHARD G. ANDREWS, U.S.D.C.J.

- - -

Valerie J. Gunning
Leonard A. Dibbs
Official Court Reporters

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1 P R O C E E D I N G S

2

3 (Proceedings commenced in the
4 courtroom, beginning at 8:30 a.m.)

5

6 THE COURT: All right. Good morning,
7 everyone. Please be seated.

8 I just wanted to say that I did
9 look at the resumes' of all of the experts and I
10 did read the amended statement of facts, which I
11 took to be mostly resolving limitations so that
12 there was no question that they're not in
13 dispute. So with that, I'm ready to go.

14 Plaintiff, are you ready?

15 MS. BOURKE: Yes, your Honor. We
16 are.

17 THE COURT: And defendants, you're
18 ready?

19 MR. LOMBARDI: Yes, we are, your
20 Honor.

21 THE COURT: All right. Let's have
22 an opening statement.

23 MR. LADOW: Good morning, your
24 Honor. Dan Ladow for the plaintiffs.

1 Your Honor, opioid addiction is a
 2 major public health challenge, one that has
 3 grown to epidemic proportions with the increased
 4 use of painkillers, and this has led to a surge
 5 in addiction with a tripling of overdose deaths
 6 in recent years. And the plaintiff, Reckitt
 7 Benckiser Pharmaceuticals, which is now known as
 8 Indivior, but we'll be using Reckitt Benckiser
 9 Pharmaceuticals, or RBP through the proceedings,
 10 that's how all the documents are denominated, is
 11 the pioneer in opioid addiction treatment, and
 12 it has been a world leader in this treatment
 13 space for over 20 years.

14 Our co-plaintiff, MonoSol Rx, is
 15 the pioneer in the new area of pharmaceutical
 16 prescription films, and together, the two
 17 companies are addressing this crisis in
 18 addiction with the medication that's the subject
 19 of this case.

20 In 2002, the FDA approved RBP's
 21 opioid dependence treatment product, Suboxone
 22 tablets, which contain two active ingredients,
 23 buprenorphine and naloxone.

24 Buprenorphine is an opioid that

1 can satisfy cravings and reduce opiate drug
 2 abuse and it's safer than other opioids, and
 3 naloxone is an opiate antagonist or opioid
 4 blocker that when taken orally does not produce
 5 an effect, but it's an abuse deterrent, so that
 6 if the patient abuses the drug and tries to
 7 inject it, it can put the patient into
 8 withdrawal.

9 Now, the tablets were a huge
 10 advance in treatment, but they had different
 11 disadvantages, the tablet dosage form, such as
 12 dissolution time, taste, subject to crumbling
 13 and being subject to abuse and diversion, such
 14 as by crushing them and trying to inject them or
 15 snort them or something like that.

16 Now, to provide patients with a
 17 significantly better dosage form and improved
 18 dosage forms, RBP's addiction medication experts
 19 joined forces with MonoSol's film technology
 20 experts to make Suboxone sublingual film, which
 21 is a new dosage form.

22 And you see here on the slide what
 23 this product look like. On the right-hand side,
 24 there's a picture of the eight-milligram film.

1 And as you may recall from the Markman
 2 proceedings, it's placed in the mouth of the
 3 patient, it's mucoadhesive, it sticks under the
 4 tongue and then it dissolves rapidly in the
 5 mouth, and the buprenorphine active ingredient
 6 is absorbed through the oral mucosa.

7 Now, compared to tablets, Suboxone
 8 film dissolves faster, tastes better, does not
 9 crumble, and is less readily diverted and abused
 10 than tablets, and because of these advantages,
 11 it's preferred by both doctors and patients, and
 12 it's the leading medication for opioid
 13 dependence. And it's the very success of the
 14 film, your Honor, that has brought us here
 15 today, and it's why the defendants have copied
 16 it.

17 Now, prescription, prescription
 18 pharmaceutical films are a new dosage form.
 19 The major reason why they're so recent is that
 20 making them is very complex and they present
 21 challenges in formulation and manufacturing that
 22 are very different from tablets. And, in fact,
 23 no prescription pharmaceutical films were
 24 approved by FDA prior to just 2009. This is not

1 like technology that has been around for
 2 decades. This is new stuff.

3 Now, defendants are going to point
 4 to things like Listerine strips and Chloraseptic
 5 strips that became available in the early to
 6 mid-2000s, but these are not prescription
 7 pharmaceutical films that need FDA approval and
 8 have to meet the uniformity standards that are
 9 associated with FDA approval.

10 And, in fact, sublingual film, the
 11 commercial product at issue here, was the very
 12 first sublingual film approved by the FDA in
 13 2010, and this dosage form is so new, that these
 14 cases before this Court right now are the very
 15 first ANDA cases that involve a prescription
 16 pharmaceutical film.

17 Going to the patents, as your
 18 Honor knows, there are three Orange Book patents
 19 at issue in the case. Each of the three patents
 20 relates to a different aspect of pharmaceutical
 21 film innovation that resulted in Suboxone film,
 22 and the infringement and validity issues for
 23 each patent are really separate and distinct.

24 To just briefly introduce the

1 patents, the '514 patent solved the drug content
2 uniformity problem in pharmaceutical
3 prescription films. And as you can see here in
4 this excerpt on the top, if you have a failure
5 to achieve -- this is an excerpt from the
6 patent -- a high degree of accuracy with respect
7 to the amount of active in the cut film, this
8 can be harmful to the patient. Of course, for
9 safety reasons and efficacy reasons, you want
10 the patient to get the right dosage.

11 And when the patent was filed, the
12 inventors noted that about that world regulatory
13 authorities required that the dosage amounts in
14 dosage forms not vary by more than about ten
15 percent of the desired amount of the active, and
16 concluding that that basically mandates
17 uniformity in the film. And what the present
18 invention of the '514 provides, as it says in
19 that last excerpt highlighted, is exceptionally
20 uniform film products when attention is paid to
21 reducing the aggregation of the compositional
22 components.

23 I'm going to say a very brief, and
24 really a very brief word about the '832 patent

1 since it at least relates in part to commercial
2 success, which you'll be hearing about in this
3 trial, but I'm not going to address it any
4 further because infringement and validity of the
5 '832 is going to be done in December.

6 THE COURT: All right.

7 MR. LADOW: This '832 patent is
8 basically directed to the Suboxone film
9 formulation, and the patent reports the
10 inventor's surprising discovery about the
11 absorption of buprenorphine, which was contrary
12 to prior art teachings about pH partition
13 theory, which you'll hear more about in
14 December, and led directly to Suboxone film.

15 And as the first excerpt
16 indicates, the point of the patent was to
17 provide a new dosage form, a film dosage, that
18 would be bioequivalent to Suboxone tablets,
19 which had been on the market for some years.

20 The '150 patent, the '150 patent
21 is relating to a polymer profile for fast
22 dissolving, mucoadhesive pharmaceutical films,
23 and it provides a pharmaceutical polymer profile
24 for Suboxone film. And it teaches that if you

1 want to balance the properties of adhesion, the
2 mucoadhesion in the mouth, dissolution, the good
3 tear resistance, the strength of the film, that
4 what you can do is include about 50 to
5 75 percent of low molecular weight polyethylene
6 oxide, which you are going to hear a lot about,
7 your Honor, or PEO, optionally combined with a
8 small amount of a higher molecular weight PEO,
9 with the remainder of the polymer component
10 contains a cellulosic polymer like HPMC. So it
11 provides this polymer profile that you need to
12 do this.

13 Now, the '514 patent, the asserted
14 claim are the ones that you see here, there's
15 one independent claim, 62, and then four
16 dependent claims, infringement of this patent,
17 your Honor, is going to be addressed in
18 December. We're just doing validity in this
19 trial.

20 Plaintiffs' expert on the validity
21 of the '514 patent is professor Robert Langer.
22 He's an MIT Institute professor. He has over a
23 thousand articles and issued patents and he's
24 one of the most decorated scientists in our

1 country. He's an expert in the chemical
2 engineering and pharmaceutical drug delivery
3 forms.

4 The defendants' two main
5 invalidity arguments are indefiniteness and
6 obviousness. And before addressing
7 indefiniteness, a little background first about
8 the cast film process that relates to the
9 pharmaceutical films that we're talking about.
10 And basically that process, as Dr. Langer will
11 explain, consists of about five basic steps.
12 It's obviously a lot more complicated, but there
13 are about five basic steps.

14 So the first one is that you
15 dissolve one or more polymers into a solvent and
16 then you mix it.

17 Step two, the active ingredient is
18 mixed in, and you do that to form a, what's
19 called a casting solution or a casting
20 dispersion.

21 Step three, the casting solution
22 is then cast by a roller, as you see here, onto
23 a sheet in a continuous casting process, as
24 depicted on the slide.

1 And then a conveyor belt moves the
 2 sheet through a controlled drying process,
 3 drying out the solvent, and this results in a
 4 dry film which is then cut into individual
 5 dosage units as you can see in the bottom
 6 illustration.

7 These are the claim terms we've
 8 highlighted that relate to the indefiniteness
 9 issue that defendants have raised with respect
 10 to this patent.

11 So as you can see on the top, it's
 12 a drug delivery composition. It's independent
 13 claim 62. Cast film comprising a flowable water
 14 soluble film forming matrix. And I'm going to
 15 skip down to the last clause, where the flowable
 16 film-forming matrix is capable of being dried
 17 without loss of substantial uniformity, and
 18 that the uniformity subsequent to drawing and
 19 casting of the matrix is this plus and minus
 20 ten percent of the desired amount that I
 21 mentioned before.

22 Now, Watson, defendants contend
 23 that the claims are indefinite because they say
 24 a final dried cast film cannot be flowable or

1 though it has already been dried is contrary to
 2 the specification, it's contrary to common sense
 3 and how one of ordinary skill would understand
 4 this. What it really is, is a belated claim
 5 construction argument that we think should be
 6 rejected. And as Dr. Langer will testify, a
 7 person of ordinary skill in the art would have
 8 no trouble understanding the meaning of these
 9 claims in this context with reasonable
 10 certainty.

11 Turning to the defendants'
 12 obviousness argument, your Honor, a key
 13 challenge in film technology was the problem of
 14 achieving what we're going to refer to, and
 15 you're going to hear a lot about, drug content
 16 uniformity, or DCU, in a pharmaceutical film.
 17 In particular, prescription pharmaceutical film
 18 that has to be approved by the FDA.

19 Drug content uniformity must be
 20 maintained throughout the manufacturing process
 21 in order to meet FDA requirements and ensure
 22 proper dosing just as we talked about before so
 23 the patient gets the right amount of the drug,
 24 not too much, not too little. It has to be safe

1 have a viscosity or be capable of being dried.
 2 But the final cast film is not required to be
 3 flowable, as the defendants assert.

4 As Dr. Langer will explain, the
 5 reference to flowable here in the claims can't
 6 mean that the final dried solid film is
 7 flowable. That wouldn't make sense to anybody
 8 let alone a person of ordinary skill in the art
 9 of this technology. Instead, what flowable
 10 clearly means is that the polymer matrix must be
 11 flowable during the casting process, as I showed
 12 on the other slide.

13 And the film is a cast film
 14 because it was made by a casting process.
 15 That's why it's called a cast film. And the
 16 final film, whose uniformity, as I said, must be
 17 within ten percent of the desired amount, is, as
 18 the claim says, subsequent to casting and drying
 19 of the matrix.

20 So the defendants' argument that
 21 the claim is indefinite because it supposedly
 22 requires the impossible that the final dried
 23 film also be flowable and that it also have
 24 viscosity and be capable of being dried even

1 and efficacious.

2 This was a major challenge
 3 because, as Professor Langer will explain, there
 4 are quite a few forces or gradients that can
 5 cause aggregation or migration of an active
 6 during the process, during those five steps that
 7 I described in making a cast film, including
 8 during mixing and including during casting and
 9 drying. And all of these different forces and
 10 gradients can cause aggregation that results in
 11 lack of uniformity of a film. And it was the
 12 '514 patent that was the first to solve this
 13 drug content uniformity problem in
 14 pharmaceutical films.

15 The '514 patent recognized, as Dr.
 16 Langer will explain to you, that by rapidly
 17 increasing viscosity and locking in the, locking
 18 in the active in place together with using
 19 controlled drying procedures to avoid
 20 aggregation, that you could produce the film
 21 having the requisite uniformity and drug content
 22 uniformity.

23 And as we see here in this
 24 excerpt, the patent is the '514 patent talks

1 about uniform films having equally sized dosage
 2 units with substantially equal amounts of
 3 compositional components, such that, skipping
 4 down to the last highlighted section, each
 5 individual dosage film unit will contain the
 6 proper predetermined amount of the drug. And as
 7 we said, claim 62 requires that that amount be
 8 within, not vary by plus or minus of ten percent
 9 of the label or desired amount.

10 Now, you're going to hear from the
 11 defendants, of course, and their experts, and
 12 they are going to tell you that everything about
 13 pharmaceutical films was obvious, even including
 14 how to get drug content uniformity in a
 15 pharmaceutical film, but it's just not the case.
 16 And Dr. Langer is going to testify to that based
 17 on his years and decades of experience in the
 18 field. And it's also contradicted by numerous
 19 articles in the area that both recognize the
 20 problem of drug content uniformity and that it
 21 was a major challenge, and give MonoSol credit
 22 for solving it.

23 And just as an example, here's a
 24 2011 article written by one of defendants' own

1 uniformity during casting and drying. It's just
 2 not addressed. Chen's examples only mention
 3 homogeneity in the context of mixing excipients
 4 for the casting dispersion before the active
 5 ingredient is even added to it.

6 And the data in Chen, there's no
 7 data supporting drug content uniformity, but the
 8 data in Chen, to the extent there is any, that
 9 could speak to this issue which is Figure 5,
 10 which we'll hear more about, shows, if it shows
 11 anything, that Chen's films lack the drug
 12 content uniformity required by the claims of the
 13 '514 patent.

14 So for these reasons and others
 15 that you will hear from Dr. Langer, the '514
 16 patent is not obvious. Rather, it solved a
 17 difficult problem that others tried and failed
 18 to solve, drug content uniformity.

19 This is the '150 patent, your
 20 Honor. The asserted claims against Watson are
 21 claims 1 and 4. The infringement of claims 10
 22 and 13 by Par are meant to be tried in December,
 23 and the validity of all four claims are at issue
 24 in this trial.

1 experts, Dr. McConville. And what does he say?
 2 Since the early development of medicated films,
 3 content uniformity has been a major challenge
 4 for the pharmaceutical scientist. And he refers
 5 to Yang.

6 Yang is one of the MonoSol
 7 inventors, so we're talking about the '514
 8 patent, indicated that self-aggregation was one
 9 of the main reasons why films usually show poor
 10 uniformity, and is crediting MonoSol and Yang
 11 with solving that problem.

12 Now, it's because achieving drug
 13 content uniformity in a prescription
 14 pharmaceutical film was, in fact, a real
 15 challenge, a real-world challenge, and one first
 16 solved by MonoSol that defendants argued
 17 obviousness arguments in this case must file.
 18 None of the prior art that they cite teaches how
 19 to solve that problem. The main reference that
 20 the defendants rely on is a reference called
 21 Chen. There are a couple Chen references, but
 22 they are essentially the same.

23 Chen does not teach anything, as
 24 Dr. Langer will testify, about how to maintain

1 Plaintiffs' expert on the
 2 infringement of the '150 patent is Dr. Lon
 3 Mathias. He's emeritus from the University of
 4 Southern Mississippi, co-founder and director of
 5 the Polymer Science Center and an expert in the
 6 characterization of polymers. He is the only
 7 witness giving an opinion on infringement.

8 Dr. Yau, whose picture is
 9 underneath, is a longtime Dow chemical company
 10 scientist, who is one of the leading experts in
 11 the world on analytical technique called GPC, or
 12 gel permeation chromatography. Dr. Yau is the
 13 co-author of the standard textbook on the
 14 subject and he did some tests that Dr. Mathias
 15 is relying on for his infringement analysis.

16 So this is claim 1 of the '150
 17 patent, which is being asserted against Watson.
 18 We've checked off some boxes in terms of
 19 limitations that are acknowledged to be
 20 infringed.

21 And the dispute on infringement,
 22 your Honor, basically relates to what's labeled
 23 here as limitation number four, relating to PEO
 24 molecular weight. And what the claim requires

1 is that the PEO -- you see in the prior
2 limitation that the polymer component can have
3 75, has 75 or more percent PEO and up to
4 25 percent of the cellulosic polymer.

5 So then if we go down to the
6 fourth limitation, it says that the PEO
7 comprises, as the Markman order said, basically
8 two sets of PEOs, and one set is low molecular
9 weight PEOs and another set is higher molecular
10 weight PEOs where the molecular weight of the
11 lower weight set is 100,000 to 300,000, this is
12 all in daltons, an atomic unit of weight, and
13 the molecular weight of higher molecular weight
14 PEOs are in the range of 600,000 to 900,000,
15 with the final requirement being that the lower
16 molecular weight portion, so the one that
17 averages a hundred to 300,000, is about
18 60 percent or more of the whole polymer
19 component.

20 Now, the PEO that Watson uses is a
21 PEO that's called Polyox N80 that's sold by Dow.
22 And when that Polyox N80 is analyzed using GPC,
23 the gel permeation chromatography I mentioned
24 before, infringement is established. GPC

1 analysis is required to determine if the accused
2 polymer sample meets the required molecular
3 weight ranges of the claim.

4 What GPC testing does is that it
5 separates the molecules by size and it produces
6 a bell curve showing a molecular weight
7 distribution from low molecular weight on the
8 left going to higher molecular weight on the
9 right. And if you draw a vertical line or a
10 partition on this molecular weight distribution
11 curve at 600,000 daltons -- and, by the way, the
12 6.0 doesn't line up with the 600,000 because
13 it's a log scale on the bottom and the 6.0 is
14 actually more than 600,000, so that should not
15 confuse anyone.

16 So if you draw that partition, as
17 Dr. Mathias will explain, the PEOs that are to
18 the left, that 98 percent portion, has a
19 viscosity average molecular weight that falls
20 within the low molecular weight range of the
21 claims, and the, about two percent to the right
22 of the partition falls within the higher
23 molecular weight range of the claims.

24 And the -- he will also testify

1 that that two percent of the high molecular
2 weight is not a negligible trace or, in the
3 Court's words, stray amount from the Markman
4 order in this formulation because the much
5 higher molecular weight molecules are long chain
6 molecules and they get entangled with others,
7 and so they have a disproportionate effect. So
8 it's not two percent of apples to apples, it's
9 two percent of elephants to mice. And so it has
10 a disproportionate effect on the, on the
11 formulation, and is not stray for that reason.

12 Dr. Mathias will also testify that
13 when the cellulosic polymer, which is not shown
14 on this chart, is taken into account, that the
15 lower molecular weight PEO makes up 60 percent
16 or more of the whole polymer component,
17 including the cellulosic polymer and the rest,
18 and all of the PEO.

19 Now, defendants are going to tell
20 you that the mathematical GPC values of 95,895
21 viscosity average molecular weight for the low
22 molecular weight set of PEO and the mathematical
23 value of 900,318 for the higher molecular
24 weight set fall just outside the claims. But as

1 Dr. Mathias will testify, those numbers would be
2 understood by anybody in the field as meaning a
3 100,000 and 900,000 due to sample variability,
4 and thus would be understood to be within the
5 range of the claims. And overall, the analysis
6 that we've described, you'll hear testimony that
7 this is an accepted scientific approach for
8 determining fractions in a molecular weight
9 distribution.

10 And as our experts will also
11 explain, the applicable average molecular
12 weight, which I will talk about more in a
13 minute, is viscosity average molecular weight.
14 And for these reasons, as Dr. Mathias will
15 testify, Watson's proposed films infringe
16 claim 1 of the patent.

17 Now, Watson asserts that its
18 proposed films don't have the higher molecular
19 weight set of PEOs, the 600,000 to 900,000, and
20 they assert that they don't infringe because
21 they use one type of PEO, a Polyox N80. In
22 effect, the one bottle that we had talked about
23 during the Markman. But as the Court held in
24 the, in the opinion on the Markman, the source

1 of the PEOs, whether from one bottle or
2 two bottles, isn't relevant, and what's really
3 relevant is, are the two discrete sets in the
4 formulation? And that's what we were looking at
5 with the molecular weight distribution.

6 And Polyox N80, as you'll hear,
7 has, in fact, as I just showed you with that
8 bell curve, a very wide molecular weight
9 distribution, which is common for commercially
10 made polymers, and, in fact, it's made by
11 blending batches of PEO.

12 The PEOs are differing molecular
13 weight that comprise the distribution fall into
14 discrete sets that meet the limitations of the
15 claim. So, in other words, Polyox N80 itself is
16 a combination of discrete polymers, sets, which
17 meet the limitations of the claim, and as shown
18 by the testing on the last slide, this one
19 bottle of Polyox has a molecular weight
20 distribution that covers and meets the
21 requirements of the claims.

22 I'm going to turn now to the
23 validity issues on the '150 patent. Plaintiffs'
24 expert is Dr. Robert Prud'homme, who has been a

1 long tenured professor at Princeton University.
2 He's a past president of the U.S. Rheological
3 Society. He has been a longtime member of the
4 Dow Technical Academy Advisory Board, and he's
5 an expert in the development of pharmaceutical
6 dosage forms.

7 The defendants' two main
8 invalidity arguments are obviousness and
9 indefiniteness, and I'm going to take the second
10 one first.

11 The Court construed the claims of
12 the '150 patent to refer to an average molecular
13 weight, and the patent does not expressly
14 specify what type of molecular weight average
15 that is going to be. And the defendants want to
16 say that because it does not specify and because
17 there are different ones that in theory could
18 apply, that it's indefinite.

19 Now, while there are in theory
20 different average molecular weight labels that
21 exist in science, our experts, your Honor, will
22 testify that a person of ordinary skill would
23 understand that viscosity average molecular
24 weight is the appropriate molecular weight

1 measurement here, and this is partly because, as
2 the person of ordinary skill would appreciate,
3 the file history shows that the Dow PEO product,
4 and this is the Flick reference in the file
5 history, is sold by viscosity. And they would
6 also know that viscosity average molecular
7 weight is the most common and precise way to
8 use, the measurement to use for this kind of
9 polymer.

10 And the person -- you'll probably
11 hear from the defendants that there are other
12 average molecular weight labels, such as MN, or
13 number average molecular weight or MZ, which is
14 another kind of a label, but as you'll hear from
15 our witnesses, these are irrelevant to our case,
16 and the reason for that is, is that MN is very
17 much tilted or skewed to the low, to the low
18 molecular weight molecule because it's
19 emphasizing numbers, so there's a lot more of
20 the low stuff, whereas MZ is very much skewed to
21 the high molecular weight molecules.

22 So someone trying to determine
23 what should be used here, somebody who
24 understands the nomenclature, those exist in the

1 art, but they wouldn't be applied here.

2 The other molecular weight average
3 that's commonly talked about is weight average
4 molecular weight. And, in fact, the weight
5 average molecular weight is very close to
6 viscosity average molecular weight here and
7 there's not really that much difference between
8 them. But for the reasons that I expressed and
9 as the experts will explain, the person of
10 ordinary skill would use viscosity average
11 molecular weight as Dow does and as would make
12 more sense for the calculations that are
13 required to be done here.

14 So for these reasons, the person
15 of ordinary skill would understand that
16 viscosity average molecular weight is the right
17 measurement, the boundaries of the claim would
18 be understood by the person of ordinary skill
19 with reasonable certainty, and the claims are
20 not indefinite.

21 Turning to obviousness of the '150
22 patent, another challenge in making a
23 pharmaceutical film is trying to find the right
24 blend of polymers to provide the desired film

1 properties.

2 Now, your Honor, there are many,

3 many polymers that can be used in these films.

4 At least 30, I think, are listed in one of the

5 patents. And PEO, polyethylene oxide, is just

6 one of them. And then even when you talk about

7 PEO, it's not, it's not like you just buy a

8 single one. There's -- there's a very broad

9 spectrum, a broad range of PEOs that are

10 available, you know, from very low molecular

11 weight. The lowest molecular weight ones are

12 referred to as PEGs, the ones that are below

13 20,000 or so referred to as PEGs, that can go

14 all the way up to eight million or more.

15 Before the '150 patent, no one

16 ever taught combining intermediate weight PEOs,

17 and what I'm talking about there is, PEOs

18 averaging between about a hundred thousand to

19 900,000, that intermediate range in the claims,

20 so not less than 100,00 and not more than

21 100,00, not up like at three or five million.

22 So no one ever taught combining

23 intermediate weight PEOs that I just described

24 where, and then on top of that, the low

1 molecular weight range of the 100 to 300,000 was

2 60 percent or more of the polymer component, all

3 of those combinations.

4 This approach to balancing film

5 properties like mucoadhesion, tear resistance

6 and dissolution, simply was not in the prior

7 art, and you are going to hear the defendants

8 point to a lot of pieces of prior art, but it's

9 just not there.

10 There is art like the Schiraldi

11 reference that you will hear about that has

12 very, very high and very, very low PEO, which

13 was a typical approach at the time.

14 And then there's some that is

15 mainly the PEG, or the very low. That's like

16 the Keith reference. And then there are other

17 references that simply don't say anything about

18 the relationship of PEO molecular weight to film

19 properties, and examples of those would be the

20 Chen and Fuller references.

21 And then there are other

22 references that involve dosage forms that

23 wouldn't teach one of ordinary skill in the art

24 what to use in a film. So an example of those

1 are Apacella, which relates to tablets, Fuller,

2 which was directed to a study about tablets even

3 though they made some film, but to study

4 tablets. And there's also a reference called

5 Verma, which relates to coating films on

6 capsules.

7 So defendants also point to a

8 reference called Yang, so that name may be

9 familiar because we saw it before. In fact,

10 Yang is one of the MonoSol inventors. And Yang,

11 the Yang reference is actually the parent

12 application of the '150 patent.

13 And Dr. Prud'homme will explain

14 that the '150 patent has a priority date of

15 May 28, 2003, based on the filing of the 902

16 application that led to the '150 patent. And

17 Yang has a filing date in 2005, which means that

18 it wouldn't be prior art.

19 More specifically, your Honor, the

20 defendants contend that the 902 application

21 filed, as I said, in 2003, does not disclose all

22 three of the following: The 60 percent or more

23 of the low molecular weight of the polymer

24 component, some of the high, and then also

1 having some cellulosic. So they contend that

2 that is not disclosed and the somehow the

3 priority does not go back to this 902

4 application. But Dr. Prud'homme will explain

5 and take you through that, that, in fact, the

6 902 application expressly discloses those

7 claimed elements so that priority clearly goes

8 back to 2003.

9 Now, finally, a person of ordinary

10 skill, your Honor, would have no reasonable

11 expectation of success to arrive at the

12 invention of the '150 patent, and Dr. Prud'homme

13 is going to address this further.

14 Basically, there would be such a

15 large number of variables that the person of

16 ordinary skill would be confronted with,

17 polymers to choose from, the mixtures of the

18 various polymers, the concentrations to use,

19 that as Dr. Prud'homme will explain, this would

20 take so much experimentation, it would actually

21 take years just doing the math to come up with

22 that, and so there would be no reasonable

23 expectation of success.

24 And what you'll, what you'll hear

1 is that defendants' obviousness arguments have
2 to resort really to hindsight, to cherry-picking
3 different pieces from different pieces of art,
4 and then saying that somehow they could all be
5 brought together, cherry-picking different
6 pieces that are isolated in those pieces of art
7 and that are being taken out of context. But
8 there's no basis for showing obviousness here,
9 and as Dr. Prud'homme will explain, that kind of
10 analysis would not lead one of ordinary skill at
11 the time to the invention.

12 Turning now to objective indicia
13 of nonobviousness, plaintiffs have two
14 experts. The first is Bernd Wollschlaeger, who
15 is an addiction medicine specialist, expert in
16 the treatment of patients with opioid use
17 disorder. He has years of experience of
18 treating opioid-dependent patients, and he'll
19 explain how the film has benefited the patients
20 in his practice.

21 Our other expert is Dr. Greg Bell.
22 He's an economist at Charles River Associates.
23 He heads the global life sciences practice. He
24 has a very deep experience in the pharmaceutical

1 industry, and he's an expert in the economics of
2 that industry.

3 These experts will further address
4 the advantages of Suboxone film over the tablets
5 and how those advantages translated into its
6 great commercial success, including, as I said
7 before, because it dissolves faster, tastes
8 better, does not crumble, and is less readily
9 diverted and abused as compared to the tablets.

10 Now, defendants are going to tell
11 you that this was all just a line extension,
12 that it was all about marketing, that it was all
13 about trying to avoid generic competition, and
14 that the aspects of film technology embodied in
15 the three Orange Book patents-in-suit that were
16 needed to make Suboxone film were all obvious.
17 But the facts will show, and our experts will
18 testify, your Honor, that there would have been
19 no Suboxone film at all if the inventors had not
20 overcome the special challenges in this area,
21 including, for purposes of formulating a
22 pharmaceutical film, solving the problem of drug
23 content uniformity, and in regard to a film
24 containing buprenorphine, discovering that

1 buprenorphine didn't follow pH partition theory.
2 Again, that's for December.

3 If the film had been obvious, it
4 wouldn't have taken seven years or more for it
5 to appear after the tablet was launched.

6 Now, the evidence will show that
7 the film's success is due to advantages that I
8 just mentioned, which make it the preference of
9 doctors and patients, including over generic
10 tablets which have been on the market for
11 two-and-a-half years, including a generic tablet
12 sold by Watson during that period of time.

13 Now, defendants may allege also,
14 as part of painting the situation as if it, if
15 there are no advantages to the film and it was
16 all a marketing gimmick, that the film's success
17 is due to the withdrawal of the tablet from the
18 market in March 2013, and that the film's
19 success was allegedly driven by price
20 advantages. But as Dr. Bell will testify, the
21 film was an established commercial success a
22 year-and-a-half before the tablets were
23 withdrawn, and essentially, that's an irrelevant
24 issue. And that the film has maintained its

1 dominant share and its leading position in the
2 market even after two-and-a-half years after the
3 launch of generic tablets, so that really tells
4 you something. There's a generic tablet on the
5 market, and for two-and-a-half years, this brand
6 product has held its market leading position, so
7 it tells you that there's something else going
8 on here. It's not marketing. It's about
9 product advantages.

10 And, in fact, if the film had no
11 advantages over the tablet, it's hard to
12 understand why Watson, which is one of the
13 biggest generic companies in the world, would
14 have -- would be so interested in pursuing a
15 generic version of the film and spending so much
16 time and effort in doing that.

17 So in sum, your Honor, the
18 proposed, Watson's proposed film copies Suboxone
19 film and infringes the patents, and the
20 defendants cannot show that the patents are
21 invalid.

22 Thank you, your Honor.
23 THE COURT: All right. Thank you,
24 Mr. Ladow.

1 Defendants?
2 MS. BOURKE: Your Honor, perhaps a
3 mishap in-house keeping duties. We had some
4 binders of the opening. Would the Court like me
5 to hand up copy?

6 THE COURT: I think one would be
7 enough.

8 MS. BOURKE: Just one?

9 THE COURT: Yes.

10 MR. LOMBARDI: I will just hand up
11 mine at the same time.

12 THE COURT: You can hand up more
13 than one.

14 (Binders to the Court.)

15 MR. LOMBARDI: Good morning, your
16 Honor. May it please the Court, George
17 Lombardi. I'm representing Watson, and I'm
18 speaking on behalf of both defendants here for
19 purposes of the opening this morning.

20 And, your Honor, I want to talk
21 about some of the background, and actually, it's
22 right where plaintiffs' counsel left off,
23 because I think the background is not only
24 important to you understanding how we got here

1 today with Suboxone and the Suboxone film, but
2 it's very important to resolving the issues of
3 secondary considerations and commercial success
4 as we go through the case.

5 So the background of this is,
6 actually buprenorphine and naloxone have been
7 known as a combination for a long time. They go
8 back decades. But the tablets for buprenorphine
9 and naloxone actives, whereas counsel points
10 out, out on the market in the early 2000s,
11 starting in 2003. I believe they were FDA
12 approved in 2002.

13 At the time that the plaintiff
14 here came out with that tablet form, they knew
15 at that moment that there was going to be a
16 limited period of exclusivity. They had
17 something called orphan drug exclusivity, which
18 lasted seven years, and they knew that that was
19 going to expire.

20 During that period of time, they
21 could exclude everybody else, including generics
22 and anybody else, from selling the tablets.
23 They also knew that they didn't have any patent
24 coverage, no patent coverage over the tablets.

1 So once that exclusivity expired, they were
2 going to face competition in the market. And so
3 they took steps. They took steps and hatched a
4 strategy to deal with that problem, an it's
5 something that is referred to colloquially, it's
6 informally, as product hopping, your Honor.

7 And so what they did was, they
8 filed an NDA with the FDA, and they said that
9 they're coming out with this new formulation to
10 be a line extension of their Suboxone tablets,
11 and it was going to be a film, the product that
12 we're talking about here. And their in-house
13 documents, their internal documents show that
14 the idea was to replace the tablet that they had
15 on the market with the strip, which is the film,
16 before the launch of generic competition. So
17 they wanted to move the market away from the
18 tablet and to the film so they could avoid
19 competition.

20 And here's a timeline that kind of
21 summarizes what you are going to be hearing
22 about, your Honor. At the bottom here are the
23 dates related to the Suboxone tablet. As I
24 said, FDA approval back in 2002, that started

1 the orphan drug exclusivity. The launch by
2 plaintiff in 2003, and then the tablet
3 exclusivity would expire in 2009.

4 So what plaintiff did was they
5 entered into after development agreement with
6 MonoSol. MonoSol is the party that actually
7 developed a film. They filed for an NDA for
8 that Suboxone film in 2008, and then they got
9 approval and launched in 2010.

10 So the film came on the market,
11 and at the same time they are going through this
12 process, they sought patents. And the three
13 patents that are at issue in this case were
14 filed during this time period, the '514, the
15 '150, and the '832, the idea, of course, being
16 that if they could get patents to cover the
17 film, they would have moved the market to the
18 film and then have patents to prevent others
19 from coming on and competing. This actually
20 isn't all they did. They made an unsuccessful
21 attempt to persuade the FDA, once their tablet
22 that had moved to the film, and they had taken
23 their tablet off the market, they tried to
24 persuade the FDA that it was unsafe to sell the

1 tablet for reasons related to child safety.
 2 That failed, but it shows what their intention
 3 was here and what they were up to.
 4 Now, in fact, the film is the same
 5 as the tablet in all material respects.
 6 Obviously, the delivery form is business, but in
 7 the material respects, Judge, they have the same
 8 actives. They have the same buffers. They're
 9 administered the same way, under the tongue, and
 10 they treat the same thing, the opioid
 11 dependence. So, really, it's an attempt to
 12 extend their exclusivity over Suboxone tablets,
 13 over Suboxone generally from the tablets into
 14 the films.
 15 Now, Judge, I just put this slide
 16 up briefly just for context, and counsel came up
 17 with some category in which Suboxone was the
 18 first to get FDA approval. We're not here to
 19 talk about FDA approval. We're here to talk
 20 about the patents, and the idea that we're
 21 working on is, in some of these patents is
 22 whether it was obvious to come up with this kind
 23 of film, and this kind of film has been out on
 24 the market.

1 You may have seen the Listerine
 2 little packs that you can buy in convenience --
 3 there are Listerine little packs that are
 4 available commercially right now that you can
 5 buy in stores and you use them the same way.
 6 There are oral pharmaceuticals that have been
 7 available since 2004, and Suboxone actually was
 8 not the first oral pharmaceutical approved by
 9 the FDA. Onsolis actually was the first.
 10 So that's the background here,
 11 Judge, and with that, I will jump to the patents
 12 that we are going to be talking about this week.
 13 I won't address issues that aren't coming up
 14 this week.
 15 And the first one I want to talk
 16 about is the '150 patent. And this is the
 17 patent -- I know your Honor dealt with this at
 18 some length at Markman and in your Markman
 19 order, but this is the patent that basically
 20 deals with the polymer composition of the films,
 21 and with what the various components of that
 22 polymer composition are going to be.
 23 And our position, as your Honor
 24 knows, is that we do not infringe, Watson does

1 not infringe the asserted claims of the '150
 2 patent, and here's a representative claim. And,
 3 as your Honor is aware, there are portions above
 4 the lighted portion that deal with the polymer
 5 component, and PEO being in combination with an
 6 HCP. But the part we're talking about for
 7 noninfringement purposes is what I have
 8 highlighted here.
 9 And so the question here really
 10 comes down to the PEOs. And, your Honor, if I
 11 didn't say it already, PEO you will hear
 12 frequently for polyethylene oxide. The PEO
 13 requirements here are set out in the highlighted
 14 portion, and there are two types of
 15 requirements. One is that there be two PEOs, so
 16 the language says the PEO comprises one or more
 17 low molecular weight PEOs and one or more higher
 18 molecular weight PEOs.
 19 So we're talking about two PEOs,
 20 and then further on to define the weights for
 21 those PEOs.
 22 As your Honor has seen from the
 23 claims, but just to review, the low molecular
 24 weight PEOs falls within that 100 to 300,000

1 dalton range, and the higher molecular weight
 2 PEO falls within the 600 to 900,000 dalton
 3 range.
 4 And, your Honor, your claim
 5 construction, as I noted, you dealt with these
 6 issues, but a few of the points that were made
 7 during the claim construction that I think are
 8 going to be important to the noninfringement
 9 analysis here, your Honor recognized that it was
 10 clear from the patent that it has to be discrete
 11 sets of low average molecular weight PEOs and
 12 high average molecular weight PEOs. So discrete
 13 sets has to be at least two, one in each
 14 category.
 15 Your Honor recognized that it
 16 needs to be a combination of low and high
 17 molecular weight PEOs.
 18 And your Honor made an important
 19 observation, I think, at the bottom, about stray
 20 amounts of high molecular weight PEO. Your
 21 Honor observed that if there is a low molecular
 22 weight PEO that contains stray amounts of higher
 23 molecular weight PEOs, that wouldn't be
 24 sufficient to be within the terms of the claims.

1 And we'll be talking about that as the case goes
2 on.

3 Now, the patent does talk about
4 the molecular weight of PEOs and does talk about
5 the PEOs that were used as part of the patent.
6 And I believe you dealt with these tables in the
7 course of the Markman, your Honor, but just to
8 review, Table 21 has a variety of the
9 ingredients and notes specifically that the PEO
10 is available from the Dow Chemical Company. And
11 then the very next table, Table 22, it discusses
12 various weight PEOs: 100,000, 200,000, 300,000,
13 900,000. And what is significant about this,
14 your Honor, is, when the patent refers to the
15 molecular weight of the PEOs, it's referring to
16 the weight assigned to it by Dow. So this is
17 the manufacturer's weight. The version of the
18 molecular weight is used in the patent.

19 And so with that background, your
20 Honor, what is the evidence that you're going to
21 see about infringement of Watson's product? As
22 you heard from plaintiffs' counsel, Watson uses
23 something called Polyox N80, no dispute about
24 that, but that's the only PEO that Watson uses.

1 It is the only one. It does not use any other
2 PEO. And the evidence is going to show that a
3 person of ordinary skill in the art would rely
4 on what the manufacturer deems the molecular
5 weight of its PEO in determining what the PEO
6 weight is for purposes of these claims.

7 So what is the molecular weight of
8 Watson's PEO? According to the manufacturer --
9 this is an excerpt from a brochure that you will
10 have in evidence, your Honor, from Dow, and it's
11 an excerpt that shows what the molecular weight
12 of the various, of its PEOs are. And you see
13 the N80 is what we've highlighted and the
14 molecular weight that Dow gives that PEO is
15 200,000, 200,000 daltons.

16 And on the right, I've put the two
17 key elements of the claim terms, and we would
18 concede, of course, that that 200,000 falls
19 within the low molecular weight PEO limitation
20 of between 100,000 and 300,000. But where the
21 noninfringement lies is we don't have any high
22 molecular weight PEO in the ranges of 600,000 to
23 900,000. We have one PEO, and that PEO falls in
24 the low molecular weight category. There is no

1 high molecular weight PEO in that range. That's
2 an element missing from the claims, and that is
3 the very definition of noninfringement.

4 So what do plaintiffs do when
5 faced with one PEO that is only a low molecular
6 weight PEO as set forth and consistent with the
7 way PEO is measured in the patent?

8 And, Judge your Honor this is
9 where we have a very different view than was
10 expressed the other day about the strength of
11 plaintiffs' infringement case. We think it is
12 extraordinarily weak.

13 So what do plaintiffs do?
14 Plaintiffs did their own analysis of this N80
15 PEO and they came up, came up with this curve,
16 and this is a distribution of the molecular
17 weights in the sample. And the first thing
18 you'll notice about this curve, Judge, is, it
19 has one peak, it has one peak. That means it's
20 one PEO with one average molecular weight, and
21 the average molecular weight is at that peak.
22 That's what it means.

23 But what plaintiffs do, they do
24 something that nobody anywhere does or has done.

1 They draw a line at 600,000, and as plaintiffs'
2 expert agree, that was the line that was drawn
3 because the attorneys told them to draw a line.
4 It wasn't drawn for a scientific reason. The
5 attorneys said to draw a line. And then they
6 said, okay. We're going to compute an average
7 molecular weight for the right side of the red
8 line and then we're going to compute one for the
9 left side of the red line, and voila, we have
10 two different molecular weights and two
11 different PEOs.

12 Now, there are all kinds of
13 problems with that, your Honor, which we're
14 going to talk about in some detail today and
15 tomorrow.

16 But the first thing to note is, as
17 I said, their own chart shows a unimodal
18 distribution, and unimodal, of course, means one
19 mode, and the mode being the peak there, Judge.
20 If this was multiple PEOs, you would see
21 multiple peaks. If it was two PEOs, you would
22 see two peaks. But it does not show that.
23 Their own testing does not show that. It shows
24 a unimodal distribution.

1 **Second, this analysis that they're**
 2 **promoting here in court, which I think they call**
 3 **partitioning because they partition with that**
 4 **red line, is not an accepted industry practice.**
 5 **It's not in the patent as a technique for**
 6 **measuring molecular weight. It's not in the art**
 7 **as a technique for measuring molecular weight.**
 8 **It's something that was invented as a means of**
 9 **trying to create an infringement case here.**
 10 **It's not out there.**

11 **In fact, Judge, you're going to**
 12 **hear a very brief deposition excerpt. It's**
 13 **about three minutes from one of the inventors in**
 14 **this case. And he's going to be asked how he**
 15 **determined the molecular weight of the samples**
 16 **that he worked with, and he's not going to say**
 17 **he did this kind of partitioning. He's going to**
 18 **say he accepted the molecular weight that was**
 19 **given to him by the manufacturer, just as we're**
 20 **suggesting you should do in this case, your**
 21 **Honor.**

22 **The third thing, your Honor, is**
 23 **that even if you accept this partitioning**
 24 **analysis with the red line, how much of this is**

1 **really high molecular weight PEO?**

2 **Even if you accept their terms,**
 3 **which obviously we're saying you shouldn't, but**
 4 **if you look at the line, the high PEO, the high**
 5 **molecular weight PEO is the part to the right of**
 6 **the red line that is crosshatched on the chart**
 7 **under the curve.**

8 **So it's a very small part of the**
 9 **whole. It's, in fact, less than two percent of**
 10 **the whole. That's precisely, your Honor, we**
 11 **think, the kind of stray amount of high**
 12 **molecular weight PEO that does not satisfy the**
 13 **claims in this case and fits your construction,**
 14 **which eliminates that kind of high molecular**
 15 **weight PEO, that amount of high molecular weight**
 16 **PEO from being infringing.**

17 **But, Judge, even if you accept all**
 18 **of this, all of these things that plaintiff said**
 19 **and, of course, we say and hope you won't, but**
 20 **even if you would, they still can't get**
 21 **infringement. They do their own calculations.**
 22 **They figure out the numbers, and when they**
 23 **figure out the numbers, the numbers they get are**
 24 **still outside the ranges of this patent.**

1 **So they do this partitioning thing**
 2 **and they say, look, we have a low molecular**
 3 **weight PEO, but it falls outside the band,**
 4 **outside the 100 to 300,000 band.**

5 **They say, we have a high molecular**
 6 **weight PEO, but it falls outside the band.**

7 **So for all of these reasons,**
 8 **Judge, we think, we think that this is a**
 9 **contrived attempt to try to create the**
 10 **impression of two PEOs where, in fact, there's**
 11 **only one, and when anybody of skill in the art**
 12 **in this area would realize that there's only**
 13 **one. So that is what the evidence is going to**
 14 **be concerning noninfringement.**

15 **Now, we also have invalidity**
 16 **defenses, as counsel pointed out, on the '150**
 17 **patent. And the first thing I want to talk**
 18 **about is indefiniteness, because it relates to**
 19 **what we just talked about.**

20 **And if your Honor does not accept**
 21 **our contention that it's right there in the**
 22 **patent how you measure PEO, is you look to what**
 23 **the manufacturer says the weight is, if you**
 24 **ignore that that is there, the patent does not**

1 **provide any information on how to understand how**
 2 **to weigh, how to determine the molecular weight**
 3 **of PEO. And I think counsel admitted that. I**
 4 **think he said, there's nothing in the patent**
 5 **that tells you what you can do. And, in fact,**
 6 **there are a number of ways of measuring**
 7 **molecular weight.**

8 **And the thing about this, Judge,**
 9 **is, that the way you measure it makes a**
 10 **difference to the outcome. Measuring it the**
 11 **same, measuring the molecular weight of the same**
 12 **substance four different ways will arrive at**
 13 **four different results, and you can see that**
 14 **because plaintiffs' own expert did this kind of**
 15 **testing as part of this case.**

16 **And so plaintiffs' expert did four**
 17 **different calculations of molecular weight and**
 18 **got four different results. And, in fact, from**
 19 **top to bottom, there's something along the lines**
 20 **of a seven or eightfold difference from top to**
 21 **bottom of these calculations.**

22 **Whether there's infringement or**
 23 **not will depend on the technique you use, but**
 24 **the technique you should use is not specified in**

1 the patent. And that is classic indefiniteness,
2 your Honor. That's right within the classic
3 definition of indefiniteness, and that is why we
4 assert that this patent is indefinite, the
5 claims of this patent are indefinite and invalid
6 for that reason.

7 As to obviousness, your Honor, I
8 think this is, this might be slightly unusual
9 compared to the normal obviousness situation
10 that your Honor deals with, and I say that
11 without knowing for sure, but I think it may be.
12 And that's because the obviousness case really
13 comes down to what the correct priority date
14 is.

15 If we're right about the priority
16 date, plaintiffs won't even be offering expert
17 testimony to rebut our obviousness case. If
18 we're wrong about the priority date, we're not
19 going to be asserting that the claims are
20 obvious.

21 So it comes down to the priority
22 date. And as your Honor knows, the priority
23 date in this case is, in an obviousness case, is
24 the date at which you determine what is the

1 prior art that's relevant.

2 So if you have an earlier priority
3 date in this case, you'll have less prior art
4 that's relevant to the obviousness defense. If
5 you have a later priority date, you'll have more
6 prior art that's relevant to the obviousness
7 defense. That is what the priority date role is
8 in an obviousness defense.

9 And so in this case, in this case,
10 we have to consider and determine what the
11 priority date is for the relevant claims. This
12 is a representative claim again, Judge. To
13 determine priority date, the analysis is you
14 take that claim and you go back through the
15 applications that were filed and find the
16 application where the entirety of that invention
17 was described. Where was it first described and
18 where it's all described is where the priority
19 date is.

20 And so for purposes of just our
21 presentation this morning and to make it a
22 little bit faster, Judge, there are three basic
23 elements to this claim. Obviously, I've
24 numbered them. There's the PEO in combination

1 with HCP. There's the size of the PEO, which
2 we've been talking about that's number two. And
3 then there's the third one, where the PEO of low
4 molecular weight comprises about 60 percent or
5 more in the polymeric compound.

6 Now, this is a timeline, Judge,
7 and the boxes are applications that were filed
8 in the course of this prosecution, and so we
9 look at these applications to see where all
10 three of those elements are first mentions.

11 Plaintiffs would have you believe
12 that it's in the May 28, 2003 application, but
13 if you look at that application, we'll concede
14 that number one, element number one, the PEO and
15 HCP is there, and we'll concede that the
16 molecular weight PEO and high molecular weight
17 PEO is there. But the third category is not.
18 The low molecular weight PEO that's greater than
19 or equal to 60 percent of the combination of the
20 PEO and HCP is not in the 2003 application.

21 So our position is, that is not
22 the priority document, that is not the priority
23 date that's relevant to obviousness here.

24 On the other hand, the April 2008

1 application does have all three, and that's the
2 first time all three elements are in an
3 application. The specification of the, of the
4 invention was actually amended at that time in
5 that application to include element three, and
6 so we say April 22nd of 2008 is the relevant
7 date, and that's when, and that's when the
8 priority date should be.

9 So as far as obviousness is
10 concerned, with that 2008 date in mind, our
11 position is going to be that a reference called
12 Yang is the relevant obviousness reference, and
13 that it renders all of the elements of the
14 claims obvious, and they will have no expert who
15 will rebut our expert's testimony on that
16 particular point.

17 So that's the '150 patent, your
18 Honor. And so I'm going to move now to the '514
19 patent, and this is the patent that counsel was
20 talking about that talks about, and stated
21 broadly, the uniformity of the active ingredient
22 throughout the film in question.

23 And I should say right off the
24 bat, Judge, just to focus things, we're not here

1 to address all issues related to films or all
2 solutions related to those issues. We're here
3 to look at this particular patent and its claims
4 and determine whether those claims are obvious.
5 And when you look at these claims, I think
6 you'll be struck by how simple they are, and how
7 simple the logic is, and that's going to be
8 reflected in the prior art. This is just things
9 that are all available in the prior art, and
10 were available in the prior art at the relevant
11 time.

12 Now, a word about uniformity
13 first, your Honor. Uniformity is nothing new in
14 the pharmaceutical world. It's the goal always,
15 because uniformity is what ensures that when you
16 have a bottle of pills, that you have the same
17 active ingredient in all of those pills, so to
18 make sure you are not taking, inadvertently
19 taking too much of an active ingredient or
20 getting too little of an active ingredient.

21 So uniformity is a goal that has
22 always been there in the pharmaceutical world,
23 and the ten percent uniformity from this patent
24 and this particular claim is not something new

1 to plaintiffs. It has been the goal in FDA
2 regulation for quite some time with respect to
3 all dosage forms, is that kind of uniformity.

4 But let me just walk you through
5 these claims really quickly. There's a lot of
6 words there, but when you break it down, it's
7 really not too much.

8 You start with polymers. No
9 dispute about that. Films have always used
10 polymers known in the art. You're going to add
11 a particulate active that has a particle size of
12 200 microns or less. Particulate actives, been
13 used in films, known in the art. The idea of
14 200 microns or less known in the art,
15 encompassed in the art.

16 So you put your particulate
17 actives in there. When I say "particulate
18 actives," those are the active ingredients that
19 are going to help the therapeutic effect. So
20 that's the important part ultimately of the
21 drug.

22 Now, that particulate active needs
23 to be substantially uniformity stationed in the
24 matrix. Matrix is referring to the polymer.

1 And it has to be uniformly stationed because you
2 want to have it mixed and uniform so that when
3 it becomes a film, you're going to have a
4 uniform distribution of the active. Now,
5 the idea that you would want to have a uniformly
6 stationed, not a surprising idea, not a new
7 idea, and it's in the art. You'll see lots of
8 steps in these, in the prior art about mixing
9 and making homogenous mixtures and uniform
10 mixtures. That's nothing new in the art.

11 And they say you want to make sure
12 that once you're finished mixing, that those
13 particulate actives actually stay more or less
14 where they are, so that you still have
15 uniformity. You don't want them to clump
16 together or aggregate or fall to the bottom and
17 be all in one place.

18 So it says, wherein said matrix
19 has a viscosity sufficient to aid in
20 substantially maintaining non-self aggregating
21 uniformity of the active in the matrix. And so
22 what they are saying is, viscosity, your Honor,
23 is just basically thickness. They are saying,
24 make that matrix thick enough so that the

1 particles will stay more or less in place, and
2 they won't, they won't clump together.

3 That really is as close as you get
4 in this patent to a technique for maintaining
5 uniformity, but viscosity is something that has
6 been known for centuries, your Honor, and the
7 study of suspensions and particles in
8 suspensions like this and what you need to do to
9 make sure the particles stay at uniform
10 distances in suspensions is extraordinarily
11 well-known and is nothing new.

12 Then you get to the part -- and
13 remember that plaintiffs' counsel talked about
14 this. He says, well, you put the matrix into a
15 cast for the film and it has to be capable of
16 being dried without losing that substantial
17 uniformity. Again, it's obvious that you want
18 to maintain the uniformity and you need to do
19 something with the thickness to make sure that
20 it's thick enough that those particles don't
21 move around. And then when you get down to the
22 point of actually cutting it up, the film up
23 into the dosage form, you want to make sure that
24 each dosage form has the same amount of active

1 ingredient, and that's, there's a specific
2 number they put. This is the number that people
3 of skill in the art would have sought, the ten
4 percent. They don't want a variance of more
5 than ten percent of the desired amount of active
6 from a dosage form or dosage unit to dosage
7 unit.

8 So, your Honor, that is what this
9 patent is about. As I say, these are concepts
10 that are well-known in the art. We're going to
11 talk about two in specific. In addition to some
12 background art, the two are Chen, as counsel
13 noted, and Bess, but we will also be talking
14 about background art in this area, and we will
15 show that all of the elements of the claimed
16 invention are rendered obvious.

17 We will talk about indefiniteness,
18 and the problem that plaintiffs have with
19 indefiniteness is that they wrote a claim that
20 does not make sense, and you'll hear from the
21 experts on this.

22 But just briefly, your Honor, you
23 can see they say that this is a system that has
24 a cast film, so that's a film that has actually

1 been cast and has been dried and cut, but they
2 say that the matrix is supposed to be flowable.
3 And you will hear from experts in this case
4 that that is simply a contradiction, and that
5 kind of contradiction renders the claims
6 indefinite.

7 And so let me return to where we
8 started, Judge. The secondary consideration
9 evidence. As your Honor knows, in an obvious
10 case, they're entitled to come in and show
11 commercial success, among other things, to try
12 to show that this patent is novel, that these
13 claims are novel. And it's not enough, as your
14 Honor knows, just to show that you sold a lot of
15 these strips. It's not enough to show that you
16 made a lot of money. You have to show that the
17 sales or the success, the commercial success
18 here is tied to the patents, is tied to the
19 claims of these patents, and that the success is
20 due, is due to the claimed elements of the
21 invention.

22 And our position, Judge, is, that
23 they're not going to be able to prove that,
24 because whatever commercial success this film

1 has had is not a matter of the market reacting
2 to the sale of these films, the availability of
3 these films and saying, gee, what a great --
4 what a great product. It's totally a matter
5 of plaintiffs' strategy to move the market from
6 the tablet to the film, from the tablet to the
7 film. They have done absolutely everything they
8 can do to move the market from the tablet to the
9 film. And so the commercial success they are
10 talking about here is not something that is
11 attributable to the product here or to the
12 claims of the invention here. The commercial
13 success is due to their product hopping
14 strategy.

15 So the evidence briefly, your
16 Honor, on commercial success is, first, we're
17 going to want to talk about what constitutes
18 commercial success here, because the Suboxone
19 film has never reached the market share that the
20 tablets reached despite everything that
21 plaintiffs have done.

22 So in the context of Suboxone,
23 generally, the film has not been the commercial
24 success that plaintiffs portray it to be. As I

1 said, the film sales are attributable to the
2 product hopping strategies. And plaintiffs need
3 to show, they need to show that there's a nexus,
4 a connection between the film sales and the
5 asserted claims, and they have failed to do
6 that. They will fail to do that in this case.

7 So, your Honor, that is our
8 opening. I am not going to introduce you to
9 all of our experts at this time. I will let
10 you meet them as they come to the witness
11 stand.

12 Thank you very much.

13 THE COURT: All right. Thank you,
14 Mr. Lombardi.

15 All right. Plaintiff?

16 MS. BOURKE: Your Honor,
17 plaintiffs call as their first witness Dr. Bernd
18 Wollschlaeger. I have some very small very
19 small notebooks.

20 (Ms. Bourke handed notebooks to
21 the Court.)

22 PLAINTIFFS' TESTIMONY

23 ... BERND WOLLSCHLAEGER, having
24 been duly sworn as a witness, was

1 examined and testified as follows ...

2 **DIRECT EXAMINATION**

3 **BY MS. BOURKE:**

4 Q. Good morning, Doctor.

5 A. Good morning.

6 Q. Can you introduce yourself to the

7 Court, please?

8 A. My name is Bernd Wollschlaeger.

9 I'm a physician.

10 Q. And what type of physician are

11 you?

12 A. I'm a board-certified family

13 physician and addiction specialist.

14 Q. Do you maintain those

15 certifications today?

16 A. Yes, I do, maintain those

17 certifications.

18 Q. You said that you are

19 board-certified in addiction? You're an

20 addiction specialist; is that right?

21 A. That is correct.

22 Q. Can you explain to the Court what

23 your practice is with respect to addiction

24 medicine?

1 A. My practice is about 80 percent

2 family medicine and 20 percent of addiction

3 medicine, and I treat patients suffering from

4 diseases ranging from opioid dependence to

5 alcohol dependence.

6 Q. You said -- is there a broader

7 term that is used for addiction medicine,

8 sometimes called substance abuse?

9 A. It's called, according to the

10 DSM-IV, substance use disorders treatment.

11 Q. Okay. Thank you.

12 And what percentage of the

13 patients that you treat suffer from substance

14 use disorder?

15 A. About 20 percent.

16 Q. And what percentage of that suffer

17 from opiate dependence or opiate use?

18 A. About at least 80 percent plus.

19 Q. Now, you said you treat patients.

20 Can you describe for the Court exactly what that

21 entails?

22 A. Well, addiction to medicine

23 entails screening diagnosis and treatment of

24 substance use disorders, and the treatment in a

1 practice based setting, medication-assisted

2 treatment assisted by substance abuse

3 counseling.

4 Q. And how many patients do you

5 directly treat at any given time that suffer

6 from opiate dependence and other dependence?

7 A. Between 40 and 50 patients at any

8 given time for opiate dependence, and for other

9 dependence, it can range anywhere between 20 to

10 30.

11 Q. And for what length of time do you

12 do that?

13 A. Treating them between three

14 months, six months, to 13 to 14 years is my

15 longest patient.

16 Q. All right. Thank you, Doctor.

17 And in addition to treating

18 patients, do you engage in any other activities

19 as it relates to your addiction specialist

20 occupation?

21 A. Yes, I do. I'm a voluntary

22 faculty member of different universities and

23 teach medical students, family medicine

24 residents, advance nurse practitioners in my

1 practice, and I also treat physicians on a local

2 and national level about the treatment of

3 substance use disorders.

4 Q. What percentage of your time is

5 spent teaching as opposed to treating patients?

6 A. Well, most of my teaching,

7 90 percent is in practice teaching, and the

8 remainder is out of my office in lectures, ten

9 percent.

10 **MS. BOURKE:** So at this time, your

11 Honor, we'd like to offer Dr. Wollschlaeger as

12 an expert in addiction medicine and the

13 treatment of opiate use disorders.

14 **THE COURT:** All right. You may

15 proceed.

16 **BY MS. BOURKE:**

17 Q. So, Doctor, can you explain to the

18 Court how you got motivated to enter the field

19 of -- the treatment of opiate use disorders?

20 A. It was a personal and professional

21 motivation. Personally because I,

22 unfortunately, witnessed as a young boy the

23 destruction of a family of a father's friend of

24 mine, who the son suffered from heroin

1 addiction, which impressed me, and shattered
2 also my life. On the other hand, I also
3 witnessed a good friend of mine die from heroin
4 overdose.

5 So I became professionally
6 interested in understanding something that was
7 not widely taught in medical school at that
8 time, which is called addiction illness, and I
9 became trained and certified in addiction
10 medicine.

11 Q. Can you describe for the Court
12 what is the status of opiate use disorder in
13 this country as a health issue today?

14 A. Well, opiate use disorder is an
15 epidemic. It encompasses, unfortunately, all
16 ages, genders and races in our society.

17 Q. And are you aware of any
18 statistics that have been published in the
19 recent years?

20 A. Yes, I have.

21 Q. Okay. And who were they published
22 by?

23 A. Published by Disease Control, U.S.
24 Department of Health and Human Services.

1 Q. Can you turn to JTX-84 in the
2 exhibit binder, please.

3 A. Yes, I have.

4 Q. Are these the statistics to which
5 you refer?

6 A. That is correct.

7 Q. Can you direct the Court to the
8 key findings in your opinion?

9 A. In --

10 Q. With respect to that paper?

11 A. In the first paragraph under the
12 third sentence, it summarizes the opioid
13 analgesic sales that are tripled from 1999 to
14 2010, and from 1990 to 2012, opioid-related
15 deaths have more than tripled.

16 Q. Are there any other aspects of
17 that paper that you found important, Doctor?

18 A. On page 2, Figure 3, that is the
19 figure. It emphasizes the pervasiveness of the
20 disease which spans now across multiple, all age
21 groups, affects all genders, and does not spare
22 any racial or ethnic group.

23 Q. Thank you, Doctor. You can put
24 that away for now.

1 When did you first start treating
2 opioid use disorders?

3 A. I started treating opioid use
4 disorders during my training at the Mount Sinai
5 Medical Center Addiction Treatment Center in
6 Miami Beach, starting in 1998. And at that
7 time, we resorted to in-patient treatment of
8 patients suffering from opioid dependence, as we
9 called it at that time.

10 Q. By "inpatient," you mean this was
11 in the hospital, hospital setting?

12 A. Hospital-based in a controlled
13 setting, in a so-called locked unit.

14 Q. All right. Did there come a time
15 when you were able to treat patients suffering
16 from opioid use disorder in an office-based
17 setting?

18 A. Well, with the Drug Abuse
19 Treatment Act, so-called data act of 2000,
20 physicians in private practice were offered the
21 opportunity and option to treat patients in an
22 office-based setting with medication to treat
23 opioid dependence.

24 Q. And did you take advantage of that

1 act?

2 A. I absolutely got certified and
3 registered, which required a specific
4 registration certification process offered by a
5 the Drug Enforcement Administration.

6 Q. How many years did that involve?
7 What was the training and months that was
8 involved in that?

9 A. That involved an eight-hour
10 certification course for those physicians who
11 regularly obtained the DEA license and needed an
12 additional X certificate it was called, which
13 was then issued by the DEA after satisfaction of
14 the additional training requirement.

15 Q. And in your opinion, did the
16 ability to prescribe prescription approved
17 narcotics in the office-based setting have
18 any impact on the treatment of opiate use
19 disorder?

20 A. It had a dramatic impact on the
21 treatment because it opened up the bottle next
22 that, to that point in time existed, where
23 patients had to resort to inpatient units or to
24 methadone clinics, and now they could access

1 private physicians in an office-based setting.

2 Q. And what were the prescription
3 approved narcotics that you were able to
4 prescribe in the office-based setting?

5 A. Well, the FDA approved at that
6 point in time only one medication and two
7 formulary. The first one is also known as
8 Silbotech (phonetic), and the other known as
9 Suboxone.

10 Q. Okay. And who was the company
11 that sought and gained approval of those two
12 prescription narcotics?

13 A. That was Reckitt Benckiser
14 Pharmaceuticals.

15 Q. And did you have a relationship
16 with Reckitt?

17 A. Several years after I started
18 treating patients with the Suboxone, and I
19 joined the treatment advocate program of the
20 company.

21 Q. And what's a treat advocate?

22 A. A treat advocate is a physician
23 who assists in the education and training of
24 other physicians to implement quality care

1 guidelines in the management of opioid
2 dependence treatment.

3 Q. As a treatment advocate, do
4 you advocate per the Suboxone or Reckitt
5 products?

6 A. No. We were not advocating for
7 the legalization of Suboxone products. We were
8 advocating for the quality limitation, quality
9 guideline.

10 Q. Can you slow down in your answers
11 because it may be hard for the court reporter to
12 keep up.

13 A. We were not advocating for the
14 treatment of opioid dependence with Suboxone,
15 but advocating for the implementation of quality
16 care guidelines in the management of opioid
17 dependence.

18 Q. Thank you, Doctor.

19 Were you compensated by Reckitt
20 for that work?

21 A. Yes, we were, and we are
22 compensated, and I am compensated with a
23 honorarium.

24 Q. What's an honorarium?

1 A. An honorarium is compensated from
2 the medical practice, which I'm engaged in
3 during my time, and it ranges anywhere between
4 500 to \$750 per presentation.

5 Q. Is it a significant source of your
6 income?

7 A. No. It is far less than ten
8 percent of my practice income.

9 Q. Let's talk a little bit about the
10 prescription approved narcotics that Suboxone
11 and the Subutex. First, what is the dosage form
12 that those are in?

13 A. They're being utilized, or were
14 utilized at that time as tablets.

15 Q. And what's the route of
16 administration?

17 A. Route of administration is a
18 sublingual, under-the-tongue form. So not to be
19 swallowed.

20 Q. And they both contain
21 buprenorphine; right?

22 A. They both contain buprenorphine,
23 that's correct.

24 Q. And what is the function of

1 buprenorphine in those formulations?

2 A. Buprenorphine is a partial opioid
3 agonist, meaning it stimulates the oral
4 receptor. Therefore, mimicking an opioid effect
5 but reducing the withdrawals and cravings for
6 patients that's getting off of their drug of
7 choice.

8 Q. How does that differ from, say,
9 methadone that was used before?

10 A. Well, methadone, which, methadone,
11 which is being used since 1972, is a direct
12 opioid agonist, meaning it directly stimulates
13 the opioid receptor and has a dose-dependent
14 effect, meaning the more you give, the more
15 effect you have, and the more adverse effects
16 there are, unfortunately, to the point of
17 overdose, which cannot happen with
18 buprenorphine.

19 Q. That's because the buprenorphine
20 has a ceiling effect?

21 A. Buprenorphine levels off at a
22 certain dosage, about 16 milligrams, where it
23 saturates more than 95 percent of the opioid
24 receptors. Therefore, cannot induce any kind of

1 overdose related effect.

2 Q. So I believe you said that

3 Suboxone tablets has an additional active

4 ingredient, naloxone; is that correct?

5 A. That's correct.

6 Q. And what is the purpose and

7 function of naloxone in that formulation?

8 A. Naloxone is an opioid antagonist

9 blocking the effect of opioids, which was added

10 in order to avoid abuse of the prescription

11 narcotic. What it means is that if a patient

12 decides to crush and dissolve the tablets,

13 Suboxone tablet, the injected naloxone would

14 exert an immediate effect and precipitate a

15 withdrawal and craving, which is very

16 uncomfortable.

17 Q. All right. Doctor, you have, have

18 you prescribed Suboxone tablets to your

19 patients?

20 A. Yes, I do, and, yes, I did, to the

21 point it was available.

22 Q. And what, if any, feedback did you

23 receive from your patients about the Suboxone

24 tablets?

1 A. Over the course of time, I

2 received feedback ranging from complaints about

3 taste disturbances, dissolution time problems,

4 of problems with the length of the time that it

5 took to dissolve related to the life of

6 production and the accidental swallowing of the

7 product.

8 Q. Can I stop you there? What do you

9 mean, what's this accidental swallowing and why

10 is that significant?

11 A. The tablet takes a lot about three

12 to six minutes to dissolve at least, and it's

13 individually different, of course, can trigger

14 saliva production. And in some patients, they

15 complained that they had to swallow the product

16 instead of waiting for it to dissolve because

17 there was so much saliva produced.

18 Q. And why is that a bad thing?

19 A. Because the product is not

20 workable, and it does not serve the effect once

21 it's swallowed. It only affect the patient by

22 sublingual transmission.

23 THE COURT: Ms. Bourke, could you

24 move the mike a little closer?

1 MS. BOURKE: Certainly, your

2 Honor. Is that better?

3 THE COURT: Yes.

4 BY MS. BOURKE:

5 Q. What other feedback did you get

6 from the patient? We talked about taste. You

7 talked about the dissolution time. Did you get

8 any others?

9 A. The other problem the patients

10 note was the friability of the tablets, meaning

11 the tablets broke down in the bottle, and I

12 noticed that when I was counting tablets, in

13 order to ascertain that the patient complied

14 with the prescribed dosage. And specifically,

15 the last third of the remaining bottle, last

16 third of the treatment base, I noticed

17 broken-down tablets even to the point that

18 powder remnants formed from the bottom of the

19 bottle.

20 Q. And why is that a bad thing?

21 A. Because the patient could not dose

22 the tablet appropriately. Instead of taking,

23 for example, a full eight-milligram tablet, they

24 had to fish -- that was a term used by one of my

1 patients -- fish out product that made up

2 approximately eight milligrams and then apply it

3 under the tongue, which was often difficult.

4 Q. Aside from the patient feedback

5 that you got, as a practicing physician in the

6 field of opiate, treatment of opiate use

7 disorder, are you aware of any other issues that

8 were around with respect to the tablet?

9 A. Yes. The availability of the

10 tablets and the ability to dissolve the tablet

11 in the solvent led to the theoretical potential

12 of injection and abuse specifically, but

13 buprenorphine as well as Suboxone. And my

14 patients reported, and I heard it from other

15 physicians that I communicated with, that

16 intravenous abuse of Suboxone was rising,

17 and also notification boards used by Suboxone

18 users.

19 Q. Anything else?

20 A. Also the potential that bottles

21 were accidentally discarded in garbage, or

22 garbage containers led itself to the

23 accessibility of products by children. This was

24 a unique feature of the, of the tablets, that

1 they're friable in forming a powder on the
2 bottom of the bottle, which is an orange-tinged
3 powder, and it's an orange color similar to
4 candy.

5 So children or toddlers
6 specifically may confuse that with candy, and if
7 gained access, could lick and taste the product
8 remnants.

9 Q. And what would happen to the
10 children if they did that?

11 A. Well, any child less than two
12 years of age that take the lick and taste
13 of a the product as a risk and exposure to
14 opioids that included nausea, vomiting, altered
15 mental status, stupor, and unfortunately, even
16 death.

17 Q. All right. Did there come a time
18 when an additional buprenorphine naloxone
19 product was available on the market?

20 A. Yes. In 2010, Suboxone film was
21 introduced on the market and made available for
22 prescribing physicians like I am.

23 Q. When the Suboxone film became
24 available, how did you address that treatment

1 option with the patient?

2 A. I informed my patients about the
3 availability of the additional product and new
4 product on the market, and discussed with them
5 if it would be suitable for them or an option
6 for them to utilize.

7 Q. And did any, any of your patients
8 select that as an option?

9 A. Those patients that complained
10 about taste disturbances, prolonged dissolution
11 time, friability issues of the tablet which
12 resulted in dosing problems, I offered the
13 opportunity to try it out and they wanted to try
14 it out, and to see and compare its effect and
15 the adverse effect, the negative effect that
16 they had with the tablet with the film.

17 Q. And what feedback did you receive
18 from your patients with respect to the use of
19 the Suboxone film?

20 A. Overwhelmingly positive effect and
21 positive response. So they then requested to
22 continue taking it, and I continued prescribing
23 this medication for them.

24 Q. Can you be specific about what

1 they told you about the film?

2 A. That, number one, the taste has
3 improved. There's more taste neutral. That
4 because it adheres to the mucous membrane under
5 the tongue, it dissolves faster, between a
6 minute to three minutes.

7 Then the friability issue was
8 excluded because they put -- they were films
9 that they even applied the whole film under the
10 tongue and there was no break product, and
11 actually portability because of the single
12 packaging.

13 Q. What about the potential abuse
14 issue?

15 A. The film preparation increased a
16 threshold overview because the film could not be
17 easily crushed, and cannot be easily crushed as
18 a result and dissolved unless one takes
19 extraordinary effort to do so, and therefore it
20 does not lend itself to injection drug abuse.

21 Q. What about the risk of pediatric
22 exposure?

23 A. The pediatric exposure also is
24 significantly reduced because it is prescribed.

1 And if taken as prescribed properly, the patient
2 opens up the pouch, takes out the film, takes
3 the film under the tongue and when discarding
4 the pouch, there's no active product in the
5 remnant of the pouch, and therefore children
6 that have gained access to the pouch cannot
7 accidentally overdose.

8 Q. What, if any, difference was there
9 with respect to adherence or patient compliance
10 with respect to that film?

11 A. To the stated advantages of taste
12 and dissolution time and the absence of the
13 friability issue, patients felt that it's more
14 convenient and easier to take. To combine with
15 the portability makes them more compatible with
16 their professional life and, and they adhere to,
17 therefore adhere to the treatment to a better
18 extent, a greater extent than with the tablet.

19 Q. Are you aware of any
20 well-controlled clinical trial, comparative
21 clinical trial between the film and the tablet?

22 A. Yes, I am.

23 Q. Could you turn to JTX-82 in your
24 binder, please.

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1 **When did you first become aware of**
2 **this article, Doctor?**

3 **A. This is an article from "Drug and**
4 **Alcohol Dependence" in 2013, 2013, and I read**
5 **this article several months afterwards when I**
6 **went through my journal.**

7 **Q. And what was your reaction to the**
8 **finding?**

9 **A. The findings, which are listed in**
10 **the conclusions, are congruent with the findings**
11 **that I had in my clinical practice. So that the**
12 **buprenorphine-naloxone film is comparable to the**
13 **existing tablet preparations across measures of**
14 **dose effect, adverse events, plasma levels and**
15 **global clinical outcomes, and therefore it was**
16 **far easier to transfer patients between tablets**
17 **to films without dosage adjustment.**

18 **Q. Thank you, Doctor.**
19 **Anything else with respect to the**
20 **finding?**

21 **A. It clearly emphasizes that the**
22 **dissolution time is improved.**

23 **Q. I notice that if you look under**
24 **the role of funding source, if we could**

Wollschlaeger - direct 87

1 **highlight that, please, it says that the study**
2 **was in investigator-led.**

3 **Can you explain to the Court what**
4 **that means?**

5 **A. Investigator-led means that the**
6 **investigator, the principal investigator has**
7 **full control of the design, the control level of**
8 **the study, the analysis of the data and the**
9 **publication of the data.**

10 **Q. And I also notice under the**
11 **acknowledgments that it says that Reckitt**
12 **Benckiser was the -- had provided an untied**
13 **educational grant and supply, provided the trial**
14 **medications; is that right?**

15 **A. That's correct.**

16 **Q. And does that lead to any bias in**
17 **the results from this study?**

18 **A. This is not uncommon in clinical**
19 **studies and does not lead to bias, specifically**
20 **when an investigator clearly states that the**
21 **investigator has full control of the study.**

22 **Q. Doctor, a couple final questions**
23 **for you. What is your preferred opiate use**
24 **disorder treatment today?**

Wollschlaeger - direct 88

1 **A. It actually is not my preferred**
2 **opiate use disorder treatment, but what my**
3 **patients prefer, because my patients have to**
4 **adhere and comply with the treatment, and for my**
5 **patients, it's Suboxone film.**

6 **Q. And how many of your opioid use**
7 **disorder treatment patients do you treat with**
8 **opioid film?**

9 **A. More than 90 percent.**

10 **MS. BOURKE: Thank you, Doctor. I**
11 **have no further questions.**

12 **THE WITNESS: Thank you.**
13 **THE COURT: All right.**

14 **Cross-examination.**

15 **MR. SMEREK: Thank you, your**
16 **Honor.**

17 **MS. BOURKE: Your Honor, do we**
18 **need to move the JTX exhibits that were referred**
19 **to by the witness?**

20 **THE COURT: I assume the JTX were**
21 **the ones that came in yesterday?**

22 **MS. BOURKE: Pre-admission?**

23 **THE COURT: I'm basically assuming**
24 **that if I don't hear anything, that it's**

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1 **admitted without objection.**

2 **MS. BOURKE: Okay. Thank you,**
3 **your Honor.**

4 **MR. SMEREK: Dr. Wollschlaeger,**
5 **may it please the Court, Steve Smerek from**
6 **Winston & Strawn on behalf of the defendant.**

7 **CROSS-EXAMINATION**
8 **BY MR. SMEREK:**

9 **Q. Dr. Wollschlaeger, good morning.**

10 **A. Good morning to you.**

11 **Q. Do you recall we've met**
12 **previously? I took your deposition in Miami,**
13 **Florida back in June; is that correct?**

14 **A. Absolutely.**

15 **Q. And I would just like to ask you**
16 **some questions regarding your testimony. And**
17 **specifically, first, you prepared an expert**
18 **report in this matter; is that correct?**

19 **A. Yes, I did.**

20 **Q. And just to be clear, you didn't**
21 **conduct any kind of quantitative analysis in**
22 **preparing this expert report; is that correct?**

23 **A. That is correct.**

24 **Q. And you talked about the Suboxone**

1 tablet and Suboxone film today, and you've
 2 prescribed both in your practice; is that
 3 correct?
 4 A. That is correct.
 5 Q. And I'm correct that there are no
 6 differences in clinical outcomes between the use
 7 of Suboxone film and the Suboxone tablet or the
 8 generic buprenorphine naloxone tablet; is that
 9 correct?
 10 A. There's no difference in clinical
 11 outcome between the tablet and the film. The
 12 generic tablets, I have limited experience
 13 because my patients hardly use them.
 14 Q. Thank you.
 15 And it's true that all patients
 16 are sensitive to out-of-pocket costs for the
 17 medications like Suboxone; is that correct?
 18 A. That is correct.
 19 Q. And, in fact, cost of Suboxone is
 20 a driving factor; is that correct?
 21 A. That is not correct because there
 22 are multiple factors influencing a patient's
 23 decision, and even price cannot be often
 24 properly determined from patient to patient. So

1 it cannot be used as the only factor.
 2 Q. And I'm sorry. I was perhaps
 3 unclear in my question. I'm correct that cost
 4 or price of Suboxone is a driving factor; is
 5 that correct?
 6 A. That is correct.
 7 Q. And when Reckitt launched the
 8 Suboxone film product, at that time the only
 9 other buprenorphine naloxone product on the
 10 market was the Suboxone tablet; is that correct?
 11 A. That is correct.
 12 Q. And when Reckitt launched the
 13 Suboxone film, they told doctors like yourself
 14 in the treatment advocate group that there would
 15 be significant savings for patients who switched
 16 over to the film; is that correct?
 17 A. Well, we were informed that there
 18 were savings like there were savings with the
 19 tablets, there would be savings with the film,
 20 which would be adjusted and help the patient to
 21 cover the co-pays, which is not unusual in the
 22 industry for any product.
 23 Q. So it's going to be affordable for
 24 patients to switch to the film; is that correct?

1 A. That there would be no obstacle to
 2 those patients that choose to take the film.
 3 Q. You talked about Exhibit JTX-82.
 4 That was the Lyntzeris paper. Do you recall
 5 generally this is the paper that you were
 6 discussing?
 7 A. That is correct.
 8 Q. And if I could look at Section
 9 3.4, adverse events, blow that up here on the
 10 screen.
 11 And according to the Lyntzeris
 12 paper, just to be clear, there's no significant
 13 difference between side effects experienced by
 14 patients administered tablets or film; is that
 15 correct? Nothing reported?
 16 A. That is correct.
 17 Q. And if we look down a little bit
 18 further in that same adverse events, after,
 19 there are some side effects reported, but then
 20 there are problems that patients reported with
 21 the film; is that correct?
 22 A. That is correct.
 23 Q. And we discussed these problems a
 24 little bit at your deposition?

1 A. That is correct.
 2 Q. And here, according to this, I
 3 think you said it was a well-conducted study
 4 that you relied upon. And it said, respondents
 5 reported film got stuck to the teeth. That's
 6 because the film gets sticky when it's wet; is
 7 that correct?
 8 A. If it's not used properly, then
 9 it's being sticky.
 10 Q. And so here, what percentage of
 11 people, what percentage of the respondents
 12 indicated that the film got stuck to their
 13 teeth?
 14 A. 65 percent.
 15 Q. Okay. And then we move on, and I
 16 guess there were more problems with people
 17 having it stuck to the roof of the mouth. And
 18 how many people reported that problem?
 19 A. 30 percent.
 20 Q. And others had it stuck to the
 21 cheek. How many reported that problem?
 22 A. Eight percent.
 23 Q. And then even before it got to the
 24 mouth, there were others that were having

1 **problems just picking the film up. And how many**
 2 **had that problem?**
 3 **A. 16 percent.**
 4 **Q. And it got stuck to, you said wet**
 5 **fingers, and there were 14 percent here.**
 6 **Now, I have to assume, when you**
 7 **read this, did you assume that there was some**
 8 **overlap in these problems, in the people having**
 9 **these problems?**
 10 **A. Overlap as?**
 11 **Q. Well, I'm looking at it, and if I**
 12 **add all of those percentages up, it is more than**
 13 **a hundred percent of the respondents are having**
 14 **trouble getting, getting the film under their**
 15 **tongue where it's supposed to be, so when I read**
 16 **it, I just assumed that there had to be some**
 17 **overlap in those percentages. And I'm just**
 18 **asking you, when you read this report, did you**
 19 **believe that there was overlap, or did you**
 20 **believe that nobody actually got the film under**
 21 **their tongue?**
 22 **A. Well, there was probably and**
 23 **definitely an overlap of the 42 participants in**
 24 **this, that were counted.**

1 **Q. All right. And am I correct that**
 2 **if you don't get the film under the tongue so**
 3 **that it can dissolve like the tablet, that that**
 4 **could lead to problems with the correct dosage**
 5 **being delivered?**
 6 **A. If not properly educated, that's**
 7 **always the premise that the patient needs to be**
 8 **properly educated, then these reported events**
 9 **occur, which almost never occurred with my**
 10 **patients.**
 11 **Q. And so in your expert opinion, the**
 12 **respondents, the people who participated in this**
 13 **study, were not properly educated with respect**
 14 **to how you use the film?**
 15 **A. I would assume, because I did not**
 16 **conduct and participate in the study, that many**
 17 **of those reported side effects and adverse**
 18 **effects are related to improper education and**
 19 **handling of the film strips.**
 20 **Q. So here in this study, this**
 21 **well-done study, as you called it, the patients**
 22 **were having these problems with the film because**
 23 **they weren't properly trained by the persons who**
 24 **conducted the study, in your opinion?**

1 **A. I would assume that that is the**
 2 **conclusion.**
 3 **Q. Okay. And if we could turn to**
 4 **page 4, Section 3 .2, just back up a little**
 5 **bit here. I'm sorry. Section -- yes. Thank**
 6 **you.**
 7 **And hear it talks about patient**
 8 **preference; is that correct?**
 9 **A. That's correct.**
 10 **Q. Okay. And let's see here. The**
 11 **two groups reported similar subjective ratings**
 12 **for dose effects.**
 13 **Do you see that?**
 14 **A. That is correct.**
 15 **Q. And those two groups, the one**
 16 **group is the film group and one group is the**
 17 **tablet group. That's how you read that?**
 18 **A. Yes.**
 19 **Q. Okay.**
 20 **A. That's fine.**
 21 **Q. And then a little bit, right after**
 22 **we pick up a little bit further in that**
 23 **sentence, so dose ratings, sedation craving and**
 24 **withdrawal effects, those are all, those are all**

1 **reported as similar. And then it says, ease of**
 2 **use, convenience and taste between the tablet**
 3 **and the film groups.**
 4 **So similar subjective ratings in**
 5 **this well-controlled study that you, that you**
 6 **have talked about, ease of use, convenience and**
 7 **taste, were all seen as similarly subjective**
 8 **ratings between tablets and films, according to**
 9 **the study reports; is that right?**
 10 **A. That is correct.**
 11 **Q. Okay. We can go ahead and take**
 12 **that off.**
 13 **Overall patient satisfaction. Are**
 14 **you aware that Reckitt internally has done**
 15 **studies from time to time with respect to the**
 16 **overall satisfaction of patients with the**
 17 **tablets or then subsequently with Suboxone**
 18 **film?**
 19 **A. I've heard about internal studies,**
 20 **but I'm not privy to the results.**
 21 **Q. All right. And so you have**
 22 **never -- you've never seen any results of those**
 23 **studies?**
 24 **A. No, I did not.**

1 Q. And in connection with preparing
2 your report on commercial success on the
3 attributes and what patients think, Reckitt
4 didn't share any of that information with you?

5 A. You referred to my expert report;
6 is that correct?

7 Q. I'm just asking at any point if
8 they shared it with you?

9 A. No. Reckitt did not provide me
10 with any kind of information.

11 Q. Okay. You spoke a little bit
12 about diversion today. Diversion is still a
13 problem for Suboxone film; is that correct?

14 A. Diversion is a problem for
15 Suboxone and all prescription narcotics.

16 Q. And you spoke about abuse.
17 Specifically, abuse of Suboxone tablets. Abuse
18 is still a problem for Suboxone film; is that
19 correct?

20 A. That has been reported. That's
21 correct.

22 Q. And you talked about dissolution
23 time and dissolving and the difference between
24 tablet and film, in your opinion.

1 Do you know, would it be possible
2 to add disintegrant ingredients to the tablet to
3 make it dissolve faster?

4 A. Theoretically, it's possible, but
5 I'm not privy to any information to substantiate
6 that.

7 Q. That would be outside of your
8 expertise, the formulation of tablets?

9 A. Absolutely.

10 Q. Okay. And you spoke about
11 friability, the tablets breaking.

12 It's correct that the problem that
13 you identified was in pill jars; is that
14 correct?

15 A. That is correct.

16 Q. And that's because the tablets,
17 when Reckitt was selling Suboxone tablets, they
18 were prescribed in just the orange pill jar that
19 you get any medication in and there would be 30
20 tablets, however many tablets you would
21 prescribe, just in a single pill jar; is that
22 correct?

23 A. That's correct. They're orange
24 tablets in a regular pill jar.

1 Q. Thank you.

2 And you agree that if those
3 tablets were individually wrapped, for example,
4 in a blister pack, that that issue of friability
5 would be addressed?

6 A. That is not absolutely correct
7 because the tablets themselves are friable.
8 Even a blister pack, for example, you squeeze a
9 blister pack, it could break. You accidentally
10 put it in a pocket, it can break. So I would
11 not consider the blister pack as the solution of
12 choice in order to address the friability.

13 Q. You recall I asked you this same
14 question at your deposition?

15 A. That is correct.

16 Q. And could I get the transcript,
17 page 124 on the screen.

18 And, Dr. Wollschlaeger, the
19 question starts on line 5:

20 So would you agree that the
21 problem associated with breaking of a pill in
22 the containers, the friability and the breakage
23 within a pill bottle would be addressed by
24 separately packaging Suboxone tablets in a

1 blister pack, correct?

2 And what was your answer at that
3 time?

4 A. That is correct.

5 Q. Thank you.

6 And if Suboxone tablets were
7 individually packaged, if we had individual
8 packaging for a tablet like there is for
9 Suboxone film, it would be just as easy to
10 carry around individual dosages; is that
11 correct?

12 A. Portability would be addressed.
13 That's correct.

14 Q. All right. And as you said, the
15 importance to proper dosing, importance to
16 safety, including pediatric safety, is addressed
17 principally in your opinion by the training of
18 the patient; is that correct?

19 A. Training is one of the components.
20 The education of the patient is one of the
21 components where the pediatric safety can be
22 addressed.

23 Q. And it is certainly important and
24 as important, if not more so, than the dosage

1 form; is that correct?

2 A. It is important independent of the

3 dosage form.

4 Q. Thank you.

5 Now, when -- at what point -- you

6 heard at some point in time that Reckitt was

7 planning to withdraw the Suboxone tablet, and

8 the stated reason for withdrawing the Suboxone

9 tablet was pediatric safety; is that correct?

10 A. One of the stated reasons was

11 pediatric safety.

12 Q. Okay. And the pediatric safety

13 issue, I think as you talked about already a

14 little bit today, is the potential unintended

15 exposure of children to this drug; is that

16 correct?

17 A. That is correct.

18 Q. And that issue was addressed in

19 Suboxone film by packaging; is that correct?

20 Not by the dosage form?

21 A. By packaging and the dosage form

22 in the film.

23 Q. And if you turn -- if I could have

24 up your deposition, page 134, please.

1 And so I asked you at line 22 at

2 your deposition: So if issue of pediatric

3 safety, in your opinion, would be related to the

4 packaging of the film, or the packaging of the

5 tablet, and whether or not it was similarly

6 child-resistant; would that be fair?

7 And your response there was?

8 A. In theory, yes.

9 Q. All right. And then I also asked

10 you later: If a Suboxone tablet was packaged in

11 individual dosage form, the same as the Suboxone

12 film, it would be as safe as the packaged

13 Suboxone film strip. And you agreed that that

14 was correct?

15 A. Can you show me that, please?

16 Q. Well, let me -- before we go

17 there, let me just ask you the question. It's

18 correct that if Suboxone tablets had simply been

19 individually wrapped in a child-safe wrapping,

20 that they would have the, be as safe from a

21 pediatric exposure standpoint as Suboxone film;

22 is that correct?

23 A. In theory, yes, but it wouldn't

24 address friability.

1 Q. So they, it is correct that

2 pediatric safety would be addressed, by

3 packaging in a pediatrically safe

4 child-resistant package; is that correct?

5 A. As part of pediatric safety

6 program, yes.

7 Q. And you didn't do anything in your

8 work here to familiarize yourself with the

9 patents or the claims in the patents at suit; is

10 that correct?

11 A. No. That was not the scope of my

12 task.

13 Q. And there's nothing in your

14 testimony regarding anything that you've

15 testified about that you believe would connect

16 any of these issues to any of the claims in the

17 patent, is there?

18 A. That is correct.

19 Q. Thank you.

20 MR. SMEREK: Nothing further, your

21 Honor.

22 THE COURT: All right. Is there

23 any redirect?

24 MS. BOURKE: Nothing further, your

1 Honor.

2 THE COURT: All right, Doctor.

3 You may step down.

4 THE WITNESS: Thank you, your

5 Honor.

6 THE COURT: Thank you.

7 All right. So why don't we take

8 our morning break? It will be 15 minutes. All

9 right? We'll be in recess.

10 (Short recess taken.)

11 - - -

12 (Proceedings resumed after the

13 short recess.)

14 THE COURT: All right. Please be

15 seated.

16 Plaintiffs, call your next

17 witness.

18 MR. BOLLINGER: Thank you, your

19 Honor. If it please the Court, we call Dr. Lon

20 Mathias to the stand.

21 Your Honor, we have a small set of

22 demonstrative slides and which we'd like to hand

23 up.

24 THE COURT: All right. Please do

1 so.
 2 (Mr. Bollinger handed slides to
 3 the Court.)
 4 ... LON JAY MATHIAS,
 5 having been duly sworn as a
 6 witness, was examined and testified as
 7 follows ...
 8 MR. BOLLINGER: Your Honor, also
 9 some exhibit books. These are the actual
 10 exhibits. If I could hand those up also?
 11 THE COURT: All right.
 12 (Bollinger handed exhibit books to
 13 the Court.)
 14 MR. BOLLINGER: Okay. If it
 15 please the Court.
 16 DIRECT EXAMINATION.
 17 BY MR. BOLLINGER:
 18 Q. Dr. Mathias, good morning. I
 19 would like you, if you could, just recognizing
 20 that your CV has already been reviewed by the
 21 Court, if you could briefly touch upon some of
 22 your experiences that relate to this, the
 23 disputes in this case?
 24 A. Sure. I started my career in

1 polymer science as an undergraduate at the
 2 University of Iowa. I moved to the University
 3 of Michigan for a Ph.D., did a post-doctoral
 4 fellowship in polymers at the University of
 5 California in San Diego.
 6 Took a -- my first teaching
 7 position at Auburn University, teaching
 8 chemistry and polymer chemistry, and then
 9 moved to the department of polymer science
 10 at the University of Southern Mississippi in
 11 1981.
 12 Q. Now, we've heard about
 13 polyethylene oxide and what we've been calling
 14 PEO for short. Have you had experience working
 15 with polyethylene oxides in the past?
 16 A. Yes, I have.
 17 Q. Can you just briefly describe
 18 those?
 19 A. We've used polyethylene oxides in
 20 our research projects. We've incorporated it
 21 into various polymers for both academic and
 22 commercial interest. We've also developed
 23 experiments using polyethylene oxides for our
 24 laboratory. We include PEO as an important

1 example of commercial polymer in the courses
 2 that we teach as well.
 3 Q. All right. And there has also
 4 been a test called GPC, or what we call gel
 5 permeation chromatography. Just touch off some
 6 of the experiences you've used that or relied on
 7 it in the past?
 8 A. We've used GPC throughout my
 9 career. It has been it's a technique that has
 10 been available for a long time. We've had -- in
 11 my research group we've had several different
 12 GPC instruments, and I've trained students on
 13 how to use those instruments and get data or
 14 characterization.
 15 Q. All right.
 16 MR. BOLLINGER: Your Honor, Dr.
 17 Mathias is, his CV, as you have seen is at
 18 JTX-008. And we'd offer Dr. Mathias as an
 19 expert in polymer chemistry and the analytical
 20 techniques for measuring polymeric properties.
 21 THE COURT: All right. You may
 22 proceed.
 23 BY MR. BOLLINGER:
 24 Q. In this case, can you tell me

1 briefly what materials you have reviewed in
 2 pursuing the objectives of your analysis?
 3 A. Sure. I looked at the '150 patent
 4 itself. I looked at the Court's claim
 5 construction. I looked at Watson's ANDA
 6 document, selected portions of that.
 7 I reviewed the expert reports of
 8 Dr. McConville and doctor empty (who? (And I
 9 looked at the expert reports of Dr. Yau.
 10 Q. And after you reviewed these
 11 materials, did you reach a conclusion about
 12 whether the -- about the question of
 13 infringement of the '150 patent?
 14 A. Yes, I did.
 15 Q. And what was that conclusion?
 16 A. My conclusion is that the Watson
 17 product infringes claims 1 and 4 of the '150
 18 patent.
 19 Q. All right. We're going to talk a
 20 little bit in detail about the underlying
 21 premise of that conclusion, but before we do
 22 that, I'd like you, if you could, just briefly
 23 explain something about your understanding of
 24 the '150 patent or technology it embraces. And

1 so we'll put that up on the screen.
 2 A. At a high level, this patent deals
 3 with dissolvable films made from various
 4 water-soluble polymers that are used in drug
 5 delivery for drugs to be delivered under the
 6 tongue.
 7 Q. Thank you.
 8 MR. BOLLINGER: And, your Honor,
 9 the actual patent is at JTX-001, which is, I
 10 think, the next exhibit in the -- as listed in
 11 the exhibit book, the larger of the two books.
 12 BY MR. BOLLINGER:
 13 Q. Now, Dr. Mathias, did you assist
 14 in preparing these slides that we're going to go
 15 through today?
 16 A. Yes, I did. I worked with lawyers
 17 and graphic artists.
 18 Q. All right. Let's turn to the next
 19 one, which I think is a breakdown of claim 1 and
 20 4. And can you describe why it's set up this
 21 way and why you're going to be referring to it
 22 in this fashion?
 23 A. The column on the right is the
 24 words of the claims themselves. The column on

1 the left are some keywords or key topic
 2 associated with the individual limitations of
 3 those claims.
 4 Q. All right. And do you have an
 5 appreciation as to what is really in dispute
 6 here? Do you know whether Watson has agreed
 7 that their product, their proposed ANDA product
 8 actually meets several of these limitations?
 9 A. Yes, I do. I read the joint
 10 statement of admissions, and this slide
 11 summarizes what is not in dispute.
 12 Specifically, limitation 5, which is claim 4,
 13 and limitations 1 through 3 of claim 1.
 14 Q. All right. Very good.
 15 MR. BOLLINGER: And, your Honor,
 16 these are the joint statement of admitted facts
 17 at paragraphs 107 to Section 117.
 18 BY MR. BOLLINGER:
 19 Q. So what does that leave us to work
 20 on today?
 21 A. That leaves limitation four
 22 concerning the PEO molecular weight properties.
 23 Q. All right. And this is -- this
 24 has already been subject to a Court's claim

1 construction. Did you have a chance to review
 2 that?
 3 A. I did, yes.
 4 Q. All right. I think that's on the
 5 next slide.
 6 A. Yes.
 7 Q. As you see, the Court has
 8 construed this. Can you briefly summarize your
 9 understanding and the way you applied this
 10 Court's construction?
 11 A. Well, at a high level, it deals
 12 with the requirement that the, the material
 13 infringing the patent have two separate or
 14 discrete sets of polyethylene oxide PEO, that
 15 they have average molecular weights within
 16 certain ranges, and that the lower molecular
 17 weight comprise certain amount of the total
 18 polymer present in the material.
 19 Q. All right. And before we get to
 20 the details of the analysis of that particular
 21 limitation, can you briefly describe why it's
 22 important to have two fractions of PEO,
 23 polyethylene oxide, a high and a low fraction as
 24 you understand it for this claim?

1 A. Yes. In fact, the next slide, I
 2 think, has a statement from the patent itself.
 3 The patent teaches that both the
 4 low molecular weight, a balance of the low
 5 molecular weight and high molecular weight is
 6 important. The low molecular weight contributes
 7 certain properties to the processing and to the
 8 film itself, such as the dissolution rate. The
 9 high molecular weight material, even in small
 10 amounts, impacts physical properties, such as
 11 tear resistance and strength.
 12 Q. All right. Now, what do you
 13 understand about Watson's proposed ANDA and its
 14 use of PEO?
 15 A. Well, ANDAs, Watson's description
 16 of their material describes only a single PEO
 17 material, the N80. I believe that's on the next
 18 slide. Yes.
 19 If we look at the composition
 20 statement, we see a list of polyethylene oxide
 21 of 200K. To find out which polymer they are
 22 referring to specifically, we look at the
 23 approved manufacture document, we see that that
 24 polymer is a Polyox 80 supplied by Dow Chemical.

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1 Q. Do you know anything about this
2 product that Dow manufactured, Polyox?
3 A. How it manufactures Polyox?
4 Q. Yes.
5 A. Yes.
6 Q. And can you briefly describe that?
7 I think we have the actual Dow brochure that was
8 an exhibit in this case.
9 A. This is the brochure that Dow
10 provides online, so it's open access.
11 The diagram that's here basically
12 summarizes the incorporation of the raw
13 materials into a reactor. That reactor carries
14 out the polymerization. Once the polymerization
15 is done, the polymer is dried and then put into
16 a storage bin.
17 The important point here is that
18 the storage bin contains more than one batch of
19 a polymer. So multiple batches are combined and
20 then sent to a blending unit where they are made
21 homogeneous.
22 It's my understanding based on
23 this diagram that that blended material is then
24 characterized to see if it meets the

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1 specifications for the target blend.
2 The arrow that's shown here going
3 back to storage seems to imply that that blend,
4 if it does not meet specification, will be
5 brought back, blended again with some additional
6 batches, and then reblended and sent to
7 packaging.
8 Q. When you say "blend," what do you
9 mean?
10 A. The material that's obtained from
11 the reactors are powders, and so the blending
12 process is a physical blending of powdered
13 material.
14 Q. Now, you also indicated that this
15 is labeled something like 200K. Do you
16 understand that to be an average molecular
17 weight?
18 A. Viscosity average molecular
19 weight, yes.
20 Q. And is there any way to determine
21 precisely what the distribution of molecular
22 weight polymer in a batch such as the N80?
23 A. Yes, there is.
24 Q. What is that technique?

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1 A. That would be GPC.
2 Q. All right. And can you briefly
3 explain to us how GPC works?
4 A. From a permeation chromatography,
5 is also called size exclusion chromatography, or
6 SEC. It involves a very simple concept
7 conceptually, but a very powerful technique for
8 analyzing polymers.
9 The diagram here on the left shows
10 a column. That column is packed with beads.
11 The beads have different size pores, and those
12 different size pores allow different size
13 polymer chains to enter or not enter, that's the
14 polymer solution transverse, the column going
15 down.
16 So what happens is, high molecular
17 weight polymer is absorbed or is able to
18 penetrate fewer of the pores and therefore comes
19 out faster than lower weight molecular material.
20 What that means is on the third graphic there on
21 the right, that the high molecular weight
22 material would come out first and then gradually
23 decrease. The molecular weight material would
24 elute from the column.

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1 Q. So the very largest molecules come
2 out very quickly from the column?
3 A. Yes.
4 Q. And then the very small ones take
5 longer, progressively smaller, progressively
6 longer?
7 A. Yes.
8 Q. All right. Thank you.
9 And what do you understand about
10 the Polyox in terms of poly dispersity? Is
11 there a characterization of the Polyox N80 that
12 you can give us?
13 A. Well, Polyox N80 is a commercial
14 polymer, and almost all commercial polymers are
15 made in such a way that the broad molecular
16 weight distribution, it's just inherent in the
17 synthesis in the way that they are made. That
18 broad distribution then leads to both low and
19 high molecular weight, and the only way to
20 figure out if they are in there is to do
21 techniques such as this.
22 Q. All right. And you saw during the
23 opening today counsel for defendant suggesting
24 that a product such as Dow was a unimodal

1 distribution. Therefore, it had no high
 2 molecular weight product. Is that a correct way
 3 to look at it?
 4 A. No.
 5 Q. And why not?
 6 A. Well, because just the shape of
 7 it, of the chromatogram doesn't tell you whether
 8 there's high and low molecular weight. You have
 9 to actually look at the values of the plot.
 10 Q. All right. And is that possible
 11 with GPC?
 12 A. Yes, it is.
 13 Q. And do you know whether GPC was
 14 done on the N80 sample? I'm sorry. I'm getting
 15 ahead of myself.
 16 I would like to, we have another
 17 slide that kind of expand on the discussion of
 18 how GPC works. Can we turn to that?
 19 A. If we start on the upper left, we
 20 have a depiction of a mixture of polyethylene
 21 oxide of different sizes, different molecular
 22 weights. After the chromatograph separation, we
 23 see a well characterized distribution from low
 24 to high molecular weight, which are plotted in

1 the bottom figure going from low on the left to
 2 high on the right. That's a long molecular
 3 weight scale, so the numbers are small, but it
 4 represents several thousands on the left to
 5 several million on the right.
 6 This is a very broad distribution
 7 consistent with this commercial source. The Y
 8 axis represents a relative amount or a mass
 9 fraction of each one of the molecular weights
 10 that is depicted on this.
 11 Q. And this diagram at the bottom,
 12 obviously, you're using it as typical for a GPC,
 13 although I'm not sure that's, whether there is
 14 such a thing as typical.
 15 Was GPC performed in this case on
 16 the N80 sample?
 17 A. Yes, it was.
 18 Q. And do you know who performed that
 19 testing?
 20 A. That testing was done by Dr. Yau.
 21 Q. All right. And can you just
 22 briefly describe your, the information you
 23 have about his background and his work on this
 24 case?

1 A. Dr. Yau has been working on GPC
 2 for longer than I have. He has been doing GPC
 3 for almost 50 years I understand. He has
 4 developed many of the new methods of analysis
 5 using GPC that provide additional information or
 6 different accuracy precision in the method. He
 7 has also authored one of the key reference books
 8 on GPC analysis, and that reference book is
 9 available in my lab. It's used by virtually
 10 everybody that does GPC.
 11 Q. Thank you.
 12 And can you tell me briefly, did
 13 you review the protocol that Dr. Yau used in
 14 analyzing the Watson's N80 Polyox?
 15 A. I did, yes.
 16 Q. And did you find it acceptable for
 17 the analysis?
 18 A. Yes.
 19 Q. Did you rely on it?
 20 A. Yes.
 21 Q. Did you look at the results that
 22 he prepared?
 23 A. Yes.
 24 Q. And do you rely on it for your

1 opinion today?
 2 A. I did, yes.
 3 Q. All right. So we're going to turn
 4 to the next figure, which is the diagram that I
 5 think we've seen several times this morning,
 6 which is the results of the analysis by Dr. Yau
 7 on the -- can you describe briefly what this
 8 is?
 9 A. Well, what Dr. Yau is did is by a
 10 commercial sample of Polyox, break that into
 11 three separate portions, and then make up
 12 solution with each one of those portions.
 13 He analyzed each portion then
 14 three times, which gave a total of nine GPC
 15 runs. All nine of those GPC runs are shown in
 16 this similar file. They overlay each other so
 17 closely that it's very difficult to separate the
 18 individual chromatograph.
 19 Q. This --
 20 A. This speaks very highly to the
 21 precision of the method and the care with which
 22 the analysis was done by Dr. Yau.
 23 Q. In reviewing this data, did you
 24 reach a conclusion as to the type of

1 distribution just demonstrated or presented
2 here?

3 A. Well, it's a broad polydisperse
4 distribution. It shows a unimodal shape, which
5 basically is one peak. It's more or less
6 symmetrical. It's the kind of peak you would
7 expect for a typical commercial PEO.

8 Q. Okay. And the fact that it's a
9 unimodal distribution, does that, in your mind,
10 remove the possibility there might be two
11 discrete sets, one high molecular weight, one
12 low molecular weight?

13 A. No, it does not.

14 Q. And why is that?

15 A. Well, one, we know that Dow
16 combines various reactor batches do make their
17 grades of PEO that they sell.

18 And, two, there has been work done
19 that shows that combining materials, combining
20 different grades of PEO can lead to and does
21 lead to unimodal distribution.

22 Q. And what work are you referring
23 to?

24 A. This is a paper by Dow

1 researchers. It was four researchers from their
2 central facility, I understand. It was
3 published in a paper that I referred to as the
4 L'Hote paper.

5 MR. BOLLINGER: Can we bring up an
6 image of the L'Hote paper? I'm sorry. I was
7 thinking the paper.

8 BY MR. BOLLINGER:

9 Q. Can you describe what the next
10 slide is?

11 A. This is an excerpt, the graph
12 table or an excerpt from this table. The
13 researchers state that one of the key questions
14 they were asking in this project was to
15 determine whether or not if they blended two
16 grades of PEO that were separated by almost
17 400,000, whether those blends would show bimodal
18 and unimodal distributions.

19 The blends themselves are listed
20 at the bottom of the table, 2575, 7525, and they
21 compare that, those blends, to a standard
22 material which was, which had a molecular weight
23 just between those two upper and lower values,
24 these blends. All six plots for the standard

1 and blended materials were given on this
2 chromatograph, this plot. What we see, there
3 is clearly only unimodal distributions given
4 here. In fact, the authors of the paper state
5 that they saw no evidence of bimodal
6 distribution.

7 Q. And does this in your mind clarify
8 the question as to whether two discrete sets can
9 reside in Dr. Yau's data from the N80?

10 A. Of course.

11 Q. And can you explain the notion of
12 how to look at a single unimodal distribution
13 and determine with GPC data how or where there
14 are multiple sets at different molecular
15 weights?

16 A. The only way we can do that is to
17 partition the data into two discrete sets, and
18 this is a method that is commonly used. We use
19 it for looking at how old you have to be to
20 retire, and we use it in college for GPA and
21 standardized test results to determine who gets
22 scholarships and who doesn't.

23 Q. Can we go to the next slide? We
24 have an illustration of how you're looking at

1 this.

2 A. Yes. This is an illustration I
3 came up with. Imagine you have a basketball
4 coach whose center pulls a hamstring and is out
5 of play. So he asks for tryouts. He recruits a
6 whole group of students who have an average
7 height of 5 feet 8 inches, but he knows that his
8 center has to have certain physical
9 characteristics, so he divides the group into
10 one group, 5 feet 2 inches high, another group,
11 5 feet 11 inches high, and he concentrates his
12 efforts for try out for the higher, the taller
13 group.

14 Q. Is this similar to -- well, let me
15 ask you this. Before we get to that, is this
16 something that has been done with the molecular
17 weight data in the past?

18 A. Yes, oftentimes.

19 Q. Can you explain briefly the types
20 of information you have been able to collect
21 when this question came up?

22 A. Yes. The, I think the next slide
23 has an excerpt from a paper that I examined.
24 This was a -- one of many papers that deals with

1 this kind of analysis. This particular paper,
 2 and the one that follows, both deal specifically
 3 with PEO. So I thought they would be
 4 appropriate examples for this kind of case.
 5 What these workers did is examine
 6 a broad molecular weight PEO similar to what is
 7 done here, and found that to understand the
 8 dynamic modules or the solution properties of
 9 that broad molecular weight sample, they had to
 10 analyze the material that's two separate
 11 fractions, one a high molecular weight
 12 fraction and the rest comprising the rest of the
 13 sample.

14 Q. And is there any other literature
 15 that you identified that relates to this concept
 16 of fractionate go a unimodal sample?

17 A. Yes. Among others is the next
 18 paper dealing with PEO.

19 Q. And is --

20 A. It didn't show up. Here we go.

21 Again, they examined a broad
 22 molecular weight fraction, compared it to some
 23 low molecular weight polymers that they had, and
 24 found that they could only correlate the results

1 if they considered the high molecular weight
 2 fraction in the broad distribution materials
 3 separately from the low molecular weight
 4 material. Then they referred to it as the tail,
 5 the upper tail in the molecular weight
 6 distribution.

7 Q. All right. Now, these articles
 8 are in the, the exhibit binder under JTX-0076
 9 and 0040, the full articles.

10 In looking at this concept, and I
 11 think we saw a slide earlier that said the
 12 lawyers picked the 600,000 for the partition.
 13 Can you tell me how that number was selected and
 14 explain kind of the thinking that went behind
 15 it?

16 A. Well, once we had the
 17 chromatographic information, we combined that
 18 with what we know about the limitations in the,
 19 in the patent.

20 One of the things we know is that
 21 the low molecular weight must comprise
 22 60 percent or more of the low molecular weight
 23 fraction. So to divide this so that that
 24 criterion is met, you would have your line drawn

1 to the right of the peak, somewhere at the upper
 2 end.

3 Looking at the patent, we see
 4 demarcations of 100 and 300,000. Those make no
 5 sense in terms of that. The 600 to 900,000 is
 6 where we concentrate, and the lower end of the
 7 600,000 is the most rational place to put that
 8 mark.

9 Q. All right. And is that the number
 10 you selected for the analysis that Dr. Yau
 11 provided?

12 A. Yes.

13 Q. And you provided that information?

14 A. To the lawyers, yes.

15 Q. And can you briefly explain what
 16 happens when you put the partition at 600,000?
 17 Go to the next slide.

18 A. You separate the PEO into two
 19 discrete sets, one of high molecular weight that
 20 comprises only about 1.9, almost two percent by
 21 weight of the total sample, and that material
 22 has an average, viscosity average molecular
 23 weight of 900,000, which is in the range of 600
 24 to 900,000.

1 Q. And if we could go to the next
 2 slide.

3 A. The remainder of the polymer
 4 sample comprises 98 percent by weight. That
 5 material has a, a viscosity average molecular
 6 weight calculated to be in the range of 100 to
 7 us to 300,000.

8 Q. All right. And in looking at
 9 those numbers, you concluded that there was
 10 infringement here; is that correct?

11 A. That's correct.

12 Q. Now, the ranges 100 to 300, 600 to
 13 900, can you give me a metaphor or an
 14 illustration of why it was appropriate to say
 15 these numbers met those ranges?

16 A. Sure. If I go to the store and
 17 buy apples, it's labeled in a five-pound bag,
 18 for example, and no one understands that that
 19 five-pound bag is exactly five pounds of
 20 apples.

21 So if we brought in a scale and
 22 measured the five bound bags from the entire bin
 23 of apples, it would be surprising if we actually
 24 found a bag that weighed exactly 5.00 pounds.

1 **Everybody understands it, from the marketing to**
 2 **the owner of the store to the customers, that**
 3 **there's a certain amount of variation in that**
 4 **five-pound designation. And if we look to the**
 5 **patent, the patent discusses PEO and PEO grades**
 6 **in increments of 100,000 units. The**
 7 **manufacturer Dow sells their material in**
 8 **increments of a hundred thousand. All of the**
 9 **suppliers I look at similar sell the material in**
 10 **increments of a hundred thousand.**

11 **So the way that it's normally**
 12 **considered in this area for PEO, 95,895, which**
 13 **is a mathematical consequence of the analysis,**
 14 **is actually 100,00.**

15 **Q. And do you have any understanding**
 16 **about the variability of the PEO sold by Dow?**

17 **A. Yes. If we look at their**
 18 **specification, say they use viscosity molecular**
 19 **weight, a concentrated solution technique. The**
 20 **ranges given for those, for the N80 sample being**
 21 **discussed here, are somewhere between, are in**
 22 **the range of 55 to 90, or 55 to 115, depending**
 23 **on which document you look at. Those ranges**
 24 **correspond to plus or minus 15 or 16 percent.**

1 **So I would use those same ranges,**
 2 **that same value, or make even a slightly smaller**
 3 **value to represent the range that would be**
 4 **represented by a given analysis.**

5 **Q. We've been kind of characterizing**
 6 **this as average molecular weight. Do you**
 7 **understand, can you express a little bit more**
 8 **precisely, we saw there are several different**
 9 **averages available.**

10 **A. Yes. One thing we can do is go to**
 11 **the -- well, first of all, we should consider**
 12 **that almost all commercial polymers are**
 13 **characterized by viscosity molecular weight.**
 14 **That's the way that is easiest, quickest, and**
 15 **most accurate to use.**

16 **I think Dr. McConville's report or**
 17 **testimony and Dr. Amogeas (phonetic), they agree**
 18 **that viscosity average, molecular weight, was**
 19 **the most commonly used.**

20 **If we look at the patent itself,**
 21 **several examples in the patent, there's Table 1,**
 22 **describe using Dow materials. Those materials**
 23 **again are characterized by viscosity, molecular**
 24 **weight.**

1 **If we look at the prosecution**
 2 **history for the patent, there's a reference to a**
 3 **book, a book by Flick on water soluble resins,**
 4 **and he again lists the molecular weight for Dow**
 5 **for Polyox grades.**

6 **MR. SMEREK: Objection, your**
 7 **Honor. There's no discussion regarding the**
 8 **Flick reference anywhere in Dr. Mathias' expert**
 9 **report, nor was there any discussion regarding**
 10 **the Flick reference at any time during his**
 11 **deposition.**

12 **MR. BOLLINGER: Your Honor, I**
 13 **disagree with that. He, Dr. Mathias actually in**
 14 **his opening report mentioned and discussed his**
 15 **review of the prosecution history, which**
 16 **obviously includes the Flick reference, and he**
 17 **also referred to this Court's Markman ruling.**
 18 **And that's at paragraph 1, I'm sorry, paragraph**
 19 **14 of the materials he reviewed.**

20 **And then in paragraph 33, he also**
 21 **spoke, I'm sorry, 34, said, given as I**
 22 **understand that the Court noted at page 8 of its**
 23 **claim construction decision viscosity related**
 24 **average molecular weight is used in regard to**

1 **commercially sold PEO, one of ordinary skill in**
 2 **the art would understand that molecular weights**
 3 **range in the '150 using the Court's construction**
 4 **average molecular weight to refer to viscosity**
 5 **average molecular weight.**

6 **And if you go to the Court's claim**
 7 **construction at that point, that's precisely**
 8 **what the Court referred to in reaching that**
 9 **conclusion, the Flick article. And that's at**
 10 **page 8 of your decision, where it identifies**
 11 **defendants argue that persons skilled in the art**
 12 **would not know of what measure, continue to the**
 13 **end.**

14 **Defendants' expert, however,**
 15 **points to prosecution history of patent using**
 16 **viscosity average. For example, DI-107-5 at**
 17 **1516, which is precisely what he's referring to**
 18 **hear.**

19 **THE COURT: All right. And so in**
 20 **his report, he never actually says Flick**
 21 **anywhere?**

22 **MR. BOLLINGER: He does not**
 23 **explicitly state it, but he does actually refer**
 24 **to the trail that you opened in your Markman**

1 ruling in construing the claim the way he did.

2 THE COURT: All right. I'm going
3 to sustain the objection.

4 MR. BOLLINGER: Thank you.

5 BY MR. BOLLINGER:

6 Q. Let's move on to the next slide.

7 A. Well, before we leave that,
8 there's actually one more piece of evidence that
9 viscosity molecular average --

10 Q. Okay. What is that?

11 A. That's the L'Hote paper. I don't
12 know if we can bring that up. There's a
13 reference there that I think is very relevant.

14 The L'Hote paper was looking
15 specifically at whether there was by molar or
16 unimodal distribution, but they also made the
17 statement -- and these are Dow researchers.
18 They made the statement that the approximate
19 molecular weights, and I'm paraphrasing, the
20 approximate molecular weights and their product
21 literature, (Viscosity average molecular
22 weight), are what are being used in this
23 evaluation.

24 Q. We'll jump back to that. I'm

1 sorry. Here it is. This is the paper you're
2 talking about?

3 A. Yes.

4 Q. And we talked a little bit about
5 that with that, those six, I'm sorry, unimodal
6 distributions. What page is on it?

7 A. I think it's on the fourth or
8 fifth page. I'm sorry. Too far down. Just a
9 little bit -- right there, yes.

10 If we look halfway down that
11 paragraph, it says, a comparison of the
12 approximate molecular weight of standard Polyox
13 WSR provided in product literature (viscosity-
14 average molecular weight) to the molecular
15 weight. The sentence goes on. But the key here
16 is that they refer to their molecular weight as
17 viscosity average molecular weight.

18 Q. Thank you.

19 And so based on that, you
20 understood the claims to mean, be expressing
21 molecular weight in what terms?

22 A. Viscosity average.

23 Q. All right. Thank you.

24 If we can go to the -- now, we've

1 answered the questions regarding the two
2 discrete sets. Can you tell me how you
3 determined whether the 60 percent limitation had
4 been established?

5 A. Yes. The next slide actually
6 shows the calculations used for that. But each
7 of the dosage amounts on the left, we know the
8 amount of PEO and the amount of HPMC in
9 milligrams that are present in those doses.
10 Knowing the, from the SEC curve the amount of
11 high and low molecular weight PEO in the
12 samples, we can divide each one of those weights
13 by the total weight, and calculate 86 percent,
14 approximately two percent, and 12 percent of the
15 HPMC, and the 86 percent is clearly more than
16 the about 60 percent required.

17 Q. All right.

18 MR. BOLLINGER: Your Honor,
19 these calculations are at tab PTX-538 A, C, D
20 and G of the evidence book and the underlying
21 calculations.

22 BY MR. BOLLINGER:

23 Q. Now, one final question. The
24 issue of whether they're stray or not, can you

1 tell me briefly what your understanding of what
2 stray is and the amount of PEO at the high
3 molecular weight satisfies or is not stray?

4 A. I think the next slide deals with
5 that. Yes. This is one of the papers I
6 referred to in which they were looking at a
7 broad molecular weight distribution to evaluate
8 its rheological properties, the practical
9 solution properties. What they found was that
10 the properties observed are mainly attributed to
11 the influence of the high molecular weight
12 fraction. This is seen in many analyses, many
13 characterizations of broad molecular weight
14 polymers, and it's one of the reasons that we
15 sell, that we use broad molecular weight and not
16 low molecular weight.

17 The broad molecular weight
18 disproportionately affects certain key
19 properties such as tensile strength. And one of
20 the reasons for that depicted in the bottom
21 slide there, that figure that's pulled out, the
22 low molecular weight polymers in any given broad
23 molecular weight sample cannot handle, but the
24 high molecular weight materials, because they're

1 so long, can undergo entanglement, especially in
2 solids and that entanglement causes increasing
3 toughness and increasing tensile strength. So
4 the broad molecular weight material, the high
5 molecular weight material, even though it may be
6 a smaller amount, has a disproportionate amount.

7 Q. Thank you. Dr. Mathias, can you
8 now summarize what your opinion is on the
9 question of infringement of claims 1 and 4?

10 A. Yes.

11 Q. Go to the next slide.

12 A. The undisputed limitations are
13 check-marked and the only disputed limitation
14 was the PEO molecular weight. As I've shown
15 from the analysis that Professor Yau or Dr. Yau
16 carried out, there clearly is high molecular
17 weight in any polymer. Calculated the low
18 molecular weight molecular weight average. It
19 falls in the range. We calculated the high
20 molecular weight set average and it falls within
21 the range. And we know that the low molecular
22 weight is present in more than 60 percent.

23 So every one of the limitations is
24 met, and, in fact, the Watson product does

1 infringe.

2 Q. Thank you.

3 MR. BOLLINGER: And, your Honor,
4 that concludes the direct testimony. I have
5 some exhibits that were not part of the JTX
6 questioning we'd move into evidence that are in
7 your book. Those are specifically PTX-41 and
8 49.

9 JTX 031 and 041, I think, are
10 pre-admitted. Correct? And so, and then we had
11 Dr. Yau's entire report, which we were -- I
12 think we were going to offer it into evidence,
13 but I don't think we want to. But the slides
14 from Dr. Yau's reports we want to offer in. And
15 so we broke those out separately as 526 E, I, J,
16 and 538 A through H. But those are already
17 admitted, too.

18 So that would be -- I think you
19 objected to the report. We don't have any
20 problem not having the whole reporting in.

21 MR. NUTTER: We obviously would
22 object to the introduction of Dr. Yau's report
23 into evidence as well as the slides or the
24 exhibits to his report. Dr. Yau will be

1 testifying next, and if they use those exhibits
2 through him, then perhaps they're admissible.

3 There is some overlap between the
4 slides that Dr. Yau used and the slides that Dr.
5 Mathias used in his report, and if they want to
6 introduce the slides that were a part of Dr.
7 Mathias' report into evidence, have him talk
8 about those, we would consider that.

9 THE COURT: All right. So
10 Plaintiffs' Exhibit 41 and 49?

11 (Plaintiffs' Exhibit No. 41 and 49
12 were admitted into evidence.)

13 MR. NUTTER: No objection.

14 THE COURT: They're admitted
15 without objection. The one from Dr. Yau's
16 report, if Dr. Yau is the next witness, why
17 don't we deal with it with him.

18 MR. BOLLINGER: Yes. And then
19 figures, it's 526 A through J -- I'm sorry. And
20 they're excerpts, they're the tables from Dr.
21 Yau's reports that have the underlying data and
22 the charts that we saw.

23 THE COURT: All right. But so the
24 526 and the 538 --

1 MR. BOLLINGER: Okay.

2 THE COURT: -- I will hold that
3 until we have Dr. Yau testify.

4 MR. BOLLINGER: Thank you, your
5 Honor. Thank you very much. And appreciate
6 your help.

7 THE COURT: All right.
8 Cross-examination.

9 MR. NUTTER: Thank you, your
10 Honor. May it please the Court.

11 THE COURT: I'm sorry. Who are
12 you?

13 MR. NUTTER: I'm sorry. This is
14 Michael Nutter.

15 THE COURT: Okay.

16 MR. NUTTER: Winston & Strawn, on
17 behalf of defendant, Watson Laboratories.

18 THE COURT: All right.

19 CROSS-EXAMINATION

20 BY MR. NUTTER:

21 Q. Good morning, Dr. Mathias.

22 A. Good morning.

23 Q. I'd like to ask you a few

24 questions about your trial testimony today. But

1 before we do so, I'd like to get a better
2 understanding of your credentials.

3 MR. NUTTER: If I could have you,
4 Mr. Young, could you pull up Plaintiffs'
5 Demonstrative 1402.

6 BY MR. NUTTER:

7 Q. And I believe during your direct
8 examination, you testified that the '150 patent
9 is directed to dissolvable films for drug
10 delivery; is that right?

11 A. Yes. Based on water soluble
12 polymers, yes.

13 Q. Okay. But on a high level, the
14 '150 patent describes how to make a thin film
15 that's dissolvable for delivery of drug into a
16 human; is that correct?

17 A. Yes.

18 Q. Now, I'd like you --

19 MR. NUTTER: Mr. Young, could you
20 pull up PDX-1018.

21 BY MR. NUTTER:

22 Q. And this is a slide from the
23 opening that shows had your credentials; is that
24 right? And it identifies you as an expert in

1 the synthesis, characterization and use of
2 polymers; is that right?

3 A. Yes.

4 Q. And your expertise is not drug
5 delivery; is that correct?

6 A. That's correct.

7 Q. You do not have a degree in
8 pharmaceutical sciences?

9 A. I do not.

10 Q. And you're not a pharmaceutical
11 drug formulator, are you?

12 A. I am not.

13 Q. And you have no practical
14 experience in developing drug formulations; is
15 that right?

16 A. That's correct.

17 Q. In fact, you've never attempted to
18 formulate a thin film for sublingual drug
19 delivery, have you?

20 A. I have not.

21 Q. And you've never taught a class
22 dealing with pharmaceutical formulation, have
23 you?

24 A. No, I have not.

1 Q. And as you sit here today, you
2 don't have the skill set to make the sublingual
3 drug film described in the '150 patent; isn't
4 that right?

5 A. I would disagree with that.

6 Q. You've never made a sublingual
7 film ever before, have you?

8 A. Now that you ask. You ask that I
9 had the skill set to do so. I could, I could
10 reproduce the process to some degree, yes.

11 Q. To some degree, but you've never
12 made a sublingual film?

13 A. I have not.

14 Q. Thank you.

15 Now I'd like to talk about
16 Watson's accused ANDA products. You understand
17 that the PEO in Watson's ANDA products is Polyox
18 N80; right?

19 A. Yes.

20 Q. And that's manufactured by Dow
21 Chemical. Yes?

22 A. That's correct.

23 Q. And Dow reports the average
24 molecular weight for Polyox N80 to be 200,000

1 daltons. Yes?

2 A. That's correct.

3 Q. And you would AGREE with me that
4 claim 1 of the '150 patent requires any
5 infringing film to have a PEO between 600,000
6 and 900,000 daltons. You'd agree with that; is
7 that right?

8 A. There has to be a PEO there that
9 has that molecular weight, yes.

10 Q. And you'd also agree with me that
11 200,000 is not between 600,000 and 900,000?

12 A. The numbers, yes, correct.

13 Q. You'd also agree that Dow only
14 reports one viscosity average molecular weight
15 for Polyox N80. Yes?

16 A. They report a range, and that
17 range spans plus or minus 60 percent.

18 Q. The viscosity average molecular
19 weight that Dow reports for Polyox N80 is
20 200,000 daltons. Yes?

21 A. Yes. I misunderstood your
22 question. That's correct.

23 Q. That's the reported viscosity
24 average molecular weight that Dow reports for

1 **Polyox N80. Yes?**
 2 **A. That's correct.**
 3 **Q. And that's a single viscosity**
 4 **average molecular weight. Yes?**
 5 **A. Yes.**
 6 **Q. But claim 1 of the '150 requires**
 7 **two average molecular weights for PEO, 1 between**
 8 **100,000 and 300,000, and 1 between 600,000 and**
 9 **900,000. Yes?**
 10 **A. That's correct.**
 11 **Q. And that's why you and Dr. Yau**
 12 **chose to partition Polyox N80, so you could come**
 13 **up with two average molecular weights; isn't**
 14 **that right?**
 15 **A. I'm sorry. Could we go back to**
 16 **your previous question? I may not have**
 17 **understood that correctly. Could you ask that**
 18 **again?**
 19 **Q. I don't know what my last question**
 20 **was.**
 21 **A. I can't remember if you said**
 22 **molecular weights or molecular weight averages**
 23 **for those.**
 24 **Q. I believe I asked does claim 1**

1 **require two average molecular weights, one**
 2 **between 100,000 and 300,000, and another between**
 3 **600,000 and 900,000. I believe you responded**
 4 **yes.**
 5 **A. That's correct. Yes.**
 6 **Q. And because Dow only reports one**
 7 **viscosity average molecular weight for Polyox**
 8 **N80, you needed to partition it; isn't that**
 9 **right?**
 10 **A. That's what anyone skilled in the**
 11 **art would do, yes. They would use GPC to do an**
 12 **analysis and then partition.**
 13 **Q. But there's no discussion of**
 14 **partitioning in the '150 patent, is there?**
 15 **A. There is not.**
 16 **Q. Thank you.**
 17 **Now, I would like to look at the**
 18 **Court's claim construction. That's JTX 244.**
 19 **Now, I believe you discussed this**
 20 **on your direct, and you reviewed this prior to**
 21 **rendering your infringement opinion, did you**
 22 **not?**
 23 **A. I did, yes.**
 24 **Q. And if we could turn to page 10,**

1 **JTX 244, page 10. Thank you.**
 2 **MR. NUTTER: Mr. Young, if you**
 3 **could highlight the words combined, for example.**
 4 **It's about the seventh line down, for example.**
 5 **BY MR. NUTTER:**
 6 **Q. Now, the claim construction**
 7 **clearly states, for example, the description of**
 8 **the invention in the patent describes combining**
 9 **small amounts of the high molecular weight PEOs**
 10 **with larger amounts of the low molecular weight**
 11 **PEOs.**
 12 **And you agree with that statement,**
 13 **don't you?**
 14 **A. That's what it says, yes.**
 15 **Q. And you agree that one of the**
 16 **requirements of claim 1 is that the low**
 17 **molecular weight PEO be combined with the high**
 18 **molecular weight PEO. Yes?**
 19 **A. In the, in with the result that**
 20 **both of those be present in the final product,**
 21 **yes.**
 22 **Q. Okay. Now, I would like to look**
 23 **at one of the slides you discussed today,**
 24 **PDX-1412. And I believe you used this slide to**

1 **better explain your infringement analysis.**
 2 **On the left, you have one group of**
 3 **people, and perhaps you referred to it as a**
 4 **basketball team? I'm not sure.**
 5 **A. Tryouts for the basketball team.**
 6 **Q. And on the right you have, you've**
 7 **broken it up into two groups of people; is that**
 8 **right?**
 9 **A. Yes.**
 10 **Q. You've separated. You had one**
 11 **group you've separated into two groups? Yes?**
 12 **A. That is correct.**
 13 **Q. So as with the '150 features**
 14 **combining two groups, in order for you to find**
 15 **infringement, you have to separate into two**
 16 **groups, don't you?**
 17 **A. Yes.**
 18 **Q. Thank you.**
 19 **Now I would like to look at the**
 20 **partition analysis --**
 21 **A. I'm sorry. Can you restate that**
 22 **question? I think I answered too quickly.**
 23 **Q. You will have an opportunity for**
 24 **your counsel to ask questions again. I'm ready**

1 to move on to another question.

2 A. All right.

3 Q. I'd like to look now at the
4 partition analysis that you and Dr. Yau
5 conducted.

6 Now, I believe you testified
7 earlier that Dr. Yau, he purchased some Polyox
8 N80; right?

9 A. That's correct.

10 Q. And he conducted a GPC analysis on
11 it; is that right?

12 A. Yes.

13 Q. And that stands for gel permeation
14 chromatography; isn't that correct?

15 A. Yes.

16 MR. NUTTER: Mr. Young, if you can
17 put up PTX-143 for me.

18 BY MR. NUTTER:

19 Q. And you've certainly seen this,
20 this chart before. Yes?

21 A. Yes.

22 Q. This comes from the results
23 section of Dr. Yau's expert report, and these
24 were the results that you relied on in forming

1 your infringement opinion. Yes?

2 A. It's part of the results, yes.

3 Q. Okay. And what we're looking at,
4 I think everyone is in agreement, it's a
5 unimodal distribution curve. That's what Dr.
6 Yau came up with after completing his GPC
7 analysis; isn't that right?

8 A. That's correct.

9 Q. And this curve is for the entire
10 sample of Polyox N80. Yes?

11 A. Yes.

12 Q. And it's the type of curve you'd
13 expect to get when you examined Polyox N80 like
14 Dr. Yau did; right?

15 A. I don't know if the shape would be
16 exactly the same, but you'd expect a plot that
17 that was unimodal, yes.

18 Q. Like most PEOs, it has a broad
19 distribution. I think you testified about that
20 during your direct; is that right?

21 A. Yes.

22 Q. And like every PEO ever made, it's
23 a combination of low and high molecular weight
24 molecules, isn't it?

1 A. I don't know if I would go as far
2 as every, but all the ones that I'm familiar
3 with, yes, a broad distribution of high and low.

4 Q. All --

5 A. Except for calibration states.

6 Now, there are specific standards that are made
7 for specific applications, such as calibrating
8 GPC columns, and those are narrower
9 distribution.

10 Q. Excluding the ones made for
11 standard calibration curve, you're not aware of
12 any PEOs that are not already a combination of
13 low and high molecular weight molecules; is that
14 correct?

15 A. Yes. I indicated there's -- the
16 actual manufacturing process results in that.

17 Q. Is that a yes?

18 A. Yes.

19 Q. Thank you.

20 And because it's a collection of
21 molecules with different molecular weights,
22 you're able to come up with an average molecular
23 weight, aren't you?

24 A. You would have to do an analysis

1 of some kind, yes.

2 Q. Sure. And usually, the average
3 molecular weight for a distribution curve like
4 this, usually it's somewhere around the peak,
5 isn't it?

6 A. Given the shape of this curve,
7 yes, it's going to be close to the peak.

8 Q. And when the average is around the
9 peak, the molecules to the left of the peak,
10 it's at least smaller than the average size; is
11 that correct?

12 A. That's correct.

13 Q. And the molecules to the right of
14 the peak are typically larger than the average;
15 correct?

16 A. That's correct, yes.

17 Q. It's what you would expect to see?

18 A. Yes.

19 Q. And just like Dow was able to come
20 up with a single viscosity average molecular
21 weight, Dr. Yau was also able to come up with a
22 single viscosity average molecular weight for
23 his characterization of Polyox N80; is that
24 correct?

1 A. That's correct.

2 Q. But that single viscosity average
3 molecular weight that he calculated, if you
4 relied solely on is that, Watson would not
5 infringe; isn't that right?

6 A. I'm not, I'm not clear on the
7 question.

8 Q. I will rephrase. Dr. Yau
9 calculated the overall viscosity average
10 molecular weight for policy oh Polyox N80 to be
11 somewhere around 105,000 daltons; isn't that
12 right?

13 A. That's correct.

14 Q. And you would agree with me that
15 105,000 daltons is not between 600,000 and
16 900,000 daltons; is that right?

17 A. Yes, that's correct.

18 Q. And so because of that, you sat
19 down with plaintiffs' attorneys and decided that
20 this curve needed to be partitioned at the
21 600,000 dalton mark, didn't you?

22 A. No.

23 Q. That came after discussion with
24 plaintiffs' attorneys; correct?

1 A. No. I cite that.

2 Q. So you cited that in your report
3 to plaintiffs' attorneys; is that correct?

4 A. We had the claim construction, we
5 had the limitations of the patent, we had the
6 plots and the data from the plot, and I looked
7 at that and chose 600,000 because it was the
8 most reasonable place to go.

9 Q. Well, you came to that conclusion
10 after talking to the attorneys; isn't that
11 right?

12 A. In what regard? I mean, I was
13 talking with the attorneys throughout the entire
14 process.

15 Q. You did not reach the decision to
16 partition at the 600,000 dalton mark until after
17 discussing that with plaintiffs' attorneys;
18 isn't that correct?

19 A. No. They supplied me the data, we
20 looked at it, we talked about it. Of course.

21 Q. Okay. Thank you.

22 And you would agree with me that
23 this 600,000 dalton partition, it's at the tail
24 end portion of the uniform distribution curve?

1 Yes?

2 A. It's at the high marker rate, yes.

3 Q. And you and the lawyers, you
4 purposefully selected the 600,000 dalton mark
5 because it's at the lower end of the upper
6 molecular weight limit for claim 1; isn't that
7 right?

8 A. That's correct.

9 Q. You chose it because the upper
10 weight range is from 600,000 to 900,000, and so
11 you drew your partition at 600,000. That's why
12 you drew it there. Yes?

13 A. That's part of the reason, yes.

14 Q. You looked at claim 1 and said,
15 let's draw the line at 600,000. Yes?

16 A. The other considerations, such as
17 the 60 percent of low molecular weight that's
18 required.

19 Q. And to be clear, none of this is
20 discussed in the '150 patent. Yes? You agree
21 with me?

22 A. That's correct, yes.

23 Q. There's no discussion about taking
24 a PEO and fractionating it into a lower

1 molecular weight portion and a higher molecular
2 weight portion. There's no discussion of that
3 anywhere in the patent?

4 A. I'm not aware of any, no.

5 Q. Now, according to your partition
6 theory, everything to the left of that line,
7 that's the low molecular weight PEO required for
8 in claim 1; isn't that right?

9 A. Yes.

10 Q. And also according to your theory,
11 everything to the right of the line, that would
12 be the high molecular weight portion as required
13 for in claim 1. Yes?

14 A. That's correct.

15 Q. And so one of the questions that
16 you need to answer in doing your analysis is,
17 does the average molecular weight of all the
18 molecules on the left-hand side, does that fall
19 between 100,000 and 300,000; is that right?
20 That's one of the questions you were trying to
21 answer?

22 A. Yes, it was.

23 Q. And the other question that you
24 were trying to answer was: Does the average

1 molecular weight of everything on the right-hand
 2 side of the line, is that a -- does that fall
 3 between 600,000 and 900,000; is that correct?
 4 A. That's correct.
 5 Q. Now, but here's my problem,
 6 Doctor. By drawing the line at the 600,000
 7 mark, you sort of rigged the outcome, didn't
 8 you?
 9 A. Not at all.
 10 Q. Well, by putting the line at the
 11 600,000 mark, you guaranteed that whatever
 12 average molecular weight that you got on the
 13 high end, it would always be greater than
 14 600,000, wouldn't it?
 15 A. We picked the best spot to start
 16 calculations. That turned out to be the last
 17 place we needed to look.
 18 Q. But by drawing the line at
 19 600,000, it guarantees that any average
 20 molecular weight that you get for the high end
 21 portion, it will always be higher than 600,000,
 22 won't it?
 23 A. Sure. That's common sense.
 24 Q. So the question is no longer does

1 it fall between 600 and 900,000. You've changed
 2 the dynamics. You've now made it so, is it
 3 greater than or lower than 900,000. That's the
 4 question now, isn't it?
 5 A. No, not at all.
 6 Q. It can never be lower than
 7 600,000. You would agree with that?
 8 A. Yes, that's correct.
 9 Q. So you've assured that in every
 10 single instance when this is measured, it can
 11 never fall -- the high end can never fall below
 12 600,000 daltons; is that correct?
 13 A. Yes.
 14 Q. Now, the patent does not say
 15 anything about conducting a GPC analysis on a
 16 PEO, does it?
 17 A. It does not specifically say that,
 18 no.
 19 Q. It does not say to go ahead and
 20 create a uniform distribution curve like Dr. Yau
 21 did, does it?
 22 A. No, it does not.
 23 Q. And it does not say anything about
 24 partitioning along the uniform distribution

1 curve and calculating an average molecular
 2 weight on either side of that partition. It
 3 doesn't discuss that, does it?
 4 A. It does not.
 5 Q. This was otherwise a litigation
 6 inspired theory for purposes of completing your
 7 infringement analysis; isn't that right?
 8 A. It was the task that I was
 9 assigned to to carry out, yes, to analyze the,
 10 the molecular weight distribution and to look
 11 for the components of that analysis that would
 12 meet claim limitations, yes.
 13 Q. All right. Thank you.
 14 Now, this curve could be
 15 partitioned anywhere; isn't that right?
 16 A. Yes.
 17 Q. There's an infinite number of
 18 possibilities where this curve could be
 19 partitioned?
 20 A. No.
 21 Q. Is there a spot on the curve that
 22 cannot be partitioned?
 23 A. I'm not sure where -- what you are
 24 talking about. I mean, why would you assume

1 there was an infinite number? You're going to
 2 pick your best shot. If the best shot is not
 3 correct, the calculated values would tell you
 4 which way to move the partition demarcation, and
 5 you would recalculate until you got close to
 6 where the final values were as close as possible
 7 to the -- to meeting the claim limitations.
 8 Q. Thank you.
 9 A. There's not an infinite number of
 10 those. There's probably only a handful.
 11 Q. Well, you can move that line
 12 anywhere along that curve, isn't that right,
 13 and you could conduct the exact same analysis?
 14 A. Well, you could, but no one would.
 15 Q. You would get different results
 16 every time, wouldn't you?
 17 A. Yes.
 18 Q. But you only tested your theory at
 19 the 600,000 dalton mark; isn't that right?
 20 A. That would be most appropriate
 21 place. We started there. It happened to give
 22 us the answer that allowed us to come to the
 23 conclusion I stated.
 24 Q. Now I'd like to look at the

1 results that Dr. Yau came up with and that you
2 relied upon. This is still JTX-143 under the
3 tab N80 statistics.

4 You've seen these two tables
5 before; correct? These are the results that you
6 relied upon in forming your infringement
7 opinion, Doctor?

8 A. Yes.

9 Q. I'd like to focus first on the --
10 on the table on the left. This is the results
11 that Dr. Yau obtained after doing nine runs of
12 the Polyox N80; isn't that right?

13 A. These are analysis of, of parts of
14 the chromatographs, yes.

15 Q. And just so under sample name,
16 there's a number of letters and numbers your
17 Honor and those represent nine different runs
18 that Dr. Yau conducted of the exact same sample
19 each time; isn't that correct?

20 A. Different portions of that sample,
21 yes.

22 Q. Okay. And a couple columns over,
23 there's a column MW. That stands for weight,
24 average molecular weight; is that right?

1 A. That's correct.

2 Q. And there's a column next to it
3 that is MV. That stands for viscosity, average
4 molecular weight; is that right?

5 A. That's correct.

6 Q. And so if we focus on the first
7 column, weight average molecular weight, Dr. Yau
8 concluded that that weight average was, on the
9 low end was 107,469; is that right?

10 A. That number is a result of a
11 calculation, yes.

12 Q. A very precise calculation. The
13 way you said that in your direct, that Dr. Yau
14 is very direct.

15 A. If I divide two by three, I get
16 .66666 forever. Does that make that number more
17 physically meaningful? No.

18 Q. I'm sorry. Was the work Dr. Yau
19 did precise or not?

20 A. It was very precise.

21 Q. Thank you. We agree that 107,469,
22 that's between 100,000 and 300,000. I think you
23 both agree with that. Yes?

24 A. Yes.

1 Q. Okay. So I'd like to move to the
2 next column, which is the viscosity average
3 molecular weight that Dr. Yau calculated. And
4 he came up with 95,895; is that right?

5 A. That's the calculated value from
6 the data, yes.

7 Q. And I think we both agree that the
8 reference to average molecular weight in the
9 patent, that's a reference to viscosity average
10 molecular weight. Yes?

11 A. Yes.

12 Q. And here, the results that Dr. Yau
13 obtained, they were less than 100,000; is that
14 correct?

15 A. A little bit less, yes.

16 Q. Okay. So the 95,895 does not fall
17 within the 100,000 to 300,000 range. Agreed?

18 A. I disagree.

19 Q. 95,895 is less than 100,000; is
20 that correct?

21 A. Well, that number is less, but
22 it's understood in the art that because of
23 experimental error and because of lot-to-lot
24 variations in polyethylene oxide, 96,000 is

1 100,000. That's how the range is sold.

2 Q. I'm glad you mentioned that.
3 First you said two reasons. You said
4 experimental error. That was your first reason;
5 right?

6 A. Yes.

7 Q. We already established this was
8 done very precisely. Okay? That's number one.
9 You agree with that. Very precisely conducted.
10 Yes?

11 A. Very precisely.

12 Q. You also said lot-to-lot
13 variation. Was that the other reason to round?

14 A. Yes.

15 Q. But you only, you only tested one
16 sample. There's no lot-to-lot variation here.
17 There's only one sample being tested. Agreed?

18 A. That's correct.

19 Q. Okay. Now, I would like to look
20 at the individual results that Dr. Yau got for
21 each one of his nine runs for viscosity average
22 molecular weight.

23 For each one, each one of his
24 results were less than 100,000; is that correct?

1 A. That's correct.

2 Q. He did not get a single result,

3 not a single result that falls within the

4 100,000 to 300,000 range, did he?

5 A. He did not calculate any viscosity

6 molecular weight for the low molecular weight

7 that fell within that range, that's correct.

8 Q. Thank you.

9 Now, just below the 95,000 number,

10 there's a reference to standard deviation.

11 That's 623. Yes?

12 A. Yes.

13 Q. And standard deviation, that just

14 takes into consideration potential errors in the

15 equipment. That for a layperson means you can

16 take that 95,895 plus or minus 623. Isn't that

17 generally correct?

18 A. It's a measure of the precision of

19 measurement, yes.

20 Q. So even giving the benefit of the

21 doubt that it was measuring low, the closest you

22 could get to 100,000 is approximately 96,518; is

23 that right?

24 A. If you do that mathematical

1 calculation, that's correct, yes.

2 Q. All right. Now I'd like to switch

3 gears and I would like to talk about your

4 opinion that the 1.9 percent of the high

5 fraction does not amount to a stray amount. And

6 that number is calculated to the right. That's

7 where that 1.9 percent comes from?

8 A. From these calculations, yes.

9 Q. All right. And actually, before

10 you move on to stray amount, I want to go to the

11 second table, the high end portion. So if we

12 can -- it's over here. I want to reorient you.

13 This is Tab A. This is where Dr. Yau calculated

14 the weight average molecular weight and

15 viscosity average molecular weight for the high

16 end portion; isn't that right?

17 A. The results of those calculations,

18 yes.

19 Q. And it is the same nine runs;

20 right? That's why there are nine individual

21 results?

22 A. Yes.

23 Q. Okay. And for the weight average

24 molecular weight, he determined that the result

1 was 917,865. Yes?

2 A. That's what he calculated, yes.

3 Q. And you'd agree with me that

4 917,865 is greater than 900,000?

5 A. A little bit, yes.

6 Q. And in your expert report, you

7 rounded 917,865, you rounded that to 920,000,

8 didn't you?

9 A. That's correct.

10 Q. And with respect to the viscosity

11 average molecular weight column, the -- the

12 total that he came up with was 900,318; is that

13 right?

14 A. Yes.

15 Q. Again, you'd agree with me that

16 900,318038, that is greater than 900,000. Yes?

17 A. In terms of calculations, yes.

18 Q. And one more point that I forgot

19 to make with respect to the first, the lower

20 fraction. The number 95,895, I know you

21 testified during your direct that that should be

22 rounded to 100,000. Yes?

23 A. It would be considered to be a

24 hundred thousand.

1 Q. But --

2 A. I mean, that's how these materials

3 are sold. That's what everybody understands the

4 molecular weights correspond to.

5 Q. But in your expert report, you

6 rounded it to 96,000, didn't you?

7 A. As a matter of mathematical

8 rounding, yes.

9 Q. Okay. And you used that 96,000

10 number as a basis for your noninfringement

11 opinion; isn't that right?

12 A. Yes, I did.

13 Q. Okay. Now I'd like to move to

14 your stray amount opinion. You believe the term

15 stray amount, that means very small or

16 incidental? Yes?

17 A. Yes. An amount that would not

18 affect the properties of material in the polymer

19 context.

20 Q. But as you sit here today, you're

21 unable to associate any numbers with the word

22 "stray" based on the Court's claim construction;

23 is that right?

24 A. Were there any numbers in the

1 claim construction? Is that what you are
2 asking?

3 Q. No. As you sit here today, you
4 are unable to associate any numbers with the
5 word stray based on the Court's claim
6 construction; is that correct?

7 A. That's correct.

8 Q. You could not quantify what
9 percent amount of the higher PEO fraction you
10 would consider to be a stray amount; is that
11 correct?

12 A. I don't have a number for that,
13 exact number for that, no.

14 Q. You're just certain that
15 1.90 percent is more than a stray amount; is
16 that right?

17 A. That's correct.

18 Q. But you didn't do any testing to
19 determine whether, in fact, 1.90 percent has any
20 functional significance on Watson's film
21 product, did you?

22 A. I didn't have to.

23 Q. You said that's how you defined
24 the term stray amount, based on whether it has

1 any functional significance; is that correct?

2 A. That's correct.

3 Q. And you didn't do any testing;
4 isn't that correct?

5 A. That's correct. I did not. I
6 didn't need to.

7 Q. Now I'd like to look at some other
8 calculations that you made for Watson's ANDA
9 product. This is PDX-1423.

10 I believe you talked about this
11 during your direct examination. This is where
12 you described the entirety of Watson's polymer
13 component and you broke it down by weight
14 percent; isn't that right?

15 A. Yes, it is.

16 Q. And you calculated that the higher
17 fraction of Watson's Polyox N80 in comparison to
18 the higher polymer component, it's 1.7 percent
19 by weight of the entire component; isn't that
20 correct?

21 A. That is correct.

22 Q. Okay. Now, if I can now refer you
23 to PX-1424, the other thing that you calculated,
24 you calculated that the entire PEO content is

1 1.9 percent of the total weight of the entire
2 film formulation.

3 A. The high molecular weight set is
4 1.9 percent. Is that what you said?

5 Q. I --

6 A. If that's what you said, yes.

7 Q. No. I understood it to mean that
8 the tire PEO, 5.34 milligrams, that's
9 1.9 percent by weight of the entire film
10 formulation. Isn't that what that indicates?

11 A. That -- that's not correct. This
12 refers only to the 900,000. Oh, I'm sorry, yes.
13 I was misreading that.

14 The total PEO was 5.34. The
15 amount of high molecular weight is .1. So you
16 would divide those to get the 1.9 percent. You
17 have to add them together. I'm sorry. You
18 divide those to get 1.9 percent.

19 Q. Dr. Mathias, is your reference to
20 1.9 percent here, is that the total PEO in the
21 film by weight or is it total type fraction
22 portion of the film by weight?

23 A. It's the fraction of the PEO
24 that's the high molecular weight fraction.

1 Q. Now I would like to talk about
2 some of the documents that you discussed during
3 your direct examination and I would like to
4 start with the Dow product safety assessment.
5 That's JTX-41.

6 And you talked about this during
7 your direct examination, didn't you?

8 A. Yes, I did.

9 Q. And if we can refer to page 2, and
10 if we can blow up the diagram. And if you
11 include the process statement just above the
12 diagram.

13 I believe during your direct
14 examination, you talked about the process, and
15 you talked about the fact that the batches are
16 stored and then they're blended. You talked
17 about that. Yes?

18 A. I did, yes.

19 Q. And I believe your testimony -- I
20 wrote it down. You said the PEO comes from
21 various reactor batches; is that right?

22 A. Yes. That's what it says.

23 Q. You're not suggesting that Dow is
24 blending PEO of different viscosity average

1 molecular weights, are you? They're blending
2 PEOs of the same average viscosity weight,
3 aren't they?

4 A. No, no, that's not what I'm
5 saying.

6 Q. So you are suggesting that they
7 are actually blending PEOs of different
8 viscosity average molecular weights?

9 A. Yes. I think any given reactor
10 batch is going to have a specific molecular
11 weight and molecular weight distribution.
12 Whether or not that meets the specification for
13 the targeted grade that they are making this
14 material for, that's something they analyze.
15 That's the reason they blend multiple batches
16 together, because there is variation in the
17 synthesis process.

18 Q. Now, you see on the process, it
19 says the Polyox reference, they're produced in
20 batch reactors uses proprietary processes and
21 material. It says that; right?

22 A. Yes.

23 Q. So the process is proprietary?

24 A. Yes.

1 Q. So you don't know, in fact, how
2 Dow creates the PEO reference, do you?

3 A. I know in general how they make
4 them. They use an ionic polymerization. This
5 is how you make Polyox reference commercially.

6 Q. Now, lower down on the page under
7 product description --

8 MR. NUTTER: Can you blow that up
9 for me, Mr. Young? The second paragraph. Both
10 paragraphs are fine.

11 BY MR. NUTTER:

12 Q. It indicates that the Polyox
13 reference, they typically contain more than
14 95 percent PEO with smaller amounts of fumed
15 silica and calcium salts.

16 Do you see that?

17 A. Yes.

18 Q. That's what is being blended.
19 It's the PEO with the fumed silica and the
20 calcium salts; isn't that right?

21 A. No.

22 Q. Why not?

23 A. Because that's not what the
24 product synthesis process describes.

1 Q. Well, the fumed silica and the
2 calcium salts, they're blended with the PEO at
3 some point, aren't they?

4 A. They may be part of the synthesis
5 process.

6 Q. Thank you.

7 And that's, in fact, what Dow is
8 referring to when they talk about a blend; isn't
9 that right?

10 A. No. I'm not sure what you -- you
11 mean this particular combination? That's not
12 the way I interpret that.

13 Q. That's not the way you interpret
14 it. Yes?

15 A. That's not the way I interpret it.

16 Q. Now I'm going to talk about the
17 L'Hote article. This is JTX 31. This is the
18 L'Hote article that you talked about during your
19 direct. Yes?

20 A. Yes.

21 MR. NUTTER: And if we could turn
22 to Figure 2, I think it's on page 3. And I
23 think -- there you go, Mr. Young. If you can
24 blow that up.

1 BY MR. NUTTER:

2 Q. Now, I believe this is the figure
3 that you relied upon to support your partition
4 analysis theory. Yes?

5 A. No. This was designed to, or this
6 was used to support the argument about unimodal
7 versus bimodal peak shapes in a GPC analysis.

8 Q. And I think you pointed out that
9 this, this article was written by Dow employees.
10 Right?

11 A. That's correct.

12 Q. And so at least you were
13 suggesting that they're following Dow protocol;
14 is that correct?

15 A. I -- I don't know that. I would
16 assume that, but I don't know that for sure.

17 Q. And I note that in the legend
18 when, in fact, they are discussing a blend, they
19 identify it as a blend, don't they?

20 A. I'm not sure what your question
21 asks. It's indicated as a blend. Yes, it's a
22 blend.

23 Q. Right. And they don't identify
24 Polyox N80 as a blend though, do they?

1 **A. Polyox N80 is not described in**
2 **this article.**

3 **Q. But Dow does not characterize or**
4 **describe Polyox N80 as a blend, does it?**

5 **A. They do not, but they do describe**
6 **it as a blend in their synthesis process.**

7 **Q. We covered that. A blend with the**
8 **calcium salts and the fumed silica.**

9 **A. A blend of batch reaction**
10 **products.**

11 **Q. Okay. Now, I would like to also**
12 **refer you to the second table in this article.**
13 **It's on page 2.**

14 **Now I note that in your direct**
15 **testimony, you said persons of ordinary skill in**
16 **the art, they round all measurements for PEOs to**
17 **the hundred thousand; isn't that right?**

18 **A. When talking about commercial**
19 **materials, yes. When talking about GPC**
20 **analysis, no.**

21 **Q. And the analysis that Dr. Yau**
22 **conducted, that was GPC analysis?**

23 **A. Right. And he reported his actual**
24 **data to several community --**

1 **Q. Thank you.**

2 **A. Just like he did here.**

3 **Q. And the weight average molecular**
4 **weight calculated by these authors, and the**
5 **number average molecular weight calculated by**
6 **these authors, that was for the whole sample.**
7 **It wasn't for a partition of the sample; isn't**
8 **that right?**

9 **A. Yes.**

10 **Q. And I believe you talked about a**
11 **couple of the papers. The Eshuis. Am I saying**
12 **that correctly?**

13 **A. I don't know. We talked about**
14 **that.**

15 **Q. Okay. There was Eshuis, I think**
16 **that's JTX-76, and the Kulicke paper JTX-40.**

17 **Do you remember talking about**
18 **those?**

19 **A. Yes.**

20 **Q. If you take into consideration the**
21 **L'Hote article, the Eshuis article, the Kulicke**
22 **paper, none of those papers deal with**
23 **pharmaceutical formulations, do they?**

24 **A. They do not.**

1 **Q. None of those papers, not a single**
2 **one of those papers partition a polyethylene**
3 **oxide and then calculate the average molecular**
4 **weight on either side of that partition like**
5 **you've done; isn't that correct?**

6 **A. The Eshuis paper does partition**
7 **and does calculate weights. They don't actually**
8 **calculate individual weight averages because**
9 **that's not what they were looking for. They**
10 **do a partition, just like it was done in this**
11 **case.**

12 **Q. Doctor, not a single one of the**
13 **papers that you rely on partition a PEO and**
14 **calculate the average molecular weight on either**
15 **side of partition as you are asking this Court**
16 **to do; isn't that correct?**

17 **A. It's a two-part question. Did any**
18 **of those papers partition? Yes. Did they**
19 **calculate the average molecular weights of those**
20 **partitions? No.**

21 **MR. NUTTER: I have no further**
22 **questions.**

23 **THE COURT: All right. Before you**
24 **do redirect, Doctor, you mentioned during your**

1 **direct testimony something about 105,000**
2 **daltons. Do you remember what that was?**

3 **THE WITNESS: That was the**
4 **viscosity average calculated for the entire N80.**

5 **THE COURT: All right. So Dow**
6 **says 200,000; right?**

7 **THE WITNESS: Yes.**

8 **THE COURT: Are they describing a**
9 **different kind of molecular weight?**

10 **THE WITNESS: Dow uses a, a**
11 **specification that includes a very broad range**
12 **of viscosity. So their materials can vary by as**
13 **much as 16 or 20 percent.**

14 **THE COURT: But even if you vary**
15 **by 16 or 20 percent from 200,000, you don't get**
16 **105,000?**

17 **THE WITNESS: No. This is**
18 **something we've talked about at length and I**
19 **don't have a real answer on.**

20 **THE COURT: Okay. The other**
21 **question I had was: Is there a scientific**
22 **principle that led you to select 600,000 for the**
23 **partitioning?**

24 **THE WITNESS: Well, you always**

1 make your best first guess, and --

2 THE COURT: First guess at what?

3 THE WITNESS: Well, again, you're
4 looking at the claim limitations, you are
5 looking at the way the distribution is supplied,
6 and you know that you have to be to be on the
7 right side of that peak because of the
8 60 percent or more.

9 THE COURT: So was basically what
10 you were doing is, you were seeing whether there
11 was any place where you could partition the
12 unimodal distribution to meet the claim
13 limitations? Is that what you were trying to
14 do?

15 THE WITNESS: We were testing to
16 see if it met the claim limitations, yes.

17 THE COURT: But in terms of
18 picking the 600,000 as the point to try, that
19 was essentially based on the idea that that
20 looked like a good place to pick with having a
21 reasonable probability based on your expertise
22 of being able to come up with two viscosity
23 average molecular weights that will meet the
24 claim limitations?

1 THE WITNESS: That's correct.

2 THE COURT: But in terms of there
3 being a scientific reason for picking 600,000,
4 there isn't?

5 THE WITNESS: You make your best
6 first guess and then you adjust based on what
7 that calculation -- if we had done values that
8 were off completely from the ranges given, we
9 would have moved the calculation, or -- towards
10 the value that would have given some more
11 likelihood. This is standard scientific
12 procedure. You make your best first guess and
13 you do your calculation, adjust afterwards and
14 see what occurs. We just happened to get lucky
15 on the first guess.

16 THE COURT: All right. Thank you.
17 Go ahead, Mr. Bollinger.

18 MR. BOLLINGER: Thank you your
19 Honor.

20 REDIRECT EXAMINATION

21 BY MR. BOLLINGER:

22 Q. Just a quick followup on those
23 last series of questions. When you look and
24 partition at different locations, and we didn't

1 do it here, but do you change the data in any
2 way?

3 A. No. In fact, that's an excellent
4 point. The high molecular weight fraction is
5 still there. All we're doing is calculating
6 what its average viscosity molecular weight is
7 and then determining how much weight percent it
8 corresponds to.

9 Q. If you looked at a partition that,
10 at a different location, and it does not meet
11 the claim limitation, does that show that
12 there's no infringement at that spot?

13 A. No. It shows that that
14 calculation does not show any infringement.

15 Q. The sample is the same, and so the
16 600,000 just gave you what you felt showed
17 infringement; isn't that right?

18 A. That's correct.

19 Q. Thank you.

20 Earlier in the cross, that 600,000
21 molecular weight partition was discussed, and I
22 think you indicated it was someplace that
23 somebody skilled in the art. Can you explain
24 why you thought somebody skilled in the art

1 would choose that?

2 A. Well, you look at the limitations
3 and 600,000 to 900,000 is the upper range.
4 That's the area you would choose for that.

5 Q. And there --

6 A. If you picked the higher end, it's
7 going to be too high, so picking the lower end
8 is the -- is the logical place to go. That's
9 where we pick it.

10 Q. Is it possible that there will be
11 types of PEO that won't satisfy, there will not
12 be a partition that will actually meet the claim
13 limitations?

14 A. Yes.

15 Q. All right. A couple of other
16 things.

17 MR. BOLLINGER: Can we bring up on
18 the screen the Court's claim construction and
19 compare page 9, and highlight the same section
20 that counsel highlighted, the combining.
21 Probably drill in a little bit more.

22 BY MR. BOLLINGER:

23 Q. This says, for example, the
24 description of the invention, combining small

1 amounts of PEOs and large amounts.
 2 Now, when you read claim 1, did
 3 you understand it to have a combining step that
 4 was sort of like a method?
 5 A. I understood that to mean that the
 6 product would have those amounts. The combining
 7 results in a combination, so I interpreted it as
 8 the analysis needed to be done on the actual
 9 combination.
 10 Q. You understand the claim to be a
 11 composition claim, a film?
 12 A. Yes.
 13 Q. And so when you did your analysis,
 14 were you just trying to find out just to see if
 15 the PEO and the fractions defined by the claim
 16 were in there?
 17 A. That's the only way you can do the
 18 analysis. You have to look at the actual
 19 materials used.
 20 Q. Another point came up about Dr.
 21 Yau's, the accuracy, precision of his data. Is
 22 there a difference between precision and
 23 ultimate accurate see of the results?
 24 A. Yes. You can have extremely

1 precise data but still have errors associated
 2 with the actual number that you determine. The
 3 example I use in my class in teaching is
 4 shooting at a target with a bow and arrow. You
 5 can shoot your arrows and have them very close
 6 together, which will give you very precise
 7 results, but you could not hit the bulls-eye.
 8 You could still miss the bulls-eye and still
 9 have very precise results.
 10 Errors creep in experimental
 11 analysis, and inherently, experimental analysis
 12 due to variations in temperature, insolvent
 13 purity, in how old the columns are, how old the
 14 column equipment is.
 15 The pumps wear out. So there's an
 16 inherent error associated with any variation
 17 that's made.
 18 MR. BOLLINGER: And just briefly,
 19 if we could bring up the Flick article, and I
 20 think the page that references the centipoise.
 21 MR. NUTTER: I now renew my
 22 objection to the Flick reference.
 23 THE COURT: Yes. I think, I don't
 24 think you're going to do this.

1 MR. BOLLINGER: Well, I was going
 2 to because I think he opened the door. He asked
 3 him about it.
 4 THE COURT: I don't recall that.
 5 MR. BOLLINGER: He specifically
 6 asked about the lot-to-lot variability, and this
 7 is the evidence on the lot-to-lot variables.
 8 THE COURT: Well, I don't think
 9 that opens the door.
 10 MR. BOLLINGER: Okay. We'll move
 11 on.
 12 BY MR. BOLLINGER:
 13 Q. So if you can, in talking about
 14 the high molecular weight fraction, did that
 15 inform your choice on the 600 partition?
 16 A. Yes. We knew we -- we knew that
 17 we needed only a small amount of the high
 18 molecular weight fraction. This is consistent
 19 with the teachings in the patents. It's
 20 consistent with what we know about how high
 21 molecular weight material fractions affect
 22 properties. So we knew that we didn't need very
 23 much of at this time, two percent,
 24 three percent, but it had to be within the

1 specific range for the average molecular weight
 2 calculated.
 3 Q. And, in fact, claim construction
 4 said a small amount; is that correct?
 5 A. It does say that, yes.
 6 Q. And in the lot-to-lot variation,
 7 ignore the Flick article, is it well-known in
 8 the industry, there is meaningful lot-to-lot
 9 variation in polymer manufacture?
 10 A. It's very common. In fact, that's
 11 why Dow uses the specification numbers that they
 12 use.
 13 Q. All right.
 14 MR. BOLLINGER: Your Honor, it
 15 came up in the cross, the exhibits, the tables
 16 with the calculated values, and I would offer
 17 those into evidence. It's PTX-538, A through H.
 18 And these are just the excerpts of his report,
 19 the tables, the tabulated calculations that back
 20 up the 1.9 percent and the, the 86 percent.
 21 MR. NUTTER: JTX-143, which is the
 22 exhibit that I used, that is already admitted
 23 into evidence. I do believe what he's talking
 24 about might be snapshots of different portions

Yau - direct 190

1 of that. I would have to clarify the exhibit.
2 THE COURT: Why don't you talk
3 about it over lunch.
4 MR. BOLLINGER: Very good. Thank
5 you, your Honor. And thank you, Dr. Mathias.
6 THE COURT: All right. And do you
7 have any further questions since I asked him
8 questions? You don't have to.
9 MR. NUTTER: No, your Honor.
10 THE COURT: All right. Thank you,
11 Dr. Mathias. You may step down.
12 (Witness excused.)
13 THE COURT: All right. I guess
14 Dr. Yau is your next witness?
15 MR. BOLLINGER: That's correct,
16 your Honor. If it please the Court, we call Dr.
17 Wallace Yau.
18 THE COURT: All right.
19 ... DR. WALLACE YAU,
20 having been duly sworn as a witness, was
21 examined and testified as follows...
22 MR. BOLLINGER: Your Honor, we
23 have the same collection of books.
24 THE COURT: All right.

Yau - direct 191

1 (Mr. Bollinger handed notebooks to
2 the witness.)
3 DIRECT EXAMINATION
4 BY MR. BOLLINGER:
5 Q. Dr. Yau, good afternoon.
6 A. Good afternoon to you.
7 Q. Did you help prepare some slides
8 for today's, illustrating your testimony?
9 A. Yes.
10 Q. And I would like to first just
11 briefly discuss some of your background. I know
12 the Court has already reviewed your CV, so if
13 you could just touch upon highlights that you
14 want to bring out that would be relevant to
15 today's analysis that you did.
16 A. Yes. I majored in the University
17 of Massachusetts with a Ph.D. in polymer
18 physical chemistry in 1966. Then I joined
19 DuPont back in Wilmington, Delaware for
20 26 years.
21 Q. Welcome back.
22 A. So a long time ago. And recently
23 worked for Dow Chemical.
24 My industrial research emphasis

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1 has been in polymer characterization, separation
2 science, dealing with different types of
3 polymers, including polyethylene oxide. And in
4 early days, I have used basically the first,
5 second GPC industry ever built, and contributed
6 some inventions along the way on the GPC
7 technology.
8 Q. Can we bring up the first -- can
9 you tell me a little bit about what's on the
10 slide right now?
11 A. Yes. This is the image of the
12 cover of the book, the second edition published
13 more recently. It's an update from my first
14 edition, which was published in 1979.
15 MR. LOMBARDI: Could I ask that
16 the doctor speak into the microphone? I'm
17 having difficulty hearing him.
18 THE COURT: All right.
19 MR. BOLLINGER: Pull the mike
20 towards you.
21 THE WITNESS: I'm sorry.
22 MR. BOLLINGER: That's fine.
23 Your Honor, the exhibit says on
24 the slide PTX-076. I think it's actually now a

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1 joint exhibit, JTX-032.
2 BY MR. BOLLINGER:
3 Q. And, Dr. Yau, have you performed
4 GPC analysis in your career?
5 A. Yes, I did.
6 Q. Can you just give me a rough
7 estimate of how many you've done?
8 A. Must be over many thousands.
9 Q. All right. Thank you.
10 And are these mostly in the
11 polymer field?
12 A. Yes.
13 Q. Okay.
14 MR. BOLLINGER: Your Honor, we'd
15 offer Dr. Yau as an expert in analytical
16 techniques as they relate to polymer science,
17 and specifically the determination of properties
18 as synthetic polymers.
19 THE COURT: All right. You may
20 proceed.
21 MR. BOLLINGER: Thank you.
22 BY MR. BOLLINGER:
23 Q. Were you asked to perform some GPC
24 analysis in this case?

1 A. Yes.

2 Q. And what was the sample that you

3 were asked to analyze?

4 A. It's Polyox N80. It's a

5 commercial polyethylene oxide sample from Dow

6 Chemical.

7 Q. And can you tell me a little

8 briefly what you know about Polyox? Had you

9 worked with it in the past?

10 A. Well, chemically, long chain

11 molecules with a very broad molecule

12 distribution with the repeating units of

13 ethylene oxide.

14 Q. Were you -- do you recall what you

15 specifically asked to do by plaintiff?

16 A. Yes. To look into the molecule

17 weight and the molecule distribution of that

18 product.

19 Q. The Polyox PEO N80; is that

20 correct?

21 A. That's correct.

22 Q. And what way is the best way to do

23 that?

24 A. The best way and also the only way

1 I recommend is using GPC to look at the molecule

2 weight distribution.

3 Q. In now addressing this question

4 from plaintiff, did you do some research?

5 A. Yes. Well, to complete the task,

6 I did the research to find and design the best

7 protocol to GPC. Then I contacted your internal

8 laboratory provides such services, that there

9 are so many, I picked the most credible one I

10 can find.

11 Q. Yes. Were you familiar with the

12 quality of their work?

13 A. Yes. I know the director of the

14 lab.

15 Q. All right. And did you retain

16 them to perform the protocol you designed?

17 A. Yes, I did.

18 Q. And did you communicate with them

19 regarding the testing as they were performing

20 it?

21 A. Yes. And I realized the

22 importance of this test, so I made sure

23 everything was done correctly.

24 Q. All right. And what did the lab

1 do?

2 A. The lab communicated with me and

3 we set up the column protocols, how to prepare

4 samples, and derivation curves and actually did

5 the GPC runs and provide me the results, but

6 also the raw data, I can do additional

7 calculations.

8 Q. All right. Well, let's go to the

9 next slide. Can you explain what this is?

10 A. Yes. That's the result already

11 shown several times by Dr. Mathias. I think

12 it's a molecular weight distribution curve prior

13 to the log scale as they should be.

14 Q. All right. So the X axis is a log

15 scale?

16 A. Yes.

17 Q. Even though there are integers

18 there?

19 A. Pardon me?

20 Q. We'll move on.

21 I don't want to get into the

22 details about the nine runs, but let me ask you:

23 Were there any problems in the data that came up

24 in signal to noise or any other issue?

1 A. The way I received the data, I was

2 so impressed with it. There are nine GPC runs

3 altogether and you can barely see any of the

4 noise. If you look for noise, you have to go to

5 the two extremes on both sides. But certainly,

6 there's no signal-to-noise issue here to affect

7 the average calculations in the molecule.

8 Q. All right. And did you -- the

9 data that was sent to you by the lab, did you do

10 any further analysis on that data?

11 A. Yes, I did.

12 Q. What did you do?

13 A. Well, I was looking -- I was asked

14 to look for publishing and to see the two

15 separate sets of, or subsets of the molecule

16 weight distribution.

17 Q. And how was that possible with GPC

18 data? Did you have to do anything to it to

19 allow for that type of analysis?

20 A. To partition into two sets, that's

21 the way to interpret the data. That's what I

22 did.

23 Q. And have you ever done that

24 before?

1 A. Yes.

2 Q. And is it an accepted practice in
3 the field?

4 A. Oh, yes. In fact, in the polymer
5 manufacturing, I think there's an EPA
6 recordation because of control of organic
7 volatized. So the polymer product will have to
8 be created by EPA so that the molecule weight
9 below 500 molecule weight percentage is not
10 allowed to be produced.

11 Q. All right. And in this case, were
12 you able to, when you partition it, were you
13 able to determine viscosity averages of
14 molecular weight for the two fractions?

15 A. Yes.

16 Q. And can we go to the -- let me ask
17 you this: How did you do those calculations?
18 Were they done on a calculator or computer?

19 A. Computer.

20 Q. Can you give me more detail?

21 A. Yes. Once I received the raw data
22 from the lab, I can set the data arrays in a way
23 to separate it into two pots. One product is
24 lower than 600,000 molecular weight. Other

1 product is higher than that. In fact, in the
2 spirit of to be helpful and transparent, I had
3 included a template, an Excel spreadsheet in my
4 opening report, so anybody can check it and
5 adduce whatever they want to.

6 Q. Very good.

7 MR. BOLLINGER: And can we go to
8 the last slide?

9 BY MR. BOLLINGER:

10 Q. I just want to confirm, this has
11 already been discussed, this is the data you
12 generated from your spreadsheet?

13 A. Yes.

14 Q. And why so many significant
15 figures? Why all of this data? Obviously, it
16 has come up in Dr. Mathias' testimony. Can you
17 explain why these figures are presented the way
18 they are?

19 A. The way is a weigh to explain what
20 I said about the signal to noise, because with
21 the 900 than runs, individual variants with all
22 these significant digits, those are required in
23 order to calculate the statistics of those
24 samples and coming up with the standard

1 deviation. That's helpful to show the high
2 precision of the data.

3 Q. In characterizing Polyox material
4 such as in the analysis you did here, are you
5 aware of any particular need to have those
6 additional digits' details?

7 A. Not to say computers are stupid,
8 but those are the calculated variables. They
9 don't interpret how people use them. So these
10 numbers, within three standard deviations or two
11 standard deviations, is not for me to decide.
12 And people interested in the sample, how they
13 perform, the property, that's where you draw the
14 line.

15 MR. BOLLINGER: Thank you.

16 Your Honor, we're going to offer
17 the exhibits that Dr. Mathias talked about and
18 now Dr. Yau has talked about into evidence. I
19 think they're the ones -- I'm not sure there's a
20 challenge.

21 MR. SMEREC: Your Honor, I would
22 object only in as much as I think the testimony
23 has been about Yau Exhibit B, which is already
24 admitted into evidence at JTX-143. We've agreed

1 to admission. And I think --

2 THE COURT: Is there any sort of
3 dispute about the numbers? Just looking at the
4 5.6 I, J, G, Y, I mean, it doesn't seem like
5 this is where the controversy is.

6 MR. SMEREC: If plaintiffs will
7 just agree that's what they pulled from the
8 exhibit, we'll withdraw any objection.

9 THE COURT: All right. They'll be
10 admitted for that caveat.

11 MR. BOLLINGER: Thank you. Thank
12 you, your Honor. All right. We have no further
13 questions.

14 THE COURT: All right. Thank you,
15 Mr. Bollinger.

16 All right, Mr. Smerek.

17 MR. SMEREC: Thank you, your
18 Honor.

19 CROSS-EXAMINATION

20 BY MR. SMEREC:

21 Q. Good afternoon, Dr. Yau.

22 A. Good afternoon.

23 Q. Mr. Yau? Dr. Yau?

24 A. Either way is fine.

1 Q. I will go with Dr. Yau. Good
 2 afternoon. We have not met before. I'm Steven
 3 Smerek and I'm going to ask you a fewer
 4 questions here. Okay?
 5 A. Definitely. Thank you.
 6 Q. Now, the first thing I just wanted
 7 to clear up a couple of questions that you were
 8 asked. You said a Polyox N80, you were familiar
 9 with that before you were approached by
 10 plaintiffs in this case; is that correct?
 11 A. Yes. To certain degree, yes.
 12 Q. And you described it as long chain
 13 PEO polymers; is that correct?
 14 A. Yes. They are solvents, and
 15 millions of them.
 16 Q. And you said that Dow Polyox N80
 17 is known to have a very broad weight
 18 distribution; is that correct?
 19 A. Yes.
 20 Q. And that would have been known
 21 prior to 2003. That has been known for a long
 22 time; is that right?
 23 A. 2003? Yes. Could you repeat the
 24 question?

1 Q. Sure. You said that Dow Polyox
 2 N80 is known to have a very broad distribution
 3 of, very broad weight, molecular weight
 4 distribution; is that correct?
 5 A. Yes. With specific to PEO, all
 6 commercial polymers over any significance will
 7 have that property.
 8 Q. And so I just want to focus on Dow
 9 Polyox N80. That's the subject of your
 10 testimony; is that correct?
 11 A. Okay.
 12 Q. And it's a commercially available
 13 PEO grade; is that correct?
 14 A. Correct.
 15 Q. And it has been available since
 16 before 2003; is that correct?
 17 A. I don't know.
 18 Q. Well, you looked at the patent,
 19 the '150 patent. You at least briefly looked at
 20 it; is that correct?
 21 A. Oh, yes, I did.
 22 Q. And that Polyox N80 that we're
 23 talking about, that was identified in the
 24 patent; is that correct?

1 A. I don't even remember the date of
 2 that '115 patent.
 3 Q. Thank you. But my question right
 4 now is that the Polyox N80 is identified in the
 5 patent; is that correct?
 6 A. I'm not even sure about that.
 7 Q. Okay.
 8 A. Because I honestly never go
 9 through the detail of it.
 10 Q. And you would agree with me that
 11 anybody looking at any commercially available
 12 PEO product like Polyox N80 would understand
 13 that it has the broad distribution weight that
 14 you found in your study; is that correct?
 15 A. I think that covered what I
 16 already replied. Almost all commercial polymers
 17 have the broad distribution.
 18 Q. And that would include Polyox N80;
 19 is that correct?
 20 A. Yes, definitely.
 21 Q. And that would have been
 22 well-known in the art; is that correct?
 23 A. Yes.
 24 Q. Okay. And you indicated that the

1 only way that you would recommend to determine
 2 molecular weight of a PEO sample was by a GPC or
 3 gel permeation chromatography analysis; is that
 4 correct?
 5 A. Looking at my --
 6 MR. BOLLINGER: I'm going to
 7 object. I don't think that is what he said.
 8 THE COURT: Can you rephrase the
 9 question?
 10 Q. I think his exact words, and you
 11 can tell me if this isn't what you said, but you
 12 were approached to look into the weight of the
 13 N80 sample; is that correct?
 14 A. Weight?
 15 Q. The molecular weight, the
 16 molecular weight distribution of the Polyox N80
 17 sample that you obtained; is that correct?
 18 A. Correct.
 19 Q. And you said that the only way I
 20 would recommend for that pass would be a GPC
 21 analysis; is that correct?
 22 A. To look into molecular weight
 23 distribution.
 24 Q. And that's not described anywhere

1 in the patent, GPC analysis; is that correct?
 2 A. I don't know.
 3 Q. And when you determined what
 4 approach you would take to evaluate or
 5 characterize the molecular weight of the Dow
 6 Polyox 180, N80 sample that you received, you
 7 didn't look to the patent to figure out how that
 8 should be done; is that correct?
 9 A. I mean, there's no relationship.
 10 I was asked to do something, so I do it.
 11 Q. And I just want to get for the
 12 record, to be clear, you did not consult the
 13 patent to figure out the appropriate method to
 14 characterize the molecular weight of the Polyox
 15 N80 sample; is that correct?
 16 A. Yes. With my experience in GPC, I
 17 don't need to consult a patent to do that.
 18 Q. So you just determined on your own
 19 based on your 40 or 50 years of experience how
 20 you would recommend to characterize the
 21 molecular weight of the sample; is that correct?
 22 A. I hope so.
 23 Q. And your determination was you
 24 should use gel permeation chromatography even if

1 that wasn't identified anywhere in the patent;
 2 is that correct?
 3 A. I don't know if it's your patent
 4 or not.
 5 Q. And you are aware that Dow does
 6 not use a GPC analysis to characterize the --
 7 well, strike that question. Let me state it a
 8 little differently.
 9 You recognize that Dow reports the
 10 molecular weight of Dow Polyox N80 as 200,000
 11 daltons; is that correct?
 12 A. Correct.
 13 Q. And Dow doesn't use a GPC analysis
 14 to determine that molecular weight, does it?
 15 A. No. Dow, every division have a
 16 GPC analysis, and I think one of the papers put
 17 up the -- she reported data on Polyox also.
 18 Q. But when Dow reports how it
 19 determines the molecular weight of Polyox N80,
 20 it specifically states that it's not using GPC
 21 analysis; is that correct?
 22 A. I don't know whether they say it
 23 uses GPC or not. I don't know.
 24 Q. They use a rheological method,

1 don't they?
 2 A. You should have asked that
 3 question. That I do know.
 4 Q. Okay. So does Dow, does Dow use a
 5 rheological measurement to determine molecular
 6 weight?
 7 A. They call that rheological, but
 8 basically, it's concentrate solution viscosity.
 9 The word "viscosity" is kind of confusing at
 10 this point.
 11 Q. And I'm sorry. So they use
 12 rheological measurements in order to determine
 13 the molecular weight of -- the reported
 14 molecular weight of their Polyox N80; is that
 15 correct?
 16 A. I am repeating myself. The
 17 concentrated solution viscosity.
 18 Q. And that's different, that's
 19 different from the GPC analysis that you did; is
 20 that correct?
 21 A. That's correct.
 22 Q. Okay. And given your experience
 23 with characterizing polymers and GPC analysis, I
 24 just want to be clear, you don't have any

1 experiments in developing pharmaceutical
 2 products; is that correct?
 3 A. No, I don't.
 4 Q. All right. I would like to, if we
 5 could call up -- actually, let's just flip on --
 6 can we turn on the Elmo? Thank you.
 7 Now, you gave two expert reports
 8 in this matter; is that correct? There was your
 9 first opening report and then you also did a
 10 reply report?
 11 A. Yes, I did.
 12 Q. All right. So this is -- I'm
 13 showing you a copy of plaintiffs' reply report
 14 of Dr. Wollschlaeger. This is your reply
 15 report?
 16 A. Yes.
 17 Q. And you, in your reply report, you
 18 talked some about the calibration standard you
 19 used in your GPC analysis; is that correct?
 20 A. That's correct.
 21 Q. And without getting too down into
 22 the weeds on the science, one of the ways that
 23 you calibrate your GPC is you go out and you buy
 24 special molecular weight PEO that has been

1 standardized into different discrete sets of
2 different discrete weights; is that correct?

3 A. I did purchase a calibration set
4 purposely designed for GPC, and it's nothing
5 close to the commercial Polyox product, which
6 would be very broad.

7 Q. And two different things. One is
8 sold as a commercial grade of 200,000 dalton,
9 and the other one is sold as a calibration
10 standard, and it has very, very specific
11 discrete sets of molecular weight PEO; is that
12 correct?

13 A. Yes. Narrow -- narrow viscosity,
14 like weight of a number close to one.

15 Q. And you do this in order to make
16 sure your GPC, the chromatography is working, is
17 all calibrated to give you the correct results;
18 is that correct?

19 A. Well, if I have to interpret it
20 more scientifically, in the GPC, you get
21 dilution time of the model coming through the
22 system. The time would have to recalibrate
23 against the molecular weight to come up with the
24 final weight of molecular weight distribution.

1 That's what these are about.

2 Q. And there's a figure in your reply
3 report that shows those, the distribution of
4 that set of PEO; is that correct?

5 A. Yes.

6 Q. And I've got here now a figure --
7 this is from your expert reply report. And the
8 axis here, it's very similar to what you plotted
9 for the overall Polyox N80 sample; is that
10 correct? That unimodal single peak sample we've
11 been looking at?

12 A. Well --

13 Q. This is also plotted on a
14 logarithmic scale?

15 A. It says the retention patent
16 there.

17 Q. Okay. And is this showing us also
18 here many modes, and each one of those modes are
19 going to correlate to a different weight of PEO
20 from your calibration set?

21 A. I have difficulty to understand
22 your question. If a weight -- we keep on
23 talking about different weight. I'm having
24 difficulty understanding that.

1 Q. Different molecular weight --
2 sorry. So if I'm looking at this chart from
3 your reply report, each of those peaks correlate
4 to a different part of the calibration standard
5 representing a different molecular weight; is
6 that correct?

7 A. Different molecular weight, yes,
8 for calibration. Yes.

9 Q. Thank you.

10 And now, Dr. Yau, you mentioned in
11 your report you prepared an Excel spreadsheet, a
12 table, in order to analyze your results; is that
13 correct?

14 A. Yes.

15 Q. And we've seen that a little bit,
16 and you've said that anybody can use that in
17 order to determine molecular weight averages
18 based on the partition that you've put into
19 place; is that correct?

20 A. They can check that.

21 Q. Okay.

22 MR. SMEREK: So if I could have up
23 JTX-143, please.

24 BY MR. SMEREK:

1 Q. There are a number of tabs at the
2 bottom. And you've created all of those tabs;
3 is that correct?

4 A. Yes.

5 Q. And if we can go first to overlay
6 600K, the one in red. Okay. We'll go there.

7 And this is the chart that we've
8 seen today; is that correct?

9 A. It looks like it.

10 Q. Okay. And then we see little tabs
11 at the bottom, and they start N80A1, N80B1. And
12 there's a separate tab for the results of each
13 one of the runs that you did; is that correct?

14 A. That's correct.

15 Q. And actually you only have one
16 sample of Dow Polyox N80 that you analyzed; is
17 that correct?

18 A. We purchased, yes.

19 Q. And the way you did your nine runs
20 is you, you separated out three different groups
21 of N80, excuse me, of Polyox N80, and then in
22 those three different groups, you then did three
23 different tests, one -- three for each of the
24 three groups to get a total of nine; is that

1 correct?

2 A. Correct.

3 Q. Okay. See N80A1 that path shows
4 the results of one of the analyses that you did;
5 is that correct?

6 A. Correct.

7 Q. And I believe Dr. Mathias had
8 testified that the overlays for those nine runs
9 were so close, that they really can't be
10 distinguished. Would that be your opinion as
11 well?

12 A. Define distinguished.

13 Q. I don't know. Let me ask you:
14 Would you distinguish them? Do you think
15 they're so close that we can look at one of them
16 as representative of all nine?

17 A. No.

18 Q. Okay. So you would have to look
19 at the different ones? Did you find material
20 differences in the results from each of the nine
21 runs you did?

22 A. Yes. Mathematically, and the
23 overlay indicates the different runs and the
24 three different vials, more or less I have a

1 similar, very close molecular weight of,
2 molecular weight distribution.

3 Q. And so they're materially the
4 same?

5 A. The data suggests that.

6 Q. Thank you.

7 So we're just going to focus on
8 this one sample, N80A1, and if I understand this
9 chart, we have on the right half of this page
10 starting at about Column U, we see the graph
11 that's now specific to this sample; is that
12 correct?

13 A. Yes. Could you show the top row?

14 Q. Yes. Absolutely. Does that help
15 you?

16 A. Yes.

17 Q. All right. Now, if we could roll
18 back up just so we get the whole graph in, right
19 there.

20 MR. SMEREK: Your Honor there's a
21 box on the left of the screen starting at column
22 N and in red, at line 8, that eight -- can we
23 move that over a little?

24 BY MR. SMEREK:

1 Q. All right. And column N at line
2 18, there's a number, and that's in red, and it
3 says, 600,000.

4 And, Dr. Yau, can you tell us what
5 that number is?

6 A. Yes. That's the molecular weight.
7 I was asked to do the partition of the data for
8 the analysis.

9 Q. Okay. So the red 600,000 is your
10 input through the attorney that says, slice
11 this, slice this data at 600,000 daltons, and so
12 you put that in. And then am I correct that the
13 other numbers in this table are then
14 automatically calculated based on the
15 experimental results and then your computations
16 of those results?

17 A. Yes, because the order is -- the
18 formulas are linked.

19 Q. And so now if we go down, when you
20 partition at 600,000 -- and let me just do this
21 to keep us on track.

22 MR. SMEREK: Can I get the Elmo
23 back up? Okay.

24 BY MR. SMEREK:

1 Q. Now, you were asked to do a
2 partition, and you were asked to do a partition
3 to divide the segment into low molecular weight
4 and high molecular weight; is that correct?

5 A. I divide the data, not the
6 example.

7 Q. Okay. So you're looking at
8 dividing the data. And where you were asked to
9 divide it was 600,000 daltons?

10 A. Yes.

11 Q. Okay. And when you divide it by
12 600,000 daltons -- so I'm going to put partition
13 here at 600,000. And that's where you were
14 asked to divide it; is that correct?

15 A. Yes.

16 Q. All right. Now, if we could go
17 back to -- zoom out a little bit on this so we
18 can see it. Thank you.

19 All right. And if we could go
20 back to your spreadsheet, there's an area
21 percentage, and that is in column N, line 22.
22 And what are the numbers that that relate to? I
23 see a 98 percent under low molecular weight and
24 a 1.97 percent high molecular weight.

1 **What do those percentages**
 2 **correlate to?**
 3 **A. Correlate to the percentage of the**
 4 **area separated by the two subsets.**
 5 **Q. Okay. So essentially what we have**
 6 **here is you had the partition at 600,000 and**
 7 **that's represented by the dotted line; is that**
 8 **correct?**
 9 **A. Correct.**
 10 **Q. And now you're saying that**
 11 **everything to the left is low molecular weight**
 12 **PEO; is that correct?**
 13 **A. Low molecular weight molecules,**
 14 **yes.**
 15 **Q. And everything to the right is**
 16 **high molecular weight; is that correct?**
 17 **A. Yes.**
 18 **Q. Okay. And then so area percentage**
 19 **tells us the percent on either side of that**
 20 **divide; is that correct?**
 21 **A. That's what it says.**
 22 **Q. Great. If we drop down, the next**
 23 **one is MW, and that's in column N, line 23, and**
 24 **that's the weight average molecular weight?**

1 **A. Yes.**
 2 **Q. And so this chart has calculated**
 3 **the weight average molecular weight for the low**
 4 **part of this partition and then differently for**
 5 **the high part in column P; is that correct?**
 6 **A. That's correct.**
 7 **Q. All right. So what I'd like to do**
 8 **is focus on the viscosity molecular weight. And**
 9 **can you tell me where is viscosity molecular**
 10 **weight on this chart?**
 11 **A. Yes. That's in row O-24 and P-24.**
 12 **Q. And can you tell me what the low**
 13 **viscosity molecular weight is that you, you came**
 14 **up with for a partition sample partitioned at**
 15 **600,000?**
 16 **A. No. You have to repeat that**
 17 **question. I don't understand.**
 18 **Q. Sorry. This was your analysis**
 19 **with a partition at 600,000; is that correct?**
 20 **A. Correct.**
 21 **Q. And in column O, it tells us your**
 22 **calculation based on your analysis of the**
 23 **average molecular weight for the low part; is**
 24 **that correct?**

1 **A. The low subset, yes.**
 2 **Q. And based on your calculation,**
 3 **what is the low average viscosity molecular**
 4 **weight with a partition at 600,000 for run**
 5 **N80A1?**
 6 **A. You want me to read the number?**
 7 **Q. That would be helpful. Thank you.**
 8 **A. Okay. 97,223.**
 9 **Q. 97,223. So if we can go back to**
 10 **the Elmo. Under low molecular weight, a**
 11 **partition at 600,000, your calculations came up**
 12 **with 977,223; is that correct?**
 13 **A. No.**
 14 **Q. I'm sorry. 97. I've got an extra**
 15 **seven in there. 97,233; is that correct?**
 16 **A. I think so.**
 17 **Q. All right. Let's go back. We**
 18 **can't get those both up; correct? All right.**
 19 **And then the high molecular**
 20 **weight, what is that then for the average**
 21 **viscosity molecular weight high?**
 22 **A. Yes. 900,534.**
 23 **Q. 900,534. So if we can go back to**
 24 **the Elmo, 900,534. Great.**

1 **So let's go back to your chart.**
 2 **Now, you were explaining that you had done this**
 3 **so people can run the partition anywhere they**
 4 **would like; is that correct?**
 5 **A. Yes.**
 6 **Q. And, in fact, this sample can be**
 7 **partitioned anywhere you would like to partition**
 8 **it; is that correct?**
 9 **A. Sample cannot be partitioned.**
 10 **Q. The analysis can be partitioned?**
 11 **A. Yes. The data is partitioned, but**
 12 **it does not change the data set, it does not**
 13 **change the sample.**
 14 **Q. And, in fact, that is because just**
 15 **because you've partitioned the data, you've**
 16 **partitioned the results, that actually doesn't**
 17 **change how the Polyox N80 was made or whether --**
 18 **whether it was ever comprised of two discrete**
 19 **sets. It just says you can take the data and**
 20 **divide it any way you want; is that correct?**
 21 **A. No, that's not correct. Well,**
 22 **like I said, the partition does not change the**
 23 **sample. The question is, are there materials in**
 24 **the sample that have those --**

1 Q. Okay. So if we look here and I
2 want to go back to cell N18. And now if I
3 wanted to partition this at, say, 300,000
4 daltons instead of 600,000 daltons, that's a --
5 that's another partition that you've heard about
6 here today from the patent. It's another
7 molecular weight identified in the patent.

8 Am I correct that I could just
9 type in 300,000 in this cell and hit calculate?

10 A. Yes. I started saying that at the
11 beginning. You're repeating.

12 Q. That is why you calculated this
13 sheet, so you could make this analysis; right?

14 A. Make this template to be helpful
15 to anybody.

16 Q. Thank you.

17 So let's go ahead and do that. So
18 we've done 300 and we hit calculate. Now we see
19 in the graph the partition moved; right? And it
20 moved to the left?

21 A. It should be.

22 Q. And now if we, if we decided to
23 partition this sample at 300,000 daltons, what
24 is the average viscosity molecular weight for

1 the lower portion?

2 A. It's lower.

3 Q. And what is it specifically?

4 A. It's 81,340.

5 Q. Okay. And then if we look over at
6 the high viscosity molecular weight, what is the
7 average high viscosity molecular weight now?

8 A. It's 511,309.

9 Q. Okay. So just by moving the
10 partition, we change the average molecular
11 weight of our high set and our low set; is that
12 correct?

13 A. We change the two sets.

14 Q. Okay. And I didn't actually
15 change the sample, as you said.

16 A. Exactly.

17 Q. I just changed the analysis?

18 A. Yes.

19 Q. Okay.

20 A. The way you interpret it.

21 Q. So can we jump back to the Elmo.

22 So when I do 300,000, I did a low
23 molecular weight viscosity, low average
24 molecular weight viscosity of 81,340, and a high

1 of 511,309.

2 Now, let's go back to your
3 exhibit. This is a very helpful. Thank you for
4 preparing it. And I think this is really
5 critical to understand goes exactly how the
6 partition is used to calculate average molecular
7 weights.

8 A. I was trying to be helpful.

9 THE COURT: Mr. Smerek, do you
10 have a question?

11 MR. SMEREC: I do. Thank you,
12 your Honor.

13 BY MR. SMEREC:

14 Q. Now, if we change this now to
15 100,000 and hit enter, now, this will tell us
16 the average molecular weights on either side of
17 a partition at 100,000; is that correct?

18 A. Yes.

19 Q. Okay. And so here, the average
20 molecular weight for the low viscosity average
21 is 46,842; is that correct?

22 A. Correct.

23 Q. I'm sorry?

24 A. Yes.

1 Q. And the high viscosity average
2 molecular weight now is what?

3 A. 225,306.

4 Q. Okay. And if we can go back to
5 your chart. And if we now cut it at 900,000,
6 which is the other number identified in the
7 patent, and enter. And now your chart shows us
8 we have a high -- excuse me. It partitioned at
9 900,000. The low average viscosity molecular
10 weight was 102,673; is that correct?

11 A. Yes.

12 Q. And now the high average viscosity
13 molecular weight is 1,260,077; is that correct?

14 A. Correct.

15 Q. Okay. So if we can go back to the
16 Elmo for a moment.

17 So all of these numbers that we
18 are looking at with the partition at 900,000,
19 600,000, 300,000, 100,000, all of the numbers
20 shown here for low molecular weight and high
21 molecular weight on either side of the partition
22 were derived from the same Polyox N80 sample; is
23 that correct?

24 A. Correct.

1 Q. And the only difference here is
2 where the partition line is drawn; is that
3 correct?

4 A. Yes. Yes.

5 Q. Okay. And now if I could get
6 JTX-1, I believe it's the '150 patent, up, and
7 if we could look at claim 1.

8 MR. BOLLINGER: Your Honor, he has
9 not testified about the claim at all. He's not
10 here offering opinions regarding this patent.

11 THE COURT: So you can ask him a
12 question. You don't need claim 1 to do that.

13 MR. SMERЕК: Thank you, your
14 Honor.

15 BY MR. SMERЕК:

16 Q. Looking at -- if we go back to the
17 Elmo. Looking at where you were asked to draw
18 the line 600,000, you will agree with me that
19 the low molecular weight 97,223, that is less
20 than 100,000; is that correct?

21 A. Yes.

22 Q. And if I move the partition now,
23 if I slide the partition lower and lower and
24 lower from 600,000, my lower molecular weight

1 average gets lower and lower and lower. It
2 moves away from 100,000; is that correct?

3 A. Could I make a comment?

4 Q. I -- I would just like to -- I
5 want to make sure I'm understanding how the
6 partition operates in your analysis.

7 A. The calculation works.

8 Q. So if I set my partition at
9 600,000, if I move my partition lower, lower
10 than 600,000, my had low molecular weight
11 average is going to become lower and lower and
12 lower than 97,000; is that correct?

13 A. Yes. That's obvious.

14 Q. Okay. And now if I'm at 600,000
15 and I move my partition higher than 600,000, as
16 reflected here, it's going to be the high
17 average molecular weight is going to be higher
18 and higher and higher than 900,000; is that
19 correct?

20 A. Yes.

21 Q. Okay. So in any way I slice this
22 data, whether I move my partition higher or I
23 move my partition lower, there's no way that I
24 can slice this data that would give me both an

1 average low molecular weight less -- in the
2 range of 100 to 300,000, and at the same time
3 give me a high average molecular weight between
4 600 and 900; is that correct? 600 and 900,000;
5 is that correct?

6 A. Yes. This is a clear observation
7 from the data, yes.

8 Q. Okay.

9 MR. SMERЕК: Nothing further, your
10 Honor.

11 THE COURT: All right. Any
12 redirect?

13 MR. BOLLINGER: Yes. Just
14 briefly.

15 Can you put that back up on the
16 Elmo?

17 MR. SMERЕК: If you would like to
18 use it, we would move to admit it under 1,006 as
19 a summary of Exhibit JTX-143.

20 THE COURT: What's your position?

21 MR. SMERЕК: Certainly, I think if
22 they're going to use it for questioning --

23 MR. BOLLINGER: I won't use it.
24 We don't think it's appropriate to be part of

1 the record.

2 THE COURT: All right. Well, it's
3 not admissible.

4 MR. SMERЕК: Thank you.

5 REDIRECT EXAMINATION

6 BY MR. BOLLINGER:

7 Q. Thank you, Dr. Yau. And I just
8 have a brief followup now.

9 The analysis of selecting
10 different partitions doesn't change the overall
11 data set; is that correct?

12 A. Not the data set or the sample.

13 Q. All right. But when you partition
14 at different spaces, you're actually changing
15 the discrete sets. The high and the low,
16 they're changing. The data that now you're
17 looking at has changed; is that right?

18 A. The whole data doesn't change, but
19 the division of the two subsets changed.

20 Q. Right. So there's fewer molecules
21 in the low molecular weight slice if you
22 partition at a lower value. There's just less
23 molecules being considered; is that right?

24 MR. SMERЕК: Objection, your

1 Honor. Leading.

2 THE COURT: Overruled.

3 THE WITNESS: Yes. When you moved

4 the way to interpret the data, things change.

5 BY MR. BOLLINGER:

6 Q. And in the lead-up during the

7 cross, counsel had repeatedly asked you whether

8 the data from GPC was a molecular weight, and

9 that you had been asked to do molecular weight

10 calculation. I think you were saying it was

11 molecular weight distribution. Is that what GPC

12 calculates?

13 A. Yes. GPC is a technique, so

14 molecular weight distribution of polymers can be

15 analyzed.

16 Q. And when you do a rheological or

17 viscosity measurement to determine an average

18 molecular weight, can you tell anything about

19 the distribution of that sample?

20 A. No.

21 Q. So that wasn't available as a

22 technique at that time if you needed a

23 distribution like we wanted to show here?

24 A. I don't know whether that's a --

1 that's available at that time, because I don't

2 know what that time is.

3 Q. I'm sorry. I didn't mean to leave

4 it. We'll leave it like that.

5 Now, you had wanted to say

6 something in response to one of the questions

7 that counsel for defendants asked, and

8 rightfully, he asked you to save it for

9 redirect.

10 Is there something you wanted to

11 add to your testimony today?

12 A. One thing is that I should have

13 said that it's that, the Dow uses the so-called

14 rheology measurement. It's actually, I said

15 that it's a concentrate solution viscosity, but

16 that's some empirical way they try to get result

17 of viscosity average molecular weight. But the

18 most fundamental way to get the viscosity

19 average molecular weight is to produce solution

20 viscosity that GPC offers.

21 MR. BOLLINGER: All right. Thank

22 you, your Honor. I have no further questions.

23 THE COURT: Thank you.

24 MR. SMEREK: Your Honor, I just

1 have one question, please.

2 THE COURT: Sure.

3 RECROSS EXAMINATION

4 BY MR. SMEREK:

5 Q. And, Dr. Yau, at your deposition,

6 you testified that rheological measurements were

7 not accepted molecular weight technique; is that

8 correct?

9 A. Yes.

10 Q. Thank you.

11 A. In general.

12 THE COURT: All right. Dr. Yau,

13 thank you. You may step down.

14 THE WITNESS: Thank you.

15 (Witness excused.)

16 THE COURT: All right. Well, I

17 guess we'd better break for lunch, so we'll take

18 an hour. Be back here at five of 2:00. All

19 right?

20 (Luncheon recess taken.)

21 - - -

22 Afternoon Session, 1:57 p.m.

23 THE COURT: All right. Please be

24 seated. Let's continue.

1 Am I right, is this where the

2 plaintiff rests on infringement and we move over

3 to the other side?

4 MR. BOLLINGER: As it relates to

5 the '150 patent, your Honor, evidence is done,

6 but because we have other patents, I guess our

7 case isn't completely over.

8 THE COURT: Okay. Right. I

9 forgot about that. All right. Well, call your

10 next witness.

11 MR. LOMBARDI: Your Honor, while

12 we're getting that organized, I guess, I believe

13 the '150 evidence on infringement is done with

14 respect to our clients, and I suspect you wanted

15 to take this at the end of the case, but I will

16 just say that we have a motion that they have

17 not met their burden of proof on infringement.

18 THE COURT: Okay. Don't let it

19 slow you down from putting on a case.

20 MR. LOMBARDI: No, we're not. And

21 we're going to bring, we're going to introduce

22 the next witness, which will be a deposition

23 clip.

24 THE COURT: Okay. Because both of

Myers - designations 234

1 your other patents against Watson are in
2 December?

3 MR. BOLLINGER: That's correct.
4 After the '150 on infringement and validity with
5 Watson, then we go to the invalidity, their
6 challenge to the '514 patent.

7 THE COURT: Okay. All right.
8 MS. LACKEY: Yes, your Honor.
9 Melinda Lackey for defendants.

10 THE COURT: Hi, Ms. Lackey. How
11 are you doing?

12 MS. LACKEY: Good. Thank you.
13 We're about to play a short clip
14 of the deposition of Mr. Gary Myers taken in
15 this case.

16 Mr. Myers is an employee of
17 MonoSol and a named inventor on the '150, '514
18 and '832 patents at issue in this case.

19 THE COURT: Okay.
20 MS. LACKEY: The clip is under ten
21 minutes. He refers to an exhibit marked Myers
22 14 in the deposition that was Bates labeled
23 MSL0002715 to 2763, and this is an excerpt from
24 the file history of the '832 patent. And that

Myers - designations 235

1 has been pre-admitted in this case, your Honor0,
2 as JTX-0006, and we'd just like for it to be
3 recognized that way.

4 THE COURT: Okay.
5 MS. LACKEY: Okay.
6 (Videotaped deposition clip of
7 Gary Myers played as follows.)
8 "Question: Good morning,
9 Mr. Myers. Are you presently employed?
10 "Answer: Yes.
11 "Question: What is your present
12 position?
13 "Answer: I'm the development -- I
14 work in the R&D group, or I did work in the R&D
15 group. Now I changed jobs recently. I'm more
16 into corporate technology.
17 "Question: And for what
18 corporation?
19 "Answer: MonoSol Rx.
20 "Question: Dr. Myers, I've marked
21 as Exhibit Myers 14 a document with production
22 numbers MSL_2715 running forward to 2763. I
23 would just ask you to flip through this and let
24 me know if you recognize it.

Myers - designations 236

1 "Answer. (Reviewing.)
2 "Yes.
3 "Question: Would you go forward
4 to paragraph 33.
5 "And my question for you is, does
6 the -- first of all, does the commercial
7 Suboxone film strip product use the combination
8 of high molecular weight, 600,000 to 900,000,
9 with low molecular weight, 100,000 to 300,000,
10 polyethylene oxide that's described in this
11 sentence?
12 "Answer: Yes, sir.
13 "Question: And have you ever made
14 a film strip meeting the description here of a
15 high molecular weight, 600,000 to 900,000,
16 polyethylene oxide, and a low molecular weight,
17 100,000 to 300,000, polyethylene oxide?
18 "Answer: Have I ever --
19 "Question: Have you ever made
20 such a --
21 "Answer: I'm sure I have, yeah.
22 "Question: How did you determine
23 the molecular weight of each of the two
24 polymers?

Myers - designations 237

1 "Answer: Those are, as you
2 probably well know, are commercial Polyox
3 numbers.
4 "Question: And so, for example --
5 Polyox is a brand name of Dow --
6 "Answer: Correct.
7 "Question: -- Dow Chemical,
8 correct?
9 "Answer: (Moving head up and
10 down.)
11 "Question: And so if -- so for a
12 high molecular weight polymer of, say, 900,000,
13 you purchased Polyox 900,000?
14 "Answer: Correct.
15 "Question: And for the low
16 molecular weight product, you purchased Polyox,
17 say, 200,000?
18 "Answer: 100,000, 200,000.
19 "Question: And --
20 "Answer: 300,000.
21 "Question: And did you ever
22 separately measure the molecular weight of
23 those --
24 "Answer: No, sir.

1 **"Question: To your knowledge, did**
2 **anyone at MonoSol ever separately measure the**
3 **molecular weight of those polymers?**
4 **"The Witness: No, sir."**
5 **(End of videotape clip.)**
6 **MR. LOMBARDI: That's the end of**
7 **the deposition clip, your Honor.**
8 **THE COURT: All right.**
9 **MR. LOMBARDI: And we're now going**
10 **to be calling Dr. Jason McConville.**
11 **THE COURT: All right.**
12 **DEFENDANTS' TESTIMONY.**
13 **... JASON MCCONVILLE, having**
14 **been duly sworn as a witness, was**
15 **examined and testified as**
16 **follows...**
17 **MR. NUTTER: Your Honor, as you**
18 **expect, we have some binders of material. May**
19 **we approach?**
20 **THE COURT: Yes. Sure.**
21 **(Ms. Lackey handed binders to the**
22 **Court.)**
23 **MR. NUTTER: Nut may it please the**
24 **Court?**

1 **DIRECT EXAMINATION.**
2 **BY MR. NUTTER:**
3 **Q. Good afternoon, Dr. McConville.**
4 **A. Hi.**
5 **Q. Can you please state your full**
6 **name for the record?**
7 **A. Jason McConville.**
8 **Q. Dr. McConville, what do you expect**
9 **to testify about today?**
10 **A. Today I'm going to specifically**
11 **talk about whether Watson's ANDA product**
12 **infringes on the '150 patent.**
13 **Q. I'd like to first look at what has**
14 **been marked as JTX-15. Is this your curriculum**
15 **vitae?**
16 **A. Yes, it is.**
17 **Q. And is this a true and correct**
18 **description of your educational and employment**
19 **background?**
20 **A. Yes.**
21 **Q. Can you very briefly provide the**
22 **Court a description of your education and**
23 **professional history?**
24 **A. Yes. Sure. In 2002, I graduated**

1 **with a Ph.D. in pharmaceuticals from the**
2 **University of Strathclyde in Scotland. I**
3 **focused my research there on all drug delivery**
4 **products.**
5 **After that, I moved to the**
6 **University of Texas at Austin, did a**
7 **post-doctoral position before joining the**
8 **faculty there in 2006 as an assistant professor**
9 **of pharmaceuticals. And my research focus was**
10 **there on inhaled pharmaceuticals as well as all**
11 **solid dosage forms as well.**
12 **Then in 2012, I moved to the**
13 **University of New Mexico, obtained tenure, and**
14 **currently an associate professor of**
15 **pharmaceuticals. My research areas here**
16 **principally are involved now with films for**
17 **delivery to the oral cavity. I also work on**
18 **inhaled pharmaceuticals and some oral solid**
19 **dosage forms.**
20 **And I currently have an adjunct**
21 **position as well at the University of Bonn in**
22 **Germany.**
23 **Q. Do you specialize in any**
24 **particular drug formulation technology?**

1 **A. Yes. Lots of my current research**
2 **is on pharmaceutical films for the buccal**
3 **administration, which is the cheek, or the**
4 **sublingual delivery, under the tongue.**
5 **Q. And as part of your pharmaceutical**
6 **training, do you have experience with the use of**
7 **polyethylene oxide and sublingual films?**
8 **A. Yes. This has been incorporated**
9 **in several of the research films that I've**
10 **looked at.**
11 **MR. NUTTER: Your Honor, at this**
12 **time Watson would like to offer Dr. McConville**
13 **as an expert in the field of sublingual drug**
14 **delivery and formulation.**
15 **THE COURT: All right. You may**
16 **proceed.**
17 **BY MR. NUTTER:**
18 **Q. Dr. McConville, first, I'd like to**
19 **just look at the '150 patent, which has been**
20 **marked as JTX-1. In a very general sense,**
21 **what's the subject matter of the '150 patent?**
22 **A. Well, simply this patent is**
23 **related to the preparation of thin film**
24 **formulation using polyethylene oxide and**

1 specifically targeting the sublingual area of
2 the mouth.

3 Q. Now, do you have an understanding
4 of what it takes to be a person of ordinary
5 skill in the art as it relates to the '150
6 patent?

7 A. Yes, I do.

8 Q. What's your understanding?

9 A. Well, I have a slide taken from my
10 expert report on this. And basically I believe
11 a person of ordinary skill in the art should
12 possess a Bachelor's degree in pharmaceutical
13 sciences or a related field with at least two to
14 five years of relevant experience, preferably
15 with film formulation experience in mind.

16 Alternatively, if they have a
17 higher degree, a Master's degree or Ph.D., then
18 perhaps a little less of this practical
19 experience.

20 Q. All right. Thank you.

21 Now, do you know which claims of
22 the '150 patent have been asserted against
23 Watson?

24 A. Yes. Claims 1 and 4.

1 Q. Now, you were in the courtroom
2 this morning, and you heard Dr. Mathias testify?

3 A. Yes.

4 Q. And you heard him opine that
5 Watson's ANDA products infringe claims 1 and 4
6 of the '150 patent; is that right?

7 A. Yes, I heard that.

8 Q. Do you agree with him?

9 A. No, I do not.

10 Q. Why not?

11 A. Well, I have another slide which
12 takes us through the key areas of my contention
13 here.

14 So, first of all, I believe
15 Watson's ANDA products do not include discrete
16 sets or two different PEOs, one of a low
17 molecular weight and one of a high molecular
18 weight.

19 And, in fact, my second point here
20 is that Watson's ANDA products, in fact,
21 practice the prior art as they only have one PEO
22 component.

23 Then if we move on to Dr. Yau and
24 Mathias' partition theory, it's fundamentally

1 flawed when you apply it to this '150 patent
2 when you consider the polyethylene oxide are
3 included.

4 And if we move on thinking about
5 that partition theory, I do not believe that
6 they find numbers within the claim range, so
7 they're outside, and at best, they only find a
8 stray amount of PEO in the high molecular weight
9 range.

10 Q. Thank you.

11 Now, before we start reviewing
12 your noninfringement opinion, what legal
13 standard did you use to analyze the issue of
14 infringement?

15 A. I have another slide with that.
16 And basically, in consideration of Watson's ANDA
17 product, it's my opinion that they do not
18 contain every limitation of the asserted claims
19 1 and 4 of the '150 patent.

20 Q. Thank you.

21 Now I'd like to take a look
22 specifically at claim 1 of the '150 patent.
23 This is JTX-1, claim 1.

24 Now, I've highlighted numerous

1 references to the term polyethylene oxide, which
2 I think everyone in the room now knows is also
3 referred to as PEO.

4 Can you very briefly explain to
5 the Court in your own words what polyethylene
6 oxide is and how it's manufactured?

7 A. Yes, sure. I have another slide
8 that shows that more clearly.

9 So basically, we have ethylene
10 oxide monomers, which are reacted together to
11 form the polyethylene oxide polymer. So in the
12 reaction vessel, over time the ethylene oxide
13 joins together to polymerize and form a
14 distribution of molecular weights. At a certain
15 point in time, this process is stopped, and we
16 have distribution of molecular weights around an
17 average.

18 Q. Now, I see the title of this
19 demonstrative 2.8 is unimodal size distribution
20 of polymers. What do you mean by unimodal size
21 distribution?

22 A. It's quite straightforward. This
23 really refers to the fact that there's one peak.
24 It's a unimodal distribution of particle sizes.

1 **Q. And how is the average molecular**
2 **weight determined when there's one peak?**

3 **A. Well, basically, with this type**
4 **of normal distribution, we look at the middle**
5 **and we find that that is where an average would**
6 **be.**

7 **Q. Now, I see I guess what I would**
8 **call tails on the bottom portions of the left**
9 **and right side. What do those tail portions**
10 **represent?**

11 **A. Well, really, these are very small**
12 **amounts on the left and on the right. The tail**
13 **ends of this, these are tiny amounts of smaller**
14 **molecular weight PEO on the left and small stray**
15 **amounts of PEO at the larger molecular weight on**
16 **the right. But what you've got to remember,**
17 **this is a normal distribution with only one**
18 **average in the middle. We're taking the average**
19 **of all of that range.**

20 **Q. And is it fair to understand that**
21 **this is a graphical distribution of a single PEO**
22 **sample?**

23 **A. Absolutely, yes.**

24 **Q. Now, how would you expect the**

1 **distribution to look if it was a sample of two**
2 **blended PEOs?**

3 **A. I've got another slide to show you**
4 **that. Basically, I would expect a biomedical**
5 **distribution. I would expect if we mixed two**
6 **PEOs that had different average molecular**
7 **weights, is that we would see something like**
8 **this (indicating) for the bimodal distribution,**
9 **where the two peaks are combined.**

10 **Q. Now, let's go back and look at the**
11 **language of claim 1 of the '150 patent. Can you**
12 **explain to the Court all of the requirements of**
13 **claim 1?**

14 **A. Yes. Sure. We can start at the**
15 **top. And really, if we look here, it must have**
16 **a water-soluble polymer component, and this**
17 **water-soluble polymer component consists of the**
18 **PEOs with the hydrophilic cellulosic polymer.**
19 **And I've shown this in purple, in green, so you**
20 **can follow along within the claim language.**

21 **The PEO itself consists of two**
22 **types of PEO. They consist of a low molecular**
23 **weight PEO, between the ranges 100 to 300,000**
24 **daltons, and this has also a high molecular**

1 **weight PEO, in the ranges of 600 to 900,000**
2 **daltons, as shown in the claim language.**

3 **Q. Now, when you say 100 to 300,000,**
4 **you mean 100,000 to 300,000; is that right?**

5 **A. Yes. Sorry.**

6 **Q. When you said 600 to 900,000, you**
7 **meant 600,000 to 900,000?**

8 **A. That's correct, yes.**

9 **Q. And then what's the final**
10 **requirement of claim 1?**

11 **A. Well, this low average molecular**
12 **weight PEO component must comprise greater than**
13 **or equal to 60 percent of the entire film**
14 **polymer component.**

15 **Q. Okay. Thank you for that.**

16 **Now I would like to talk about**
17 **your first opinion, which is that Watson's**
18 **ANDA products do not include discrete sets of**
19 **low molecular weight and high molecular weight**
20 **PEOs.**

21 **Turning again to claim 1, JTX-1 of**
22 **the '150 patent, which limitation in claim 1**
23 **includes this requirement?**

24 **A. Well, it specifically tells us**

1 **that there must be a low molecular weight**
2 **polyethylene oxide in the range of 100,000**
3 **daltons to 300,000 daltons, as I've just**
4 **described, as well as a high molecular weight**
5 **PEO from 600,000 to 900,000 daltons, as I've**
6 **described earlier.**

7 **Q. Now, did the Court construe this**
8 **specific limitation?**

9 **A. Yes, they did.**

10 **Q. Okay. I'd like to refer you to**
11 **what has been marked as JTX-244. This is at**
12 **page 7.**

13 **How did the Court construe the low**
14 **and high molecular weights at issue here?**

15 **A. Well, it specifically indicates**
16 **that there must be at least two PEOs any way,**
17 **because we have to have one or more PEO with a**
18 **lower average molecular weight, and one or more**
19 **PEO with a higher average molecular weight.**

20 **Q. Now, earlier you mentioned the**
21 **term discrete sets, and I don't see that shown**
22 **here.**

23 **Is there elsewhere in the Court's**
24 **claim construction order where the term discrete**

1 sets was applied?

2 A. Yes. I believe it's on page 10 of
3 this description.

4 Q. What --

5 A. Basically --

6 Q. What is your understanding of the
7 term discrete sets?

8 A. Well, my understanding of the term
9 discrete sets is that we have two components
10 here. And each discrete set, if you like, would
11 be this -- one would be a low average molecular
12 weight PEO, and one would be a high average
13 molecular weight PEO. It goes on to indicate
14 that combining small amounts of the high
15 molecular weight PEOs with larger amounts of the
16 low molecular weight PEOs are necessary. It's
17 this combination. When you combine things,
18 you're adding them together.

19 Q. Now, is there any support in the
20 specification of the '150 patent for your
21 understanding that the term discrete sets
22 requires a combination of PEOs?

23 A. Yes, there is.

24 Q. All right. I'd like to return you

1 to JTX-1 at column 18, lines 11 through 21.
2 Please explain to the Court why you believe this
3 section supports your understanding of the term
4 discrete sets.

5 A. Well, essentially, this portion of
6 the patent really outlines the entire claim
7 language in claim 1. It shows us that there is
8 a -- to combine high molecular weight PEO,
9 600,000 to 900,000 daltons, with low molecular
10 weight PEO, 100,000 to 300,000. And these are
11 the PEOs in the polymer component.

12 It then, in fact, tells us why
13 that is useful. It tells us that certain film
14 properties, such as fast dissolution rates and
15 high tear resistance, may be attained by
16 combining small amounts of high molecular weight
17 PEOs with the low molecular weight PEOs.

18 It actually goes further to tell
19 us that there must be 60 percent or greater
20 levels of the lower molecular weight PEO in
21 that.

22 Q. Now, before we continue, would you
23 ever consider a single PEO has been partitioned
24 to be a combination of a low and high average

1 molecular weight?

2 A. No, I would not.

3 Q. Okay. I'd like to go to a
4 different portion of the '150 patent. This is
5 JTX-1 at column 51, lines 30 through 34, as well
6 as table 22.

7 How does this portion of the '150
8 patent also support your understanding that
9 discrete sets requires a combination?

10 A. Well, this table shows us examples
11 of the polymer combinations that I've been
12 talking about, that are present in the patent.
13 And this excerpt is taken from the bottom.

14 Beneath the table it says that the
15 tear resistance of lower levels of PEO was shown
16 to be improved by combining small amounts of
17 higher molecular weight PEOs. And I showed this
18 in this table highlighted in red just as before,
19 with the lower molecular weight PEOs, and I will
20 show that in blue on the table.

21 Also included is the hydrophilic
22 cellulosic component, which we show in green
23 from before. And we can see that actually,
24 these compositions DT and DU taken from this

1 Table 22 of the enabling example is the only two
2 compositions that meet all the polymer
3 requirements of claim 1.

4 Q. Now, is there any example anywhere
5 in the '150 patent of a single grade PEO that
6 has been partitioned into two parts, each with
7 its own average molecular weight?

8 A. No, there is not.

9 Q. Okay. Now, before we look
10 specifically at Watson's ANDA products, I'd like
11 to first refer you to Table 21 of the '150
12 patent.

13 Can you briefly explain what's
14 being shown in Table 21?

15 A. Yes, absolutely. These
16 compositions here and the amounts of them are
17 basically examples of films which could be made
18 using the guidance of the patent. And at the
19 top, we can see that PEO is outlined.

20 Q. Now, I see a footnote one
21 identified with that PEO. What's that in
22 reference to?

23 A. Well, that tells us that this PEO
24 is available from the Dow Chemical Company.

1 Q. And what does this information
2 teach a person of ordinary skill in the art?

3 A. That the Dow Chemical company's
4 product is dictating the average molecular
5 weight that we should be considering to be
6 applicable in this patent.

7 Q. And how does Dow report the
8 average molecular weight for its PEO products?

9 A. They always report it as viscosity
10 average molecular weight, like every other
11 supplier.

12 Q. Now, what various viscosity
13 average molecular weight PEO products does Dow
14 offer for sale?

15 A. They offer a wide range of PEO
16 products for sale. And, in fact, their range
17 varies from about a hundred thousand into the
18 millions, but they're very specific about those
19 different grades that are available and they
20 always refer to them with this viscosity average
21 molecular weight.

22 Q. Now, why would a person of
23 ordinary skill in the art want to use different
24 viscosity at the molecular weight PEOs in a

1 sublingual drug formulation?

2 A. Well, the patent describes this as
3 well, and my experience tells me that the
4 different grades of PEO impart different
5 functional properties to a film when you use
6 them.

7 Q. Now, is there any teaching of
8 average molecular weight in the '150 patent
9 other than this reference to Dow Chemical
10 Company and its viscosity average molecular
11 weight?

12 A. No, there's nothing else.

13 Q. Now, let's talk specifically about
14 Watson's ANDA products.

15 Which company manufactures the PEO
16 that Watson uses in its ANDA products?

17 A. They specifically use Polyox N80,
18 which is available from the Dow Chemical
19 Company.

20 Q. Now, what viscosity average
21 molecular weight does Dow report for Polyox N80?

22 A. 200,000 daltons.

23 Q. Does Watson use any other PEO in
24 its ANDA products other than Polyox N80?

1 A. No. They only use a single
2 average molecular weight, viscosity average
3 molecular weight polymer. There's only one.

4 There's not a combination of PEOs in there.

5 Q. Now, how does the fact that Watson
6 only uses Polyox N80 in its ANDA products
7 support your opinion that Watson does not
8 infringe claim 1?

9 A. Well, just as I've said, this is a
10 single, considered to be a low average molecular
11 weight PEO, as the patent puts it. This is
12 200,000 daltons. There isn't any other PEO
13 that's used. This is it. So I mean it really
14 can't infringe because it does not have more
15 than one PEO.

16 Q. Thank you.

17 Now I'd like to talk about your
18 second opinion, which is that Watson's ANDA
19 products practice the PEO teachings of the prior
20 art. And to do that, I'd like to refer you to
21 the prosecution history, which has been marked
22 as JTX-4, and specifically pages 1,169 through
23 1170.

24 Just to orient you, this is

1 applicant's response to an obviousness rejection
2 in an office action, and the rejection was based
3 on a combination of references, the Schiraldi
4 prior art reference in view of the Flick prior
5 art reference.

6 Did you review the Schiraldi prior
7 art reference?

8 A. Yes, I did.

9 Q. Can you briefly explain to the
10 Court what is disclosed in that Schiraldi
11 reference?

12 A. Yes. Sure. If we look down here
13 in the second part of the highlighted paragraph,
14 basically, Schiraldi indicates that a
15 homopolymer of ethylene oxide should have a
16 relatively high molecular weight. In other
17 words, they're indicating this homopolymer of
18 ethylene oxide, which is another way of terming
19 PEO, it's the same thing, there's only one PEO
20 used in the films that Schiraldi suggests. It
21 can have a high, a large range of which PEO is
22 used, but there's only one used. The range
23 given by Schiraldi was 100,000 and preferably
24 above three million.

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1 Q. Now, what did the patent
2 applicants argument to the PTO to distinguish
3 the claimed invention from what's disclosed in
4 Schiraldi?
5 A. Well, they specifically state that
6 Schiraldi does not disclose any kind of
7 suggestion of a molecular weight combination.
8 Q. Now, how does that support your
9 noninfringement opinion?
10 A. Because Schiraldi is using a
11 single PEO in exactly the same way as Watson's
12 ANDA product.
13 Q. Thank you.
14 Now I'd like to talk about your
15 third opinion, which is that Dr. Yau and
16 Mathias' partition theory is fundamentally
17 flawed.
18 Now, you heard both Dr. Yau and
19 Mathias explain this morning why they believe
20 their partition data shows that Watson's ANDA
21 product infringes; is that correct?
22 A. Yes, I heard that.
23 Q. Do you agree?
24 A. No, I do not.

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1 Q. I'd like to refer you now to
2 JTX-143. It's a snippet from the data that Dr.
3 Yau provided in support of Dr. Mathias'
4 infringement opinion.
5 Can you explain what is being
6 shown by this curve?
7 A. Well, fundamentally enough, this
8 is exactly what I expect to see from PEO. This
9 is a unimodal distribution of a polymer, and
10 it's a single peak.
11 Q. Now, how would Dow report the
12 average molecular weight of a unimodal
13 distribution curve like this?
14 A. Well, it's a nice, normal
15 distribution, so we would look in the middle and
16 draw a line and we would get our average.
17 Q. Now, did Dr. Yau and Mathias rely
18 on the reported viscosity average molecular
19 weight that do you provided?
20 A. No, they did not.
21 Q. What did Dr. Yau and Mathias do
22 instead?
23 A. Well, they chose not to draw a
24 line in the middle to get the average. They

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1 decided to draw a line at the 600,000 dalton
2 mark on this unimodal distribution.
3 Q. Now, what do Drs. Yau and Mathias
4 consider everything to the right of that red
5 dotted line?
6 A. High molecular weight.
7 Q. And why was that line drawn?
8 A. Well, it's my understanding that
9 plaintiffs' attorneys asked Dr. Yau to put that
10 line there.
11 Q. And you said everything to the
12 right was the high molecular weight; is that
13 right?
14 A. Yes.
15 Q. And what's everything to the left
16 of that red dotted line?
17 A. The low molecular weight.
18 Q. Now, as a pharmaceutical
19 formulation scientist, do you agree with the
20 partition approach of Dr. Yau and Mathias?
21 A. Absolutely not. I've not seen
22 this done before for formulation.
23 Q. And why do you not agree with this
24 approach?

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1 A. Well, with basically artificially
2 creating two average molecular weights that
3 aren't there, there's already a single
4 distribution, and we're, in fact, ignoring what
5 the data is telling us.
6 Dow reports the average molecular
7 weight in the middle. That's what I look at is
8 a normal distribution. There's an average
9 there.
10 I mean, we are not chopping up the
11 sample or anything, so we can't obtain in
12 reality two average molecular weights. It's
13 just not possible.
14 Q. Now, can this single PEO sample be
15 partitioned at locations other than the 600,000
16 dalton mark?
17 A. Well, of course. You could ask me
18 to draw that line anywhere if I was analyzing
19 this unimodal peak.
20 Q. All right. Well, let's do that.
21 So let's draw the line at the 100,000 dalton
22 mark.
23 Now, if you buy into Dr. Yau's
24 partition theory, what would everything to the

1 right of this line represent?

2 A. Again, that would be the high
3 molecular weight.

4 Q. And everything to the left side?

5 A. The low molecular weight.

6 Q. So now according to Dr. Yau and
7 Mathias, the same Polyox N80 sample can have
8 different average molecular weights on the high
9 side and the low side, depending on where you
10 partition the sample?

11 A. Yes, exactly. We can move this
12 line, put it anywhere we like, and obtain
13 different average values. It's the same sample.
14 You know, this has got an average already.
15 We're just creating two averages out of thin air
16 by doing this, by moving the line wherever we
17 want.

18 Q. How about multiple times? Under
19 Dr. Yau's theory, can Watson's PEO be
20 partitioned more than once?

21 A. Yes, of course. You could put
22 several lines and say there were several
23 averages on either side of each of those lines.
24 You could put line after line after line. You

1 could put an infinite number of lines on there
2 if you wanted.

3 Q. And, again, a pharmaceutical
4 formulation scientist, does it make sense that
5 the same Polyox N80 sample can have an infinite
6 number of average molecular weights?

7 A. No, it does not. There's a
8 viscosity average molecular weight reported on
9 the bottle, and that is what I would use as a
10 formulation scientist in making a film.

11 Q. Now, in your opinion, is Dr. Yau's
12 partition analysis as relates to the '150
13 patent, is that in any way useful to a person of
14 ordinary skill in the art?

15 A. Absolutely not. I mean, you've
16 got to remember that this type of GPC analysis,
17 it seems to be quite an exhaustive approach, and
18 I'm -- I'm to make a film formulation. I've got
19 a bottle which has the average molecular weight
20 on it. I'm not going to run a GPC analysis to
21 then try and convince myself that what's on the
22 bottle is wrong, you know. It's, it's, it's
23 just not useful at all to a formulation
24 scientist to approach that. And that's not what

1 I see in the '150 patent.

2 Q. Thank you.

3 Now, in your 20-plus years of
4 experience with oral drug formulations, have you
5 ever used a single PEO sample with two different
6 reported viscosity average molecular weights?

7 A. Never.

8 Q. Now, is Dr. Yau's and Mathias'
9 partition theory, is that shown or described
10 anywhere in the '150 patent?

11 A. No, it is not.

12 Q. How about in the examples? Are
13 there any examples in the '150 patent where a
14 single sample of PEO is partitioned and then
15 described as having two average molecular
16 weights?

17 A. I have never seen this in any
18 formulation articles that I've looked at.
19 Whether it be film formulation articles or
20 tableting articles that use PEO, they have never
21 described a single PEO obtained from the Dow
22 Chemical Company or any other supplier as having
23 more than one average molecular weight.

24 Q. Okay. Thank you.

1 Now I'd like to talk about your
2 final opinion, which is that even if applicable,
3 the Yau/Mathias data still shows
4 noninfringement. And to do that, I would like
5 to look at the data. Specifically, again, at
6 JTX-143E, and this is under the N80 statistics
7 tab.

8 Can you very briefly explain to
9 the Court what is being shown in this table?

10 A. Yes. Basically, all of the data
11 we see in the table is selected from information
12 to the left of that 600,000 dalton mark line.

13 So basically, if I'm concerned
14 with the claimed range of the low end of the low
15 molecular weight portion, I'm looking at the
16 100,000 to 300,000 as being the claimed range,
17 and then I would use the data all to the left of
18 the 600,000 line to obtain this information.

19 Under the sample name here, we do
20 see nine different sample names, but what you've
21 got to remember is that this is only one lot of
22 Polyox N80 that was analyzed. It's just nine
23 repeat runs of the same sample.

24 Q. Now, I see a column a couple over,

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1 **MW.**

2 **Do you see that?**

3 **A. Yes.**

4 **Q. What does MW stand for?**

5 **A. That's the weight average**

6 **molecular weight.**

7 **Q. I see a column just to the right**

8 **of that, MB column. What does MB stand for?**

9 **A. That's the viscosity average**

10 **molecular weight.**

11 **Q. What is the difference between**

12 **weight average molecular weight and viscosity**

13 **average molecular weight?**

14 **A. Well, to put it in very basic**

15 **terms, the weight average molecular weight**

16 **considers that every PEO molecule has a**

17 **different weight, a different chain length. So**

18 **the atomic weight is slightly different -- I'm**

19 **sorry. The molecular weight is slightly**

20 **different.**

21 **So we obtain this weight average**

22 **molecular weight based on their molecular**

23 **weight, the polymer chain molecular weight. The**

24 **viscosity average molecular weight in a similar**

McConville - direct 267

1 **fashion understands that the polymer chain would**

2 **have a slightly different inherent viscosity.**

3 **So the viscosity average molecular weight is**

4 **calculated by taking that into consideration.**

5 **But I will point out that there**

6 **has been no sort of rheological evaluation of**

7 **this, no viscosity measurement to determine**

8 **these. These are back-calculated from the**

9 **spreadsheet that Dr. Yau presented. So they are**

10 **subject to the same variance in that data set.**

11 **They are not measured using a viscosity**

12 **analysis.**

13 **Q. Thank you.**

14 **Let's focus specifically on the MW**

15 **column, the weight average molecular weight.**

16 **What does Dr. Yau report as the**

17 **weight average molecular weight for the lower**

18 **fraction of Watson's Polyox N80?**

19 **A. 107,469 daltons.**

20 **Q. And is his number between 100,000**

21 **and 300,000?**

22 **A. Yes.**

23 **Q. Okay. Now let's turn to the next**

24 **column, the MV column, which is viscosity,**

McConville - direct 268

1 **average molecular weight.**

2 **What does Dr. Yau report as the**

3 **viscosity average molecular weight for this**

4 **lower weight fraction of Watson's Polyox N80?**

5 **A. 95,895 daltons.**

6 **Q. Now, how does Dr. Yau's**

7 **determination that the lower viscosity average**

8 **molecular weight is 95,895 daltons, how does**

9 **that number support your noninfringement**

10 **opinion?**

11 **A. It's outside of the claim range**

12 **between 100,000 and 300,000 daltons.**

13 **Q. Okay. Now let's look at the MV**

14 **data. For each of the nine runs, do any of the**

15 **reported calculations as reported by Dr. Yau, do**

16 **any of those average molecular weights fall**

17 **within the claimed range?**

18 **A. No. They are all outside of the**

19 **claimed range.**

20 **Q. Okay. Now, Dr. Mathias opines**

21 **that a person of ordinary skill in the art would**

22 **know to round the average molecular weight of**

23 **95,895 to 100,000.**

24 **Do you agree with that?**

McConville - direct 269

1 **A. No, I do not.**

2 **Q. Why not?**

3 **A. Well, the deviation, the standard**

4 **deviation as depicted by the relative standard**

5 **deviation, the small percentage at the bottom,**

6 **actually gives us confidence in this number. So**

7 **one wouldn't round this. We've already been**

8 **told it is quite a precise measurement, and**

9 **there's just no inclination to round this number**

10 **at all. It's reported as is. All the numbers**

11 **fall below the claim range. Why would you round**

12 **it above it?**

13 **Q. Okay. Thank you.**

14 **Now I would like to look at Dr.**

15 **Yau's calculation for the higher fraction of**

16 **the, of Watson's Polyox N80 PEO.**

17 **And to orient us, this is, again,**

18 **on JTX-143 at the N80 statistics tab. It's just**

19 **a little farther to the right.**

20 **Can you very briefly explain again**

21 **what is being shown in this table?**

22 **A. Yes. Now, this is again the same**

23 **nine runs performed with the same single lot**

24 **nine times. But this is all the data taken to**

McConville - direct 270

1 the right of the 600,000 dalton line. So that's
2 what we would see in this table, both for the
3 weight average molecular weight and the
4 viscosity average molecular weight calculated
5 from the spreadsheet.
6 Q. Okay. And, again, focusing on the
7 MW column, what does Dr. Yau report as the
8 weight average molecular weight for this higher
9 fraction of Watson's Polyox N80?
10 A. 917,865.
11 Q. And how does that number support
12 your noninfringement opinion?
13 A. This is outside of the claim range
14 between 600,000 and 900,000 daltons.
15 Q. And let's look at the individual
16 runs that Dr. Yau did to determine the weight
17 average molecular weight. Are any of those
18 numbers that I've highlighted here, are any of
19 them lower than, or fall within the claimed
20 range of 600,000 to 900,000?
21 A. No. They are all outside the
22 claim range. They're all above 900,000.
23 Q. Okay. Now, let's change the focus
24 to the MV column again, which is viscosity

McConville - direct 271

1 average molecular weight.
2 What does Dr. Yau report as the
3 viscosity average molecular weight for the,
4 again, the higher fraction of Watson's Polyox
5 N80?
6 A. 900,318 dalton.
7 Q. And how does that number support
8 your noninfringement opinion?
9 A. Again, this is outside of the
10 claimed range.
11 Q. Now, again, Dr. Mathias testified
12 that a person of ordinary skill in the art would
13 know to round 917,865 and 900,318 to 900,000.
14 Do you agree with that?
15 A. No. Again, we have a small
16 relative standard deviation giving us confidence
17 in that number. This number is taken from nine
18 runs. I don't believe you should just start
19 rounding numbers when you got this type of
20 average.
21 Q. Okay. Now, let's do a quick recap
22 of why you believe, even if applicable, Dr.
23 Yau's data shows that Watson's ANDA products do
24 not infringe. And if you could start with Yau's

McConville - direct 272

1 viscosity average molecular weight data.
2 A. Sure. So just -- I show here the
3 range of viscosity average molecular weights on
4 a diagram and the claim range for the low
5 average molecular weight is shown in blue, and
6 the range for the high average molecular weight,
7 viscosity average molecular weight, is shown in
8 red.
9 Basically, Yau's reported
10 viscosity average molecular weight falls below
11 the claim range for viscosity average. And the
12 reported average of 900,318 falls too high to be
13 in the claim range for the viscosity average
14 molecular weight, which the industry generally
15 relies on, this viscosity molecular weight.
16 Then if we were to use the weight average
17 molecular weight as it has been reported in the
18 data from Dr. Yau and Mathias, we do see that
19 the reported range, size of 107,469 does fall
20 inside the claim range for that one. However,
21 when we look at the upper end, the 917,865 is
22 outside of the claim range as before.
23 Q. Okay. Thank you.
24 Now I'd like to talk about your

McConville - direct 273

1 final opinion, which is that even if applicable,
2 the Yau/Mathias data shows noninfringement
3 because there's only a stray amount of high
4 molecular weight PEO.
5 And to do that, I'd first like to
6 go back to the Court's claim construction. This
7 is JTX-244 at 10.
8 What does the highlighted passage
9 on this demonstrative 2.029, what does that
10 represent?
11 A. Well, basically, this point at the
12 bottom where it says, the Court agrees with the
13 defendants that the product cannot be comprised
14 of only low average molecular weight PEOs, that
15 to me is Watson's ANDA product. It's only a low
16 average molecular weight PEO present.
17 But then it goes on to say, or
18 only low average molecular weight PEOs with
19 stray higher average molecular weight PEOs.
20 That, at best to me, is what Dr. Yau and Mathias
21 have demonstrated. Perhaps they have found a
22 stray amount in the tail of a low molecular
23 weight PEO product, only one of which they've
24 analyzed.

1 Q. Now, just focusing on the term
2 stray higher average molecular weight PEOs,
3 what's your understanding of what it takes to be
4 a stray amount?

5 A. In my experience with films, as
6 films are thin this -- small areas for
7 dissolution, dissolution and tear resistance,
8 very important, as we've seen in the patent.
9 You need an amount that is going to have a
10 functional impact on that film, and anything
11 less than ten percent, I would say, wouldn't be
12 able to affect the functional properties of a
13 given film.

14 Q. Okay. Now, is there any support
15 in the '150 patent for your opinion that
16 anything less than ten percent would only be a
17 stray amount?

18 A. Yes, there is.

19 Q. I'd like to refer you again back
20 to the '150 patent. This is JTX-1 at columns
21 50, lines 13 through 33, table 22.

22 Please explain why you believe
23 this table, the highlighted portions, supports
24 your understanding of the term stray amount.

1 A. Well, if we look at this 900,000
2 PEO, which is the high average molecular weight
3 PEO present, the lowest that's present in any of
4 the examples that they show is about ten
5 percent.

6 Q. Now, do you know what number
7 doctor I can't and Mathias reported to be the
8 amount of the high molecular weight portion of,
9 or high molecular weight fraction of Watson's
10 Polyox N80?

11 A. Yes. They reported it as
12 1.9 percent. It's shown in the highlighted area
13 here.

14 Q. Now, just to be clear, would you
15 consider that to be a stray amount?

16 A. Absolutely. It's way below this
17 ten percent, my experience as well as what the
18 patent shows us is the lowest amount considered,
19 it's way below that. You've got to remember
20 that this is a film, and to impart any
21 functionality in a film, it's not the same as a
22 tablet, for example. You need to have an
23 appreciable amount. This thing is going to
24 dissolve very quickly any way. So in order to

1 effect that, you do need a good amount.
2 1.9 percent is just a stray amount in the
3 finished product.

4 Q. Now, you understand that Dr.
5 Mathias testified that 1.9 percent of the higher
6 average molecular weight, that actually
7 represents trillions of individual molecules.

8 Did you hear that testimony?

9 A. Yes.

10 Q. Does that change your opinion that
11 1.9 percent of higher average molecular weight
12 PEO is a stray amount?

13 MR. BOLLINGER: Your Honor, there
14 was no touch testimony.

15 THE COURT: Well, I'm not sure
16 that there was or wasn't. I thought maybe there
17 was, but if there isn't, then I guess there's no
18 point.

19 But go ahead, ask the question.

20 BY MR. NUTTER:

21 Q. I will just repeat the question.
22 If, in fact, 1.9 percent represented trillions
23 of molecules and that's in the higher molecular
24 weight portion, would that change your opinion

1 that 1.9 percent is just a stray amount?

2 A. No, absolutely not. What you have
3 to remember, we see a little insert here. This
4 1.9 percent, if you calculate trillions of
5 molecules in that little tail end at
6 1.9 percent, how much do you think is in the
7 bulk of the polymer? I will tell you. It's
8 quadrillion. It's a thousand times more than
9 that little tail end. That tail end would
10 always be a stray amount no matter what kind of
11 fiddle factor you multiply it by.

12 Q. Okay. Thank you.

13 Now, finally, I'd like to briefly
14 talk about the L'Hote article that Dr. Mathias
15 discussed during his direct examination, and
16 that's JTX-31.

17 Now, you reviewed this article; is
18 that correct?

19 A. Yes, I have.

20 Q. I'd like to go to Figure 2, which
21 I believe is the figure that Dr. Mathias relied
22 upon.

23 Can you explain in your own words
24 your understanding as to why Dr. Mathias relied

1 upon this figure in support of his infringement
2 opinion?

3 A. Right. It's my understanding that
4 Dr. Mathias indicated that this is not a bimodal
5 distribution of polymers. I mean, there's a
6 couple of things to point out here.

7 In order to best explain this, I'd
8 first like to go back to Figure 1, if I could,
9 in the same article.

10 Q. If we can go to Figure 1.

11 A. Right. Okay. So this looks very
12 similar. I realize that. This is actually the
13 individual PEOs as they were used before they
14 were mixed together to obtain Figure 2.

15 So I look at this, and they're
16 almost the same. The average molecular weight
17 is almost identical around a million. It's
18 about the same in every single different sample
19 they're talking about.

20 We're interested mostly in this
21 Polyox 205 and Polyox N-12, these different
22 molecular weight, average molecular weight
23 polymers that Dow has prepared for this
24 analysis.

1 And if we go back to Figure 2,
2 let's look here. I think importantly -- well,
3 look at the 50/50 blend. That would give us the
4 best shot I think to see some sort of effect on
5 the graph, and that's indicated by this magenta
6 part.

7 And I follow the magenta line.
8 I'm sorry, but I cannot see that we can make out
9 anything from this plot very easily. We are on
10 a log scale. All of the samples were about a
11 million daltons in size mixed together, what you
12 expect to see from this.

13 My contention is that it should
14 have been more adequately presented. Perhaps if
15 we had seen this on a linear scale, you would
16 see the same bimodal distribution I was
17 describing earlier when you blend polymers.

18 The other point about this is that
19 I want to make, and I've said it already. These
20 are all about a million daltons in size. The
21 patent is calling for a low molecular weight and
22 a high molecular weight.

23 If we mix those together, we would
24 clearly see two peaks. There's no doubt in my

1 mind that we would see that. But I have a slide
2 prepared to talk you through this issue about
3 the scale.

4 Q. I would like to refer to
5 Defendants' Demonstrative Exhibit 2.33.

6 Please explain to the Court how
7 you believe that this explains what you think
8 why the L'Hote article does not support Dr.
9 Mathias' infringement opinion?

10 A. Okay. Well, I fooled around with
11 that a little bit. I created two hypothetical
12 PEOs with a normal distribution about around the
13 means, but with around a million daltons in
14 size.

15 One is shown by the dotted blue
16 curve and one is shown by the solid blue curve.
17 And this is the log scale.

18 So you can imagine this is like
19 Figure 1 when we showed the individual
20 polymorphs run through the system, and we can
21 see somewhat of the different shapes on that.

22 If you deposit the same thing on
23 the linear scale, this is what I'm saying. I've
24 not changed the data. All I've done is changed

1 the scales. They are not squished up any more
2 like they are on the log scale.

3 This is, if you like, stretch
4 things out, so we can see what's going on.

5 And you can clearly see that the
6 division of these two different hypothetical
7 PEOs I've created.

8 Now, let's look at how it would
9 appear in the paper, if we had Figure 2, using
10 my hypothetical PEOs.

11 And, unfortunately, I didn't have
12 access to the full data. This is the L'Hote
13 article. Had I had that, I would have applied
14 the same logic to it.

15 Well, this is what you would see.
16 You would see a beginning, upward part of server
17 from one of the samples, because it's at the
18 leading edge. And the downward slope from the
19 other sample on the other edge.

20 However, it would appear as one
21 peak on the log scale, if you get my drift. It
22 squishes things up, so they overlay a lot.

23 If we did the same analysis on the
24 lineal scale, remember we wouldn't be able to

1 see what was being mashed in the middle here.
 2 We would see that bimodal distribution that I am
 3 saying would be present if you blended two PE.

4 And, in this case, they are very,
 5 very similar, my hypothetical PEOs, to the
 6 L'Hote article of a million daltons.

7 Q. Thank you, Doctor.

8 Finally, I would like to take you
 9 to Claim 4 of the '150 patent.

10 You understand that Claim 4 four
 11 has been asserted against Watson, yes?

12 A. Yes.

13 Q. Can you just very briefly explain
 14 to the Court why you believe that Watson does
 15 not infringe Claim 4?

16 A. Well, since Claim 4 is dependent
 17 upon Claim 1, for all of the reasons I've
 18 outlined as to why Watson's product does not
 19 infringe on Claim 1 of the '150 patent. I also
 20 believe the same is true for Claim 4.

21 MR. NUTTER: I have no more
 22 questions.

23 THE COURT: All right.

24 Thank you. Cross-examination?

1 not have of what the content is of the film that
 2 Watson is planning on making?

3 A. Right. I agree.

4 Q. It doesn't matter how somebody
 5 gets to that film. There's no process steps
 6 associated with a combination -- I'm sorry -- in
 7 a composition claim, correct?

8 A. There are various elements in the
 9 claim which need to be met --

10 Q. Correct.

11 A. -- the way I see it, yes.

12 Q. Right. But I think you suggested
 13 that you add things together, and if you don't
 14 add things together, you don't infringe as it
 15 relates to PEO. I think you said that. I wrote
 16 it down here. That you have to add things
 17 together to infringe this claim?

18 A. Claim 1 specifically tells us we
 19 have to have a low-molecular weight PEO and a
 20 high-molecular weight PEO.

21 It clearly tells us the different
 22 average molecular weight ranges. And, you know,
 23 I know, and everybody said so far that these
 24 products are available from the Dow Chemical

1 MR. BOLLINGER: Thank you, your
 2 Honor.

3 **CROSS-EXAMINATION**

4 BY MR. BOLLINGER:

5 Q. Good afternoon, Dr. McConville.
 6 How are you?

7 A. Hi. Good. Thank you.

8 Q. In this case, as I understand it,
 9 you expressed three separate bases for
 10 non-infringement as presented in your slides,
 11 and I would like to talk a little bit about
 12 that, but I want to know that we're all on the
 13 same page here.

14 You'll agree with me that this
 15 claim is directed to a film product, right?

16 A. Yes.

17 Q. Okay. So you understand that when
 18 a claim is directed to a film, or film, it's a
 19 composition claim, so what we're interested in
 20 is what's in the accused product.

21 You'll agree with that, right?

22 A. Yes.

23 Q. And, so, the analysis is
 24 predicated on whether there's an infringement or

1 Company. The Dow Chemical Company always
 2 reports a single viscosity average molecular
 3 weight, and one skilled in the art we know
 4 that's where to look when combining these
 5 products to make the film of Claim 1.

6 Q. Yes. But that was not -- had
 7 anything to do with the question I asked.

8 Could I ask you to answer my --
 9 really, the question I asked was, was there
 10 anything in Claim 1 that required to you add
 11 things together?

12 A. The answer is, yes, there is.

13 Q. Okay. So what element in Claim 1
 14 says you have to add something together?

15 A. The combination of the
 16 low-molecular weight PEO and the high-molecular
 17 weight PEO.

18 And I don't think it's too much of
 19 a stretch to realize that they must be combined.

20 Q. Okay. And Watson has to do the
 21 combination? They actually have to physically
 22 combine them together to infringe?

23 A. Well, they don't do that, do they?

24 Q. Well, if they didn't do it, and

1 they had to do it, then you would be right, but
 2 I'm asking you, do they have to add two things
 3 together to infringe, under your view of this
 4 claim?

5 A. Exactly. A low-molecular weight
 6 and a high-molecular weight.

7 Q. Okay. So it's kind of a hybrid.
 8 It's not just a composition claim. It's a
 9 composition plus method claim, because you have
 10 to have this step of adding things together?

11 A. Not at all. I mean, they listed
 12 that. I mean, you know, it's quite apparent to
 13 me that you've got two different things that
 14 have to be in the same product as the claim.

15 I'm sorry. I can't see any other
 16 way. It doesn't say you have to make mix them
 17 together. It shows them separate.

18 Q. Well, let's move on, because I
 19 think maybe we disagree or maybe I'm not making
 20 myself clear.

21 But let me ask you this:

22 Let's say we have a bottle, right,
 23 and Watson comes to you and they say, we want to
 24 use this in our film, and we don't know where it

1 came from, we don't how it was made, and all we
 2 know about it is that it's PEO, and we think
 3 it's going to work in our film.

4 Dr. McConville, do we infringe,
 5 will we infringe this patent?

6 I can't tell you how this bottle
 7 came together. I don't know if it was mixed
 8 from two bottles, three bottles, or four
 9 bottles. All I know is, it's in one bottle.

10 Can you tell me, you don't have to
 11 worry, because the one bottle that you are
 12 buying, it's not going to infringe?

13 A. Just to clarify, was it with two
 14 different PEOs mixed together?

15 Q. You don't know. That's the
 16 hypothetical. You don't know.

17 A. Well, I'm not going to be asked to
 18 give an opinion on that either way, because I
 19 don't know what's in the bottle, right?

20 Q. You don't know what's in the
 21 bottle.

22 So you would say you can't decide
 23 whether it infringes, because you don't know
 24 what's in the bottle. You don't know. But the

1 reason you're saying you don't know if it
 2 infringes or not, because up don't know whether
 3 it was mixed from two sources, or it was made
 4 separately as a single source, is the question?

5 A. I just don't know what's in the
 6 bottle. If you tell me what's in the bottle, if
 7 those two different PEOs that have been combined
 8 together are put in that bottle, and then, you
 9 know, it's suggested that that could satisfy the
 10 claim, then that -- that would infringe.

11 Q. All right.

12 Let's do this:

13 Let's say I gave you the bottle,
 14 and I asked you, can you tell me whether there
 15 are two PEOs in here? And I can't tell you
 16 anything else.

17 Is there a test out there that you
 18 might perform on that bottle to determine
 19 whether there's two separate PEOs? A
 20 high-molecular weight and low-molecular weight
 21 fraction?

22 A. If there was a bimodal
 23 distribution you mean?

24 Q. I'm just asking you the question

1 the way I phrased it.

2 A. Well, I guess you might give it to
 3 some, you know, polymer expert to say, analyze
 4 the sample.

5 Q. Or give it to Dr. Yang, right?

6 A. Possibly. It depends on what the
 7 average molecular weights at the end it came out
 8 to be.

9 Q. Okay. So then it comes back, and
 10 the results show a bimodal distribution, right?

11 You have your PEOs that you are
 12 showing in your illustration that you created.

13 And, so, now, can you tell Watson -- and let's
 14 say there are two three peaks. Each of the
 15 peaks falls within the low range and one in the
 16 high range.

17 Can you tell whether they infringe
 18 or not?

19 A. You know, then that would -- that
 20 sort of information would lead me to try and
 21 discover what had happened in the bottle before,
 22 because, obviously, it's not just one PEO.

23 Q. Right. Right. So you would want
 24 to know where's this stuff coming from, right?

1 A. Of course.

2 Q. And then if it came from two
3 sources you might say, well, we might have a
4 problem?

5 A. What I will say is that all of the
6 information, for example, on the had L'Hote
7 paper, when there was a blend, they always
8 indicated there was a blend. So I would expect,
9 even if Dow had provided a blended product, they
10 would write it on the bottle to show us what the
11 blends of molecular weights were, as they had in
12 the article.

13 Q. And, quite frankly, Dow has
14 indicated that they make blends, as you heard
15 from Dr. Mathias this morning, they actually
16 take their product and blend it before they sell
17 it.

18 Did you see that diagram?

19 A. You're inferring that those are
20 different molecular weights the PEOs that are
21 blended, and I absolutely disagree with that.

22 Q. Well, let me ask you this:

23 You say you're a film formulator.
24 Are you an expert in polymer chemistry, too?

1 A. Oh, no.

2 Q. Okay. So you've to Dow's plant, I
3 take it, right?

4 A. No, I haven't.

5 Q. Do you have any idea of the actual
6 details of their manufacturing process.

7 A. It is proprietary.

8 Q. Well, we actually have some people
9 here that work for Dow for many years who,
10 consulted for them and they testified.
11 So it may be proprietary, but there's certainly
12 a lot of information that people who are experts
13 in polymer chemistry know, but they're in the
14 industry, and I understand you're a film
15 formulator, right?

16 A. Yes.

17 Q. That's right. But you are
18 familiar with the PEOs that we're talking about
19 in this case, because you use them quite a bit?

20 A. I have used them, yes.

21 Q. Right. But you don't do GPC, do
22 you?

23 A. No, I do not.

24 Q. And your lab doesn't have a GPC

1 device, does it?

2 A. No. We're always short of the
3 grades we have of the PEOs.

4 Q. Okay. And you, in fact, you trust
5 the label that the manufacturer puts on for a
6 precise measurement of a PEO, average molecular
7 weight?

8 A. Absolutely. There have been some
9 in this product for decades.

10 Q. Did you look at the discrepancy of
11 the reported values in the L'Hote paper from the
12 actual values on the bottles?

13 A. You mean in terms of the viscosity
14 average molecular weight?

15 Q. Right. I mean, you presented to
16 the Judge. You said there were six samples.
17 Actually, there were four different grades. And
18 you said they were all about an average of a
19 million. That's what you said.

20 Because you could tell by looking
21 at Figure 1, they are all a million on average,
22 right? Do you know what Dow reports them at?

23 A. The reason why --

24 Q. Please, answer my question.

1 A. I don't know what Dow reports on
2 those individual grades in the L'Hote paper.

3 Q. Yes.

4 A. There's a table in there.

5 Q. Right. And one was at 600,000,
6 right?

7 A. Not that I recall, no.

8 Q. All right.

9 A. Not one of the ones in the blends,
10 no.

11 Q. Are you sure?

12 A. Yes.

13 Q. Okay. We're going to bring it up
14 and we're going to go through it in a few
15 minutes.

16 There's one at 900,000, right?

17 A. Yes.

18 Q. And then there was one at a
19 million?

20 A. Right.

21 Q. Those were the three. And you
22 said they were all about the same.

23 A. All the ones that are important in
24 the blends about the same, of course.

1 Q. Important in the blends? Okay.

2 A. That were reported in Figure 2,

3 the blends.

4 Q. Let me ask you this:

5 You said that -- and you'll agree

6 with me that the high-molecular weight fractions

7 in the '150 patent, the ones that are called out

8 in that claim, they play an important role in

9 the final performance of that film.

10 Would you agree with that?

11 A. Yes. The patent explicitly states

12 that.

13 Q. Right. And it's gives examples of

14 ten percent in one instance of the

15 high-molecular weight, a 900,000 from the bottle

16 from Dow, and that's a fairly large amount of

17 high-molecular weight, correct?

18 A. No.

19 Q. All right. So it's not in your

20 view, but that's fine.

21 I guess my question is:

22 Where in the paper, in that

23 patent, did it actually say that ten percent was

24 the minimum to get the performance they were

1 asking for?

2 A. Sorry. In the paper or the

3 patent?

4 Q. The patent.

5 A. It gave lots of examples of

6 different compositions and --

7 Q. Please.

8 MR. BOLLINGER: I'm sorry, your

9 Honor.

10 BY MR. BOLLINGER:

11 Q. Can you answer my question?

12 THE COURT: I think he actually

13 is.

14 MR. NUTTER: Thank you, your

15 Honor.

16 THE WITNESS: Actually, the lowest

17 reported one in that patent was ten percent.

18 Now, I believe that if they had

19 found that a lower percentage was important for

20 this claim, they would have indicated in their

21 enabling examples that a lower amount of a

22 high-molecular weight PEO should be made in the

23 film. There was no examples of films which had

24 less than ten percent.

1 It jives with what I'm saying as

2 being a minimum effective amount for

3 functionality in a film.

4 BY MR. BOLLINGER:

5 Q. I was just inquiring whether you

6 saw any indication in the patent by the

7 inventors saying that they had to have a certain

8 threshold amount to get the performance. I

9 couldn't find it. I just wanted to know whether

10 you actually saw that language in the patent.

11 MR. NUTTER: Objection, your

12 Honor. Counsel is testifying about what --

13 THE COURT: You can answer the

14 question.

15 THE WITNESS: I believe the

16 example showing ten percent is indicative of the

17 minimum effective concentration of that

18 high-molecular weight polymer. It agrees with

19 what my experience in this field is.

20 BY MR. BOLLINGER:

21 Q. And, so, you made a film products

22 for dissolvable films in the accordance with the

23 patent, in the '150 patent?

24 A. I've made dissolvable films.

1 Q. Specifically, in the accordance

2 with the claims of the '150 patent?

3 A. No.

4 Q. Okay. And you've never tested

5 anything in this case, have you?

6 A. No, I haven't.

7 Q. So let me get back to another

8 hypothetical.

9 Let's say we have a bottle, and

10 it's come from a manufacturer, and we'll say

11 it's from Dow, and it is poly ox, and we -- you

12 do a test on it, and you find -- you send it to

13 Dr. Yau for GPC.

14 And he comes back and he says,

15 it's an amazing product. It has a unimodal

16 distribution, but it's incredibly poly-

17 dispersed.

18 Now, you understand what I mean by

19 that, right?

20 A. Yes.

21 Q. Okay. So instead of what the

22 is --

23 THE REPORTER: You turned your

24 head. I couldn't understand you.

1 **MR. BOLLINGER: I'm sorry. Amd now**
 2 **the base extends way out on both sides, right?**
 3 **So now you've got instead of one of these, it's**
 4 **one of the -- I don't know what -- we're talking**
 5 **about channel humps, and things like that, it's**
 6 **a like a igloo dome, okay?**
 7 **Now, Watson comes to you and says**
 8 **it's a single source. Do we infringe?**
 9 **What do you tell them?**
 10 **A. There has been no combination of**
 11 **PEOs.**
 12 **Q. Okay. And let's say that when Dr.**
 13 **Yau does the analysis on that, he shows a line**
 14 **-- and he draws a line at the 600 point, and he**
 15 **shows the averages falling precisely within the**
 16 **two ranges, but now at the high range of instead**
 17 **2 percent, it's 15 percent. And yet it's still**
 18 **only coming from one bottle, and it's only one**
 19 **manufactured product.**
 20 **Still no infringement?**
 21 **A. It's only one PEO.**
 22 **Q. And let's talk about the Schiraldi**
 23 **patent.**
 24 **You actually made kind of this**

1 **prior art argument. Watson's practicing the**
 2 **prior art, and my question is -- and we can go**
 3 **into whether you really are or not -- but I**
 4 **don't think you're the witness to do that with,**
 5 **but you did cite --**
 6 **THE COURT: So, Mr. Bollinger, you**
 7 **know, the colloquies are for yourself in your**
 8 **questions. Maybe you can cut things down and**
 9 **ask questions.**
 10 **MR. BOLLINGER: I apologize. I**
 11 **was really trying to get a question in mind.**
 12 **THE COURT: You can do it in 15**
 13 **seconds and no one will complain.**
 14 **BY MR. BOLLINGER:**
 15 **Q. So we have Schiraldi, right? And**
 16 **I think you said it shows a single PEO, but on**
 17 **the slide it indicated that it was between**
 18 **100,000 and eight million.**
 19 **Is it your understanding that**
 20 **Schiraldi teaches a single PEO with a range of**
 21 **100,000 to eight million?**
 22 **A. I said over three million,**
 23 **actually.**
 24 **Q. So the single PEO that you're**

1 **talking about, was well outside of the ranges**
 2 **that are at issue in this case, with Schiraldi,**
 3 **correct?**
 4 **A. No. The range that Schiraldi**
 5 **indicates falls within the range of a**
 6 **low-molecular weight PEO.**
 7 **Q. All right.**
 8 **Maybe I misunderstood your last**
 9 **answer. I thought you said it was between three**
 10 **and five million.**
 11 **Isn't that what Schiraldi teaches?**
 12 **A. 100,000. Preferably above three**
 13 **million daltons.**
 14 **Q. Anyways. But they say, use**
 15 **100,000 or 300,000.**
 16 **They don't say, use both, do they?**
 17 **A. They said the homo polymer of**
 18 **ethylene oxide is a single PEO that's used in**
 19 **the Schiraldi teaching.**
 20 **Q. And it's your understanding that**
 21 **Schiraldi teaches a single PEO that ranges from**
 22 **100 to three million?**
 23 **A. No, no, no, no. That's a**
 24 **misinterpretation.**

1 **Q. Well --**
 2 **A. Actually, because it goes back to**
 3 **there being different grades available. And all**
 4 **Schiraldi is saying is, there are a lot of**
 5 **grades available. Choose anyone of these.**
 6 **Q. All right.**
 7 **I'll disagree with that, but since**
 8 **it's not central?**
 9 **Let's go to L'Hote now. And can**
 10 **we bring that slide up?**
 11 **And I think, you know, we've**
 12 **established now --**
 13 **MR. BOLLINGER: This is going to**
 14 **be the third time we're bringing this up, your**
 15 **Honor, and I apologize for that, but I think**
 16 **it's an important point of discussion.**
 17 **BY MR. BOLLINGER:**
 18 **Q. In this document you have now**
 19 **created some sort of simulation, right? You've**
 20 **made some diagrams that you think what actually**
 21 **this data would show?**
 22 **A. I believe that it would be helpful**
 23 **to indicate that a degree of squishing occurs**
 24 **with a log scale in particular.**

1 **Q. All right.**
 2 **And these are experiments that you**
 3 **could have easily undertaken to do to**
 4 **demonstrate what you were talking about,**
 5 **correct?**
 6 **A. Do you mean repeat this paper?**
 7 **Q. Repeat the analysis that they did,**
 8 **so you could demonstrate that there is a bimodal**
 9 **distribution?**
 10 **A. The GPC analysis in there, right?**
 11 **Q. Right.**
 12 **A. So I already said I don't do GPC**
 13 **analysis.**
 14 **Q. Well, there's -- you'll agree with**
 15 **me, it's a longstanding capability that is**
 16 **fairly common and available for people to use,**
 17 **right?**
 18 **A. Not, no at all. I mean, I work**
 19 **with films, I work with polymorphs. I don't do**
 20 **GPC. I don't know any of my colleagues that**
 21 **work in pharmaceutical film formulations that**
 22 **routinely run GPC.**
 23 **And do you know why?**
 24 **Because they have the Dow Chemical**

1 **product label and that's what they use in**
 2 **manufacturing films.**
 3 **Q. Well, let's bring up the table**
 4 **that shows the difference between what the label**
 5 **says, and what you said, and what Dow actually**
 6 **calculated with GPC.**
 7 **All right.**
 8 **And, so, if you look at this**
 9 **table, you'll see that the first column shows**
 10 **the various products. And that the poly ox 1105**
 11 **is a product that they list at nominal 900,000**
 12 **molecular weight. Viscosity average -- sorry --**
 13 **viscosity average of molecular weight.**
 14 **A. I'm looking for the viscosity**
 15 **average of the molecular weight.**
 16 **Where is that?**
 17 **Q. Well, I'm sorry. These are weight**
 18 **averages here.**
 19 **MR. BOLLINGER: If you can go to**
 20 **the page where it shows the calculation in**
 21 **viscosity averages?**
 22 **(Pause)**
 23 **BY MR. BOLLINGER:**
 24 **Q. Okay. If you look at this, you**

1 **see that Dow reports that -- and it says**
 2 **there -- these -- the weight average of**
 3 **molecular weights of poly ox 1105 was very**
 4 **similar to the standard deviation of .36S from**
 5 **the GPC column, correct?**
 6 **A. Sorry. What's the viscosity**
 7 **average of the molecular weight again?**
 8 **Q. It's the next line.**
 9 **What I was trying to get across**
 10 **was, they were identifying that their product**
 11 **literature reports this in viscosity average of**
 12 **molecular weight, correct?**
 13 **A. I'm a little confused as to what**
 14 **you're talking about, because we're trying to --**
 15 **you know, that -- you're trying to make the**
 16 **point that Dow is reporting a viscosity average**
 17 **molecular weight for these products, the 1105,**
 18 **the 205, and the --**
 19 **Q. Right.**
 20 **A. -- and 12.**
 21 **And I don't know those viscosity**
 22 **average molecular weights. You were trying to**
 23 **get me to look at the graph, and see how they**
 24 **compare to what the deviation might be**

1 **associated with that.**
 2 **And I'm having a -- I don't know**
 3 **what the viscosity average molecular weights**
 4 **are.**
 5 **Q. Well, let's go back to the graph,**
 6 **and we'll go to Figure 2, which shows the**
 7 **blends, right?**
 8 **A. Yes.**
 9 **Q. Now, you'll agree that this draft**
 10 **doesn't show anything about molecular weight, in**
 11 **terms of a calculated average, right?**
 12 **A. It doesn't show the viscosity**
 13 **average molecular weight, no.**
 14 **Q. Okay. And what does this actually**
 15 **show? This is the just molecular weight**
 16 **distributions?**
 17 **A. This is the -- yes, as far as I**
 18 **can tell, the GPC analysis that is performed on**
 19 **the -- well, on these blends, or on the single**
 20 **poly ox 1105.**
 21 **Q. Right. And in looking at this**
 22 **data, was it your understanding that the Dow**
 23 **researchers were specifically asking whether**
 24 **there was a bimodal distribution when you**

1 blended in these three ratios here form a 600
 2 and a million together?
 3 A. It's my understanding I --
 4 MR. NUTTER: Your Honor, this is
 5 the third time he's used the term "600." He has
 6 yet to show the number 600 in the paper.
 7 THE COURT: Overruled.
 8 MR. BOLLINGER: It's in there,
 9 your Honor. I would just like to quickly go
 10 through in this one last topic.
 11 THE COURT: Okay.
 12 BY MR. BOLLINGER:
 13 Q. Specifically, the -- if I can, if
 14 you look at it you say, is this showing a
 15 bimodal distribution, and you can't tell,
 16 because you want to look at in a different
 17 scale.
 18 But do you know what Dow
 19 researchers concluded? Did you read the paper
 20 and understand what they concluded?
 21 A. Dow researchers didn't process
 22 this on the linear scale.
 23 I told you that I think the
 24 molecular weights of the individual ones are

1 very close together. I think they would have
 2 put their best foot forward having presented
 3 this on a linear scale. And I just showed you
 4 that if you put molecular weights that are close
 5 together on a log scale, you can't separate them
 6 out, and that's, to me, is exactly what this
 7 figure is showing.
 8 Q. Right. My question was simply:
 9 Did the Dow researchers, who
 10 studied and had all the data that you chose not
 11 to create, did they actually concludes that this
 12 was all uni-modal distribution, blends and
 13 non-blends together? Was that their conclusion?
 14 A. That is what they said about their
 15 figure, yes.
 16 MR. BOLLINGER: Okay. Thank you.
 17 Your Honor, I have no further
 18 questions.
 19 THE COURT: All right.
 20 Thank you. Any redirect?
 21 MR. NUTTER: No, your Honor.
 22 THE COURT: All right. Thank you.
 23 Do you have anything more, Watson?
 24 MR. LOMBARDI: We do, your Honor.

1 We're calling Dr. Dyar.
 2 THE COURT: Okay.
 3 MR. LYNCH: Good afternoon, your
 4 Honor.
 5 James Lynch of Watson for the
 6 defendants.
 7 THE COURT: I thought you were Dr.
 8 Dyar.
 9 Good afternoon, Mr. Lynch.
 10 MR. LOMBARDI: Your Honor, just
 11 for organization, we're moving to the invalidity
 12 part of the presentation of this.
 13 THE COURT: Does that mean that
 14 you have rested on infringement?
 15 MR. LOMBARDI: Yes.
 16 THE COURT: All right.
 17 And does that mean the plaintiff
 18 has nothing further on infringement for the '150
 19 patent, right?
 20 MR. LADOW: No, your Honor, except
 21 on validity.
 22 THE COURT: Right, right. Infringement.
 23 MR. LADOW: Yes, your Honor.
 24 THE COURT: Correct. So,

1 basically, the '150 infringement, we're done?
 2 MR. LOMBARDI: Yes, your Honor.
 3 THE COURT: Okay. That that's all
 4 I wanted to establish.
 5 All right. Invalidity.
 6 MR. LYNCH: Your Honor, may I
 7 approach with the binders?
 8 THE COURT: Yes, Mr. Lynch.
 9 ... STEPHEN CRAIG DYAR, having
 10 been duly sworn as a witness, was
 11 examined and testified as follows ...
 12 MR. LYNCH: May I proceed?
 13 THE COURT: Yes.
 14 DIRECT EXAMINATION
 15 BY MR. LYNCH:
 16 Q. Dr. Dyar, could you please
 17 introduce yourself to the Court.
 18 A. Yes. Stephen Craig Dyar. I go by
 19 Craig Dyar.
 20 Q. You've been asked to provide
 21 expert opinion in this case?
 22 A. Yes, I have.
 23 Q. Please turn to Tab 1 in the binder
 24 that's in front of you, please, Exhibit DTX-1316

1 marked for identification.
 2 Do you have it there?
 3 A. No, sir.
 4 Q. You don't have a binder yet?
 5 MR. LYNCH: Your Honor, May I
 6 approach?
 7 THE COURT: Sure.
 8 (Pause)
 9 BY MR. LYNCH:
 10 Q. All right.
 11 Tab 1, do you have it there in
 12 front of you?
 13 A. Yes, I do.
 14 Q. Do you recognize this document?
 15 A. Yes, I do.
 16 Q. Is this a current copy of your
 17 Curriculum Vitae?
 18 A. Yes, it is.
 19 Q. And does this document accurately
 20 reflect your education and professional
 21 experience?
 22 A. Yes, it does.
 23 MR. LYNCH: Your Honor, the
 24 defendants move DTX-1316 into evidence.

1 THE COURT: I thought all the
 2 resumes were already in evidence?
 3 MR. LYNCH: We would have thought
 4 it would have been, your Honor, but there was an
 5 objection last night that was not resolved.
 6 THE COURT: Okay. Any objection
 7 to this?
 8 MR. LYNCH: It wasn't articulated,
 9 other than to say an objection.
 10 THE COURT: Is there an objection?
 11 MR. BRAHMA: No objection.
 12 THE COURT: No.
 13 What's the exhibit?
 14 MR. LYNCH: DTX-1316.
 15 THE COURT: 1366, okay. Thank
 16 you.
 17 MR. LYNCH: Thank you.
 18 BY MR. LYNCH:
 19 Q. And, Dr. Dyar, you have a prepared
 20 slides to assist your testimony today?
 21 A. Yes, sir, I have.
 22 Q. Can you briefly tell us how your
 23 educational background relates to the opinions
 24 you've prepared?

1 A. Yes. I started out with an BS in
 2 Biology in 1984, where I was studying chemistry,
 3 physics, and other courses. I moved on to a BS
 4 in pharmacy in 1987.
 5 I took a little break, seven years
 6 as a pharmacist. Then went back and got my
 7 Ph.D. in 19 -- from 1994 to 1998,
 8 three-and-a-half years, and that was in
 9 pharmaceutical science, which is basically the
 10 study of dosage form development and design,
 11 including formulations of suspensions,
 12 solutions, tablets, and capsules.
 13 I then proceeded to work in 1998
 14 to 2008 for Parke Davis and Pfizer, evaluating
 15 and developing drug delivery systems.
 16 I left Parke Davis Pfizer in 2008,
 17 and became an Assistant Professor at South
 18 University, where I teach graduate courses in
 19 pharmaceutics and pharmacokinetics.
 20 Pharmaceutics is, again, the study
 21 of how to develop a dosage form. And
 22 pharmacokinetics is the study -- mathematical
 23 study of what happens to the drug in the body.
 24 At the same time, in 2008, I

1 started my own pharmaceutical consulting
 2 company, where I advised large to small
 3 companies on drug delivery research and
 4 development, from discovery to its launch. And
 5 I currently do the same -- have the same
 6 position.
 7 And in 2010, I joined Blachman
 8 Consultants, again, helping companies fix
 9 problems in the drug delivery arena and continue
 10 to do so.
 11 Q. Thank you.
 12 And, Dr. Dyar, in your teaching of
 13 students at the School of Pharmacy, do you spend
 14 any time in a lab?
 15 A. Yes. Approximately, 50 percent of
 16 my time in the lab or directing students in the
 17 lab.
 18 Q. And, Dr. Dyar, what experiences do
 19 you have in working with films?
 20 A. I did some work, feasibility
 21 benchwork early in my Parke Davis days, to
 22 evaluate and developing a film, and found it was
 23 very easy to do.
 24 Q. Do you have any other experience

1 working with films, whether it's sprayed or
2 cast?

3 A. Yes. Tablet coating is one way we
4 create a suspension of a color, to change the
5 color of the tablet and make it identifiable.
6 And we spray that on to the tablet and dry the
7 tablet.

8 I also worked in the area of hot
9 melt extrusion, which is where we heat up
10 polymers, and drew a screw immediately on to a
11 tray, on to a belt, which are air cooled.

12 MR. LYNCH: Your Honor, defendants
13 offer Dr. Dyar as an expert in pharmaceutical
14 science, drug development, and dosage form.

15 THE COURT: All right.

16 MR. BRAHMA: No objection.

17 THE COURT: You may proceed.

18 **DIRECT EXAMINATION**

19 BY MR. LYNCH:

20 Q. Doctor, can you please summarize
21 the opinions you've reached in this case?

22 A. Yes, sir. The asserted claims of
23 the '514 patent are invalid as obvious, in view
24 of Chen, and Bess, connected with the knowledge

1 of a person of skill in the art. And they are
2 also invalid as indefinite.

3 Q. And, Dr. Dyar, can you please
4 identify for us which of the asserted claims in
5 the '514 patent you're prepared to testify about
6 today?

7 A. Yes, sir. Independent Claim 62
8 and Dependent Claims 64, 65, 69, and 73.

9 Q. And those are the claims displayed
10 in JTX-2?

11 A. That's correct.

12 Q. All right.

13 And are you familiar, Dr. Dyar,
14 with the Court's claim construction as it
15 relates to these claims?

16 A. Yes, I am, and I applied that in
17 my opinion.

18 Q. Before we turn to the substance of
19 your opinions, have you formed an opinion with
20 respect to your testimony regarding the
21 definition of a person of ordinary skill in the
22 art in the context of these '514 claims you are
23 testifying about?

24 A. Yes, I have.

1 Q. What is that?

2 A. It's a person who possesses a
3 Bachelor's Degree in Pharmaceutical Science,
4 Chemistry, or related field, plus two to five
5 years of relevant experience in developing drug
6 formulations. And/or it could be a person
7 having a Master's Degree, or a Ph.D., with less
8 experience.

9 Q. Dr. Dyar, can I trouble you to
10 speak just a little closer to the microphone?

11 A. Sure.

12 Q. Thank you.

13 Are you aware, sir, that the
14 plaintiffs have proposed a slightly different
15 definition of a person of ordinary skill in the
16 art?

17 A. Yes, I am. And it doesn't change
18 my opinion.

19 Q. All right.

20 Let's begin with your analysis of
21 the Independent Claim 62.

22 Can you tell us, in plain
23 English --

24 THE COURT: When you say it

1 doesn't change your opinion, do you mean that
2 your opinions on invalidity would be the same
3 using the other sides definition?

4 THE WITNESS: Yes, sir.

5 MR. LYNCH: Thank you, your Honor.

6 BY MR. LYNCH:

7 Q. Turning to your analysis of
8 Independent Claim 62, can you tell us in plain
9 English what this claim means?

10 A. Well, there are four parts.

11 There's a uniformity component,
12 there's a cast film component, there's a taste
13 masking component, and a particulate active.

14 Those are the four key components
15 that are discussed. And when I read this patent
16 the first time, I was trying to identify what
17 they may have in it, because that was the type
18 work that I always have done in the past, in
19 looking at patents, to understand what the
20 invention may be.

21 And I realize, in my reading of
22 this patent, that I did not find anything unique
23 or different that I didn't already know at the
24 time of this patent.

1 Q. All right.

2 And you've identified four
3 categories of claim limitations and you're
4 prepared to testify about each of those?

5 A. Yes, sir.

6 Q. You just stated that the claims,
7 in your opinion of the '514 patent are obvious
8 in light of the Chen and Bess, and the knowledge
9 of a person of ordinary skill in the art.

10 Beginning with Chen, can you
11 briefly explain why Chen is relevant to your
12 opinions in this case?

13 A. Yes. Chen talks about a cast film
14 that is uniform, has a taste masking agent, and
15 contains a particulate active.

16 Q. And why is it the Bess reference,
17 though, to your opinions in this case?

18 A. For the same reasons. It teaches
19 uniformity, it has a taste masking agent, and a
20 particulate active.

21 Q. In your opinion, Dr. Dyar, would a
22 person of ordinary skill in the art have been
23 motivated to combine the teachings of Chen and
24 Bess?

1 A. That's what I always do. And when
2 I teach my students to read any relevant
3 patents, and combine those, when it's
4 appropriate.

5 Q. All right.

6 Let's turn to the process of
7 making a cast film.

8 And I know you're looking at Chen,
9 which is JTX-187 at Page 40, Figure 2.

10 Can you tell us what this depicts
11 and how it relates to making a cast film?

12 A. Yes. Specifically, Figure 2 --
13 and I'll just do a real quick overview, and then
14 show you a little animation that makes it become
15 a little clearer.

16 You have a mixing tank, you have a
17 belt, you have a dryer... you have a mixing
18 tank, you have a belt, you have a dryer, you
19 have a die cutter, and then you have a container
20 that collects the materials.

21 And here's an animation of this
22 step, just a little slower.

23 You have a motor, you have a
24 shaft, you have blades that are stirring in this

1 tank where you put the matrix or the suspension.

2 Q. Okay. When you refer to the
3 matrix, or the suspension, does that contain
4 every component of what becomes the final
5 product?

6 A. Yes, it does. And, actually, the
7 yellow is the matrix, and the little blue dots
8 that we made here are the active -- particulate
9 active.

10 So that is being mixed, stirred,
11 and has sufficient viscosity that it can be
12 meted out by gravity on to the belt. The film
13 goes forward. It goes through the oven. You
14 will see that it's uniform.

15 And it comes out the other side of
16 the oven. It's dried at this point, it rotates
17 up, and then it's cuts into individual dosage
18 units and then dropped into a container from
19 which it is going on to be packaged.

20 Q. And can you return to Chen Figure
21 2 and describe for us a little bit more about
22 the drying process that is depicted in Chen?

23 A. Yes. Again, this is where the
24 oven was located. This is indicated there as

1 the drying oven with an aeration controller.
2 And as you can see from the first aeration
3 control, which is where the film is wet, it's a
4 matrix, it's liquid, it can move, and we don't
5 want to force a lot of air directly down,
6 because imagine what you do would if you would
7 force air directly down onto water. It would
8 cause waves, and we don't want that. But we
9 diffuse the air on the first step. As it
10 becomes dryer, the angles steepen, so more air
11 goes directly down so it can dry a little
12 faster.

13 And in the third aeration
14 controller, the air is pointing directly
15 down. So basically at that point, it's mostly
16 dry.

17 Q. Dr. Dyar, were there any examples
18 of commercial cast films before the '514 patent?

19 A. Yes. And this is the '298 patent,
20 which was mentioned earlier. And JTX-183, page
21 6, this is specifically to the Listerine
22 PocketPaks.

23 MR. BRAHMA: Objection, your
24 Honor. He has previously offered no opinions

1 that this patent covers that product.

2 MR. LYNCH: Your Honor, this is

3 not prior art. It is background. He mentioned

4 it in his opening report in paragraph 57.

5 He's simply provide background about the

6 technology before we get into his discussion

7 of the art.

8 THE COURT: All right. Well, it's

9 mentions in paragraph 57?

10 MR. BRAHMA: The two things aren't

11 linked. They're both mentioned in the

12 paragraph. They're just linked in the cover.

13 THE COURT: I'm going to allow it.

14 THE WITNESS: So this again is the

15 fast dissolving orally consumable film,

16 Listerine PocketPak. It was made at

17 Warner-Lambert Company in Morris Plains, New

18 Jersey, which is the parent company of

19 Parke-Davis at that time later bought by Pfizer,

20 across the street from where I worked. I worked

21 in Morris Plains.

22 In 1999, this is when the patent

23 came into existence.

24 Q. Dr. Dyar, did you have any

1 experience working with these kind of thin films

2 before the '514 patent?

3 A. Yes. I did do some consulting

4 work in regard to the Listerine PocketPak, and I

5 also did some thin skill laboratory work around

6 the feasibility of film.

7 Q. Thank you. Let's turn to the

8 first set of limitations in the '514, claim 62,

9 and that concerns uniformity.

10 Let me begin by asking: Is

11 content uniformity in your opinion important in

12 drug development?

13 A. It is an absolute tenet in

14 pharmaceutical development to have content

15 uniformity for the very reasons as mentioned in

16 the opening, that you need to have a product

17 that is uniform to give a safe, efficacious

18 drug, and not have toxic side effects. If it

19 varied by more than ten percent, you could be

20 getting into those toxic ranges.

21 And actually the '514 patent, as

22 indicated here, JTX-2 on page 38, which is the

23 background of related technology, specifically

24 states, currently, as required by various world

1 regulatory authorities, dosage forms may not

2 vary by more than ten percent in the amount of

3 the active. When applied to this based on

4 films, this virtually mandates that uniformity

5 in the film be present.

6 Q. Did this regulatory requirement

7 for uniformity, dose uniformity, exist prior to

8 the time of the '514 patent?

9 A. Yes. I was aware of it in 1984,

10 when I first started pharmacy school, and it has

11 been around since before then. It is actually

12 the basis for the FDA, the Federal Drug

13 Administration being in existence.

14 Q. And in your opinion, Dr. Dyar,

15 would a person of ordinary skill in the art be

16 motivated to target a dose uniformity of five

17 percent or less?

18 A. Absolutely.

19 Q. And what's your basis for that

20 opinion?

21 A. My experience is on various

22 projects that I've worked on directly at a

23 number of different companies, that I've gone in

24 to help them fix problems and advised them on

1 how to develop a product that all of the world

2 and help people to do that, and five percent is

3 the target that we always try to find.

4 Q. Are there any practical reasons in

5 the manufacture of pharmaceuticals why you would

6 target a uniformity variation that's lower than

7 the required regulatory standard?

8 A. Yes. The main reason is you do

9 not want product recalls. You don't want it to

10 go back to the manufacturer. We don't want to

11 have to take it back in because it costs money

12 if you do.

13 If you were to hit 11 percent,

14 say, or 16 percent, you would have a problem.

15 You would have to have the product recalled and

16 all the issues associated with that.

17 So the further away you are from

18 that mandatory requirement of ten percent to

19 five percent, the safer you are and the more

20 room you have to have potential changes in the

21 percentage.

22 Q. Dr. Dyar, in your opinion, what

23 does this regulatory requirement tell you about

24 the motivation of a person of ordinary skill in

1 the art when targeting a uniformity variance
 2 limitation?
 3 A. It is a requirement. They would
 4 definitely be motivated to do it.
 5 Q. All right. Thank you.
 6 Let's turn now to the specific
 7 sub-elements of the uniformity limitations.
 8 The first in the '514 patent is a particulate
 9 active substantially uniformly stationed in the
 10 matrix. First of all, what does that mean?
 11 A. That means that if it does not
 12 clump up. It sits there and it's separated out.
 13 It's uniformly distributed throughout the matrix
 14 that it's in.
 15 Q. Is there a common example of what
 16 the matrix is here, what the liquid is here,
 17 which particulate actives are added?
 18 A. Well, you can think of, since it's
 19 getting close to Christmastime, chocolate chip
 20 cookies is the batter that the cookie, chocolate
 21 chips are in. So if you have them, if you have
 22 the batter too thin, the chocolate chips fall to
 23 the bottom and don't get distributed. The right
 24 viscosity, you can have them mix it up and you

1 can meter it out to make the right appropriate
 2 chocolate chip cookies with even distribution
 3 that we all like. Right?
 4 Q. Does the Chen reference the
 5 JTX-187 disclose this limitation?
 6 A. Yes. On page 17, it talks about
 7 the active agent being dispersed or dissolved
 8 uniformly in the hydrocolloid solution, and then
 9 this is the matrix. Even though it says
 10 solution, we have it dispersed within that
 11 solution, so that makes it a suspension.
 12 Q. Thank you.
 13 And turning to the next limitation
 14 in the '514 patent, claim 62, which refers to a
 15 viscosity sufficient to aid in substantially
 16 maintaining non-self-aggregating uniformity of
 17 the active in the matrix. First of all, what
 18 does that mean?
 19 A. That means it's thick enough that
 20 the active won't settle out and will remain
 21 uniform within the matrix.
 22 Q. With respect to viscosity that's
 23 referenced there in that part of the claim
 24 language, what does the '514 patent say about

1 viscosity?
 2 A. The '514 of JTX-2 on page 43 talks
 3 first about, this is a cup of water, which
 4 centipoise is a unit of measure for water, of
 5 our viscosity, and water has one centipoise
 6 viscosity. Motor oil, on the other hand, has
 7 400 centipoise, and sour cream has 100,000
 8 centipoise.
 9 This is a very broad range. It
 10 covers almost any viscosity that you would use
 11 in a pharmaceutical film or formulation.
 12 Q. Does the '514 make suggestions
 13 about any particular viscosity within the broad
 14 range you've just identified that should be used
 15 in making the kind of film disclosed in that
 16 patent?
 17 A. No, it doesn't teach you how you
 18 should narrow it down and what you should really
 19 be targeting.
 20 Q. Are there any equations or other
 21 disclosures in the '514 patent that relate to
 22 viscosity?
 23 A. Yes. There are a number of
 24 equations that relate to viscosity in the '514

1 patent.
 2 Q. Is there anything, including those
 3 equations or anything else in the '514 patent
 4 about viscosity that was new as of the date of
 5 the '514 patent?
 6 A. No, there's not anything new in
 7 the '514 patent, as I read it numerous times.
 8 Q. All right. And prior to the '514
 9 patent, would a person of ordinary skill in the
 10 art have known that viscosity is a factor in
 11 establishing and maintaining uniformity?
 12 A. Yes.
 13 Q. How is that?
 14 A. I'm turning to my next slide. And
 15 this, Stokes law, which he developed in 1851.
 16 Very complicated looking equation, but I will
 17 simplify it in just a minute.
 18 This is from a reference in
 19 Carstensen in 1973. Again, this is a textbook
 20 reference that I have used over the years.
 21 JTX-173 on page 12. And I will make it a little
 22 easier.
 23 So it talks about is sedimentation
 24 rate. In other words, how fast a solid will

1 fall in the matrix. It's multiplied times the
2 radius of the sphere. So, in other words, the
3 size of the particle.

4 The particle density comes into
5 play, how much it weighs. The density of the
6 liquid and also as everything tends to fall upon
7 a gravitational constant that comes to play in
8 the equation.

9 On the bottom we have the
10 viscosity of the liquid, and that's multiplied
11 times nine. Viscosity of the liquid is how
12 thick it is.

13 So it has a huge impact because if
14 we increase the viscosity of the liquid, it's a
15 nine fold increase in the viscosity on the
16 bottom, so that the corresponding decrease,
17 significant decrease in the sedimentation
18 rate.

19 The other factor that we can
20 change is the particle size. Those are the two
21 that we primarily change.

22 Q. And can you explain how Stokes law
23 relates to your opinion that this claim
24 limitation is obvious?

1 A. It's one of the primary ways that
2 we use to change a suspension and in order to
3 make it uniform is by adjusting particle size,
4 by adjusting the viscosity of the liquid, and,
5 of course, we can use stirring or shaking.

6 Q. And, Dr. Dyar, in your opinion,
7 would a person of ordinary skill in the art have
8 reasonably expected that viscosity could be
9 adjusted to achieve and maintain uniformity?

10 A. Absolutely.

11 Q. Are there any other art, prior
12 art on which you rely to support your opinion
13 that this claim limitation is obvious?

14 A. Yes.

15 Q. And --

16 A. And this directly is from Chen,
17 JTX-187, on page 15, where he states, a factor
18 that place a significant role in determining the
19 properties of mucosal surface-coat-forming
20 composition is the viscosity of the
21 hydrocolloid. That basically says that a film
22 depends upon the viscosity of the matrix.

23 Q. All right. So turning now to the
24 third limitation relating to uniformity, and

1 that refers to the capability of being dry. Can
2 you explain what this limitation means in plain
3 language?

4 A. Yes. It means that when you run
5 it through the dryer, it doesn't become uniform.
6 It stays uniform through, as you dry it. So the
7 viscosity is sufficient, that it maintains that
8 uniformity through the drying steps.

9 Q. And is this claim limitation
10 directed to any particular drying method?

11 A. No. There's not a specific drying
12 method claim in the '514 patent. It only
13 discusses conventional drying techniques,
14 several of which I've listed here. Microwave
15 drying, room temperature drying, tray drying,
16 bottom airflow, controlling air speed and
17 temperature. Those are all conventional
18 techniques you could use to dry film.

19 Q. Is there prior art, Dr. Dyar, that
20 you rely upon to support the opinion you just
21 expressed?

22 A. Yes. I've already discussed the
23 Chen JTX-187 on page 40, Figure 2. We've
24 discussed that earlier. And there's also the

1 Lachman reference from 1986.

2 And Lachman is a primary, again,
3 referenced textbook used in the pharmaceutical
4 field, and it's JTX-238 on page 13, where he
5 talks about, to achieve uniform drying, there
6 must be a constant temperature and a uniform
7 airflow over the material being dried.

8 Q. Dr. Dyar, your opinion, would a
9 person of ordinary skill in the art have been
10 enabled prior to the '514 patent to maintain
11 uniformity throughout drying?

12 A. Yes, because if you didn't
13 maintain uniformity throughout drying, you
14 wouldn't have a uniform product. And that is
15 going back to the tablet coding example. You
16 wouldn't have a uniform product that was
17 covered.

18 Q. Thank you.

19 And turning now to the last
20 uniformity limitation, a cleaving a final
21 product with a dose variance of less than ten
22 percent, can you explain what that limitation
23 is, please?

24 A. Yes. So this is talking about

1 subsequent to casting and drying of the matrix
2 is measured by a substantially equal size of
3 individual units to where we have ten percent of
4 the desired amount of at least one active.

5 And this figure from Chen, again,
6 JTX-187, page 43, is Figure 5. And this shows a
7 dissolution profile. Well, what is a
8 dissolution profile? Well, that's one of these
9 measures that we use to determine content
10 uniformity and release profile in the
11 pharmaceutical field prior to taking it into a
12 human study.

13 Q. What does the chart depict in
14 particular and what are the bars on the top and
15 bottom of the various dots along the lines?

16 A. Okay. So the X axis on the bottom
17 is time in minutes and it goes from zero to
18 ten minutes. On the Y axis, you have percent
19 release, which goes from zero. The scale gets
20 to 120, but we're really concerned about the
21 hundred percent, really, so that means a hundred
22 percent of the drug that you expect to be in
23 there is released.

24 The lines or the dots, the

1 markers, the circles and the triangles, are all
2 the mean values for the examples that are being
3 tested. And then you additionally have error
4 bars associated with those means.

5 Q. What is the purpose of running a
6 dissolution study, and what does this study from
7 Chen convey to you?

8 A. The purpose of the dissolution
9 study is to determine the release profile or how
10 fast it releases or how slow it releases. And
11 you can see that these three are basically over
12 each other and are very rapid and then level
13 out.

14 I'm going to use the big color
15 pointer. Sorry. All right. Okay.

16 And level out. Okay? And here,
17 you can see that the error bars are very tight
18 at a hundred percent, a hundred percent release
19 at ten minutes.

20 Q. In other words, that at ten
21 minutes of the dissolution study, 100 percent of
22 the active content has been released and there's
23 a variation that appears to be within ten
24 percent of the expected amount of active?

1 A. That's correct.

2 Q. And how does that support your
3 opinion that Chen enables the development of
4 films with a dose variability of ten percent or
5 less?

6 A. Because this is, looking at this
7 type of data helps you determine what the, the
8 content uniformity is around that dosage form,
9 and shows that it is very tight, or very good,
10 and you would likely take it into a human
11 clinical study.

12 Q. Are you aware, Dr. Dyar, that
13 during the prosecution of the '514 patent, the
14 patentees relied on Figure 5 in arguing to the
15 PTO that the Chen films were not uniform?

16 A. Yes, I am.

17 Q. And do you agree with that?

18 A. I do not agree with that.

19 Q. And why is that?

20 A. Because this figure to me, after
21 having looked at thousands of these over my
22 20-plus years of experience and helping
23 companies solve problems shows me that we have a
24 very good release profile, and we have at a

1 hundred where we can see that it's tight, where
2 we can see the data a little clearer. That we
3 have very tight content uniformity that looks to
4 be at least close to ten percent, if not less
5 than ten percent. It also indicates to me if
6 he's not at ten percent, that a little bit more
7 experimentation, he could easily get there.

8 Q. And is that kind of
9 experimentation you just referred to a standard
10 part of development?

11 A. Yes. It's a standard part of
12 development. I'm actually working with a couple
13 companies right now to help them fix problems
14 that are very similar to this.

15 Q. Do the release profiles here in
16 Chen Figure 5 suggest anything to you about
17 whether the films that are being studied here
18 could be developed into a marketable and
19 approved product?

20 A. Yes, they do. They tell me at
21 this stage, at this type of development, the
22 profiles that I see indicate that he could
23 develop a film product to be put on the market.

24 Q. Did you have occasion, Dr. Dyar,

1 to compare the uniformity data in this Chen
 2 reference, JTX-187, to data in the '514 patent?
 3 A. Yes, I did.
 4 Q. And how do they compare?
 5 A. I did not find any dissolution
 6 data of this type in the '514 patent.
 7 Q. And, Dr. Dyar, your opinion based
 8 on the disclosure in Chen, would a person of
 9 ordinary skill in the art reasonably expect to
 10 achieve a film that satisfies the ten percent
 11 variance limitation?
 12 A. Yes.
 13 Q. Dr. Dyar, are you aware that Dr.
 14 Langer, who has testified for the plaintiffs,
 15 relied on some references after the '514 patent
 16 to opine that the films in Chen were not
 17 uniform?
 18 A. Yes.
 19 Q. And have you read the references
 20 Dr. Langer cited?
 21 A. Yes, I have.
 22 Q. Do any of those references change
 23 your opinion that the prior art enabled a person
 24 of ordinary skill in the art to make a uniform

1 film?
 2 A. They did not.
 3 Q. Why is that?
 4 A. Primarily because none of them
 5 discuss Chen at all. None talk about the
 6 uniformity was a problem after Chen, and none
 7 criticize uniformity within Chen.
 8 Q. Did any of the search references
 9 that are depicted here on DDX-3.021 conduct and
 10 report any independent scientific analysis?
 11 A. Not in regard to how to develop a
 12 product as shown by Chen, and actually there
 13 were many copy-and-paste criticisms from the
 14 '514 patent and related application.
 15 Q. Did any of the references that you
 16 read establish that content uniformity was an
 17 unsolved problem that was solved by the '514
 18 patent?
 19 A. Not in my opinion.
 20 Q. The Perumal references that are
 21 listed there, did that reference replicate any
 22 of the Chen films?
 23 A. It did not replicate the Chen
 24 films, no.

1 Q. And to summarize, Dr. Dyar, would
 2 the uniformly limitations in the '514 patent
 3 that you just testified about have been obvious
 4 to a person of ordinary skill in the art as of
 5 the time of the '514 patent?
 6 A. Yes, they would.
 7 Q. Turning now to the next set --
 8 THE COURT: Mr. Lynch, rather than
 9 turning now, why don't we take our afternoon
 10 break.
 11 MR. LYNCH: Thank you.
 12 THE COURT: So we'll take about
 13 15 minutes and we'll come back.
 14 (Short recess taken.)
 15 - - -
 16 (Proceedings resumed after the
 17 short recess.)
 18 THE COURT: All right. Please be
 19 seated.
 20 All right. You may continue,
 21 Mr. Lynch.
 22 MR. LYNCH: Thank you, your Honor.
 23 BY MR. LYNCH:
 24 Q. Dr. Dyar, before the break, we

1 were talking about your obviousness opinion
 2 regarding independent claim 62 in the '514
 3 patent, and we had just turned to what you had
 4 identified as the cast film limitations.
 5 Can you first explain what the
 6 first cast film limitation is?
 7 A. The first cast film limitation
 8 is -- does it sound good?
 9 Q. Yes, sir. Thank you.
 10 A. Perfect. In regard to a cast film
 11 comprising a flowable water-soluble or water
 12 swellable film-forming matrix comprising one or
 13 more substantially water-soluble or water
 14 swellable polymers.
 15 Again, the first reference here is
 16 Chen, JTX-187 on page 22. This is the same Chen
 17 reference we talked about earlier.
 18 And the films were prepared
 19 according to examples 1 through 3. Here, also
 20 additional, on page 23, in Table 5, show
 21 examples 5, 6, 7 and 8, which correspond to the
 22 graph that we showed earlier on the dissolution
 23 data. And it comprises a water soluble, water
 24 swellable polymer. It's methocel shown here.

1 **Q. And are the examples that you just**
2 **identified examples of cast films?**

3 **A. Yes, they are.**

4 **Q. Do those same examples disclose a**
5 **flowable matrix?**

6 **A. They show a flowable matrix, but**
7 **the final product is not flowable. There's a**
8 **matrix comprising, but the final cast film is**
9 **not flowable.**

10 **Q. Thank you.**

11 **Turning to the next cast film**
12 **limitation, can you explain what that is?**

13 **A. Yes. It's talking about the**
14 **desired amount of the at least one active, and**
15 **this is table, this is Chen, 187, JTX-187 on**
16 **page 23.**

17 **Table 5 is talking about nicotine**
18 **is an active, hydromorphone is an active.**
19 **Oxybutynin is an active in example 7, and**
20 **Estradiol in example 8 is an active.**

21 **Q. So examples 5 through 8 in Chen**
22 **that you've just identified teach the limitation**
23 **that you just identified from '514 about having**
24 **a cast film with the desired amount of at least**

1 **one active?**

2 **A. That is correct.**

3 **Q. And the bottom part of this slide**
4 **that we are looking at, which is taken from**
5 **JTX-187, page 18, it refers to examples 5**
6 **through 8 being depicted in Figure 5. Can you**
7 **explain?**

8 **A. Yes. The Figure 5 that we saw**
9 **earlier showing the dissolution profiles, these**
10 **are the examples, and the corresponding amounts**
11 **of drugs in each of those.**

12 **Q. Thank you.**

13 **Let's turn next to the limitations**
14 **in claim 62 that you have identified as**
15 **taste-masking agent.**

16 **A. Yes. And from the '514 patent, it**
17 **talks about a taste-masking agent selected from**
18 **the group consisting of flavors, sweeteners,**
19 **flavor enhancers, and combinations thereof to**
20 **provide taste-masking.**

21 **Q. Now, what is your opinion, Dr.**
22 **Dyar, about whether the Chen reference discloses**
23 **a use of a taste masking agent?**

24 **A. Yes. Chen discloses it on page**

1 **11. It talks about encapsulation of the active**
2 **agent to achieve masking of taste for active**
3 **agents that are bitter.**

4 **And on page 12, it talks about**
5 **taste modifying agents, which are flavoring**
6 **agents, sweetening agents and taste-masking**
7 **agents.**

8 **Q. Turning now to your last category**
9 **of claim limitation in claim 62 regarding a**
10 **particulate active, can you explain what the**
11 **'514 claim limitation is?**

12 **A. Yes. The '514 claim limitation is**
13 **a particulate active uniformly stationed in the**
14 **matrix. And the particulate active in reference**
15 **to showing Chen of 187 on page 6, and on page 9**
16 **and page 11 all talk about an active agent being**
17 **encapsulated or as an individual particle, and**
18 **that identifies the particulate active.**

19 **Q. So is it your opinion, Dr. Dyar,**
20 **that the Chen reference discloses using a**
21 **particulate active in a pharmaceutical cast**
22 **film?**

23 **A. Yes, it does.**

24 **Q. Does the Chen reference disclose a**

1 **particulate active of a specified size?**

2 **A. Chen does talk about particulate**
3 **actives that are greater than 25 microns,**
4 **leaving a gritty or unpleasant taste in the**
5 **mouth when they are placed within the mouth as**
6 **in a quick-dissolving-type tablet. So he**
7 **teaches that you need to have a small particle**
8 **size and not to have a gritty taste in the**
9 **mouth.**

10 **Q. Other than the mouth feel, would a**
11 **person of ordinary skill in the art have been**
12 **motivated for any other reason to use smaller**
13 **particles for the particulate active?**

14 **A. Yes. Going back to Stokes law,**
15 **where we talked about the particle size being**
16 **small in order to decrease the settling rate or**
17 **and correspondingly increasing the uniformity of**
18 **the dosing form.**

19 **Q. And are there any other references**
20 **that disclose more specific particle sizes?**

21 **A. Yes. Actually, the Bess reference**
22 **that I mentioned earlier, 184 on page 8, talks**
23 **about the particle size of 200 microns or less,**
24 **and specifically about active agents, complexes**

1 between 55 and 160 are probably between 60 and
2 150, which are both below 200 microns.

3 Q. And that's Bess JTX 184?

4 A. Yes. On page 8.

5 Q. All right. So can you summarize
6 your opinion that all the limitations of claim
7 62 were obvious as of the time of the '514
8 patent?

9 A. Yes. Based upon this color-coded
10 scheme, we can see that we've already talked
11 about the uniformity and that is shown in Chen.
12 We've talked about cast film being known. We
13 have talked about taste-masking agent being
14 known and particulate active less than
15 200 microns, which covers the entirety of the
16 independent claim 62 as being obvious to someone
17 skilled in the art.

18 Q. And, Dr. Dyar, do you have an
19 opinion regarding whether the claims of the '514
20 patent would have been obvious even if Chen did
21 not actually teach a uniform film?

22 A. Yes, I do.

23 Q. And what is that?

24 A. That he taught how to make a film,

1 and with a little bit of additional
2 experimentation if it was needed, you could, I
3 could at the time the patent was issued be able
4 to make the film prior to that date.

5 Q. Let's turn now to the dependent
6 claims that you identified.

7 Can you summarize your opinion
8 regarding whether these dependent claims were
9 obvious as of the time of the '514 patent?

10 A. Yes. Let's talk about claim 6 tea
11 four, which is specifically the hundred microns
12 or less. Again, I already mentioned earlier
13 that the Chen teaches small particles. Bess
14 teaches particles less than 100 microns. So
15 that is obvious.

16 Claim 65 --

17 Q. Can I pause you before you move
18 on, Dr. Dyar?

19 A. Yes.

20 Q. Is there anything about these
21 particle size and the specified microns that are
22 identified that is out of the ordinary for this
23 type of a pharmaceutical?

24 A. Absolutely not, because you would

1 want small particles within a film that is very
2 thin, so you wouldn't have a rough surface. So
3 that goes without saying.

4 Q. Please continue.

5 A. Claim 65 is talking about less
6 than five percent by weight. Again, I already
7 alluded to the uniformity requirement that a
8 person of skill in the art would be motivated to
9 reach and obtain so that they would not have
10 product that would be outside of that range and
11 have to have product recalls.

12 Q. And in your opinion, would a
13 person of ordinary skill in the art have been
14 motivated to obtain a variation in dose
15 uniformity of five percent or less?

16 A. Yes.

17 Q. And in your opinion, would a
18 person of ordinary skill in the art reasonably
19 expect to succeed in achieving a dose variance
20 of five percent or less?

21 A. Absolutely.

22 Q. And have you formed an opinion
23 regarding whether claim 6 tea nine is obvious?

24 A. Yes. Claim 69 is talking again

1 about taste-masking agent presented in an amount
2 of .1 to 30 percent. That's a very broad range.
3 It covers basically everything that we've used
4 in taste-masking.

5 The Chen examples 4 through 8
6 contain one percent peppermint oil, which is a
7 taste-modifying agent, taste-masking agent.

8 Q. And have you formed an opinion
9 regarding whether claim 73 is obvious?

10 A. Yes. Claim 73 is obvious in light
11 of the Chen example 6, which contains
12 hydromorphone, which is an opiate.

13 Q. Thank you.

14 Dr. Dyar, let's turn to your
15 second category of opinions regarding the '514
16 patent as being indefinite.

17 Can you explain briefly the basis
18 for your opinion that the claims are indefinite?

19 A. Yes. Well, a better slide, again,
20 color-coded, trying to group things to go here.

21 The green being the final product,
22 and it is a drug delivery composition of cast
23 film. And looking at the bottom, it's uniformly
24 subsequent to casting and drying of the matrix

1 is measured by equally sized individual unit ten
2 percent or less. That is the final product.

3 What's also claimed is that the
4 cast film must have, or must be flowable, which
5 is impossible, practically impossible for it to
6 be a final product that must be solid and not
7 move around on the table that you can take at
8 any point in time afterward within the shelf
9 life of the product and it be the same as when
10 you get it the first day, you get it from the
11 pharmacy.

12 So it cannot be flowable because
13 that implies that it moves, and the only thing
14 that moves are liquids or air. A solid does not
15 move.

16 Q. When you refer to a final product,
17 are you referring to the opening line of claim
18 62, which describes, quote, "a drug delivery
19 composition"?

20 A. Yes.

21 Q. Comprising?

22 A. Yes, that's correct.

23 Q. All right. Is it physically
24 possible for a drug delivery composition that is

1 a cast film to also be flowable at the same
2 time?

3 A. That is practically impossible for
4 it to occur.

5 Q. And --

6 A. Not to be stable.

7 Q. And is it physically possible for
8 a drug delivery composition that is a cast film
9 to also have a viscosity at the same time?

10 A. It is not because viscosity
11 implies or the only way you can have a viscosity
12 is from a material that flows.

13 Q. And, Dr. Dyar, with respect to
14 your observation that claim 62 claims a drug
15 delivery composition final product, do you have
16 an understanding about whether the '514 patent
17 covers also intermediate form of that product
18 during the process of it being made?

19 A. Yes. And this goes to the claims
20 covering the final product, and --

21 MR. BRAHMA: Objection, your
22 Honor. He has not been qualified as an expert
23 on submitting documents to the FDA for listing
24 patents in the Orange Book.

1 MR. LYNCH: Your Honor, he replied
2 in his reply report to arguments made by Dr.
3 Langer for plaintiffs that there were
4 intermediate steps in the process that could be
5 flowable, and that's in his reply report.

6 THE COURT: So I think the
7 objection is not that he didn't put this in the
8 report. I think the objection is it exceeds the
9 scope of his expertise.

10 And so maybe you want to ask him a
11 question or two, because I'm not a hundred
12 percent sure that -- I don't know whether this
13 is or is not within his expertise.

14 MR. LYNCH: Right. Thank you.

15 BY MR. LYNCH:

16 Q. So, Dr. Dyar, what is your basis
17 for concluding that claim 62 does not cover
18 intermediate steps in the manufacturing process?

19 MR. BRAHMA: Objection, your
20 Honor. The same objection. I don't think that
21 goes to his expertise.

22 THE COURT: Well, Doctor, what's
23 your experience with understanding Orange Book
24 listings?

1 THE WITNESS: Okay. I actually
2 teach this in pharmacy school to pharmacy
3 students what the Orange Book listing means, and
4 my work at Pfizer was involved with helping them
5 list drug products in the Orange Book.

6 THE COURT: And do you understand
7 where these sorts of questions are being asked
8 here, who provides this information and what it
9 means?

10 THE WITNESS: Yes. This
11 information is provided by the drug, the company
12 that's developing the product. Specifically in
13 the area of the attorneys, and that area that
14 cover the patents, provide that information as
15 part of the filing.

16 THE COURT: All right. I'm
17 prepared to let him answer the question
18 unless -- I assume you're Mr. Brahma?

19 MR. BRAHMA: Yes.

20 THE COURT: Is there any question
21 you want to ask him before he goes ahead?

22 MR. BRAHMA: Let him go ahead.

23 THE COURT: You can repeat your
24 question.

1 **MR. LYNCH: Thank you, your Honor.**

2 **BY MR. LYNCH:**

3 **Q. So, Dr. Dyar, is there any other**

4 **support for your conclusion that the claim 62**

5 **refers to a final drug product and not to any**

6 **intermediates?**

7 **A. Yes. As Reckitt request for the**

8 **Orange Book listing shown here as JTX-250 on**

9 **page 2 talks about the drug product composition**

10 **formulation, and it says, does the patent claim**

11 **the approved drug product as defined in 21 CFR**

12 **314.3? And they responded yes.**

13 **The second question asked: Does**

14 **the claim, does the patent claim only an enter**

15 **intermediate? And they indicated no.**

16 **MR. LYNCH: Thank you. No further**

17 **questions at this time.**

18 **THE COURT: All right.**

19 **Mr. Brahma?**

20 **MR. BRAHMA: Thank you, your**

21 **Honor.**

22 **CROSS-EXAMINATION**

23 **BY MR. BRAHMA:**

24 **Q. Good afternoon, Dr. Dyar.**

1 **A. Good afternoon.**

2 **Q. Let me first ask you this: You**

3 **have not published any papers or been involved**

4 **as an inventor on any patents or as a presenter**

5 **on pharmaceutical films; right?**

6 **A. I have not published or presented**

7 **on pharmaceutical films, no.**

8 **Q. You mentioned earlier you did some**

9 **work on pharmaceutical films; right?**

10 **A. That's correct.**

11 **Q. And it's true that that was a**

12 **single research project that you did at**

13 **Parke-Davis?**

14 **A. On a product to be developed as a**

15 **pharmaceutical film at the final dosage form,**

16 **yes, that was a single project at Parke-Davis.**

17 **However, I've worked on film-related technology**

18 **in the tablet coating, as I mentioned, and in**

19 **the hot metal extrusion technology.**

20 **Q. All right. But you have never**

21 **developed a cast, pharmaceutical cast film that**

22 **actually contained a pharmaceutical active, a**

23 **drug; is that right?**

24 **A. A pharmaceutical cast film as in**

1 **the final dosage form that contained an active,**

2 **no.**

3 **Q. And this project that you were**

4 **working on at Parke-Davis, that was a**

5 **feasibility study they were doing to determine**

6 **whether they should proceed with a**

7 **pharmaceutical cast film dosage form; is that**

8 **right?**

9 **A. No, sir, that's not what the**

10 **discussions were about. And in particular film,**

11 **there were discussions about seeing if we could**

12 **make a pharmaceutical film. And I did some**

13 **bench scale work as we discussed earlier in**

14 **regards to that.**

15 **Q. And at the end of your work, they**

16 **decided -- they never made a pharmaceutical**

17 **product from that cast film work you did; is**

18 **that right?**

19 **A. They never made a pharmaceutical**

20 **product from the cast film work that I did, that**

21 **is correct.**

22 **Q. And in addition to never making a**

23 **cast film with an active drug in it, you've**

24 **never done any experimental testing on any cast**

1 **film that contained an active drug ingredient;**

2 **is that right?**

3 **A. I have not tested any films as a**

4 **pharmaceutical final product that were cast**

5 **films. I have tested a hot metal extrusion film**

6 **technology that was used in the tablets, as we**

7 **discussed.**

8 **Q. And this patent is not about hot**

9 **metal extrusion films; right?**

10 **A. It's related technology.**

11 **Q. So for your entire 28-year career,**

12 **you have never made or tested a single cast film**

13 **with a pharmaceutical active in it; is that**

14 **right?**

15 **A. Not in a cast film sense, but I**

16 **have again in the hot metal extrusion, which is**

17 **an alternate technology used to make films.**

18 **Q. And even for the purposes of your**

19 **work on this case, you never tested any of the**

20 **pharmaceutical film formulations that were**

21 **discussed in the prior art you cite; is that**

22 **right?**

23 **A. I have not tested the**

24 **pharmaceutical films that were discussed in the**

1 prior art.

2 Q. In fact, you've never done any
3 independent analysis of whether any of the films
4 mentioned in the prior art that you cite
5 actually met the drug content uniformity
6 limitations in the claims of the '514 patent; is
7 that right?

8 A. Could you define independent
9 analysis?

10 Q. You never tested any of those
11 products to determine what their drug content
12 uniformity was; is that right?

13 A. I never physically tested the
14 products for content uniformity, no.

15 Q. And aside from Chen Figure 5,
16 which we'll get to what your interpretation of
17 that is now, you point to no data in any of the
18 prior art that you looked at in which the prior
19 art itself reports drug content uniformity
20 testing data; is that right?

21 A. I did not point to any -- would
22 you ask the question again? Sorry.

23 Q. Sure. Putting aside Chen for a
24 moment because we're going to discuss that in

1 more detail, none of the prior art you looked at
2 other than Chen reported any drug content
3 uniformity data; is that right?

4 A. They did not report any content
5 uniformity data. However, as I mentioned
6 earlier, if you're developing a pharmaceutical
7 product, you would necessarily be developing a
8 uniform film.

9 Q. Well, you said it was a critical
10 regulatory requirement to get within that ten
11 percent uniform, drug content uniformity level;
12 right?

13 A. I said it is are critical to get
14 the content uniformity there for the product
15 prior to you placing it on the market. That's
16 correct.

17 Q. And if you could, you would get
18 even tighter than that; is that right?

19 A. I did say if you could get
20 tighter, you would be motivated to get tighter.

21 Q. And specifically, you said a
22 person of ordinary skill would be motivated to
23 get within five percent; right?

24 A. I said my targets were always five

1 percent, and you would want to get as low as you
2 possibly could so that you would not have
3 product recall. That's correct.

4 Q. And you didn't cite any document
5 showing that a person of ordinary skill in the
6 art would try to get within a five percent
7 uniformity requirement; is that right? That's
8 just your own standard?

9 A. That is my standard based upon,
10 you know, 28, 30 years worth of experience and
11 working with numerous pharmaceutical companies
12 across the world to help them solve the
13 problems.

14 Q. And none of them published the
15 document that you cited that shows that a person
16 of ordinary skill in the art would want to get
17 within a five percent uniformity requirement; is
18 that right?

19 A. I did not cite anything.
20 However --

21 Q. Okay.

22 A. -- sometimes things are based upon
23 an absolute need and other times they are based
24 upon what is the best for the company. And so

1 they're internal metrics that are not always
2 published.

3 Q. So you were saying earlier that
4 anyone who was trying to develop a
5 pharmaceutical cast film in this time period
6 would have tried to meet the ten percent drug
7 content uniformity level in order to meet
8 regulatory requirements; is that right?

9 A. I don't think I said anyone. I
10 think I said someone that was going to develop a
11 product to put on the market. If they are doing
12 bench research at a university, it's not common
13 for them to necessarily be worried about content
14 uniformity.

15 Q. Okay. So tests of films that were
16 made for bench research at a university wouldn't
17 necessarily have met the ten percent content
18 uniformity requirement; is that right?

19 A. They would not necessarily have
20 met it depending on if they tested it or not.

21 Q. But the products that were being
22 prepared for commercial production, a company
23 that was trying to make that product would have
24 certainly tested drug content uniformity; is

1 that right?

2 A. Not necessarily. It depends on
3 what stage of development they were in.

4 Q. Well, ultimately, they'd have to
5 submit it to the FDA; is that right?

6 A. And at that stage you would be
7 correct, they would test it at the appropriate
8 stage when they are going to submit the package
9 to the FDA.

10 Q. And the way to tell if your film
11 meets that drug content uniformity requirement
12 within ten percent or within five percent of the
13 desired amount of drug, the way to do that is to
14 do a test; is that right?

15 A. The way to test content uniformity
16 is to do a test.

17 Q. Right.

18 A. That's correct.

19 Q. To do an experiment; right?

20 A. That's correct.

21 Q. All right. And none of the prior
22 art you looked at included that test, putting
23 aside Chen for a moment?

24 A. Did any of the prior art that I

1 looked at conduct a test for a film
2 specifically, or in general?

3 Q. Well, you have looked at film
4 prior art; right?

5 A. Right.

6 Q. That's what you've been looking
7 at?

8 A. Yes.

9 Q. Putting aside Chen, none of the
10 prior art relating to cast films provided any
11 data on content uniformity; right?

12 A. No, and I wouldn't necessarily
13 expect it to because, again, it's a primary
14 responsibility of when you're developing a drug
15 product, that you develop it with content
16 uniformity. Otherwise, you will not have the
17 requirements, and you would not a safe,
18 efficacious drug.

19 Q. Okay. So for those other pieces
20 of prior art, instead of looking for
21 experimental data on drug content uniformity,
22 you looked at general statements about
23 homogeneity or uniformity of the matrix; is that
24 right?

1 A. I saw statements that stated that
2 the matrix was homogeneous or uniformly mixed.

3 Q. Okay.

4 A. Which, again, support the fact
5 that they were intending to develop such a
6 product and there would be no reason why
7 they would not be targeting the FDA requirement,
8 so it's understood that that would be the
9 target.

10 Q. So you applied an assumption that
11 if a prior art reference doesn't report drug
12 content uniformity data, then the films it
13 describes are likely to be uniform in drug
14 content; is that right?

15 A. I did not apply that assumption
16 necessarily. You are saying that if they
17 did not report it, they were necessarily
18 uniform?

19 Q. I said the assumption that you
20 applied is that if a prior art reference doesn't
21 report uniformity data, then the films it
22 describes are likely to be uniform in drug
23 content. That's the assumption you applied; is
24 that right?

1 A. The assumption I applied was they
2 were intending to make a uniform product.
3 Whether they actually met it at that point in
4 the development or not, I don't know if they did
5 or not because there wasn't necessarily data
6 there because, again, it's understood, that is
7 your target.

8 Q. Okay. So then if I understand
9 correctly, what you're saying now on the stand
10 at trial is that the only reference you can rely
11 on as potentially showing drug content
12 uniformity within the ten percent or
13 five percent limit in the claims of the '514
14 patent is the Chen reference, because that's the
15 only one with data; is that right?

16 A. That's not what I'm saying. I'm
17 saying there's not data, but there's the
18 understanding that when you are developing a
19 drug product, that it would have content
20 uniformity. Otherwise, you wouldn't be
21 applying for approval from the FDA to market the
22 product.

23 Q. And you don't know that any of the
24 prior art films ever led to a request for

1 approval from the FDA for any particular drug
2 product; right?

3 A. I did not do an analysis in regard
4 to any products that were, that currently are on
5 the market or that have been on the market in
6 regard to any of the film technology.

7 Q. Okay. And none of those, none of
8 those films in Chen with those active
9 ingredients, none of those are FDA approved drug
10 product even today; is that right?

11 A. I don't know the answer to that
12 question.

13 Q. You didn't even check that; is
14 that right?

15 A. I do not know the answer to the
16 question.

17 Q. Let's talk about the Chen
18 reference, and I'm going to start, and that's
19 JTX-0187. And I'm going to start with Figure 5.

20 A. I just want to make sure I have it
21 here.

22 Q. You have it on the screen in front
23 of you, Dr. Dyar?

24 A. Yes.

1 Q. Okay. And we've previously talked
2 about this at your deposition, too; right, Dr.
3 Dyar?

4 A. That's correct.

5 Q. All right. And when we talked
6 about this at your deposition, you told me --
7 well, let me take a step back. You see that
8 some of those data points there on the curves
9 are above 100 percent; is that right?

10 A. That's correct.

11 Q. And you said in your report, the
12 fact that some of the data points -- this is a
13 quote. The fact that some of the data points
14 are above 100 percent signifies a problem with
15 the experiment itself.

16 Right?

17 A. I stated that it could signify a
18 problem with the experiments and I stated a
19 number of reasons why that would be the case.

20 Q. All right. And at that time you
21 said you couldn't rely on the data in Chen to
22 show anything about drug content uniformity; is
23 that right?

24 A. I don't -- that is not correct. I

1 think your specific question, as I recall it at
2 that time, was, can I tell precisely, and can I
3 say that this would be an FDA guide and I said
4 no, because I do not have the precise data that
5 is behind this to be able to tell you, yes, it
6 would.

7 Q. Okay. Well, so, and you remember
8 me asking you this at your deposition; is that
9 right?

10 A. I do.

11 Q. So let's look at the questions and
12 the answers. And I'm going to go to page 178,
13 line 16.

14 MR. LYNCH: Can we get the
15 deposition in front of him.

16 THE COURT: Do you have a copy of
17 your deposition, Doctor?

18 THE WITNESS: No, sir, I do not.

19 THE COURT: All right. Can you
20 give him a copy?

21 MR. BRAHMA: May I approach, your
22 Honor?

23 THE COURT: Yes.

24 (Mr. Brahma handed a deposition

1 transcript to the witness.)

2 BY MR. BRAHMA:

3 Q. Okay. So we're looking at page
4 178, line 16, to page 179, line 13.

5 A. Okay. So 178, line 16? Okay.

6 Q. Okay. And is the first question I
7 asked you was: Looking at this data for the
8 hydromorphone film, does that film meet the ten
9 percent active content uniformity requirement in
10 the '514 patent claims?

11 And your answer was -- can you
12 read it for me?

13 A. Yes. Again, I can't tell you
14 without seeing the data because it's all on top
15 of each other, and again you were referring to
16 meeting the FDA requirement.

17 Q. And that FDA requirement, that ten
18 percent requirement, that's a limitation of the
19 claims, the asserted claims of the '514 patent;
20 is that right?

21 A. That is correct.

22 Q. Okay. And your testimony in that
23 deposition was, you couldn't tell from the data
24 in Figure 5 whether that limitation was met by

1 **Chen; is that right?**

2 **A. That I could not tell precisely if**
3 **the ten percent was met because the information,**
4 **the data was on top of each other. However,**
5 **looking at it, I would still -- I would say that**
6 **it appears that they're on the right path and**
7 **they could, with a little bit more**
8 **experimentation, be able to develop a**
9 **pharmaceutical film to be able to place on the**
10 **market.**

11 **Q. Okay. Your statement, your**
12 **position now on the stand is that Chen, if they**
13 **had wanted to, could have done a little more**
14 **experimentation and made a uniform film; is that**
15 **right?**

16 **A. If they did not already have a**
17 **uniform film, because, again, I don't have the**
18 **precise data.**

19 **Q. But you had the data that's in the**
20 **figure; right?**

21 **A. The data in the figure is very**
22 **difficult to be able to get the actual numbers**
23 **from the data to apply the question that you --**
24 **that I was being asked about active content**

1 **uniformity requirement of ten percent. I could**
2 **not get that by just deconvoluting the data**
3 **because it's all on top of each other.**

4 **Q. And --**

5 **A. I would have loved to have it.**

6 **Q. You would have loved to have it.**
7 **You never asked for it though; right?**

8 **A. I -- I don't recall if I asked you**
9 **for it.**

10 **Q. You didn't ask your own attorneys**
11 **for it?**

12 **A. I've been working on this case for**
13 **a year. I don't know if I -- I think I asked if**
14 **we could get the data, but I don't recall**
15 **specifically. I know there was some discussion**
16 **around that.**

17 **Q. Okay. But you were never able to**
18 **get that underlying data; right?**

19 **A. I never saw the underlying data,**
20 **no.**

21 **Q. And so you can't calculate from**
22 **what's shown on the figures how close or how far**
23 **the Chen films were from meeting that ten**
24 **percent or that five percent drug content**

1 **uniformity level; is that right?**

2 **A. I cannot calculate the actual**
3 **specific number. However, as I said earlier,**
4 **based upon examination of thousands of these**
5 **dissolution profiles, I can tell you that they**
6 **look reasonable and could be potentially**
7 **developed into a pharmaceutical film.**

8 **Q. Okay. Let's look at the data in**
9 **the figure itself. You said this was a**
10 **dissolution test; is that right?**

11 **A. Yes. That's my understanding**
12 **of -- yes.**

13 **Q. With four different -- four**
14 **different films with four different active**
15 **ingredients; is that right?**

16 **A. Four films, yes. Example 5**
17 **through 8, if I recall correctly.**

18 **Q. Okay. And you do this dissolution**
19 **test by putting it in a dissolution bath and**
20 **measuring the amount of drug released from the**
21 **film over time; is that right?**

22 **A. That is correct.**

23 **Q. All right. And the 100 percent**
24 **mark that's on this, this figure on the Y axis**

1 **where it says percent release --**

2 **A. Yes.**

3 **Q. -- that indicates 100 percent of**
4 **the amount of drug that is desired to be in the**
5 **film, the dosage; is that right?**

6 **A. That is correct.**

7 **Q. Okay. And if the curve gets to**
8 **that 100 percent mark, that means that**
9 **100 percent of the desired amount of the drug**
10 **has been released; is that right?**

11 **A. That when it plateaus out and**
12 **reaches a hundred percent, that is where**
13 **the release profile has reached that target,**
14 **yes.**

15 **Q. Okay. Well, I wanted to**
16 **disconnect those two ideas for a second. A**
17 **point above 100 percent on this figure means**
18 **that more than 100 percent, more than**
19 **100 percent of the desired amount of drug was**
20 **released from the film; is that right?**

21 **A. You're talking specifically**
22 **about -- do you want to point out a specific**
23 **point?**

24 **Q. Sure. If you take the shaded-in**

1 triangle at minute eight. It's on the nicotine?
 2 A. Okay.
 3 Q. Yes. Go ahead and circle that
 4 one.
 5 So that point is above 100 percent
 6 release; is that right?
 7 A. That point is above a hundred
 8 percent release at that time point.
 9 Q. All right.
 10 A. However, at ten, it appears to be
 11 at a hundred percent.
 12 Q. More than 100 percent release of
 13 drug from the film means that more than
 14 100 percent of the desired amount of drug was in
 15 the film in the first place; is that right?
 16 A. Not necessarily. It could mean
 17 that. It could also mean that the potentially
 18 analytical error, or a number of other issues
 19 that could occur in these type studies.
 20 Q. And you didn't point to anything
 21 about the way the Chen inventors did this
 22 experiment that suggested that they did the
 23 experiment wrong; is that right?
 24 A. Did I look at their

1 experimentation component and see, analyze it to
 2 see if they did anything wrong?
 3 Q. Correct.
 4 A. Is that your question.
 5 Q. Yes. You were talking about their
 6 analytical error. You didn't actually point to
 7 anything specific?
 8 A. I didn't point to anything
 9 specific because I don't think the details were
 10 there in order to do that evaluation.
 11 Q. And the dissolution test, that's
 12 something you learn in school; right?
 13 A. That's correct.
 14 Q. So pretty basic?
 15 A. It's basic in some sense, but
 16 there's -- there can be error associated with
 17 it, and it commonly is a range of values because
 18 these systems are not absolutely precise.
 19 Q. And you never tried to repeat
 20 these experiments; is that right?
 21 A. I did not repeat these
 22 experiments, no.
 23 Q. To get your own data about the
 24 uniformity of Chen?

1 A. No. I did not make the films or
 2 repeat the experimentation that he did.
 3 Q. Okay. In Chen, you had the exact
 4 formulation for these films; is that right?
 5 A. In Chen, I had the formulation for
 6 the films, yes.
 7 Q. And Chen says, gives you
 8 information about how they were dried; right?
 9 A. He gives information about, as I
 10 just talked earlier, about drying.
 11 Q. And yet despite all of that
 12 information, you didn't think to make the films
 13 yourself, to test their uniformity; is that
 14 right?
 15 A. I did not make the films to test
 16 their uniformity because I wasn't asked to. And
 17 this is not my current area of research.
 18 Q. Okay?
 19 THE COURT: Mr. Brahma, before you
 20 go on --
 21 THE WITNESS: Yes.
 22 THE COURT: -- Dr. Dyar, how is
 23 this example at minute eight, the thing that's
 24 coming out of the triangle looks like a nail

1 being put into it.
 2 THE WITNESS: Okay.
 3 THE COURT: What is that?
 4 THE WITNESS: That's the error
 5 bar. That is the range of values for that
 6 particular data point.
 7 THE COURT: So assuming that the
 8 scale is relatively accurate here, that would
 9 mean at minute eight, the nicotine seems like
 10 really one trial release, you know, like
 11 118 percent or something?
 12 THE WITNESS: That would be
 13 correct.
 14 MR. BRAHMA: I was just about to
 15 go into that, your Honor.
 16 THE COURT: Oh, sorry.
 17 MR. BRAHMA: No problem.
 18 THE COURT: I thought you were
 19 moving on to something else.
 20 MR. BRAHMA: We are going to spend
 21 a little bit of time on this one.
 22 BY MR. BRAHMA:
 23 Q. So to dots on the curves, those
 24 indicate the mean values measured by Chen?

- 1 A. That's correct.
- 2 Q. For each of those time points for
- 3 each of those films, they took multiple samples
- 4 and measured how much drug had been released at
- 5 is that time point?
- 6 A. That's correct.
- 7 Q. And the error bars show the
- 8 standard deviation from the mean; is that right?
- 9 A. That's my understanding, yes.
- 10 Q. Okay. So in order to get the
- 11 entire range of drug content measurements from
- 12 the samples Chen took, you would take the mean
- 13 plus or minus three standard deviations; is that
- 14 right?
- 15 A. That's correct.
- 16 Q. Okay. So those error bars, you
- 17 would have to triple them in order to see what
- 18 the entire range of sample measurements was?
- 19 A. That would be true.
- 20 Q. Okay. And you never did that?
- 21 A. However, that's not the standard
- 22 which is applied here. It's a ten percent
- 23 variation. That's what we're talking about.
- 24 Q. Ten percent variation among all

- 1 the samples you take from a film; is that right?
- 2 A. Ten percent variation among the
- 3 samples. What do you mean, all the samples?
- 4 Q. Well, the claim language talks
- 5 about taking multiple samples of individual unit
- 6 dosage, dosages of the film.
- 7 A. Can you point --
- 8 Q. And they can't vary by more than
- 9 ten percent; right?
- 10 A. Can you point me back to that
- 11 exact claim language, because I don't recall it
- 12 being that.
- 13 Q. We can use your slide. DDX-3.004.
- 14 If you look at that bottom where in limitation,
- 15 it talks about the uniformity being, quote,
- 16 measured by substantially equal size, equally
- 17 sized individual unit doses which do not vary by
- 18 more than ten percent of said desired amount of
- 19 said at least one active.
- 20 Right?
- 21 A. Yes. That's talking about at the
- 22 end point that I pointed out, where you have at
- 23 the ten-minute, if you want to go back to the
- 24 other, the figure Chen. It's not talking about

- 1 the variation across every single point is my
- 2 understanding, although you can see that there
- 3 is some tight data in the Estradiol, and in my
- 4 opinion, a little bit of additional
- 5 experimentation with getting there.
- 6 Q. Well, let's talk about Estradiol
- 7 really quickly, because before you told me that
- 8 the curve has to become constant to tell how
- 9 much drug is released from the film; right?
- 10 A. I said the curve needs to become
- 11 constant before you know when it has finished
- 12 releasing all the drug. That is true.
- 13 Q. Okay. And the Estradiol curve,
- 14 you can't tell whether it has reached the
- 15 plateau where it becomes constant; is that
- 16 right?
- 17 A. You cannot tell it, and again for
- 18 the Court, this is the Estradiol (indicating).
- 19 And you can see at eight, it's a little lower
- 20 than at ten, but you can see that it's
- 21 approaching 100 percent and it is somewhat
- 22 plateauing out.
- 23 Q. So at some future time it's going
- 24 to become constant, but for right now your Honor

- 1 every point on that curve for Estradiol is
- 2 higher than the one before it; is that right?
- 3 A. For every point on the curve of
- 4 Estradiol, the points are higher.
- 5 Q. Okay. So that's not study state;
- 6 right?
- 7 A. That's correct. That's not steady
- 8 state.
- 9 Q. Okay. The other three curves, you
- 10 have an area where it might be steady state;
- 11 right? A flat part?
- 12 A. Relatively flat. Yes.
- 13 Q. Okay. Is there -- and there's no
- 14 reason -- I mean, you said before that you would
- 15 only look at the time point at ten minutes;
- 16 right?
- 17 A. Well, the time point at ten
- 18 minutes is giving you an indication that your
- 19 system is stable at that point because it's
- 20 plateauing out, and you will have, tend to have
- 21 less variability at that point in time if you
- 22 have variability in your system.
- 23 Q. Okay. And if your system was
- 24 steady state at eight minutes, then you could

1 use those values too; right?

2 A. If your steady state is eight
3 minutes, you could use this value. Again, we
4 are talking -- we don't have the actual data, so
5 it is difficult to see what the precise numbers
6 would be. But, again, the shape of these curves
7 and the content uniformity that is being shown
8 here are consistent with the product that could
9 be developed and placed on the market.

10 Q. Okay. So if you saw, if you were
11 able to see what those values were with the
12 triple error bars, then you would be able to
13 tell what the drug content uniformity was of
14 these Chen films; is that right?

15 A. There's a potential to just show
16 that what state he currently has. It doesn't
17 mean he was absolutely able to get there. But
18 again with minimal experimentation, should be
19 able to get there.

20 Q. You said this dissolution test,
21 everyone learns it in school in this field; is
22 that right?

23 A. In pharmacy, people learn how to
24 do dissolution tests, that's correct.

1 Q. All right. And Chen would have
2 been doing this, according to you your Honor in
3 order to determine the drug content in the
4 films; right?

5 A. Chen would have been doing it to
6 determine what the content uniformity are. He
7 could have been looking at it in addition to
8 looking at the release profiles I mentioned
9 before.

10 Q. And if inventor Chen had data that
11 suggested that these films weren't uniform
12 within ten percent, your understanding is, or
13 your assumption is that she would have gone
14 back, tweaked her experiments a little bit, and
15 gotten a better film; right?

16 A. That if she didn't have, she would
17 have gone back and tweaked her results and
18 gotten better results. Is that what you are
19 saying?

20 Q. A more uniform fill. That's
21 right.

22 A. Again, based upon, based upon my
23 experience, patents need to get issued as soon
24 as possible, and we would often put out the

1 experiments and data that may not be exactly
2 what we wanted at that point in time that was
3 able to be developed and placed on the market,
4 and we would commonly do additional work in
5 order to get it moving forward and additional
6 experimentation.

7 Q. And you have no evidence that Chen
8 created any subsequent films to this; is that
9 right?

10 A. I have not looked to see if Chen
11 developed any films or worked on films. I have
12 not evaluated that.

13 Q. Okay.

14 A. No.

15 Q. Let's turn to a different part of
16 Chen. Figure 2. And actually, let's turn to
17 Dyar direct slide 19, so DDX-3. -- I'm sorry,
18 11.

19 Okay. And before you were saying
20 that those highlighted red arrows, that's the
21 airflow that hits the surface of the film as it
22 goes through the oven; right?

23 A. Yes. We're talking about these
24 three aeration controllers. That's the airflow,

1 that's diffusional airflow. That's more direct,
2 and then direct airflow. That's correct.

3 Q. Okay. So as the film goes through
4 the oven, your understanding of Chen is that the
5 airflow changes and the viscosity of the film
6 changes; is that right?

7 A. As we go through, the airflow is
8 different initially because it has a lower
9 viscosity, or the film, you know, film is not
10 dried, and by the time it gets to the end, it's
11 dry so the air can directly aim down on it.
12 Yes.

13 Q. We can move off of Chen. Let me
14 ask you quickly a couple questions, one about
15 Listerine. You mentioned working at the sister
16 company of Listerine, of the maker of Listerine;
17 right?

18 A. Yes. I worked at Parke-Davis,
19 which was the pharmaceutical division of
20 Warner-Lambert, and there was a Warner-Lambert
21 consumer healthcare, which is where Listerine
22 was being made.

23 Q. Okay. You were working at
24 Parke-Davis when the Listerine film strips were

1 being made and when you were doing your
2 feasibility study on pharmaceuticals; is that
3 right?

4 A. I was working at Parke-Davis at
5 that time, yes.

6 Q. All right. And when you were
7 looking around for film formulations to test for
8 your feasibility study, you didn't use the
9 Listerine film; correct?

10 A. I did not use the Listerine film
11 strip technology, no.

12 Q. The Listerine films, they're not
13 subject to any regulatory requirement for
14 content uniformity; right?

15 A. They do not have an active, and so
16 in the normal sense of content uniformity,
17 they're not subject to that. However, the
18 content needs to be uniform. Otherwise, they
19 wouldn't have a product to be able to place on
20 the market for consumers to use.

21 Q. But there's nothing --

22 A. And I don't know about the
23 regulatory requirements, again, because I did
24 not work in the consumer healthcare area, which

1 is a different regulatory environment.

2 Q. Right. And, in fact, you didn't
3 do any work on Listerine film strips; right?

4 A. I did not do any physical work on
5 Listerine film strips.

6 Q. No testing on Listerine film
7 strips?

8 A. I did not do any physical testing
9 on the Listerine film strips.

10 Q. And you weren't aware of any
11 internal company requirements for content
12 uniformity for Listerine film strips either; is
13 that right?

14 A. No, because, again, I was not in
15 the consumer healthcare area, and, again, I
16 wouldn't know the requirements because it's not
17 covered in my area of expertise.

18 Q. Okay. Let's switch to slide 26 of
19 your presentation.

20 You said that this statement in
21 Chen would motivate someone to not use
22 particulates or particles with greater than
23 25-micron diameter in their films; is that
24 right?

1 A. It says -- well, it says
2 specifically that many quick dissolving products
3 that you place in your mouth, if they have
4 particulates greater than 25 microns would leave
5 a gritty or unpleasant taste in the mouth, which
6 means you would like to have a particulate less
7 than that size.

8 Q. Less than 25 microns?

9 A. They could be a little larger, but
10 he is saying -- he's not saying that you have
11 to, but it leaves a less gritty taste in your
12 mouth.

13 Q. And going to the following slide,
14 the smallest particle size shown in Bess, which
15 is what you say would be combined with Chen
16 under that motivation, is 55 microns, double the
17 size; is that right?

18 A. Is 55 microns and about a
19 hundred -- yes, 55 is the number that is shown
20 there, yes.

21 Q. Okay. And I'm going to move
22 quickly to your indefiniteness argument.

23 You said that, you said that the
24 claims of the '514 patent that you've been

1 looking at are indefinite because they require a
2 dried cast film to still have a flowable matrix,
3 a matrix that is still flowing; is that right?

4 A. That's correct.

5 Q. Okay. You weren't able to find
6 any prior art films that met that requirement;
7 is that right?

8 A. That met the requirement of --

9 Q. Of being dried -- of being a dried
10 film that still has a flowing matrix?

11 A. Of being a dried film that would
12 be afloat go matrix would be practically
13 impossible, because it would be moving. You
14 place it on the table, it's going to move.

15 Q. Right. And so specifically, none
16 of the prior art that you looked at showed that
17 type of film; is that right?

18 A. No. The prior art showed a film
19 that would have flow or viscosity, because,
20 again, it's practically impossible.

21 Q. All right. Last topic. I know
22 you were in the courtroom this morning when
23 Mr. Lombardi told the story about product
24 hopping and he used slide DDX-1.006.

1 **MR. BRAHMA: Can I get that pulled**
 2 **up?**
 3 **BY MR. BRAHMA:**
 4 **Q. Do you remember that discussion?**
 5 **A. About this slide?**
 6 **Q. Yes. And the discussion about the**
 7 **product hopping. I remembered it was acute**
 8 **term.**
 9 **A. The product -- sorry?**
 10 **Q. Product hopping.**
 11 **A. Product topping?**
 12 **Q. Hopping, hopping, like a bunny**
 13 **rabbit.**
 14 **A. I don't actually recall that one.**
 15 **Q. All right.**
 16 **A. I must have missed that one.**
 17 **Q. Well, let me ask you about this**
 18 **slide because it has one piece on there that**
 19 **might be relevant to you. On there, there's a**
 20 **flag for July 10th, 2007, for whether the '514**
 21 **patent application was filed.**
 22 **Do you see that?**
 23 **A. Yes. Yes.**
 24 **Q. Okay. And within the context of**

1 **Mr. Lombardi's story, this is part, the idea is**
 2 **that Reckitt Benckiser and MonoSol got together**
 3 **in 2006 and after that they started filing all**
 4 **these patent applications that supposedly gave**
 5 **them some incentive to hop from a tablet product**
 6 **to a film product.**
 7 **Do you remember hearing that**
 8 **discussion?**
 9 **A. I do recall that discussion.**
 10 **Q. Okay. For your invalidity**
 11 **analysis though, you're not using July 10th,**
 12 **2007 as the priority date; is that right?**
 13 **A. I think I would have to look at my**
 14 **report again, because it has been awhile since I**
 15 **wrote the report, and I would be happy to look**
 16 **at that, because I think there were several**
 17 **dates mentioned there.**
 18 **Q. All right. But your analysis in**
 19 **terms of what you are presenting at trial today**
 20 **uses a priority date of September 27, 2002; is**
 21 **that right?**
 22 **A. I think that's correct, but,**
 23 **again, I couldn't confirm a hundred percent**
 24 **unless I looked at it. Would you like to...**

1 **(Pause.)**
 2 **BY MR. BRAHMA:**
 3 **Q. Okay. The September 27, 2002**
 4 **date, that would be four years before Reckitt**
 5 **Benckiser and MonoSol even entered into an**
 6 **agreement; right?**
 7 **A. You're asking me that question? I**
 8 **have no idea about that, about an agreement**
 9 **between the parties.**
 10 **Q. I'm not asking about -- I'm just**
 11 **saying that that flag for the agreement about**
 12 **Reckitt showing 2006, if you were using a date**
 13 **of September of 2002 for your priority date,**
 14 **that would be four years before that even**
 15 **happened; is that right?**
 16 **A. If I were -- but, again, I don't**
 17 **recall all the dates that I was using, because**
 18 **if I recall correctly, I think it didn't matter**
 19 **if it was 2007, but I cannot recall a hundred**
 20 **percent.**
 21 **Q. All right. Let's pull up admitted**
 22 **fact 121. Okay. I'm going to put it on the**
 23 **Elmo.**
 24 **Can you see that, Dr. Dyar?**

1 **A. Can you make it a little bigger?**
 2 **Q. Let's see if we can. It's the one**
 3 **at the top there, number 121.**
 4 **A. Yes. The asserted claims of the**
 5 **'514 patent are entitled -- can you give plea**
 6 **the paragraph before that?**
 7 **Q. It relates to a different patent.**
 8 **Would that help you?**
 9 **A. Okay. I just want to make sure**
 10 **the context I'm seeing everything.**
 11 **Q. Okay.**
 12 **A. Are entitled to a priority date of**
 13 **September 27, 2002. However, I think there was**
 14 **some additional analysis within my report about**
 15 **priority date.**
 16 **Q. Okay. But for purposes of this**
 17 **litigation, the parties have agreed that all of**
 18 **the claims were, all of the claims that we're**
 19 **talking about here from the '514 patent were**
 20 **already supported and described in applications**
 21 **that had been filed as of September 27, 2002.**
 22 **You understand that; right?**
 23 **A. I understand that, yes.**
 24 **Q. So this product hopping theory has**

1 nothing to do with the '514 pat end and your
2 invalidity analysis; right?

3 A. I'd may have no opinion with
4 regard to the topic, product hopping, product
5 topping idea.

6 MR. BRAHMA: I think that answers
7 my question. Thank you, Dr. Dyar.

8 THE COURT: Any redirect?

9 MR. LYNCH: No, your Honor. No
10 questions, your Honor.

11 THE COURT: Thank you, your Honor
12 Dr. Dyar. You may step down.

13 THE WITNESS: Okay.

14 THE COURT: All right. Okay.

15 Well, so that will be it for today, so we can
16 stop the clock.

17 How are we doing in terms of your
18 expectations of the schedule? Are we moving
19 along about as you expected?

20 MR. LYNCH: Your Honor, from
21 defendants' perspective, your Honor, I think
22 we're kind of right where we thought we would be
23 both in terms of the number of hours we got in
24 today and the witnesses we covered. I think we

1 are in good shape.

2 THE COURT: Okay. Plaintiff,
3 you're good?

4 MR. LADOW: I think so, your
5 Honor.

6 THE COURT: All right. Is there
7 anything else you want to talk about before we
8 go our various ways?

9 MR. LADOW: No, your Honor.

10 MR. LYNCH: No, your Honor. Thank
11 you.

12 THE COURT: All right. Well, I
13 guess we will be in recess then and I will see
14 you tomorrow morning, and so have a good
15 evening.

16 (Court recessed at 5:01 p.m.)

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- VOLUME 2 -

IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

- - -

RECKITT BENCKISER	:	CIVIL ACTION
PHARMACEUTICALS INC., RB	:	
PHARMACEUTICALS LIMITED,	:	
and MONSOL RX, LLC,	:	
	:	
Plaintiffs,	:	
	:	
vs.	:	
	:	
TEVA PHARMACEUTICALS	:	
USA, INC.,	:	
	:	
Defendant.	:	NO. 14-1451 (RGA)

- - -

Wilmington, Delaware
Wednesday, November 4, 2015
8:30 o'clock, a.m.

- - -

BEFORE: HONORABLE RICHARD G. ANDREWS, U.S.D.C.J.

- - -

Valerie J. Gunning
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Official Court Reporters

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4

5 -and-

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9 Counsel for Defendant
Watson Laboratories

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1 P R O C E E D I N G S

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3 (Proceedings commenced in the

4 courtroom, beginning at 8:30 a.m.)

5

6 THE COURT: All right. Good

7 morning, everyone. Please be seated.

8 Are I guess we're ready to

9 continue with the defendants' case.

10 MS. MELVIN: Yes, your Honor.

11 Good morning, your Honor. May it please the

12 Court, Emily Melvin from Latham & Watkins on

13 behalf of defendants.

14 Your Honor, our next witness, we'd

15 call Dr. Charles O'Brien. Dr. O'Brien is

16 testifying regarding secondary considerations.

17 The parties have agreed that he can be taken out

18 of order.

19 THE COURT: Okay.

20 MS. MELVIN: And, your Honor, may

21 we approach with some binders?

22 THE COURT: Sure.

23 (Binders handed to the Court.)

24

1 ... CHARLES PHILLIP O'BRIEN,
2 having been duly sworn as a witness, was
3 examined and testified as follows...

4 MS. MELVIN: And, your Honor, a
5 copy of the slides are in the front pocket of
6 the binders.

7 THE COURT: Okay.
8 DIRECT EXAMINATION

9 BY MS. MELVIN:

10 Q. Good morning, Dr. O'Brien. Can
11 you please introduce yourself to the Court?

12 A. Yes. I'm Charles Phillip O'Brien,
13 a professor of psychiatry at the University of
14 Pennsylvania.

15 Q. And do you have any particular
16 specialty within the field of psychiatry?

17 A. Well, I have spent most of my
18 career doing research on phenomenon of addiction
19 as well as setting up treatment programs and
20 taking care of patients, and also doing a lot of
21 teaching.

22 Q. And have you had some slides
23 prepared to aid in your testimony today?

24 A. Yes, I have.

1 Q. And, Dr. O'Brien, I'd like you to
2 turn to the tab numbered JTX-17, which is in
3 your binder.

4 A. Yes.

5 Q. And what is this document?

6 A. This is my curriculum vitae.

7 Q. And does this accurately summarize
8 your education and professional experience?

9 A. Yes, it does.

10 Q. And turning to your clinical
11 practice, Doctor, how long have you been
12 treating opioid addiction?

13 A. Well, I first became involved with
14 this problem in a pretty big way during the
15 Vietnam war. I was a Navy neuropsychiatrist at
16 the U.S. Navy and it turned out that quite a few
17 of, maybe even half of my patients were using
18 heroin and many of them were addicted to it, and
19 even though I hadn't learned much about
20 addiction in my training when I had two
21 residencies, I had to learn fast, and all of us
22 were learning because it was such a common
23 problem. And that was '69 to '71. And so since
24 then, treating addiction has been the major

1 diagnosis of my practice.

2 Q. And, Dr. O'Brien, I see on this
3 slide you've mentioned the center for the
4 studies of addiction. What is that?

5 A. That is a program that I
6 originally set up in 1971 at the Philadelphia
7 Veterans Hospital to not only treat veterans
8 with addictive disorders, but also to study
9 them, because at that time there was very little
10 research data on addiction, and so I saw this as
11 something that was needed to be done, and they
12 were just starting out at the institute at the
13 NIH on addiction. And so I got funding. I got
14 research grants.

15 So the Centers For Study of
16 Addiction is a large -- it became over time a
17 large research program for studying all kinds of
18 addiction.

19 Q. And, Dr. O'Brien, what is
20 the Charles O'Brien Center For Addiction
21 Treatment?

22 A. That is a private practice program
23 which was set up because the University was
24 getting a lot of referrals that were coming for

1 treatment, but not necessarily to be in a
2 research project. And all of those in the
3 center for studies of addiction were essentially
4 volunteers to be in clinical trials whereas some
5 people just came because they wanted treatment,
6 and the university decided to set up a program
7 for them which was not at the V.A., separate
8 from the V.A., and they decided to name it after
9 me.

10 MS. MELVIN: Your Honor,
11 defendants offer Dr. O'Brien as an expert in the
12 research and treatment of addiction disorders,
13 including treatment of opioid dependency.

14 THE COURT: All right. You may
15 proceed.

16 BY MS. MELVIN:

17 Q. Dr. O'Brien, have you ever been
18 called upon to give your opinion regarding
19 opioid addiction in this country?

20 A. Yes, I have.

21 Q. And can you explain?

22 A. Well, it started really during the
23 1970s. This is where the war on drugs really
24 began, and throughout the seventies and eighties

1 and nineties, I was frequently called to
 2 Washington to testify. The time that I remember
 3 that was most relevant to the matter here is
 4 during the approval process for Suboxone,
 5 because my group had done some of the original
 6 research on Suboxone, and there was a lot of
 7 opposition though because Suboxone is like
 8 methadone in many ways. And there were people
 9 who opposed this, just another addicting drug.
 10 And they also didn't like the fact that the law
 11 as was signed by President Clinton in 2000 had
 12 more liberal regulations regarding the
 13 prescription of Suboxone.

14 So I testified before the Senate
 15 Judiciary Committee at the request of Dr. -- of
 16 Senator Charles Grassley and Senator Joseph
 17 Biden about, in favor of Suboxone, and
 18 ultimately, it was approved, as I requested.

19 Q. And Dr. O'Brien, when you refer to
 20 Suboxone, you're referring to the tablet; is
 21 that correct?

22 A. Yes, I am.

23 Q. And have you served on any
 24 committees relating to opioid addiction

1 treatment?

2 A. Well, I have been on a lot of
 3 committees at the National Academy of Science
 4 and the National Institutes of Health. And
 5 we've been asked to consider how the government
 6 should respond to the addiction problem, and so
 7 I have actually been on committees, just about
 8 every drug you can imagine, and also I was the
 9 Chair of the Committee of the American
 10 Psychiatric Association that defined addiction.

11 Q. And, Dr. O'Brien, do any of the
 12 committees relate to Suboxone?

13 A. Well, all of those dealing with
 14 opioid addiction do relate to Suboxone.

15 Q. And did any specifically deal with
 16 the Suboxone tablet or safety concerns regarding
 17 Suboxone tablets?

18 A. Well, I mentioned that there was
 19 opposition to approving Suboxone back in the
 20 year 2000, and the way that they managed to
 21 compromise and get it approved was that they had
 22 to agree -- they, meaning the FDA and DEA, to
 23 set up a committee of experts to review the use
 24 of Suboxone, how it was actually being used, how

1 doctors were prescribing it, and what were the
 2 good effects and bad effects. And I was asked
 3 to be a member of that committee.

4 Q. And as part of your role in that
 5 committee, did you have any discussions
 6 regarding the safety of Suboxone tablets?

7 A. Yes, I did. That was a major
 8 subject of discussion on my committee.

9 Q. And what types of safety concerns
 10 were raised?

11 A. Well, I would say the primary one
 12 was that Suboxone being an addicting drug might
 13 just be one more drug that kids could use to get
 14 addicted to, and that would be a bad thing, and
 15 especially because we were more, allowing more
 16 liberal prescribing of it. So that was one
 17 thing that we were concerned and we tried to
 18 monitor that, and there were newspaper articles
 19 about how bad Suboxone was, and we studied that
 20 and we actually sent people out to those
 21 communities to interview some of the doctors
 22 there and see if we could figure out what they
 23 were doing wrong.

24 Q. And, Doctor, when you -- again,

1 when you were referring to Suboxone, you're
 2 referring to the tablets, to those specific
 3 discussions?

4 A. Yes.

5 Q. How, if at all, did the safety
 6 concerns that you discussed as part of that
 7 committee apply to Suboxone film?

8 A. Well, it wasn't available yet.
 9 However, we know since the last couple of years
 10 since the film has been available, that it's
 11 abused just like the tablet was.

12 Q. And, Doctor, do you recall any
 13 discussions on the part of that committee
 14 regarding the actual dosage forms of Suboxone
 15 tablets?

16 A. No. The discussions were about
 17 the doctors who were prescribing it, where the
 18 families were keeping the medication because we
 19 were also concerned about children getting
 20 access to it. But if there ever was a
 21 discussion about film versus tablet, I don't
 22 remember it. I don't think there was -- we
 23 weren't really experts. We weren't pharmacy
 24 experts. We were just clinicians, and we were

1 concerned that the doctors were not being
2 careful enough by giving, say a 30-day supply to
3 someone right after you met them.

4 Q. And, Doctor, you mentioned
5 children. Were you here for Dr. Wollschlaeger's
6 testimony here today there there's less
7 pediatric exposure for the film than the tablet?

8 A. Yes.

9 Q. And in your opinion, does the
10 change in dosage form from a tablet to a film
11 reduce pediatric exposure?

12 A. No. I don't think that it did. I
13 don't think the evidence says that it did.

14 Q. And why is that?

15 A. Well, because it's just as easy
16 to -- for a child, maybe in some cases easier
17 because they get it into their bodies more
18 quickly. So whether it's a film or a tablet,
19 it's liable to be taken in an overdose and
20 poison, as a poison for a child. So I don't
21 think that that is the solution to the child
22 overdose problem.

23 Q. And, Dr. O'Brien, are you familiar
24 with a study that compared accidental pediatric

1 exposure from films versus tablets?

2 A. Yes, I am.

3 Q. And on this slide I see here you
4 have an excerpt from JTW-246 at page 5. What is
5 the document that's excerpted here?

6 A. Well, this is a study, an
7 observational study, that is looking at the
8 outcomes of unintentional exposure to
9 buprenorphine by young children, and so they did
10 couch the exposures and the results of the
11 exposure.

12 And as you can see from the
13 excerpt there, it was a study of the gross
14 exposures and results, but it didn't
15 differentiate whether the exposure was due to
16 the formulation, meaning film or tablet, or the
17 packaging, which I think is the major factor, or
18 other factors, which is also where it was
19 stored, because it turns out that one of the
20 common root causes was having the adult and
21 family care less about where they put it, so it
22 was easily obtainable by a child. So there
23 were a lot of factors, but the study did not
24 determine that film versus tablet was an

1 issue.

2 Q. And, Dr. O'Brien, has the FDA
3 considered the data in this study?

4 A. Yes, they did, because they were
5 responding to a citizen petition.

6 Q. And just to stop you right there,
7 on the next slide I see you have an excerpt from
8 page 46 of JTX-163.

9 What is this document?

10 A. Well, this is the FDA's response,
11 and they essentially denied the petition, which
12 would have been to only, to stop allowing sales
13 of the Suboxone tablet.

14 Q. Dr. O'Brien, I believe you said
15 this was the response to the petition. Is this
16 the response to the petition or the petition
17 itself?

18 A. No. That's the petition.

19 Q. Okay. Turning to the next slide,
20 we have an excerpt from page 15 of JTX-196.
21 What is this document?

22 A. I think that is now the response
23 to the, of the FDA, and they essentially state
24 as it shows in the highlighted area there that

1 withdrawal of the Suboxone tablets is not
2 necessary for reasons of safety. And then a
3 couple lines down they say, the data suggests an
4 encouraging downward trend in accidental
5 pediatric exposure that could be attributed to a
6 variety of factors, as discussed above, which
7 means formulation itself as well as the
8 packaging.

9 Q. And what were those other factors?

10 A. Well, the other factors are, first
11 of all, the education of the patient and the
12 patient's family, and the packaging, which I
13 think is probably the pivotal factor in terms
14 of making it hard for a child to able to get
15 access to it when it's left where a child can
16 get it.

17 Q. And, Dr. O'Brien, in your opinion,
18 does the change from the film dosage form, or,
19 excuse me, from the tablet dosage form to the
20 film dosage form decrease with pediatric
21 exposure?

22 A. You know, in gross, you know,
23 accounting, it did, but that was only because
24 they didn't just change. They did multiple

1 things at the same time. And if you are doing
2 research to try to discover the root cause of
3 something, you can't change multiple things. If
4 you change multiple things, then you don't know
5 which of the changes produce the result.

6 Q. And, Dr. O'Brien, in your opinion,
7 does the film dosage form itself present any
8 benefits over the tablet dosage form with
9 respect to pediatric safety?

10 A. Well, with respect to pediatric
11 safety, probably, it could have the opposite
12 effect, because it's absorbed a little faster
13 and might mean that a child gets it into their
14 body more quickly.

15 So, you know, that's, that's a
16 theoretical -- I don't know any evidence to
17 support that, but if you are trying to, you
18 know, measure the effects of film versus tablet,
19 you have to call into play the consideration
20 that there is evidence that the film gets into
21 the bloodstream a little bit faster.

22 Q. And, Dr. O'Brien, did you hear Dr.
23 Wollschlaeger testify about the abuse potential
24 of the tablet?

1 A. Yes.

2 Q. And in your opinion, how does the
3 abuse potential of the tablet compare to the
4 abuse potential of the film?

5 A. Well, as far as we know, it's
6 approximately the same. You know, it's the
7 packaging that may make the current practice of
8 selling the film better, but it's not the film
9 itself. It's more the packaging.

10 Q. And, Dr. O'Brien, I believe there
11 was some testimony yesterday about the potential
12 to swallow the tablet. Doctor, in your
13 experience, is that a significant problem with
14 the tablet?

15 A. Well, it's a problem if you don't
16 tell the patient about it. Patients understand,
17 and especially if you tell them specifically
18 that if they swallow it, it's not going to be
19 absorbed into their bloodstream. You have to
20 hold it under your tongue.

21 The tongue is a very special place
22 where you have very thin veins, and it can get
23 across very quickly, and that makes it almost
24 like taking it intravenously with a needle. So

1 when I explain that to patients, they listen to
2 me and they hardly ever swallow it.

3 Q. And from a clinical standpoint,
4 Dr. O'Brien, do you believe that any other
5 aspect of the film is a significant improvement
6 over the tablet?

7 A. Well, you know, I think that you
8 could say that there is an advantage by having
9 it absorb quickly, because sometimes you have a
10 long line at the window, but that's not a really
11 major issue. You know, it's only about
12 60 seconds faster.

13 Q. And does that affect the safety or
14 efficacy of the drug?

15 A. No.

16 Q. And prior to the introduction of
17 the film, Dr. O'Brien, was your clinic able to
18 adequately treat patients with the tablet?

19 A. Yes, we certainly were and
20 actually still are in other countries.

21 Q. Dr. O'Brien, in sum, what is your
22 opinion regarding whether there was a need for
23 buprenorphine, the maximum dosage form prior to
24 the introduction of the film?

1 A. Well, to be honest with you, we
2 didn't really think of it -- I don't remember
3 any discussion of that. You know, if we had had
4 somebody on the committee who said, hey, you
5 know, we could change it from a tablet to a film
6 and make it safer, we might have said, gee,
7 let's try it and see what happens. But I don't
8 recall anyone suggesting that, so we didn't
9 really have an adequate discussion of that
10 possibility.

11 Q. And, Dr. O'Brien, in your view
12 prior to the introduction of the film, was the
13 Suboxone tablet sufficient for treating opioid
14 addiction?

15 A. Yes. It was working very well.

16 MS. MELVIN: No further questions,
17 your Honor.

18 THE COURT: All right. Any
19 cross-examination.

20 BY MS. BOURKE:

21 Q. Good morning, Doctor.

22 A. Good morning.

23 Q. My name is Mary Bourke. We have
24 not met before. I'm a big fan of Penn Medicine,

1 so fortunately I have not had to go to the
 2 O'Brien addiction center.
 3 A couple of questions. I
 4 understand you're a teacher, a researcher, and a
 5 director of the O'Brien Center; is that correct?
 6 A. Yes.
 7 Q. Okay.
 8 A. Actually, the -- I'm a director
 9 at -- you know, I might as well, you know, make
 10 it very clear.
 11 In the beginning, I was strictly
 12 hands-on, and over years, I've become more and
 13 more distant. But I'm still the senior
 14 clinician, and I make the recommendations to how
 15 patients are going to be treated.
 16 For the research center, I am now
 17 what's called the founding director because I
 18 founded about 45 years ago, and we have someone
 19 else in the last couple of years who has taken
 20 on the day-to-day management of the center.
 21 Q. Thank you for that, Doctor. I
 22 appreciate that.
 23 As I understand it now, you are
 24 managing and supervising a staff of prescriber

1 physicians, like I think in your deposition, you
 2 mentioned the Kyle and Emarja (phonetic); is
 3 that right?
 4 A. That's right.
 5 Q. Okay. Thank you.
 6 And I understand that when, during
 7 your time when you were actually doing the
 8 hands-on treatment of patients, you were
 9 primarily prescribing the Suboxone tablet; is
 10 that correct?
 11 A. That's correct.
 12 Q. And then in 2010, patients
 13 started, at the O'Brien Center started getting
 14 prescriptions for the Suboxone film; isn't that
 15 right?
 16 A. That's correct.
 17 Q. And then as of today, the
 18 predominant, predominant opiate use disorder
 19 treatment is the Suboxone film; isn't that
 20 right?
 21 A. Well, actually, may I tell you,
 22 you know, the various things, because --
 23 Q. Well, your counsel can ask you a
 24 question. I think you were asked a question in

1 your deposition.
 2 A. Yes.
 3 Q. And is that -- is it true that
 4 today is the dominant treatment for --
 5 A. If you compare the agonist
 6 treatment, we also have people being treated
 7 with an antagonist, and we also have them being
 8 treated with other things like Benovale and
 9 Subsol and things like that, so I can't tell you
 10 what it is today. But I guess it was during the
 11 deposition, I would say that probably we have
 12 more people on the film than on the tablet.
 13 Q. All right. Thank you, Doctor.
 14 And I believe that, you know, you
 15 put in the report where you were talking about
 16 some of the disadvantages of the film versus the
 17 tablets; is that correct?
 18 A. Yes.
 19 Q. But you think that they are
 20 basically minor differences; isn't that right?
 21 A. Yes, I do.
 22 Q. Okay. Thank you.
 23 And there are advantages to the
 24 film over the tablet; is that correct?

1 A. Yes.
 2 Q. Okay. And you reviewed Dr.
 3 Wollschlaeger's report and you generally agreed
 4 with that; is that correct?
 5 A. Yes. I mean, it's a subjective
 6 difference, and he comes down to the side that
 7 the film is better, and I'm not so sure.
 8 Q. But when you read it, and you
 9 generally agreed with it?
 10 A. Yes, I do generally agree with his
 11 report.
 12 MS. BOURKE: Okay. Thank your
 13 Honor doctor. No further questions.
 14 MS. MELVIN: No questions, your
 15 Honor.
 16 THE COURT: All right. Doctor,
 17 you may step down. Thank you very much.
 18 THE WITNESS: Thank you.
 19 (Witness excused.)
 20 THE COURT: All right. Who is
 21 next?
 22 MR. DALKE: Defendants would call
 23 Dr. Amiji, your Honor.
 24 THE COURT: All right.

Amiji - direct 421

1 **MR. DALKE: We're shifting gears**
2 **again your Honor. Dr. Amiji is a witness on**
3 **behalf of the defendants. He's going to testify**
4 **about the invalidity of the '150 patent.**
5 **THE COURT: Okay.**
6 **... MANSOOR AMIJI, having been**
7 **duly sworn as a witness, was examined**
8 **and testified as follows ...**
9 **MR. DALKE: May I approach, your**
10 **Honor with some binders?**
11 **THE COURT: Sure.**
12 **(Binders handed to the Court.)**
13 **MR. DALKE: May it please the**
14 **Court, your Honor, I'm David Dalke, Winston &**
15 **Strawn.**
16 **THE COURT: All right. Good**
17 **morning.**
18 **MR. DALKE: Representing**
19 **defendants.**
20 **DIRECT EXAMINATION**
21 **BY MR. DALKE:**
22 **Q. Good morning, Dr. Amiji.**
23 **A. Good morning. Good morning, your**
24 **Honor.**

Amiji - direct 422

1 **THE COURT: Good morning.**
2 **BY MR. DALKE:**
3 **Q. Would you state your name for the**
4 **record, please?**
5 **A. Mansoor Amiji.**
6 **Q. What is your current occupation,**
7 **Doctor?**
8 **A. I'm a distinguished professor and**
9 **chair of the department of pharmaceutical**
10 **sciences at the School of Pharmacy at**
11 **Northeastern University in Boston.**
12 **Q. Would you tell the Court generally**
13 **what experience you have in formulating drugs**
14 **for systemic delivery?**
15 **A. I have over 20 years of experience**
16 **working in pharmaceutical formulations,**
17 **primarily in polymeric drug delivery.**
18 **Q. Did you submit a copy of your CV**
19 **in connection with the pretrial order that was**
20 **filed with the Court?**
21 **A. Yes, I did.**
22 **MR. DALKE: For the record, your**
23 **Honor, that's JTX-14.**
24 **BY MR. DALKE:**

Amiji - direct 423

1 **Q. What do you intend to testify**
2 **about today, Doctor?**
3 **A. I intend to testify on the state**
4 **of the art of the '150 patent, and specifically**
5 **on the invalidity of the claims of the '150**
6 **patent.**
7 **MR. DALKE: Your Honor, at this**
8 **point defendants would offer Dr. Amiji as an**
9 **expert in the field of drug delivery and**
10 **formulation.**
11 **THE COURT: All right. You may**
12 **proceed.**
13 **BY MR. DALKE:**
14 **Q. Have you prepared a slide**
15 **presentation, Dr. Amiji, to assist the Court in**
16 **understanding your testimony?**
17 **A. Yes, I have.**
18 **Q. Would you give the Court an**
19 **overview of your testimony?**
20 **A. Yes. I am I will be opining on**
21 **the fact that the claims of the '150 patent are**
22 **invalid based on indefiniteness.**
23 **Q. And would you a briefly just**
24 **explain what your opinion is with respect to the**

Amiji - direct 424

1 **indefiniteness?**
2 **A. So the claims require the term**
3 **molecular weight. A skilled artisan would rely**
4 **on the manufacturers to provide the molecular**
5 **weight description. If a skilled artisan is not**
6 **able to rely on the information provided by the**
7 **manufacturers, then the claim is indefinite.**
8 **Q. Do you have a second opinion?**
9 **A. Yes. My second opinion is that**
10 **that claims of the '150 patent are obvious based**
11 **on the 2008 priority date.**
12 **Q. What issues are important to your**
13 **obviousness analysis?**
14 **A. So the priority date is important**
15 **because it is a disputed -- the plaintiffs**
16 **assert the 2003 priority date where as the**
17 **defendants assert the 2008 priority date.**
18 **Q. So let's turn to the '150 patent.**
19 **Do you recognize this document?**
20 **A. Yes.**
21 **Q. JTX-1, Doctor?**
22 **A. Yes.**
23 **Q. Is it the patent that you**
24 **analyzed?**

Amiji - direct 425

1 A. Yes.

2 Q. When did the '150 patent issue?

3 A. Well, it issued on September 13th,

4 2011.

5 Q. When was if application that led

6 to the '150 patent filed?

7 A. It was filed on April 22nd, 2008.

8 Q. And which of the claims are

9 asserted against the defendants?

10 A. Four claims. Claim 1 and claim 10

11 are the independent claims, and claim 4 and 13

12 are the dependent claims.

13 Q. Just generally, what are the

14 claims directed to?

15 A. They're directed to a mucosal

16 water-soluble film having a combination of

17 polyethylene oxide and hydrophilic cellulosic in

18 specific proportion.

19 Q. You mentioned polymer

20 combinations. Why are polymer combinations

21 important?

22 A. They import specific properties to

23 the film.

24 Q. Are there specific properties

Amiji - direct 426

1 you're referring to?

2 A. Yes. Tensile strength, which is a

3 measure of the mechanical integrity and

4 flexibility of the film. It allows the film to

5 be handled by the patient. Mucoadhesion, which

6 is the ability of the film to stick in the

7 mouth. And then water absorption from saliva,

8 dissolution of the film and the release of the

9 film.

10 Q. Let's move directly to your

11 indefiniteness opinion. What standard did

12 you apply in analyzing indefiniteness, Doctor?

13 A. So counsel informed me that a

14 claim is considered indefinite if a skilled

15 artisan is not able to understand the boundaries

16 of the claim with reasonable certainty.

17 Q. For purposes of the subject matter

18 of the '150 patent, what did you consider to be

19 the level of ordinary skill in the art?

20 A. A person who has a Bachelor's

21 degree in pharmaceutical sciences, chemistry or

22 related field with two to five years of

23 experience in developing drug formulations.

24 Alternatively, it could be a person with either

Amiji - direct 427

1 a Master's or a Ph.D. degree and with less

2 practical experience.

3 Q. As one of ordinary skill in the

4 art, when you see the term molecular weight in

5 the context of polymers, what does it mean?

6 A. In the context of polymer,

7 molecular weight always means average molecular

8 weight.

9 Q. And why is that?

10 A. Since polymers are synthesized so

11 that you have variability in chain length in a

12 given sample, and each of those chains will have

13 a particular molecular weight, any given sample

14 of a polymer will have average molecular weight.

15 Q. Do you understand that the Court

16 has construed the term molecular weight?

17 A. Yes, I do.

18 Q. And what was the Court's

19 construction?

20 A. The Court also construed the term

21 molecular weight to mean average molecular

22 weight.

23 Q. Did you apply the Court's

24 construction in considering your opinions?

Amiji - direct 428

1 A. Yes, I did.

2 Q. How would one of ordinary skill

3 formulating a drug dosage form know the average

4 molecular weight of commercially available

5 polymer?

6 A. They look to the manufacturers to

7 provide that information.

8 Q. And so aside from the way that a

9 manufacturer expresses polymer molecular weight,

10 are there other ways to express average

11 molecular weight?

12 A. Yes. As we heard from Dr. Yau's

13 testimony yesterday, there are other ways to

14 express molecular weight, such as using the

15 chromatography to determine molecular weight,

16 weight average, molecular weight average or

17 viscosity average molecular weight.

18 Q. In your experience, do these

19 various ways of expressing polymer molecular

20 weight yield different values?

21 A. Yes, they do.

22 Q. Are each of these methods of

23 expressing molecular weight known to those of

24 skill in the art?

1 A. Yes, they are.

2 Q. I see on the right-hand side of
3 the slide you've got a graphic. Would you
4 explain to the Court just briefly what that
5 refers to?

6 A. Yes. That's the column for the
7 gel permeation. Basically, the polymer sample
8 is put on the top and allows for the polymers to
9 separate.

10 Q. Have you ever conducted the GPC,
11 or the gel permeation chromatography analysis
12 that Dr. Yau testified about yesterday?

13 A. Yes, I have, in the context of
14 when I synthesized new polymers or looking at
15 the biodegradation properties of polymers, where
16 I need molecular weight information.

17 Q. Have you ever conducted a GPC
18 analysis when you were formulating a film?

19 A. No, I did not.

20 Q. And why not?

21 A. I rely on the manufacturers to
22 provide me that information.

23 Q. And does the patent specifically
24 identify the manufacturer or the PEOs that were

1 used in the disclosed films?

2 A. Yes. Dow Chemical.

3 Q. How does Dow express the molecular
4 weight of its PEO products?

5 A. They use a viscosity measurement
6 or rheological measurement to express molecular
7 weight.

8 Q. Do you recognize a document is
9 that on the screen, Doctor?

10 A. Yes. This is the Dow brochure.

11 Q. And for the record, the Dow
12 brochure is JTX-30.

13 And at the top on the right-hand
14 column it says, approximate molecular weight.

15 Can you explain to the Court what
16 that means?

17 A. Yes. This is the molecular weight
18 that Dow reports for its different Polyox rate
19 water-soluble polymers, and it's based on the
20 viscosity of the polymer in solution.

21 Q. How does approximate weight
22 relate, if at all, to average molecular weight?

23 A. So, again, it's because polymers
24 are known to have this variable chain length in

1 any given sample, this approximate molecular
2 weight would also be an average molecular
3 weight.

4 Q. So you mentioned before viscosity
5 and the document refers to rheological
6 measurements. Would you explain what
7 rheological measurements are?

8 A. Yes. Rheological measurement is
9 the measure of viscosity of the polymer in
10 solution. It's the measure of how thick that
11 solution is.

12 Q. You mentioned that Dr. Yau
13 calculated viscosity average molecular weight.
14 How did Dr. Yau's calculations relate to the
15 average molecular weight that do you reports?

16 A. They're different. The method
17 that Dr. Yau used was an equation to calculate
18 the intrinsic viscosity average molecular weight
19 using gel permeation chromatography whereas the
20 Dow method measures viscosity of solution and
21 then calculates the approximate molecular weight
22 based on that.

23 Q. What does the Dow brochure say
24 about the various ways to calculate average

1 molecular weight?

2 A. In the footnote of this brochure,
3 it explicitly states that the approximate
4 molecular weight that Yau calculates is
5 not comparable to the gel permeation
6 chromatography.

7 Q. To be clear, did Dr. Yau use any
8 rheological measurements in any of his
9 calculations?

10 A. No, he did not.

11 Q. What does Dow report to be the
12 average molecular weight of Polyox 1080?

13 A. 200,000 daltons.

14 Q. And as part of his analysis, did
15 Dr. Yau determine the average molecular weight
16 of the whole Polyox N80 distribution? In other
17 words, before he did any partitioning?

18 A. Yes, he did.

19 Q. Did you prepare a summary of Dr.
20 Yau's reported data?

21 A. Yes, I did. In the next slide I
22 showed the various values that Dr. Yau
23 calculated for the un-partition, or the whole
24 N80 sample when he did gel permeation

1 chromatography. He had provided the Excel
2 spreadsheet as Exhibit B to his report. I then
3 populated the values in the various cells of
4 this table.

5 Q. And when you are referring to
6 Exhibit B, that's, for the record, that's
7 JTX-143 that we spoke about yesterday.

8 What are you describing at
9 table -- I'm sorry. What are you describing at
10 the table shown on this slide?

11 A. So on the leftmost column are the
12 different molecular weights that Dr. Yau
13 calculated. The weight average, viscosity
14 average, number average. The top row refers to
15 the nine runs that he carried out.

16 He took one particular sample of
17 Polyox and then he basically had three different
18 categories of those and then ran three different
19 runs for each, so total number of runs that he
20 carried out were nine, and those are designated
21 as N80A1 up through N80AC3.

22 Q. What do you mean by nine different
23 runs?

24 A. So he took the Polyox N80 sample

1 and then had divided it into the three, and then
2 from each of those samples he carried out three
3 runs. So he got a total of nine runs.

4 Q. So according to Dr. Yau, what's
5 the average molecular weight of the whole Polyox
6 N801 distribution?

7 A. It varies depending on which type
8 of average molecular weight he has described.

9 Q. And what conclusions did you draw
10 from Dr. Yau's calculations?

11 A. So several. One is that he is
12 able to get the viscosity average, the intrinsic
13 average viscosity weight. He calculates the
14 values that he is getting are 105 to 107,000
15 daltons, which is very different from the value
16 that Dow reports of 200,000 daltons.

17 And then specifically focusing on
18 the A2 sample, the N80A2 sample, looking at the
19 molecular weight, whether you look at weight
20 average, viscosity average, number average,
21 or Z average, there's a specific difference in
22 the magnitude of these values depending on
23 which type of molecular weight Dr. Yau
24 determined.

1 For example, if you compare the
2 number average molecular weight to the Z
3 average, there's an eightfold different in the
4 magnitude of the values.

5 Q. So you focused on this N80A2
6 example. Is there any reason, any particular
7 reason for that?

8 A. No. Just one particular example
9 from the table. All the other data that Dr. Yau
10 had provided also has the same variables to
11 values.

12 Q. What average molecular weight
13 values did Dr. Yau obtain for N80A2?

14 A. So he in this case, you can see
15 that Dr. Yau calculated viscosity average to be
16 105,225, the number average to be 40,550
17 daltons, the weight average to be 132,294
18 daltons, and the Z average to be 332,372
19 daltons.

20 Q. Do any of the values that Dr. Yau
21 reported for the whole distribution correspond
22 to the values that Dow reports for Polyox N801?

23 A. No. Dow reports the molecular
24 weight of the Polyox N801 to be 200,000 daltons.

1 Q. What conclusion did you reach
2 after reviewing Dr. Yau's analysis of the whole
3 Polyox N80 sample?

4 A. So looking back at the claim of
5 the '150 patent, which requires the low
6 molecular weight be in the range of 100,000 to
7 300,000, and the high molecular weight be in the
8 range of 600,000 to 900,000, the values that Dr.
9 Yau reports, some of them do not fall within the
10 claim limitations even for the low molecular
11 weight range. Some of them do, and then some of
12 them even exceed the low molecular weight PEO
13 range that is required in the claims of the '150
14 patent. And then none of these values are
15 actually in the high molecular weight range
16 that's required in the claims.

17 Q. Based on Dr. Yau's analysis, how
18 would one of ordinary skill know if they were
19 using a PEO product that fell within the scope
20 of the claims?

21 A. They wouldn't be able to know
22 because, again, the values are, some of them are
23 within the low molecular weight range. Some of
24 them do not even fall within that claim range.

1 And then some exceed that claim range, and none
2 of these values are in the high molecular weight
3 claim range of the '150 patent.

4 Q. Do the average molecular weight
5 values that Dr. Yau calculated reflect any
6 differences in the properties of Polyox N80
7 tight?

8 A. No. This is still Polyox N80
9 sample. It's just a method that he has used to
10 calculate these different average molecular
11 weights that use different values.

12 Q. How does the '150 patent describe
13 which method a skilled artisan should use to
14 determine the average molecular weight of a PEO
15 product?

16 A. There is no disclosure in the '150
17 patent as to the method by which to measure the
18 molecular weight.

19 Q. Does the '150 patent instruct a
20 skilled artisan to conduct GPC analysis?

21 A. No. There is no mention of GPC in
22 the '150 patent.

23 Q. What is your conclusion about the
24 term molecular weight as it's used in the

1 asserted claims?

2 A. So if a skilled artisan cannot
3 rely on the molecular weight information
4 provided by the manufacture, then the different
5 molecular weight measurements provide different
6 values, so an artisan would not know
7 specifically the boundaries of the claim and in
8 this case the claim is indefinite.

9 Q. Let's move to your obviousness
10 analysis.

11 THE COURT: Actually, before you
12 do that --

13 MR. DALKE: Sure.

14 THE COURT: So I asked Dr. Yau
15 yesterday, I think. 105,000 that he got for the
16 viscosity average as opposed to Dow's 400,000, I
17 asked him what the explanation is of that. I
18 think his answer was he didn't have one. Do you
19 have one?

20 THE WITNESS: Yes, your Honor. So
21 the method that Dow measured the molecular
22 weight is based on dissolving the polymer at
23 five percent concentration and then measuring
24 the viscosity, how thick that solution is, and

1 the report on viscosity. And they basically go
2 and say, basically, if you get that viscosity,
3 your polymer is a molecular weight 200,000.

4 Dr. Yau separated various chains
5 and he applied a mathematical collusion to
6 determine the average viscosity molecular
7 weight. Yes, his values are different than what
8 Dow reports, and they're expected to be
9 different.

10 THE COURT: And is one of those or
11 both of those methods, do you have an opinion as
12 to whether they're both equally acceptable ways
13 applied differently to determine the viscosity
14 average molecular weight?

15 THE WITNESS: Well, for
16 pharmaceutical formulation, you rely on the
17 manufacturers, because, you know, it's very much
18 akin to preparing a dish. You test the final
19 product. You rely on the manufacturers to
20 provide you with ingredients of specific
21 quality, and then you test the final product to
22 make sure that it meets the strict test quality
23 control standards. So for a skilled artisan,
24 they rely on what Dow provides as the molecular

1 weight.

2 THE COURT: All right. Go ahead.

3 MR. DALKE: Thank you.

4 BY MR. DALKE:

5 Q. Let's move to your obvious
6 opinion, Dr. Amiji.

7 A. Sure.

8 Q. Do you understand that there's a
9 dispute over the priority date of the '150
10 patent?

11 A. Yes.

12 Q. And what is the dispute?

13 A. So the plaintiffs claim that the
14 patent is -- has the priority date of 2003,
15 where the defendants assert the 2008 priority
16 date.

17 Q. Why does a priority date make a
18 difference in your obviousness analysis?

19 A. So if the correct priority date of
20 2008 is applied, then there's a reference, the
21 Yang reference, that renders all the claims
22 obvious.

23 Q. What standard did you apply in
24 conducting your analysis?

1 **A. So I was informed that a patent is**
 2 **entitled to an earlier priority date if the**
 3 **earlier application satisfies three**
 4 **requirements: The written description**
 5 **requirement, the enablement requirement, and the**
 6 **indefiniteness requirement, and then I**
 7 **specifically focus on the written description**
 8 **requirement. I was informed that that**
 9 **requirement is satisfied if the inventors were**
 10 **in possession of the actual invention, not just**
 11 **the obvious variants.**

12 **Q. And how did you conduct your**
 13 **analysis?**

14 **A. So I looked at, back at all the**
 15 **different applications that are in the priority**
 16 **chain for the '150 patent and specifically**
 17 **looked at the claim limitations of the '150**
 18 **patent in order to see if all the claim**
 19 **limitations are present in those prior art**
 20 **exclusions.**

21 **Q. You mentioned three important**
 22 **limitations that you focused on. Can you**
 23 **explain to the Court what those were, please?**

24 **A. Yes. First, I focus on the term**

1 **polymer component, which is identified in the**
 2 **slide as, in the claims as polyethylene oxide**
 3 **and hydrophilic cellulosic polymer, or HCP.**

4 **Second, I focus on the**
 5 **polyethylene oxide having low molecular weight,**
 6 **which is a 100,000 to 300,000 and the high**
 7 **molecular weight of 600,000 to 900,000.**

8 **And then the third component,**
 9 **which is that about 60 percent or more of the**
 10 **polymer component has to be below molecular**
 11 **weight PEO.**

12 **Q. Did the Court construe any**
 13 **limitations in the asserted claims?**

14 **A. Yes.**

15 **Q. Did you apply the Court's**
 16 **construction in conducting your analysis?**

17 **A. Yes, I did.**

18 **Q. How did the Court's construction**
 19 **inform your analysis?**

20 **A. So the Court construed that the**
 21 **60 percent limitation that is in the claims of**
 22 **the '150 patent refers to the composition that**
 23 **has the lower molecular weight PEO in the final**
 24 **component in addition to the two PEOs, meaning**

1 **the low and the high, as well as hydrophilic**
 2 **cellulosic polymer.**

3 **MR. LADOW: Your Honor, I just**
 4 **want to note that the issue of whether**
 5 **hydrophilic cellulosic polymer was necessary or**
 6 **required by the claims was not actually**
 7 **litigated during the Markman. It may come up in**
 8 **other matters, but it wasn't before the Court at**
 9 **the time.**

10 **THE COURT: All right. You may**
 11 **proceed.**

12 **MR. DALKE: Thank you.**

13 **BY MR. DALKE:**

14 **Q. How did you conduct your analysis**
 15 **of priority date, Doctor?**

16 **A. So I looked at various**
 17 **disclosures, and since the disputed dates are**
 18 **2003, May 28, 2003, and April 22nd, 2010, I**
 19 **focused on the 902 application as well as the**
 20 **389 application, and then started to look at the**
 21 **two applications to see where for the first time**
 22 **all the three limitations of claim 1 of the '150**
 23 **patent are present.**

24 **Q. So just for the record, when you**

1 **are referring to the 902 application, you're**
 2 **referring to U.S. Application No. 60/473902?**

3 **A. Yes.**

4 **Q. And that's JTX-249. I believe you**
 5 **may have said April 2nd, 2010 in response to the**
 6 **later, the priority date. Were you referring to**
 7 **2010 or did you mean 2008?**

8 **A. Oh, I'm sorry. It's April 28,**
 9 **2003 for the 902 application, and April 22, 2008**
 10 **for the 389 application.**

11 **Q. And when you refer to the 389**
 12 **application, you're referring to the U.S.**
 13 **application 12/107389?**

14 **A. Yes.**

15 **Q. And that's JTX-4.**

16 **And, Doctor, would you explain**
 17 **what you found when you reviewed the 2003**
 18 **application?**

19 **A. Yes. So the 2003 application has**
 20 **a disclosure of the polymer component having**
 21 **polyethylene oxide and hydrophilic cellulosic**
 22 **powder as well as the low molecular weight PEO**
 23 **and the high molecular weight PEO, but it does**
 24 **not have the claim limitation that 60 percent or**

1 more, or about 60 percent or more of the polymer
2 component has low molecular weight PEO.

3 Q. What did you find when you
4 analyzed the 2008 filing?

5 A. That's the first time I found all
6 the three claim limitations of the '150 patent
7 being there.

8 Q. Where in the 389 application did
9 you find the 60 percent range limitation?

10 A. I found it in both the summary of
11 the invention as well as in the claims.

12 Q. And you said that the plaintiffs
13 contend the claims of the '150 patent are
14 entitled to 2003 priority date. What evidence
15 did the plaintiffs point to to support their
16 allocation?

17 A. Well, they go to the various parts
18 of the specification and specifically to Table
19 22 the specification of the 902 application.

20 Q. And, again, for the record, the
21 902 application is JTX-249.

22 Would you explain to the Court
23 what's shown in this slide?

24 A. Yes. This table shows on the

1 leftmost column the various film compositions.
2 The top row shows the polyethylene oxide, the
3 various molecular weight. The last column on
4 the right-hand side shows the hydrophilic
5 cellulosic polymer.

6 Q. Why is the table colored, Doctor?

7 A. So I colored the table just to
8 illustrate my point. The blue refers, the low
9 molecular weight claim range is for the
10 polyethylene oxide. The red refers to the high
11 molecular weight claim ranges of the
12 polyethylene oxide, and the green is the
13 hydrophilic cellulosic polymer.

14 Q. Did the plaintiffs identify any
15 particular film composition from the Table 22
16 that they alleged supports their claim to an
17 earlier priority date?

18 A. Yes. They identified a claim
19 composition DW.

20 Q. Do you agree that DW describes the
21 claimed film?

22 A. No, I do not.

23 Q. Why is that?

24 A. The film composition DW has

1 80 percent by weight of the 200,000 molecular
2 weight PEO, and 20 percent by weight of the
3 900,000 molecular weight PEO, but does not have
4 any hydrophilic cellulosic polymer.

5 Q. And how does film DW comport with
6 the claim language?

7 A. The claim language requires that
8 the polymer combination has PEO and hydrophilic
9 cellulosic polymer. In this case, the DW does
10 not.

11 Q. Do plaintiffs rely on anything
12 else from the 2003 application to support their
13 argument for an earlier priority date?

14 A. Yes. They rely on certain
15 passages of the specification.

16 Q. And have you reviewed those
17 portions of the specification?

18 A. Yes, I have.

19 Q. What did you conclude?

20 A. That none of those passages in the
21 specification meet the claim limitation that
22 60 percent, about 60 percent or more of the
23 polymer component, which has both PEO and
24 hydrophilic cellulosic polymer, are present in

1 the 902 application.

2 Q. How does the 2008 priority date
3 impact your invalidity analysis?

4 A. So the -- you said the 2003?

5 Q. I'm sorry. 2008.

6 A. 2008. Based on the 2008 priority
7 date, the Yang reference renders all of the
8 claims obvious.

9 Q. And what standard did you apply in
10 analyzing obviousness?

11 A. So I was informed that the patent
12 is claimed obvious to a person of skill in the
13 art if that person can use the prior art
14 references and have reasonable expectation of
15 success in combining the teachings to achieve
16 the claimed invention.

17 Q. When you say the Yang reference,
18 are you referring to JTX-178?

19 A. Yes.

20 Q. When did the Yang reference
21 publish?

22 A. It was published on February 17,
23 2005.

24 Q. How did you conduct your

1 obviousness analysis?

2 A. So I went back to the claims of
3 the '150 patent and then correspondingly found
4 various sections of the Yang reference that
5 taught the same limitations.

6 Q. Would you explain to the Court
7 what's shown on this slide?

8 A. Yes. So on the left side is
9 claim 1 of the asserted claim of the '150
10 patent, and then on the right-hand side are the
11 various -- the specific limitations that are
12 stipulated by both parties to be present. And I
13 put some checkmarks there.

14 Q. Did you also analyze claim 10?

15 A. Yes. Claim 10 has the same
16 limitations as claim 1 except for the 75 percent
17 polyethylene oxide and up to 25 percent
18 hydrophilic cellulosic is changed to a
19 hydrophilic cellulosic polymer, more than one
20 ratio with the polyethylene oxide.

21 Q. Did you also analyze claims 4 and
22 13?

23 A. Yes, I did. And, again, the
24 dependent claims have also been stipulated by

1 both parties to be present in Yang, and so I put
2 the checkmarks there.

3 Q. Which claim elements are currently
4 in dispute?

5 A. There are three. First is the
6 ratios of the polyethylene oxide hydrophilic
7 cellulosic polymer present in claim 1 and claim
8 10. And in the 60 percent or more of the
9 polymer component being made up of polyethylene
10 oxide.

11 Q. How does the Yang reference
12 renders obvious the ranges of PEO and HCP found
13 in claim 1 and claim 10?

14 A. So in Paragraph 116 of the Yang
15 reference, the PEO is in the range of 20 percent
16 to 100 percent, and the HCP is in the range of
17 zero percent to 80 percent. So the claim
18 limitations of the '150 patent are in those
19 ranges of 20 percent to 100 percent PEO, and
20 zero to 80 percent HCP.

21 Q. And the same thing with claim 10.
22 How does claim 10 in that ratio -- is that found
23 in Paragraph 116 of the Yang reference?

24 A. Yes. So paragraph 116 explicitly

1 has the four-to-one ratio disclosed.

2 Q. And how does the Yang reference
3 render obvious the about 60 percent or more
4 limitation?

5 A. So the Yang reference in paragraph
6 120 has the 50 to 75 percent low molecular
7 weight PEO, optionally combined with a small
8 amount of a higher molecular weight PEO, and the
9 remainder of the polymer component being
10 hydrophilic cellulosic polymer. And since
11 60 percent is in that range of 50 to 75, that
12 renders the claim of the '150 patent obvious.

13 Q. Have the plaintiffs identified any
14 particular properties associated with films made
15 from the HCP and PEO ratios and the about
16 60 percent PEO ranges included in the claims?

17 A. No, they have not.

18 Q. How can the disclosure at Yang,
19 paragraph 120, render the 60 percent limitation
20 obvious, but at the same time be insufficient to
21 support written description requirement?

22 A. I understand the standards are
23 different. The 50 to 75 percent disclosure in
24 Yang renders the claim limitation obvious.

1 However, the 50 percent is lower than the
2 60 percent that's required here, and 75 percent
3 certainly does not meet the claim limitation of
4 more, 60 percent or more, which would be greater
5 than 75 percent, and therefore this, the Yang
6 reference does not have enough description.

7 Q. And what is your conclusion
8 regarding the Yang reference?

9 A. So based on the fact that all of
10 the claim elements are described in Yang, the
11 Yang reference renders the claim of the '150
12 patent obvious as to the 2008 priority date.

13 Q. And did the plaintiffs dispute
14 your conclusion that the Yang reference renders
15 the asserted claims obvious?

16 A. No, they do not. They just assert
17 that the Yang reference is not prior art.

18 MR. DALKE: Thank: No further
19 questions.

20 THE COURT: All right. Thank you.

21 MR. BOLLINGER: Good morning, your
22 Honor.

23 THE COURT: Good morning.

24 CROSS-EXAMINATION

1 BY MR. BOLLINGER:

2 Q. Good morning, Dr. Amiji. How are
3 you?

4 A. Good.

5 Q. My name is Jim Bollinger. We have
6 not met. And I wanted to ask you a few
7 questions, and specifically, I wanted to talk to
8 you a little bit about viscosity average
9 molecular weight. And I think you indicated,
10 and used that term, viscosity average molecular
11 weight several times. We heard a lot of it
12 yesterday.

13 Can you tell me, did you, have
14 you -- do you recognize that as a term of art in
15 your field?

16 A. Yes. When you are measuring
17 polymers, so viscosity average molecular weight
18 in the context of this litigation as well as in
19 the art, there are two different
20 interpretations. The viscosity average
21 molecular weight that Dow reports is based on
22 measurement of the solution viscosity. They
23 measure the solution viscosity and measure how
24 thick it is and then relate that to the

1 molecular weight.

2 The viscosity average molecular
3 weight, which is the intrinsic viscosity
4 molecular weight calculated using the gel
5 chromatography is a different value and
6 therefore has different numerical values
7 associated with it.

8 Q. Well, we've seen two different
9 values in this case, so we'll talk a little.

10 I wanted to ask you though, isn't
11 viscosity average molecular weight one of the
12 most common ways of expressing average molecular
13 weight in industry?

14 A. It's -- it's used usually when you
15 are characterizing new polymers. When you are
16 synthesizing polymers, you do measure average
17 molecular weight, and you can measure weight
18 average or viscosity average. Those are the
19 most common.

20 MR. BOLLINGER: Can we put up his
21 report, paragraph 68?

22 BY MR. BOLLINGER:

23 Q. I just wanted to confirm it was
24 your testimony before was the most common way.

1 Do you recognize this from your
2 report?

3 A. Yes, I do.

4 Q. And the first two lines where it
5 says that?

6 A. So the viscosity average, what I'm
7 referring to in this report, is the method that
8 values, that it's basically -- you know, it's a
9 method where you get a range in the viscosity of
10 solution.

11 Q. Okay. And so people in industry
12 would understand viscosity average molecular
13 weight. There's also what Dow uses to
14 characterize their molecular weight values; is
15 that correct?

16 A. That's by dissolving the polymer
17 in solution and then correlating that back to
18 the molecular weight.

19 Q. And you also believe that the
20 intrinsic evidence in the '150 patent teaches
21 somebody of ordinary skill to apply viscosity
22 average molecular weight in the context of that
23 patent; is that correct?

24 A. No. What I said is that the

1 intrinsic evidence suggests that a skilled
2 artisan would rely on the manufacturer's
3 information for molecular weight.

4 MR. BOLLINGER: Can we bring up
5 his declaration, paragraph 14, from the Markman
6 hearing?

7 BY MR. BOLLINGER:

8 Q. Do you remember putting this in
9 your declaration?

10 A. Yes.

11 Q. I'm sorry. It's your -- I'm
12 sorry. It's paragraph -- claim construction
13 declaration at 14. That's what I have. Page
14 14. I'm sorry. And I have the quote, for
15 example.

16 Yes. Do you see there where it
17 says, for example, in the prosecution history of
18 the '150 patent?

19 A. Yes, I see that.

20 Q. And then at the end -- so you
21 agree with that. This reference makes clear
22 that the manufacture her calculated the average
23 molecular weight by using the viscosity average.
24 That's what you understand is a viscosity

1 average molecular weight; is that correct?

2 A. Yes. It's based on dissolving
3 the polymer in solution and measuring the
4 viscosity.

5 Q. Exactly. And you testified, you
6 said in this declaration that somebody skilled
7 in the art would rely on that in construing what
8 the term molecular weight was in this patent?

9 A. That's exactly what I said,
10 that they would rely on the manufacturers. In
11 this case, Union Carbide, which is now Dow
12 Chemical.

13 Q. Well, let's talk a little bit
14 about that.

15 MR. BOLLINGER: Can we bring up
16 example, I'm sorry, JTX-30?

17 BY MR. BOLLINGER:

18 Q. I think this is the brochure that
19 you had presented a few minutes ago. And we'll
20 go to page 16, which is the page that you
21 indicated through your testimony.

22 And there's that table. If we can
23 blow up that table that they were reciting.
24 Yes. Thank you.

1 And you see here, and
2 specifically, these were the ranges of viscosity
3 average molecular weight that do you was
4 reporting?

5 A. No. If you look at this page next
6 to it, there's actually a second part of this
7 table that shows the actual number of that
8 viscosity of polymer solutions, the ranges that
9 are calculated using this.

10 Q. Okay. So is this your
11 understanding this is viscosity average or this
12 is not viscosity average?

13 A. It's approximate molecular weight
14 based on rheological measurement, which is the
15 measurement of viscosity of the polymer
16 solution.

17 Q. And --

18 A. It is not the same as the
19 intrinsic viscosity average molecular weight
20 that Dr. Yau calculated by gel permeation
21 chromatography.

22 Q. I understand that's your
23 testimony, sir. Just looking for -- if you went
24 to the bottom, and I just wanted to correct

1 something because I think you said that Dow had
2 indicated that it was they are not directly
3 comparable, but that's not directly what it
4 says, I don't think. I think it says that it's
5 approximate -- it is not very clear on that one.
6 But I think it says actually may not be
7 comparable.

8 Do you recall that from the
9 brochure?

10 A. Well, it's known to a skilled
11 artisan that the two methods are not comparable.

12 Q. Okay. But it says here on mine,
13 it says may not be directly comparable, and it's
14 actually talking about something called light
15 scattering and other methods generally.

16 A. Well, gel permeation
17 chromatography is there as well.

18 Q. True. True. And light scattering
19 is a way to calculate viscosity average
20 molecular weight?

21 A. Again, I looked at that brochure
22 and I saw that gel permeation chromatography
23 method is not comparable.

24 Q. Okay. But light scattering

1 certainly is not comparable, right, because it
2 calculates weight average molecular weight?

3 A. You know, it may calculate other
4 methods as well, calculate other methods. But
5 for my analysis, I looked at the viscosity
6 average molecular weight that Dr. Yau calculated
7 using the gel permeation chromatography and
8 these methods are not comparable.

9 MR. BOLLINGER: Can we go to the
10 page before?

11 BY MR. BOLLINGER:

12 Q. And you will see in this page what
13 appears what Dow does here, and I just want to
14 understand, do you understand what Dow does is
15 that they measure a batch and if the viscosity
16 falls within the range of 55 to 90, anywhere in
17 that range, right, and they call it 200,000; is
18 that correct?

19 A. Yes, that's correct.

20 Q. Okay. Thank you.

21 And you know that something that
22 measures 55 is going to have a lower average,
23 viscosity average molecular weight than
24 something that measures 90.

1 **Will you agree with that?**
 2 **A. Well, as we heard yesterday, these**
 3 **polymers have polydispersity in any given**
 4 **sample, is going to have is going to have**
 5 **polydispersity and so these ranges are**
 6 **appropriate.**
 7 **Q. Right. So you would look at**
 8 **something at a centipoise of 55 and they'll**
 9 **call it 200,000 and then they'll measure a batch**
 10 **at 50 and they'll call it 100,000; is that**
 11 **correct?**
 12 **A. That is the weight it has been**
 13 **described here, but, again, these ranges are**
 14 **appropriate because any polymer sample will have**
 15 **variability. And that's what defines the**
 16 **polydispersity of polymers.**
 17 **Q. So that's a pretty wide range;**
 18 **correct? That's a significant range of**
 19 **different possible average molecular weights.**
 20 **That's why they call it approximate; is that**
 21 **right?**
 22 **A. Yes. And, you know, that's the**
 23 **value that a skilled artisan would use.**
 24 **Q. OKAY. You've mentioned that**

1 **you've done GPC before; is that correct?**
 2 **A. Yes.**
 3 **Q. And, in fact, in your lab and in**
 4 **your work you've had grad students do it and**
 5 **then you review the data; is that correct?**
 6 **A. Yes.**
 7 **Q. All right. Thank you.**
 8 **And in working with PEO, you**
 9 **recognize that the, not only is there the**
 10 **individual molecules that will have a vast array**
 11 **of different lengths, but that the individual**
 12 **batches that are manufactured will vary batch to**
 13 **batch; is that correct?**
 14 **A. Again, you know, based on the**
 15 **method that the manufacturers then determine**
 16 **molecular weight, they will assign an**
 17 **appropriate term to that. For example, N80**
 18 **would be 200,000.**
 19 **Q. Let's turn to the question of**
 20 **prior art, and you've been talking the Yang**
 21 **reference as prior art, and I just want to**
 22 **ask you a few questions. You did look at the**
 23 **file history for the Yang reference; is that**
 24 **correct?**

1 **A. Yes.**
 2 **Q. And you also studied the file**
 3 **history for the '150 patent?**
 4 **A. Yes.**
 5 **Q. And is it your understanding that**
 6 **the '150 patent is what we call a divisional of**
 7 **the Yang reference?**
 8 **A. I have not heard that term before.**
 9 **My understanding is that the Yang reference and**
 10 **then going back to 2001, there's a priority**
 11 **chain to the filing of the '150.**
 12 **Q. Okay. So they're commonly owned**
 13 **patents and patent applications; is that**
 14 **correct?**
 15 **A. That's the way -- that's the way I**
 16 **understand priority chain.**
 17 **Q. Okay. And by looking at that, you**
 18 **were able to tell that not only is Yang the**
 19 **parent of the -- the '150 patent, but during**
 20 **prosecution, didn't the examiner issue what we**
 21 **would call a double patenting rejection? Do you**
 22 **remember seeing that?**
 23 **A. No, I have not seen that.**
 24 **Q. And the applicant made clear that**

1 **it was a divisional. The examiner accepted**
 2 **that?**
 3 **A. Again, I don't have that**
 4 **information.**
 5 **Q. Okay. So do you have any -- do**
 6 **you understand that the patent, the '150 and the**
 7 **Yang reference that you're citing, all four of**
 8 **the same inventors?**
 9 **A. Yes. I looked at the names of the**
 10 **inventor, but, again, I focus on the claim**
 11 **limitation, and I did not see the third claim**
 12 **limitation in Yang.**
 13 **Q. All right. Now, and is it -- you**
 14 **know, I think you've pointed out some things**
 15 **that you think are differences in the**
 16 **specifications and teachings, but aren't they**
 17 **nearly identical?**
 18 **A. Again, I focused on, you know, on**
 19 **the claim limitations of the '150 patent and**
 20 **went through the various parts.**
 21 **Q. Okay. Thank you, sir. I**
 22 **appreciate your time.**
 23 **Your Honor, I have no further**
 24 **questions.**

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1 THE COURT: All right. Any
 2 redirect?
 3 MR. DALKE: No, your Honor. We
 4 have nothing.
 5 THE COURT: Dr. Amiji, thank you.
 6 You may step down.
 7 THE WITNESS: Thank you, your
 8 Honor.
 9 (Witness excused.)
 10 MR. LOMBARDI: Your Honor, that's
 11 defendants' last witness on invalidity of the
 12 '514 and '150 patents, so we're resting that
 13 part of our case. Obviously, as you know, we'll
 14 have a rebuttal witness later on today. That's
 15 our case-in-chief.
 16 THE COURT: Rebuttal witnesses on
 17 secondary considerations?
 18 MR. LOMBARDI: That's correct.
 19 That's correct.
 20 THE COURT: That's Ms. Lawton?
 21 MR. LOMBARDI: Lawton, yes.
 22 THE COURT: All right.
 23 MR. LADOW: Your Honor, I
 24 anticipate your answer, but plaintiffs would

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1 make a motion for directed verdict on
 2 infringement.
 3 THE COURT: Okay. I will take it
 4 under advisement with the other ones. Let's go
 5 ahead.
 6 MR. BRAHMA: Good morning, your
 7 Honor.
 8 THE COURT: Good morning,
 9 Mr. Brahma.
 10 MR. BRAHMA: Plaintiffs call Dr.
 11 Robert Langer, who will be testifying on the
 12 validity of the '514 patent.
 13 And may we hand up exhibits and
 14 demonstratives?
 15 (Demonstratives handed to the
 16 Court.)
 17 THE COURT: Sure.
 18 ... ROBERT LANGER, having been
 19 duly sworn as a witness, was examined
 20 and testified as follows ...
 21 DIRECT EXAMINATION
 22 BY MR. BRAHMA:
 23 Q. Good morning, Dr. Langer.
 24 A. Good morning.

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1 Q. Could you tell us where you're
 2 currently employed?
 3 A. I'm employed at MIT, the
 4 Massachusetts Institute of Technology, and also
 5 Boston Children's Hospital and Harvard Medical
 6 School.
 7 Q. What is your current position at
 8 MIT?
 9 A. I'm what is called an institute
 10 professor. There are 13 institute professors at
 11 MIT. That's MIT's highest honor or highest
 12 professorship.
 13 Q. What is your particular area of
 14 scientific expertise?
 15 A. Biomedical polymers and drug
 16 delivery systems.
 17 Q. And is there a field in which you
 18 teach?
 19 A. Well, I teach in those areas.
 20 Also in chemical engineering, and also
 21 pharmaceutical engineering.
 22 Q. And now I know you have received
 23 many awards, and the Court already has your CV,
 24 but have you received any particularly notable

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1 awards for your pharmaceutical work?
 2 A. Well, almost all are for that
 3 work, but as examples, last Monday I received
 4 the Queen Elizabeth prize. That's the largest,
 5 it's kind of the engineering Nobel Prize, and
 6 I've also received the two highest national
 7 awards, the National Medal of Science from
 8 President Bush and the National Medal of
 9 Technology from President Obama. There are only
 10 four people that have those.
 11 Q. Before you started working on this
 12 case, have you conducted research directed to
 13 pharmaceutical cast films?
 14 A. Yes.
 15 Q. And for how long have you been
 16 doing that research?
 17 A. I've probably started it, you
 18 know, over 40 years ago. Forty years ago.
 19 Q. And could you give us an example
 20 of the type of pharmaceutical film research you
 21 were doing?
 22 A. Well, I am involved in a number of
 23 companies. I've started companies, but a lot of
 24 what I do is kind of more basic research. And

1 where I got involved in this really goes back to
2 1974. I was doing post-doctoral work with a man
3 named Judah Falkman and we were trying to
4 isolate what would be called blood vessel
5 inhibitors, antigenesis inhibitors, and we had
6 to develop a bioassay for that, and that was
7 sort of the problem. We needed to be able to
8 release large molecules for several months.

9 So I was experimenting with
10 different ways of putting molecules into
11 polymer, various polymer systems like polymer
12 films, polymer microspheres, polymer pellets,
13 things like that.

14 Q. And in the course of your work,
15 have you also worked on drugs that are
16 being prepared for regulatory approval in
17 film form?

18 A. Well, again, in terms of, I mean,
19 the work that we've done is broad. I mean, most
20 of what we've done is model systems. I mean, I
21 have certainly advised companies, and I've been
22 involved in starting companies that have used
23 all kinds of formulations.

24 Q. Prior to 2002, were you familiar

1 with literature about pharmaceutical film
2 products based on your own research and work?

3 A. Certainly somewhat.

4 Q. And in what context, what roles
5 made you familiar with this, the literature on
6 this field?

7 A. Well, a number of things. I'm on
8 a number of what are called editorial boards of
9 scientific journals, including pharmaceutical
10 journals, like the Journal of Pharmaceutical
11 Science.

12 I've been a reviewer for, you
13 know, different federal grants, like from the
14 National Institutes of Health and various --
15 National Science Foundation. We do a lot of
16 work in our own lab on various pharmaceutical
17 things.

18 And then I also have been quite
19 involved with the FDA. I was on the FDA Science
20 Board, their highest advisory board, for eight
21 years. I was chair of it for four years.

22 MR. BRAHMA: Based on that,
23 plaintiffs proffer Dr. Langer as an expert in
24 chemical and pharmaceutical engineering as well

1 as in pharmaceutical dosage forms, including
2 pharmaceutical cast films.

3 THE COURT: All right. You may
4 proceed.

5 BY MR. BRAHMA:

6 Q. Dr. Langer, have you reviewed the
7 testimony of defendants' expert, Dr. Craig Dyar?

8 A. Yes.

9 MR. BRAHMA: And I'm going to ask
10 to put up slide PDX-1702.

11 BY MR. BRAHMA:

12 Q. Doctor, I'm going to ask you to
13 talk about a few points today, starting with
14 some background on cast film technology, then
15 moving to Dr. Dyar's two grounds for contending
16 that the '514 patent claims are invalid.
17 Namely, his obvious argument and his
18 indefiniteness argument, in that order?

19 A. Okay.

20 Q. So let's start with the state of
21 the art of pharmaceutical cast films.

22 For purposes of this litigation,
23 the litigation, the parties have agreed that the
24 priority date for the '514 patent is

1 September 27, 2002. Did you use that date in
2 your validity analysis?

3 A. I did, but I don't know that it
4 would matter that much, but I did.

5 Q. What problems were the inventors
6 of the '514 patent trying to solve in 2002?

7 A. Well, they were trying to come up
8 with a way of creating pharmaceutical cast films
9 that would have a very high drug content
10 uniformity.

11 Q. What is drug content uniformity?

12 A. Well, the way I think about it is,
13 let's say you make a film and then you cut
14 pieces of that film, and you want each piece to
15 have essentially the same, the same amount or,
16 regardless of how you cut it. And in this case,
17 they're trying to keep the variation to less
18 than ten percent.

19 Q. And in terms of patient treatment,
20 why does drug content uniformity matter?

21 A. Well, you want to be reproducible
22 in terms of both safety, which is key, and also
23 efficacy, which is key.

24 Q. Now, before 2002, had other

1 scientists tried, but failed to make, to
2 achieve drug content uniformity in
3 pharmaceutical films?

4 A. Definitely.

5 Q. So what was the, what was the
6 status of the field or what stage of development
7 were pharmaceutical cast films in in 2002?

8 A. Well, very early, I think, my
9 belief is the first product based on
10 pharmaceutical cast films was in 2009, so many
11 years later.

12 Q. And when you say it was in 2009,
13 you mean it was approved in 2009?

14 A. Correct.

15 Q. Now, we've been talking about cast
16 films. Can you show us what the general process
17 is for making a cast film?

18 A. Yes. So this is in slide -- I
19 will put -- make sure.

20 So basically, first you dissolve
21 the polymer into a solvent and then you mix.
22 Then you add the -- step two. Then you're
23 adding the active ingredient and mix the form
24 like a dispersion. Then you cast that

1 dispersion on some kind of substrate, like it
2 could be glass, it could be metal. Then you
3 dry it into a final film. A lot of things
4 happen here. You know, you're evaporating a
5 lot of things. There's a lot of shrinkage
6 actually.

7 And then finally you cut into the
8 individual dosage units and you remove it from
9 the substrate. You package it, and that's what
10 you might end up selling.

11 Q. And in 2002, were there challenges
12 unique to cast films that made them particularly
13 difficult to manufacture in the pharmaceutical
14 context?

15 A. Yes. Let me put up another
16 slide.

17 Basically, the big challenge is
18 that you have two phases. There are a lot of
19 systems where you have one phase, but here you
20 have like a solvent phase with something
21 dissolved in it, a polymer, and now you also
22 have this solid phase, which are particles. And
23 the problem is keeping them uniform through all
24 of those five steps. In other words, if at any

1 point in time you lose that uniformity in any of
2 those five steps, you are not going to get it
3 back. You can't sort of put the genie back in
4 the bottle.

5 So that's the big problem, is to
6 keep them -- is to keep them uniform through all
7 of those five steps, assuming you even got it to
8 be uniform in the first place. And some of the
9 issues are shown up here, that you have the
10 active, that's the drug. That could actually
11 migrate essentially between dosage units before
12 you cut it.

13 Also, a lot of things are going
14 on, as I mentioned. When you are drying it,
15 that's one of steps. You're applying heat
16 generally to remove the solvent, so you are not
17 only applying heat, but you are changing the
18 system. You are shrinking it a lot. I mean, a
19 real lot. You're adding different excipients.
20 Those are other substances which could interact
21 with the drug. And as I said, there are issues
22 then in uniformity in all five steps.

23 Q. As someone who has worked with
24 cast films for decades, what was your own

1 experience with trying to make uniform
2 pharmaceutical cast films prior to 2002?

3 A. Well, I guess the way I often
4 think about it, when we started doing some of
5 the work I mentioned earlier on these
6 antigenesis inhibitors and I had a graduate
7 student working on it, he once said to me trying
8 to do this reproducibly was like trying to
9 break glass reproducibly. So it wasn't easy to
10 do. So we actually in the end largely have gone
11 to other kinds of systems to try to create
12 ultimate products, like microspheres, rods,
13 things like that.

14 Q. Now, did the prior art teach a
15 person of ordinary skill how to achieve drug
16 content uniformity in finished cast films?

17 A. No, it didn't. If I could have
18 the next slide.

19 So what you see, if we go to the
20 five steps is the homogeneity. In some examples
21 of prior art, that's discussed, steps like 1 and
22 2.

23 The steps 3 and 4, where you're
24 casting it onto a dispersion onto the substrate

1 and drying it into the film, those are almost
2 uniformly ignored or not achieved in the prior
3 art.

4 And as far as I could see, I will
5 talk about this more, if you analyze the
6 literature, both patents and, and published
7 literature, I don't think there's a single case
8 where somebody showed, you know, quantitatively
9 that they had achieved uniformity.

10 Q. And --

11 A. Before 2002.

12 Q. And just to kind of line these up
13 with the animation that Dr. Dyar showed
14 yesterday, steps 1 and 2, is that relating to
15 the liquid that's in the tank before it's put
16 onto the substrate?

17 A. That's correct.

18 Q. Okay. Now that we've generally
19 talked about the prior art, were there
20 particular references that you found that
21 discussed the issue of drug content uniform tie
22 of prior art films?

23 A. Well, there are a number, and I
24 will go into them, but let me just go to the

1 next slide and just highlight two, one before
2 and one after.

3 MR. LOMBARDI: Your Honor, we had
4 a motion in limine on this series of slides, and
5 you mentioned the order, that we should go ahead
6 and preserve our objection.

7 And if it's okay with your Honor,
8 I will just read the numbers of the slides and
9 then I won't be popping up throughout, or if you
10 would like me to jump up.

11 THE COURT: No. Just tell me the
12 slides.

13 MR. LOMBARDI: It's Exhibit 1706,
14 and then 1712 through 1716. And the grounds
15 again, your Honor, these are post-filing art,
16 and there are a variety of other grounds among
17 hearsay and so forth. But that was covered in
18 the motions in and in your brief.

19 THE COURT: All right. All right.
20 Go ahead.

21 BY MR. BRAHMA:

22 Q. Now, you were saying, Dr. Langer,
23 you had two examples of statements in the prior
24 art about?

1 A. Well, these are just two and I
2 will show more later. Maybe those are some of
3 the jumping up ones, but I'm not sure.

4 But the two that I will highlight,
5 one before, Schmidt, which was 1987, wrote that
6 prior art films do not make it possible to
7 obtain the uniform active ingredient
8 distribution.

9 Perumal -- and I will go over that
10 more -- that's a thesis, and then a scientific
11 article in a review journal. And they did a
12 number of things, but in particular they
13 analyzed the literature, doing a literature
14 search, and they said that an extensive
15 literature search with respect to drug content
16 uniformity in polymeric films shows surprisingly
17 that the majority of papers did not report
18 any assay values. And they have a table on
19 that. That's six years after 2002. And
20 there's more.

21 Q. All right. So I would like to
22 discuss the extensive literature search that
23 was conducted by Perumal. So if we could look
24 at that table on sum summary.

1 So this is PTX-215. If we could
2 pull up Table 1.

3 A. Mm-hmm. Okay.

4 Q. So they list a few articles in
5 that table. How many of those were published
6 before 2002?

7 A. Well, what is it? One, two,
8 three, four, five, I believe. Six. It depends
9 on when the sixth one was published.

10 Q. All right. And for any of those
11 six references, did they find any drug content
12 uniformity assay value?

13 A. They were not reported.

14 Q. And if we go to the text slightly
15 below that table. So the line starting from the
16 lack of reported data.

17 A. So it just says, the lack of
18 reported data on this crucial characterization
19 property of any novel drug delivery system led
20 to the assumption that researchers in this field
21 may also have been experiencing difficulty with
22 this aspect of film characterization.

23 And then they continue, and this
24 is key. Yet no paper to date, to the best of

1 our knowledge, in the published pharmaceutical
2 literature has highlighted this difficulty.

3 It was only a search of patent
4 applications that confirmed the assumption that
5 difficulties with achieving uniform drug
6 distribution in films did indeed exist, as some
7 patent applications that attempted to directly
8 address the problems encountered with
9 non-uniformity in films were identified.

10 Q. And I wanted to ask you about the
11 assumption there that the Perumal authors were
12 making the assumption that if data wasn't
13 reported, then the authors of that paper were
14 having difficulty getting drug content
15 uniformity.

16 How does that compare to the
17 assumption that Dr. Dyar is making when he came
18 across prior art references that didn't have
19 data on drug content uniformity?

20 A. It would disagree with it.

21 Q. And in your view, based on your
22 experience in the field, which assumption is
23 more appropriate when faced with prior art that
24 does not report drug content uniformity

1 data?

2 A. Well, I think this is -- plus this
3 is a peer-reviewed journal, I mean where people
4 looked at it and decided that they thought it
5 was worth publishing.

6 Q. And so do you agree with the
7 authors of the Perumal article?

8 A. Yes.

9 Q. Were the authors of the Perumal
10 article actually trying to make cast films,
11 pharmaceutical cast films?

12 A. That was the whole intent of what
13 they were doing. They were trying to make cast
14 films and then they also did this literature
15 review.

16 Q. All right. And then later in that
17 highlighted quote it talks about patent
18 applications that confirm the assumption about
19 the difficulties in achieving uniform drug
20 distribution in films.

21 What patent applications are they
22 referring to?

23 A. Well, some of them were in that
24 table. I mean, there's different ones. There

1 are a range of different ones.

2 Q. Do they talk about the work that
3 was reflected in MonoSol's '514 patent?

4 A. Yes, they do.

5 Q. And what do they say about that?

6 A. Can we -- I might -- yes. If we
7 could highlight a particular portion.

8 Q. Yes. In the second column.

9 MR. BRAHMA: I think you also need
10 to get the first in that former column. At the
11 bottom, if you start at the line that says, in
12 these patent applications.

13 THE WITNESS: Yes. So if we could
14 just -- yes. Let me -- well, here, let me just
15 do it off of the book.

16 Okay. So in these patent
17 applications, it was explained that films
18 prepared by the conventional casting technique
19 as used in the literature suffered from the
20 aggregation or conglomeration of particles which
21 rendered them inherently non-uniform in terms
22 of all film components, including polymer and
23 drug.

24 It then says, it was found that

1 the formation of agglomerates randomly
2 distributed the film components as well as any
3 active present, thus leading to the poor drug
4 content uniformity. And then they cite this
5 patent, the earlier version.

6 They continue, the formation of
7 agglomerates was attributable to the relatively
8 long drying times which facilitated
9 intramolecular attractive forces, convection
10 forcers, and airflow, which aided in the
11 formulation of such conglomerates.

12 They're citing to the Yang
13 patents. Then they start to talk about other
14 attempts that were used and that were abandoned.

15 BY MR. BRAHMA:

16 Q. Okay. And we will come back to
17 the Perumal article later to discuss its own
18 work.

19 But I did want to ask you, in
20 terms of the '514 patents, patent itself, did it
21 discuss whether the prior art films achieved
22 drug content uniformity?

23 A. Yes, it did, in a number of places
24 in the beginning.

1 **Q. Okay. Do you have a slide**
2 **summarizing that?**

3 **A. Yes. If we could just go to the**
4 **next slide. And just a couple quick things on**
5 **this. They point out that Horstmann and Zerbe**
6 **are deficient because the long length of drying**
7 **time aids in promoting the aggregation of the**
8 **active.**

9 **They point out that Fuchs' films**
10 **suffer from the aggregation or conglomeration of**
11 **particles, in other words, self-aggregation,**
12 **making them inherently non-uniform. This result**
13 **can be attributed to long drying times, thereby**
14 **facilitating intermolecular attractive forces,**
15 **convection forces, airflow and the like to form**
16 **such agglomeration. And these are just some**
17 **examples.**

18 **Q. And that last quote I wanted to**
19 **ask you about, the intermolecular force, the**
20 **attractive forces and convection forces that are**
21 **mentioned in that last quote, could you explain**
22 **what those are and how they could impact content**
23 **uniformity of an active ingredient in a**
24 **pharmaceutical film?**

1 **A. Well, they, they cause -- there's**
2 **all kinds of forces. Maybe we could just go to**
3 **the next slide and I could try to explain what**
4 **actually happens.**

5 **So if you have a system where you**
6 **have these solids dispersed in this liquid and**
7 **polymer, a lot of things are going on.**

8 **So one of the things that's going**
9 **on is there's heat generally applied, so you get**
10 **evaporation. So there's thermal gradients.**
11 **Obviously, if stuff is moving out, you also have**
12 **bulk concentration gradients. There's also what**
13 **are called surface tension gradients. The**
14 **surface tension is different when you have these**
15 **air liquid interfaces, and that changes over**
16 **time.**

17 **I think that's also key. All of**
18 **these things keep changing over time. It's not**
19 **a steady thing.**

20 **You also have what are called Van**
21 **der Waal's attraction. That's like substances**
22 **sort of being attracted to each other.**

23 **I think one thing that is**
24 **important in all of this, too, is not only the**

1 **effects in what I will call the Z direction,**
2 **settling, I think you heard some of that**
3 **yesterday from Dr. Dyar, but else also occur in**
4 **the XY direction, in this direction.**

5 **Also you get what are called**
6 **Marangoni flows, and I will show a video. Like**
7 **if something evaporates, and that's what**
8 **happening here, you don't get a uniform**
9 **distribution like a coffee ring.**

10 **If you pour coffee out, you'll see**
11 **that it does not, the residue doesn't distribute**
12 **uniformly. It goes to the edge. I will show**
13 **that. That is also shown in what are called**
14 **tears of line.**

15 **There's also capillary forces.**
16 **That's the sixth point on this. Capillary**
17 **forces is kind of like wicking.**

18 **Then there's what's called**
19 **ballistic Bronian motion, and that's particles,**
20 **moving back and forth, banging against each**
21 **other.**

22 **Then there's buoyancy. There's**
23 **Stokes law. That's what Dr. Dyar talked about**
24 **yesterday. That has to do with particles even**

1 **sinking or swimming.**

2 **The point is you have all of this**
3 **going on. It's quite complex because the system**
4 **is not a static system. It's a system that's**
5 **losing material all the time, changing**
6 **temperature, and so it's quite complicated.**
7 **It's not just one thing happening.**

8 **Q. You mentioned that Dr. Dyar talked**
9 **about Stokes law, and I wanted to ask you, the**
10 **is the entire phenomenon of drying an active**
11 **particle migration, can that all be explained by**
12 **simply Stokes law?**

13 **A. I don't see how it can because**
14 **Stokes law has to do with things settling, and**
15 **like I say, a lot of these things are moving,**
16 **you know, in other directions. So it can't**
17 **explain.**

18 **Q. Now, you mentioned that you have a**
19 **video on the coffee ring?**

20 **A. This will just be a quick video**
21 **just showing the coffee ring evaporation.**

22 **(Videotape played.)**

23 **THE WITNESS: And you just see the**
24 **residue going to the edge. In other words, it**

1 does not evaporate, so it goes to the edge. In
 2 other words, if it was uniform, it would be
 3 distributed throughout, but it's not. It all
 4 goes to the edge. This is just an example of
 5 one of the phenomenon out of the eight that I
 6 mentioned. I won't show videos of the other
 7 seven.

8 Q. So this is what you would see if
 9 you saw a drop of coffee grind. Coffee drying.
 10 Is that what you are saying?

11 A. That's exactly right, over time.

12 Q. And in that example, what is the
 13 particle?

14 A. That's a coffee particle.

15 Q. All right.

16 A. I'm not an expert on coffee, but
 17 that's a coffee particle.

18 Q. Now, how do these various --

19 A. I think the key, again, is just
 20 exactly how non-uniform it is.

21 Q. How do these various forces arise
 22 in the context of the casting and drying
 23 process?

24 A. Well, it occurs in those five

1 steps. And if I just go to the next slide, so
 2 there's casting, and there you run into issues
 3 on uniformity. But drying can create or
 4 exaggerate forces that can cause drug my
 5 migration and aggregation.

6 You can get uncontrolled air
 7 currents either above or below the film and that
 8 can create non-uniformity. As I mentioned, the
 9 whole system shrinking when this happens. You
 10 can also get air be bubbles formed and you
 11 could get a surface skin when you do this.
 12 And you can get rippling and that skin can also
 13 rupture.

14 So a whole bunch of things can
 15 happen, and do.

16 Q. Now, we have been talking about
 17 forces and drying conditions that can lead to
 18 non-uniformity. Does the '514 patent teach that
 19 any one factor or process parameter is critical
 20 to preventing that problem?

21 A. No. If we could just go to the
 22 next slide.

23 Basically, what they are saying in
 24 the '514 patent, it says, if the testing shows

1 non-uniformity between the film samples, then
 2 you control the manufacturing conditions, like
 3 drying conditions, mixing conditions,
 4 compositional components, and film viscosity.
 5 And part of the key is summarized here. This is
 6 what I've seen in the, this patent that I didn't
 7 see in any of the other literature that was
 8 cited by Dr. Dyar.

9 First, the casting dispersion must
 10 have viscosity low enough to process but high
 11 enough to limit migration and aggregation of the
 12 active. And I should add, you have to couple
 13 that with all the other properties you might
 14 want. Like if you make a film, you still want
 15 it to dissolve well. You want it to release
 16 well. So that's the first thing.

17 And the second thing is this idea
 18 of locking in. In other words, given that you
 19 can get all of this kind of migration at any of
 20 these five steps and that once you get it, you
 21 can't recover, what they are teaching you in
 22 this patent is that it's a combination of matrix
 23 viscosity and drying process that quickly locks
 24 in the active particle. So it's locked in and

1 basically preventing it from moving. And then
 2 you're drying it in such a way that it keeps it
 3 that way and keeps it smooth and so forth.

4 Q. Now, you mentioned that those are
 5 the things that weren't shown in the prior art
 6 that you had seen.

7 Now, Dr. Dyar yesterday talked
 8 about the ability of a person of ordinary skill
 9 in the art, if they had produced a film that
 10 wasn't uniform, to tweak their formulation or
 11 their drying process or something else, to get
 12 to uniformity.

13 Can you, can you explain to us, in
 14 your opinion, would a person of ordinary skill
 15 in the art viewing the prior art have been able
 16 to make those tweaks and what tweaks would they
 17 have been taught to make?

18 A. Well, I don't, I didn't see any
 19 prior art -- I'm going to go into that in a
 20 second -- that went over that. In fact, future
 21 art, if anything, as I will go over will show
 22 that that didn't happen.

23 But I would add to that what I
 24 just said to you before, that if you started

1 tweaking and improving one thing, you may -- you
2 run the risk that you will hurt something else.

3 You know, like getting the wrong dissolution
4 rate, getting the wrong mouth feel and so forth.

5 But maybe the easiest way to do
6 this is, we did a literature search and post the
7 Yang patent. And let me just cite six articles
8 that talk about this not before, but actually
9 after.

10 Q. Okay.

11 A. And --

12 Q. And we'll go to that in one
13 second. I just wanted to go to the claim really
14 quickly so we remember what uniformity
15 requirements we're looking at.

16 Claim 62. What level of drug
17 content uniformity does that require?

18 A. It requires that the individual
19 doses don't vary by more than ten percent of
20 said desired amount.

21 Q. And there's also claim 65 that is
22 being asserted that talks about content
23 uniformity. What variation in drug content does
24 that require?

1 A. Five percent.

2 Q. And so now let's get to those
3 post-2002 articles. And you mentioned that you
4 had found some that you wanted to talk about
5 today.

6 Were these types of references
7 that you ordinarily rely upon in your own work
8 to determine the state of the art in the field?

9 A. Yes. Most of them are in
10 peer-reviewed journals that I peer-review myself
11 sometimes.

12 Q. Do --

13 A. I'm on the editorial board of some
14 of them, too.

15 Q. Do these articles discuss the
16 contributions of the '514 patent?

17 A. Many of them do, yes.

18 Q. And --

19 A. And they're all post 2002.

20 Q. And what do those post 2002
21 articles say about the '514 patent?

22 A. Well, if anything, they consider
23 it as I will go through a seminal patent. I
24 mean, they're highly complimentary to it. And

1 as far as I can see, none of the people, at
2 least as far as I could tell that were speaking
3 about it, had any association with MonoSol or
4 anything like that. In fact, one of them I
5 believe testified for the other side,
6 McConville, but I will get to that.

7 Q. All right. So let's go to
8 those slides. I think the first one is slide
9 1712.

10 A. Yes. That's the one I just
11 mentioned.

12 Q. Okay. And can you tell us about
13 how the Morales and McConville article impacted
14 your analysis of obviousness?

15 A. Well, it's just one more piece of
16 evidence. As I mentioned, McConville I believe
17 testified yesterday. But it's a peer-reviewed
18 journal in the pharmaceuticals area. It's in
19 2011, so that's nine years later. And they just
20 wrote, when they're discussing this whole field,
21 it's what is called a review article. So that's
22 supposed to be a critical analysis. It's not
23 original research. It's a critical analysis of
24 the field.

1 But just a couple quick quotes.

2 They said, since the early development of
3 medicated films, content uniformity has been a
4 major challenge. So I mean, that directly
5 contradicts what you heard yesterday, I believe,
6 from Dr. Dyar.

7 Then they further said that Yang,
8 et al, MonoSol, indicated that self-aggregation
9 was one of the main reasons why films usually
10 show poor uniformity, and in particular the
11 drying process was found to be crucial in
12 preventing aggregation or conglomeration, and
13 so forth.

14 Q. Now, Dr. Langer, you mentioned
15 that Dr. McConville testified yesterday. I just
16 wanted to make sure it's clear for the record,
17 he was testifying for Watson; is that right?

18 A. Correct.

19 Q. Okay.

20 A. I'm sorry.

21 Q. But he wasn't addressing the issue
22 of validity of the patent?

23 A. No, no. I was just -- no.

24 Q. Okay.

1 **A. He wasn't going over this at all.**
 2 **But I was just saying this is an article that he**
 3 **and one of his colleagues wrote.**
 4 **Q. Now, Dr. Dyar yesterday criticized**
 5 **this article and other post 2002 articles for, I**
 6 **think his words were, copying and pasting from**
 7 **the '514 patent, and not doing a, quote unquote,**
 8 **"independent analysis."**
 9 **What is your view on that?**
 10 **A. Well, I mean, it's partially**
 11 **correct, but I mean the thing is, is what people**
 12 **do, I mean, when they write -- this is a review**
 13 **article. We'll get to some other articles, too.**
 14 **But what people do is they make an analysis of**
 15 **the literature. Sometimes when they see things**
 16 **they like that other people wrote, they copy it,**
 17 **and then they attribute it to them. And that's**
 18 **what's done here.**
 19 **But the fact is, is when something**
 20 **undergoes peer review, it's usually seen by a**
 21 **number of people, scientific reviewers who are**
 22 **either in industry or faculty members, an editor**
 23 **of the journal, and they review these to see**
 24 **whether what's said is reasonable or not.**

1 **My experience has been**
 2 **peer-reviewed articles usually set a higher bar**
 3 **in terms of rigor, scientific rigor like this**
 4 **than, say, a patent in terms of analyzing**
 5 **literature. So I mean, to me, this kind of**
 6 **thing happens, this is pretty standard.**
 7 **Q. And in peer-reviewed articles like**
 8 **this, when the authors disagree with a statement**
 9 **they find in the literature, is that something**
 10 **they are supposed to note?**
 11 **A. I'm sorry. Could you repeat the**
 12 **question?**
 13 **Q. In peer-reviewed articles like**
 14 **this, if the authors found a statement in the**
 15 **literature that they disagreed with, is that**
 16 **something they would be expected to note in the,**
 17 **in their own article?**
 18 **A. Yes. Like I said, they're doing a**
 19 **critical analysis. They are doing a critical**
 20 **analysis of the whole thing, and so if they did**
 21 **disagree, and they do. Sometimes people say,**
 22 **well, I'm analyzing this, and I don't agree with**
 23 **it, or I'm analyzing this and I do agree with**
 24 **it. So that's quite standard.**

1 **Q. All right. Let's go to the next**
 2 **articles on your list there. And you have**
 3 **listed the Perumal thesis and the Perumal**
 4 **article. How did those impact your obviousness**
 5 **analysis?**
 6 **A. So we talked a little bit about**
 7 **Perumal before. So Perumal did a thesis where**
 8 **there's a Master's advisor in this case, and**
 9 **then they wrote again a peer-reviewed article.**
 10 **Again, just a couple of quick**
 11 **quotes from those that I think are, that are**
 12 **representative. Films suffered from the**
 13 **aggregation or conglomeration of particles,**
 14 **which rendered them inherently non-uniform in**
 15 **terms of all film components, including polymers**
 16 **and drug.**
 17 **That is from the thesis. The**
 18 **article, they made a statement, it was found**
 19 **that the formation of agglomerates randomly**
 20 **distributed the film components as well as**
 21 **any active present, thus leading to the poor**
 22 **drug content uniformity. And they're citing**
 23 **the 741 provisional from which the '514 claims**
 24 **priority.**

1 **Again, all we see from these is a**
 2 **quite consistent picture that post 2002, these**
 3 **were, these issues were still there and people**
 4 **were still talking about them.**
 5 **MR. BRAHMA: And just as a quick**
 6 **housekeeping matter, I'm going to move into**
 7 **evidence the Morales/McConville article,**
 8 **PTX-213, as well as the Perumal article,**
 9 **PTX-215, and the thesis, PTX-216.**
 10 **MR. LOMBARDI: Your Honor, the**
 11 **same objection that we've articulated before.**
 12 **THE COURT: All right. I'm going**
 13 **to admit them into evidence. It's something you**
 14 **can raise again post-trial briefing.**
 15 **(PTX-213, 215 and 216 were admitted into**
 16 **evidence.)**
 17 **BY MR. BRAHMA:**
 18 **Q. Now, we talked about the**
 19 **literature search that was reported in the**
 20 **Perumal article. Did the Perumal authors also**
 21 **do any experiments of their own?**
 22 **A. They did. They did that as well.**
 23 **If I could -- yes.**
 24 **So basically what they found when**

1 they tried to do it was they actually got a
 2 standard deviation of 66 percent, and here's
 3 just an electron micrograph. So they again were
 4 nowhere near when they tried to use a
 5 conventional casting technique of what Yang
 6 did.

7 Q. All right. Now, so how does that
 8 data impact your analysis of the obviousness of
 9 the claims of the '514 patent in light of Dr.
 10 Dyar's comment?

11 A. Again, all of this is is a
 12 consistent picture that even post 2002, this was
 13 still an incredibly difficult problem. People
 14 have not solved it beyond what they had done in
 15 Yang.

16 Q. And the next article on your list
 17 is the Nowak 2005 patent publication. How does
 18 that affect your obviousness analogy?

19 A. It will say the same kind of
 20 thing. Water-soluble films cast from aqueous
 21 solutions containing medications can suffer from
 22 the aggregation or conglomeration of particles.
 23 Self-aggregation of any active ingredient will
 24 make the film inherently un-uniform. But if

1 possible, portions of the film may be devoid
 2 substantially devoid of any medication.

3 I mean, the theme comes over and
 4 over again, and I did not see it come the other
 5 way at all.

6 Q. And then the last two articles on
 7 your list are the Kathpalia article, PTX-212,
 8 and the Borges 2015 article, PTX-210.

9 How do these affect your analysis
 10 of the obviousness of the '514 patent claim?

11 A. Yes. So, again, these are in
 12 peer-reviewed articles, and now they are 11 and
 13 13 years later, one being this year. The first
 14 one again makes the same point that I said we
 15 found, that all these people are finding, dose
 16 uniformity is difficult to maintain in oral thin
 17 films. That's the 2013 article.

18 The 2015 article actually is very
 19 complimentary to MonoSol and Reckitt Benckiser.
 20 As far as I know, these people have no
 21 association with them. But they say MonoSol is
 22 one of the pioneer companies in the oral film
 23 industry. The success of Reckitt Benckiser's
 24 prescription thin film proves the viability and

1 value of this pharmaceutical form in the Rx
 2 market.

3 Q. And I just wanted to clarify
 4 because there are a number of patents in this
 5 case. So when you refer to Yang in your
 6 testimony, are you referring to the applications
 7 that led to the '514 patent?

8 A. That is correct. All of these
 9 things, if I have not made that clear, all of
 10 these things talk to the '514. I have not
 11 examined the others.

12 Q. Now, collectively, do the
 13 teachings of these post-2002 references support
 14 or contradict Dr. Dyar's view of whether the
 15 prior art had already solved the problem of drug
 16 content uniformity in the pharmaceutical film?

17 A. No. They contradict it.

18 Q. Now, I would like to move to the
 19 specific prior art references and background
 20 references that Dr. Dyar cites. And Dr. Dyar's
 21 testimony focused on two references in the
 22 obviousness combination, the Chen reference and
 23 the Bess 116 patent. Then he also cited two
 24 pieces, two references as pieces of background

1 knowledge, the Leung '298 patent and the Lachman
 2 reference. I would like to go through those in
 3 order if I could.

4 A. Sure.

5 Q. Have you reviewed Dr. Dyar's
 6 testimony about the Chen reference?

7 A. Yes.

8 Q. And in your opinion, does the
 9 Chen reference, either alone or in combination
 10 with the other references Dr. Dyar discussed,
 11 render the asserted claims of the '514 patent
 12 obvious?

13 A. No, it does not.

14 Q. And do you have a slide briefly
 15 summarizing why you don't feel the Chen patent
 16 renders the '514 claims obvious?

17 A. Sure. Some of the things that Dr.
 18 Dyar said. First, there's certain references to
 19 homogeneous, but they at best apply to the
 20 dispersion. They don't cover, say, steps 3, 4
 21 and 5 that I was shown, and they don't cover the
 22 drug content uniformity of the finished film.
 23 That was actually never measured.

24 He does, Dr. Dyar used Figure 5,

1 the dissolution data, as a surrogate for drug
2 content uniformity, but, if anything, as I will
3 show, I mean, first that means that you make a
4 lot of assumptions. And, secondly, I will go
5 over them.

6 But as far as I can see, if
7 anything, Figure 5 would show the opposite,
8 that it does not have drug content uniformity.
9 Also, there's a pharmacokinetic study that Chen
10 is doing, and that to me says nothing about
11 uniformity.

12 And, finally, I mean, the whole
13 patent is not even about drug content
14 uniformity. It's really about making this kind
15 of mucosal dosage form. That's kind of the
16 invention. It does not really explain how you
17 would maintain uniformity, which, as we've
18 already seen, is a quite complex issue. It
19 does not even touch it during casting and
20 drying.

21 Q. So let's first go to the
22 statements that are in the Chen reference about
23 homogeneity or uniformity of the dispersion.

24 Have you looked at those as part

1 of your obviousness analysis?

2 A. Yes. Let me just go to four of
3 them.

4 The first one, and I'm not sure
5 where to best point. But basically, the first
6 statement says, methods are provided for making
7 a dosage unit, that include in one embodiment,
8 dissolving a hydrocolloid in a solvent so as to
9 form a substantially homogeneous preparation.

10 Later on, they're talking about
11 adding the active agent. But that does not tell
12 you that the active agent was uniformly mixed.
13 Certainly, it does not say anything about it
14 being uniformly cast or uniformly dry.

15 The second one says somewhat
16 pretty much -- well, the second one says
17 therapeutic agents were added to the homogeneous
18 mixture prior to forming the film, but it does
19 not say anything about any of those issues
20 either from the point of mixing to drying to --
21 I'm sorry, mixing, casting and drying.

22 The third one says the
23 hydrocolloid was dissolved under agitated mixing
24 to form a uniform and viscous solution.

1 Additional ingredients were then added
2 sequentially to the viscous solution. But
3 the ones that they are adding are not drug.
4 They're basically -- it basically says they're
5 adding these until they were uniformly dispersed
6 add and dissolved or dissolved in the
7 hydrocolloid. Again, I'm just going by the
8 words on these.

9 The fourth one, which I believe
10 was shown yesterday, in an embodiment of the
11 invention, the solvent casting method includes a
12 hydrocolloid that is completely dissolved or
13 dispersed in water under mixing to form a
14 homogeneous formulation. So it's homogeneous
15 there, but that's the hydrocolloid.

16 Now, it says, in addition to the
17 active agent and the hydrocolloid, any of the
18 ingredients listed above may be added and
19 dispersed or dissolved uniformly in the
20 hydrocolloid solution.

21 Personally, I think there are two
22 ways you can interpret this because they are not
23 specifying that the active agent is dispersed or
24 dissolved uniformly, but I could see where

1 that's also a possible interpretation. But
2 nonetheless, even if you take the most positive
3 interpretation, it still says nothing about what
4 happens during casting and what happens during
5 drying.

6 So nowhere in Chen if you go
7 actually -- and maybe just let me check what I
8 wanted to do.

9 But if I go to the next slide,
10 because I think this is really key. If you go
11 to the chart where I show the five tables,
12 nowhere in the Chen patent even under the most
13 generous interpretations do they deal with steps
14 3, 4 and 5. So to me, that's key. They just
15 don't deal with that at all.

16 Q. All right. So going beyond the
17 mere statements in the Chen reference, let's
18 talk about Figure 5 and the dissolution data
19 that Dr. Dyar talked about.

20 A. Okay.

21 Q. Now, did you review Figure 5 of
22 the Chen reference in connection with your
23 opinions on validity?

24 A. I have, yes.

1 **Q. Okay. And what type of testing is**
 2 **shown in Figure 5?**
 3 **A. This is what's called a**
 4 **dissolution test. So when you have, like, a**
 5 **dosage form, you know, like you might put it in**
 6 **a simulated solution and see what happens over**
 7 **time, how much drug comes out over time, and**
 8 **then you measure it.**
 9 **So what they are measuring here is**
 10 **percentage release, and a hundred percent would**
 11 **be like an estimate of if you had a hundred**
 12 **percent uniformity.**
 13 **Q. All right.**
 14 **A. So let's say, for example, just**
 15 **for the sake of argument that you put two**
 16 **milligrams in, so 100 percent would be two,**
 17 **110 percent would be 2.2, 90 percent would be**
 18 **1.8.**
 19 **But basically what they are**
 20 **measuring based on that estimate would be how**
 21 **much drug comes out over time, and I believe**
 22 **what they are showing here is standard**
 23 **deviation. It's not a hundred percent clear,**
 24 **but I believe that that is what they are showing**

1 **from other statements in the patent.**
 2 **Q. Okay. So I'm going to break down**
 3 **some of that into smaller bites.**
 4 **So is dissolution testing common**
 5 **in the pharmaceutical industry?**
 6 **A. Yes. It's routine. They do it**
 7 **all the time.**
 8 **Q. Okay. And is dissolution testing**
 9 **like the type shown in Figure 5, is that**
 10 **commonly used to measure drug content**
 11 **uniformity?**
 12 **A. No, it's not.**
 13 **Q. And why not?**
 14 **A. Well, because to do that, you have**
 15 **to make a number of assumptions. And what's**
 16 **usually used to measure drug uniformity -- I**
 17 **mean, the most common way would be to dissolve**
 18 **the entire system and each of the different**
 19 **pieces and see how much drug was left behind.**
 20 **Q. Okay. So if a person of ordinary**
 21 **skill in the art was to look at Chen's Figure 5**
 22 **and wanted to go ahead and see what it said**
 23 **about, what it might say about drug content**
 24 **uniformity, what assumptions would they have to**

1 **make?**
 2 **A. Well, I think they have to**
 3 **probably make at least three. First, that**
 4 **what's called steady state is reached, meaning**
 5 **that no more, it's not going to change over**
 6 **time.**
 7 **Secondly, that all of the drug**
 8 **that was puts in actually did come out.**
 9 **Ad, third, when you look at this**
 10 **figure -- I mean there's a lot of data points**
 11 **and standard deviations, and you would have to**
 12 **be able to pick out what those data points and**
 13 **standard deviations are. I don't know if that's**
 14 **an assumption, but it would take some analytical**
 15 **work.**
 16 **Q. And if you make these assumptions,**
 17 **does Figure 5 indicate that the Chen films have**
 18 **the content uniformity required by claim 62 and**
 19 **65?**
 20 **A. No.**
 21 **Q. Okay. And I'm going to break down**
 22 **how you would go about applying those**
 23 **assumptions.**
 24 **First, how many different drugs**

1 **were tested here?**
 2 **A. Four.**
 3 **Q. Okay. And there's an X and a Y**
 4 **axis to this. Can you explain what is being**
 5 **shown on the X axis and the Y axis?**
 6 **A. Yes. I mean, the Y axis is**
 7 **percentage release, and the X axis is time.**
 8 **Q. When it says, percentage release**
 9 **there, what does 100 percent on the percentage**
 10 **release access mean?**
 11 **A. Well, that goes to the -- what I**
 12 **was saying before. In other words, if you have**
 13 **-- if you assume that what you got a hundred**
 14 **percent was 2, then a hundred percent would**
 15 **actually be about 2.**
 16 **But, of course, a lot of times**
 17 **it's not going to be 2. It's going to be higher**
 18 **or lower, depending on how uniform it will be.**
 19 **Q. So when you say "2," what do you**
 20 **mean be that? Is that the dosage of the film?**
 21 **A. Well, that -- two would be a**
 22 **theoretical estimate of how much would be in**
 23 **each piece.**
 24 **Q. That's how much, when you were**

1 making the film, that's how much you wanted to
2 be in there?

3 A. That's correct.

4 Q. Okay. Could you show us -- so if
5 we were to draw a line across this chart at the
6 hundred percent mark -- so there are a few of
7 those points that are above the hundred percent
8 mark.

9 Does that indicate that something
10 was wrong with the way Ms. Chen did this test?

11 A. Again, I didn't see it. It's
12 certainly possible there could be things that
13 were wrong, but I don't think that, per se, says
14 anything that's wrong. I mean, that's quite
15 common.

16 Q. And in a dissolution test like
17 this, do you often get data points that are
18 above 100 percent?

19 A. You'd have to, unless it was
20 absolutely perfect, right?

21 I mean, you'd have to, unless it
22 was 0 percent error, or a 0 percent drug content
23 uniformity. I mean, you, of course, would get
24 some that were higher and some that were lower.

1 Q. So what does the point above 100
2 percent mean on this chart in terms of how much
3 drug is in the film?

4 A. Well, like I say, if you have --
5 if what you expected was 2, then it would be
6 greater than 2. Maybe 2.1, for example, 2.2.

7 Q. Now, the one point that Dr Dyar
8 mentioned earlier, if you -- if you assume that
9 this test was erroneous, or if there was some
10 analytical error, or some procedural error in
11 how this test was run, how would a person of
12 ordinary skill view the other statements in Chen
13 about homogeneity or uniformity?

14 A. Well, I think -- I mean, that's a
15 good question.

16 I mean, I think if you felt that
17 one thing was in error, I guess the question
18 would be, how would you know what in the past
19 was an error and what wasn't. You wouldn't know
20 what to trust.

21 Q. Now, looking at these --

22 A. I don't think you can cherry-pick
23 and take the things you like, and then all of a
24 sudden cherry-pick the other way, and throw out

1 the things you don't like. If you don't trust
2 some data, how do you know what -- and there's
3 in really no analysis. I mean, how would you
4 know what to trust?

5 Q. Now, going back to the graph, and
6 looking at these curves, some of them level off
7 over time.

8 What does that leveling off
9 indicate?

10 A. To me that's indicative that it is
11 probably is reaching what I called before a
12 steady state. That is plateauing.

13 MR. BRAHMA: And if we could pull
14 up the slide focusing on the Estradiol curve.

15 BY MR. BRAHMA:

16 Q. Does the Estradiol curve show it
17 reaching steady state by the 10-minute time
18 point?

19 A. No. I mean, every data point, as
20 you move along in time, is higher than the last
21 data point.

22 So the data point of 6 data is
23 higher than a 6, the data point at 10 is higher
24 than 8, so you -- it certainly does not -- you

1 can't conclude a true steady state.

2 Q. So, what, if anything, could a
3 person of ordinary skill in the art be able to
4 tell from this Estradiol curve about the content
5 uniformity of the Estradiol films that Chen
6 made?

7 A. I don't see how you could. I
8 mean, you would have to make even more
9 assumptions, and those assumptions couldn't be
10 right.

11 Q. Now, if we remove that Estradiol
12 curve, and just look at the other three on the
13 next slide, what portion of this are you saying
14 is steady state?

15 A. Well, I don't want to overstate
16 this. I mean, to me it's an estimate.

17 But it looks like, if you eyeball
18 these things like -- and I haven't done
19 statistics on it -- but if you eyeball it, it
20 looks like for four minutes to ten minutes it's
21 fairly steady. I mean, again, what I'm
22 trying to do here is give the best assumptions,
23 sort of to the other side and say, well, if you
24 assume all the things that Dr Dyar said are

1 true, you could get anything out of this?
 2 So to me, if you do that, I think
 3 for 10 minutes seem -- you know, that -- it's
 4 looks like it could possibly be a steady state.
 5 Q. Now, did Chen test multiple film
 6 samples for each of these three drugs that are
 7 listed here?
 8 A. Yes.
 9 Q. Okay. And how do you know that?
 10 A. Well, he's got error -- she's got
 11 error bars. So an error bar certainly implies
 12 that there are multiple points.
 13 Q. Okay. And the points that are
 14 actually on the curves, what do those stand for?
 15 A. I believe they stand for standard
 16 deviations.
 17 Q. Are you talking about the vertical
 18 bars or the points on the curves?
 19 A. Oh, the points on the curve are
 20 the means, and the vertical bars would be the
 21 standard deviations.
 22 Q. Okay. So using those means, and
 23 standard deviations, how would a person of
 24 ordinary skill in the art know what the entire

1 range of sample measurements was?
 2 A. I'm not sure I understand the
 3 question exactly.
 4 Q. Well, so, if you have those means
 5 and standard deviations, how does a person of
 6 ordinary skill in the art calculate what the
 7 entire region of --
 8 A. Oh.
 9 Q. -- samples values are?
 10 A. So what you do is, there's
 11 actually what is called a three- segment rule.
 12 And if we can just go to the next
 13 slide.
 14 So here are the standard
 15 deviations.
 16 One standard deviation is 68
 17 percent. Well, with the two standard deviations
 18 is 95 percent. And three standard deviations is
 19 close to 100 percent.
 20 So if people use, statistically,
 21 three standard deviations to get the whole
 22 range.
 23 So, basically, that's called a
 24 three-signal rule.

1 Q. And when you say "people use"
 2 this, is this something that is commonly applied
 3 by those of ordinary skill in your field of
 4 pharmaceutical development?
 5 A. Yes.
 6 Q. Now, can you show us what Figure 5
 7 would look like if the errors bars were triples
 8 to account for the three-signal rule?
 9 A. Yes. So these are some estimates,
 10 but you triple them, and they look like this,
 11 and they go outside that 10 percent range.
 12 Q. So what does this data -- now that
 13 you've applied all of the assumptions that are
 14 most favorable to defendants, and Dr. Dyar's
 15 position, what is the most that a person of
 16 ordinary skill in the art could possibly take
 17 out of the Figure 5, in terms of whether the
 18 Chen films were uniform for drug content?
 19 A. Yes. Well, given those
 20 assumptions, it would show you that they don't.
 21 They are not within the 10 percent range.
 22 Q. And I take it, then, if they are
 23 not within the 10 percent range, would they be
 24 within the 5 percent range of claim 65?

1 A. Pretty hard to do that. They are
 2 not in the 5 percent range either, obviously.
 3 Q. All right.
 4 Let's move on to the statement in
 5 Chen that Dr Dyar pointed to about viscosity on
 6 page 13 of his article.
 7 That's JTX-187, page 13, Lines 1
 8 and 2.
 9 (Pause)
 10 A. Okay.
 11 Q. So the sentence that Dr Dyar
 12 pointed to was, "A factor that plays a
 13 significant role in determining the properties
 14 of mucosal surface coat forming a composition is
 15 the viscosity of the hydrocolloid."
 16 And my question to you, Dr. Langer
 17 is, does that say anything -- what does that
 18 tying viscosity to, is that drug content
 19 uniformity or something else?
 20 A. No. When you read the whole
 21 patent, it really doesn't -- that's not the
 22 point of the patent. It doesn't really address
 23 drug uniformity.
 24 What it's addressing is good

1 mucosal adhesion. You know, if you swallow it,
2 you put it, say, in your mouth, would it adhere
3 well and function well?

4 So it's about something totally
5 different.

6 Q. Now, taking Chen as a whole, would
7 a person of ordinary skill in the art understand
8 how to make uniform films by changing the
9 viscosity of, or by controlling the viscosity of
10 those film formulations?

11 A. I just don't see how. I mean,
12 there's no instruction on them.

13 Q. The next reference that Dr. Dyar
14 used in his obviousness combination was the Bess
15 '116 patent.

16 Did Bess teach drug content
17 uniformity in pharmaceutical film?

18 A. Well, why don't I put up the next
19 slide.

20 Bess does not. Just some quote.

21 Bess say, "The films were prepared
22 by adding the oil mixture to the hydrated
23 polymer gel and mixing until uniform."
24 Then there is simply deaeration and casting.

1 But, basically, again, Steps 3, 4,
2 and 5 in the chart I showed, aren't there. And
3 stating the that coating preparation may be
4 uniform, doesn't mean that the finished film
5 maintains uniformity, certainly not given all
6 the things that we've seen. Another
7 statement is that the film is -- this is in the
8 bottom -- preferably air-dried, or dried under
9 warm air, and cut to a desired dimension,
10 packaged, and stored.

11 They also talk about the examples
12 being dried under warm air.

13 But, again, all of these things
14 that we've seen just show that that doesn't --
15 you just have no idea whether that is giving you
16 drug content uniformity, unless you do a careful
17 selection of these things.

18 Q. And there was a discussion today I
19 had with Dr. Dyar yesterday about drying, as
20 shown in the in the Chen reference, I believe it
21 was Slide 19 from Dr. Dyar's slides?

22 That's the one. Thank you very
23 much.

24 Okay. So Dr. Dyar put up this

1 slide, and the picture at the top there is from
2 Figure 2. That's the portion that's the drying
3 oven in Chen.

4 And he said that "The air flow
5 changes from not being directly on the film, to
6 being directly on the film, as you move along
7 the conveyer belt."

8 Did you review that testimony?

9 A. Yes.

10 Q. Okay. In your mind, is that
11 uniform drying?

12 A. It isn't, but you just can't tell.
13 I mean, there's just no information given on the
14 patent. There is no legend on the figure. You
15 can't tell what they're doing. I mean, you
16 would have to make a lot of assumptions.

17 Q. When you looked it at Figure 2 of
18 the Chen reference, did you view that as a
19 diagram of the actual drying equipment or a
20 schematic?

21 A. Well, it's certainly a schematic.

22 Q. Is there any information given in
23 the Chen reference about the particular
24 equipment used for drying, or the air flows that

1 are coming out of these vents?

2 A. I couldn't find any.

3 Q. Going back to the Bess
4 reference -- and sorry for the diversion -- does
5 the Bess '116 patent say anything about the
6 effect of film matrix viscosity on maintaining
7 drug content uniformity?

8 A. No.

9 Q. Does either Bess alone, or in
10 combination with Chen, render the asserted
11 claims of the '514 14 patent obvious?

12 A. I would not think so for one of
13 ordinary skill, no.

14 Q. Now, I just want to briefly touch
15 upon the two background references, starting
16 with the Leung '298 patent, which is JTX-183,
17 the Leung patent.

18 And can you tell me, based on your
19 review of the Leung '298 patent, how did it
20 impact your analysis of obviousness?

21 A. Well, again, it's the same kind of
22 thing. There is no disclosure of a de-active
23 content uniformity during any stage of the
24 casting process, or in the finished film. There

1 is no disclosure for particulate active or
2 particle size range.
3 You know, they actually, if
4 anything, teach the opposite. They point out
5 hydrating the film forming agents in the
6 presence of electrolytes in solution effectively
7 lowers rather than raises the viscosity of the
8 polymer gel being formed.

9 So that's actually the opposite of
10 what '514 patent. So, if anything, it would
11 teach away.

12 Q. Now, when Dr. Dyar put up the
13 Leung patent, he had a picture of the Listerine
14 pocket pack strips.

15 Those Listerine strips, are those
16 subject to the same drug content uniformity
17 requirements that a pharmaceutical would be?

18 Or, actually, let me take a step
19 back.

20 Do those even have a drug in them?

21 A. I was just going to say that
22 myself. They don't have a drug in them. And,
23 obviously, they are not subject to it then.

24 Q. And then the next background

1 reference I would like to ask you about is the
2 Lachman reference, JTX-238.

3 A. I probably should have also
4 mentioned that I was on the Warner Lambert
5 Scientific Advisory Board when a lot of that was
6 done as well. So I have a little bit of
7 knowledge about that.

8 Q. And, actually, I take it back.
9 The Lachman reference we've already discussed.
10 So I'll skip ahead.

11 Looking at these four
12 references -- so going back to Slide 1717 --
13 looking at those four references, would a person
14 working in the in the 2002 time period have been
15 motivated to combine any of these references to
16 make a pharmaceutical film with a particulate
17 active that met the drug content, that the 10
18 percent or 5 percent drug content uniformity
19 requirements of Claims 62 and 65?

20 A. I just don't see how.

21 Q. And do any of these references
22 teach a person of ordinary skill in the art how
23 they would make a pharmaceutical film with an
24 active ingredient that met those 5 or 10 percent

1 drug content uniformity requirements?

2 A. No, they do not.

3 Q. Now, I'd like to turn to Dr.
4 Dyar's indefiniteness arguments.

5 Do you understand that Dr. Dyar is
6 arguing that claim 62 is indefinite, because it
7 should be interpreted as meaning that the final
8 cast film has a matrix that is still flowable,
9 has viscosity, even after its been dried?

10 A. That -- that was my interpretation
11 of his interpretation, yes.

12 Q. Okay. Do you agree with his
13 argument that the claims of the 514 patent are
14 indefinite?

15 A. I don't, no.

16 Q. Let's go to claim 62. I think
17 slide 1730.

18 I'd like to focus on the
19 highlighted clauses.

20 So the start of the claim reads "A
21 drug delivery composition comprising a cast
22 film."

23 What does the term "cast film," as
24 used in the claim here, mean to a person of

1 ordinary skill in the art who has read '514
2 patent?

3 A. Well, I think it means what it
4 says. It means you made a film by casting it
5 and operating off the solvent.

6 Q. And when you say "casting," is
7 that the five-step process that you were talking
8 about earlier?

9 A. Yes, that's right.

10 Q. But this claim also describes the
11 cast film as comprising a matrix that is
12 quote, unquote, "capable of being dried."

13 Do you see that in that bottom
14 highlighted portion?

15 A. Yes.

16 Q. So how would a person understand
17 that limitation about the matrix of the dried
18 film?

19 A. Well, I mean, it's -- just to make
20 sure, you're talking about the very last
21 statement?

22 Q. Yes.

23 A. Well, I think it says what it
24 says. It says, "Water soluble or water soluble

1 film forming a matrix is capable of being
2 dried."

3 So that matrix is capable of being
4 dried.

5 Q. So, now, the matrix that is
6 actually in the final product is already dried,
7 correct?

8 A. In the final product that's dried,
9 yes.

10 Q. Okay. So this -- is this term
11 "flowable," does that mean that the final matrix
12 in the film has to actually flow?

13 A. I certainly don't read it that
14 way, no.

15 Q. Okay. So when does the matrix
16 that is discussed in this claim have to actually
17 be able to flow?

18 A. Well, prior to casting.

19 Q. So that would be when it's in the
20 tank in Dr. Dyar's animations?

21 A. That's fair, yes.

22 Q. Okay. And this claim also talks
23 about the matrix having a viscosity.

24 Does that apply to the matrix

1 specifications, that you could give us as an
2 example that talk about the matrix as capable of
3 being dried?

4 A. Yes. Why don't I go to the next
5 slide.

6 So here they are talking about
7 having a drying wet cast films.

8 And it says, "The wet film may be
9 dried."

10 And then further it says, "Wet
11 cast film forming methods."

12 And they point out, again, in the
13 yellow place, "The matrix formed by this
14 combination is formed into a film desirably by
15 roll-coating and then dried."

16 Q. Now, where in the specification,
17 or at least the example portions of the
18 specification, does it describe -- the matrix,
19 says "flowable and having a viscosity"?

20 A. Right. If you can go to the next
21 slide.

22 So here I'll just, again, read
23 these statements.

24 It just says, basically, "The

1 after it's already been dried, or is it, again,
2 talking about the matrix, the qualities of the
3 matrix when it's in the tank?

4 A. The qualities of the matrix when
5 it's in the tank. The latter of the two things
6 that you said.

7 Q. Okay. Now, I'd like to ask you
8 about the specification. Are
9 there examples in the specification of the '514
10 patent, where they talk about this wet casting
11 process?

12 A. Yes.

13 Q. Can you show us some of those?

14 A. Yes. So in the abstract, it says
15 "The composition may be formed by wet casting
16 methods where the film is cast and controllably
17 dried."

18 It also says, "Wet cast films" --
19 and it says in the "wet casting process."

20 And then a third example, it says,
21 "The film products of the present invention may
22 be produced by a wet casting method."

23 Q. And are there also examples in the
24 specification, or portions of the

1 flowable water soluble film forming matrix is
2 formable into a dry film."

3 Here in the second passage,
4 "Flowable water soluble film forming matrix is
5 capable of being dried."

6 All very consistent with the
7 claims.

8 And, again, the third one,
9 "Uniformity must be maintained as the flowable
10 mass was formed into a film and dried."

11 Q. And then what about examples of
12 where the specification talks about the matrix
13 always having a viscosity?

14 A. If we could go to the next slide.

15 Okay. Here we are.

16 So, again, here it just says, "In
17 addition to the viscosity of the film or film
18 forming components or matrix."

19 It goes on. Here, again, it says,
20 "In a viscol elastic fluid matrix with
21 acceptable viscosity values."

22 Q. Now, given all of that discussion
23 in the specification, and language in the claims
24 itself, would a person of ordinary skill in the

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1 art, who knew about the casting of film, have
2 understood the scope of the claims of the '514
3 patent with reasonable certainty?
4 A. I believe they would, yes.
5 MR. BRAHMA: Thank you, Dr.
6 Langer.
7 I have no further questions.
8 But I would like to, just as a
9 housekeeping matter, enter PTX-205, the Nowak
10 reference. PTX-210, the Borges II reference,
11 and PTX-212, the Kathpalia article.
12 THE COURT: All right. Okay.
13 We'll take a break in a second.
14 Doctor, you can step down if you
15 want.
16 THE WITNESS: Okay.
17 (Witness excused.)
18 THE COURT: I just want to clear
19 up now, in terms of the defendants' objection, I
20 wrote down that you objected to JTX-213, 215 and
21 216.
22 Are there any other trial exhibits
23 that you are objecting to?
24 MR. LOMBARDI: Your Honor, my list

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1 from the charts that we're looking at has 213,
2 216, as your Honor said. I believe there was a
3 205, a 212, and a 210.
4 THE COURT: That were offered by
5 Mr. Brahma.
6 MR. LOMBARDI: And that was on the
7 chart. And, so, if I neglected to say it, that
8 is part of our objection.
9 THE COURT: All right.
10 Mr. Brahma, you were offering
11 those six exhibits for what purpose?
12 MR. BRAHMA: The relevance would
13 be to show the state of the art, or state of
14 mind of a person of ordinary skill in the art,
15 with respect to their understanding of the
16 difficulty, the continuing difficulty of
17 achieving drug content uniformity in films, as
18 well as what assumptions they would make when
19 reading prior art references that had no data
20 showing uniformity.
21 THE COURT: So is it case then,
22 you are not offering them to prove any secondary
23 considerations?
24 MR. BRAHMA: There is some -- also

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1 some statements about secondary considerations
2 such as trays from the -- and we are offering
3 them for that purpose.
4 THE COURT: Okay. Well, be more
5 precise, because what I'm trying to do is narrow
6 down what is going to be disputed later on.
7 So you're offering some of these
8 for?
9 MR. BRAHMA: Well, so, for -- yes.
10 For example, your Honor, the Perumal, the
11 Morales article, and I believe the Borges
12 Article refers to -- specifically to the work
13 done in the '514 patent, as both recognizing the
14 problems that caused drug content uniformity, as
15 well as solving those, and basically creating
16 viable pharmaceutical products.
17 THE COURT: Okay. You're offering
18 these for praise, and then there's portions that
19 you are offering to essentially show what the
20 state of the art was at some later point in time
21 that you can infer back? Or are you offering --
22 well, I don't want to make your arguments for
23 you.
24 So I've the praise, and I've got

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1 something to do with the state of the art, is
2 there anything else?
3 MR. BRAHMA: I think those are the
4 two things. And if you want me to clarify the
5 argument about the state of the art, the basic
6 argument is, if it wasn't solved in 2015 or
7 2008, then it sure wasn't solved before 2002.
8 THE COURT: Okay. I think I
9 understand that argument.
10 And your objection to those for
11 argumentative purposes is what?
12 MR. LOMBARDI: Well, with respect
13 to anything going to the obvious -- not to
14 second considerations, but the prima facie
15 obviousness showing is all post-filing.
16 And, so, therefore, it's hearsay,
17 and there's no state of mind issue here.
18 THE COURT: So why is it hearsay
19 if it is post-filing, and not hearsay if it is
20 pre-filing?
21 MR. LOMBARDI: Pre-filing is prior
22 art. And the prior art has a special position
23 in obviousness.
24 As your Honor knows, post-filing

1 does not have that special position. And, so,
2 it just becomes an article written by somebody
3 who's not in court. And, so, therefore it's
4 hearsay.

5 THE COURT: Okay. So that's
6 hearsay.

7 In terms of the secondary
8 considerations, are you not objecting to the
9 extent it's offered for that basis?

10 MR. LOMBARDI: And if I
11 understand, it was the Borges' article PTX-210.
12 I think I knew specifically -- let me address
13 that.

14 I think the Borges one is the one
15 that occurred to me as one that might be
16 secondary consideration. That was something
17 about the success of the product on the market.

18 That has nothing to do with the
19 analysis that this witness did. He was not a
20 market share witness. And it doesn't say
21 anything about the technology.

22 THE COURT: Okay. So that's a
23 relevance objection, right?

24 MR. LOMBARDI: Yes. I'm not

1 stating a hearsay objection to that particular
2 part of the article.

3 MR. BRAHMA: And to the extent
4 there's a relevance objection, I'd note that all
5 of those articles were discussed by Dr. Dyar.

6 So if there are relevant for Dr.
7 Dyar's analysis, I can't see how they won't be
8 relevant for our analysis, just because
9 defendants don't agree with the conclusions,
10 your Honor.

11 THE COURT: Well, did he discuss
12 them only because he knew that you were going to
13 be discussing them?

14 MR. BRAHMA: I mean, they were
15 certainly mentioned in our reports first in
16 terms of the expert reports.

17 THE COURT: Okay.

18 MR. BRAHMA: But then he talked
19 about what they meant.

20 THE COURT: All right.

21 So there's a hearsay objection to
22 the state of the art purpose for which you
23 offered them, and there's -- and your response
24 to the hearsay objection, I'm getting from what

1 you said beforehand, is essentially experts use
2 these kinds of things.

3 Is there any other --

4 MR. BRAHMA: That's right. And
5 just to clarify on the secondary factors,
6 because there are a number them, I mean, this is
7 also -- to put it in the classic terminology, I
8 guess, this also talks about the failure of
9 others to solve the problem, right?

10 So we were talking -- it was
11 before I just summarized if they hadn't solved
12 it in 2008, they hadn't solved it in 2002. This
13 is really talking about the failure of others.

14 So, for example, Perumal looks at
15 pre-2002 articles, and notes that the films
16 don't even talk about drug content uniformity.
17 And from that drew the conclusion they must not
18 have had drug content uniformity.

19 That's failure of other evidence.

20 In terms of the argument that the
21 prior part somehow isn't hearsay, but post --
22 post-patent is hearsay, I'm not aware of any
23 case.

24 THE COURT: That's something that

1 you can brief later on.

2 Is there anything some else that
3 you want to say?

4 MR. LOMBARDI: There was one other
5 point that I did make -- I guess I've got two,
6 your Honor.

7 On the failure of others, there
8 was no discussion of failure of others in any of
9 these references with the upon exception of
10 Perumal.

11 That's not what they were offered
12 for. That's not what they did.

13 And in Borges, PTX-210, was not in
14 the witness's expert report, and he never talked
15 about these kinds of secondary considerations.

16 THE COURT: Okay. So not in the
17 expert report. That's not, I don't think, an
18 objection that you made in your Motion in
19 Limine.

20 MR. LOMBARDI: Well, I don't
21 believe that we knew that they were going to
22 present it at trial. I'll check, your Honor,
23 but I don't think we had any notice that they
24 were going to use the document at trial for this

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1 purpose, because it wasn't indicated.

2 MR. BRAHMA: In his expert report

3 at Paragraphs 142 and 143.

4 THE COURT: Okay. So that's on

5 the record.

6 See, and that's part of the reason

7 why it occurred to me that I ought to do

8 something more about this is, because, you know,

9 objections that it's not in the expert report,

10 or objections that are different than what you

11 said in the Motion in Limine, they need to be

12 fleshed out now, at least as to what the

13 parties' positions are, so that if somebody

14 wants to do something about it, they can.

15 So I think I've heard what the

16 parties' positions are. I'm not

17 suggesting you should, Mr. Brahma, but if

18 there's anything, having heard this statement of

19 what the positions are, that you want to do

20 further with Dr. Langer, I'll give you that

21 option when we come back.

22 You don't have to, but, you know,

23 I should have fleshed this out a little more at

24 the time.

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1 MR. BRAHMA: Sure. I'll confer

2 with my team and let you know, your Honor.

3 THE COURT: All right.

4 So we'll take like a 10-minute

5 break.

6 (A recess was held at this time.)

7 - - -

8 THE COURT: All right. Please be

9 seated. Please continue.

10 MR. BRAHMA: Your Honor,

11 Plaintiffs do not have any further

12 questions for the witness.

13 THE COURT: All right. Cross-

14 examination.

15 MR. LOMBARDI: May I please the

16 Court, Your Honor.

17 - - -

18 BY MR. LOMBARDI:

19 Q. Dr. Langer, my name is George

20 Lombardi. I will be asking you some questions

21 on behalf of the Defendants here.

22 A. Nice to meet you.

23 Q. Nice to meet you. Doctor, you

24 have testified in patent cases before; is that

Langer - cross 543

1 right?

2 A. Yes.

3 Q. Generally, you're not a lawyer but

4 you're familiar generally with obviousness and

5 what the analysis is for purposes of the

6 obviousness; is that right?

7 A. Well, I don't want to overstate my

8 qualifications. I have some sense of it as

9 scientist or somebody who teaches people of

10 ordinary skill. But I do not want to overstate.

11 I'm not a lawyer.

12 Q. And you understand at least from

13 your work in this case that when you do an

14 obviousness analysis, what you're really

15 looking at is the claims of the patent in

16 question; is that right?

17 A. Well, again my feeling is you look

18 at the claims in light of the specification as

19 I've understood it and in light of the prior

20 art.

21 Q. Well, let me just ask you: For

22 purposes of what you're determining what you're

23 determining, whether it's obvious or not, are

24 the claims in question; is that right?

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1 A. Well, I stand by my answer.

2 Again, I'm trying to say it as a scientist or

3 somebody who's looking at it through the eyes

4 of somebody of ordinary skill. So to me it is

5 the claims in light of the specification. I

6 don't want to get into a legal argument with

7 you. I'm just going over how I've understood

8 it to answer your question.

9 Q. And I'm trying to make you get

10 into a legal argument. I just want to

11 understand what your analysis was in this case.

12 So you understand that claim 62 of the '514

13 patent was at issue here; is that right?

14 A. I believe that's was one of them

15 among others.

16 Q. Correct, among others. But do you

17 consider this a representative claim?

18 A. It's a claim. I don't know if --

19 again, it's certainly a claim, yes.

20 Q. Well, is it okay if we talk about

21 that claim as an example?

22 A. Anything you want.

23 Q. Okay. Well, let's talk about it,

24 because in obviousness what we want to figure

1 out is what was known in the prior art. That's
2 one of the things we want to know based on
3 what's in the claims; is that right?

4 A. Again, I don't want to get --
5 claims in light of the specifications.

6 Q. Well, you did look at the claims,
7 right?

8 A. I said, yes, of course.

9 Q. So the claims set forth various
10 elements; is that right?

11 A. Yes.

12 Q. Doctor, I don't think we have a
13 dispute about some pretty significant portions
14 of these elements as part of your obvious
15 opinion. Do you agree with that?

16 A. I'm not sure what you're saying.

17 Q. Let me restate it. So there's no
18 -- you don't contend that at the relevant time
19 it was novel to come up with a cast film?
20 That's not your contention, right?

21 A. No, I agree with you.

22 Q. And you agree that it was not
23 novel to use water soluble or water swellable
24 polymers?

1 A. Again, if you're just isolating
2 individual elements, I agree.

3 Q. And you agree there was nothing
4 novel about using an active?

5 A. Again, if we're isolating
6 individual elements, I agree.

7 Q. If you skip down to 2(i) you agree
8 that there was nothing novel about using a
9 particulate active?

10 A. Again, you're only asking that
11 particular phrase and stopping there; is that
12 what you mean? You're taking about the
13 substantially uniformly stationed?

14 Q. Yes, sir, I am.

15 A. If you're taking away that, then I
16 agree.

17 Q. And you agree there was nothing
18 novel about a taste masking agent at the
19 relevant time; is that right?

20 A. Again, we're just isolating
21 individual elements in and of themselves, I'm
22 agreeing with you.

23 Q. And then where it says wherein,
24 you agree that it was not novel to use a

1 particulate active that has a size of 200
2 microns or less; is that right?

3 A. Again, with the same caveats that
4 you and I have been talking about, about an
5 isolation, I agree.

6 Q. There are a lot of references in
7 the claims and I won't pull them up but I think
8 you will know, there are a lot references in
9 the claims to the concept of uniformity. You
10 remember that, right, Doctor?

11 A. I do remember that, yes.

12 Q. Now, there was nothing novel at
13 the time of this invention about a scientist
14 being concerned about the uniformity of a
15 pharmaceutical dosage form, was there?

16 A. We're now excluding a
17 pharmaceutical film dosage form or are you
18 saying any dosage form?

19 Q. Any dosage form.

20 A. I'm not sure how to answer it. I
21 guess I would say if somebody came up with a
22 brand new dosage form -- I just want to make
23 sure we're on the same page. If somebody came
24 up with a brand new dosage form, whether it's a

1 thin film or some other dosage form, there
2 would be concerns. Any time you do something
3 new, there are concerns.

4 Q. Let me put it this way, in 2001 a
5 person of ordinary skill in the art who was
6 making a pharmaceutical dosage form would be
7 concerned with being able to make it uniform;
8 is that right?

9 A. To me that's too narrow an
10 interpretation. They would be concerned about
11 making it do what they wanted it to do. Some
12 cases uniform is not actually not what you want,
13 so it depends on the situation.

14 Q. A scientist who is trying to work
15 on a dosage form to put on the market, Doctor,
16 would want it be uniform; isn't that correct?

17 A. Not always. If you want, I'll
18 give you examples. That is not a correct
19 statement on your part.

20 Q. Well, let me ask you this: The
21 FDA had a requirement, but not -- scientists
22 not only were concerned about uniformity, but
23 they were concerned about getting uniformity to
24 this 10 percent variance level, weren't they?

1 A. In which situation? Some
2 scientists were depending on the dosage form.

3 Q. If a pharmaceutical formulator as
4 of 2002 were pursuing a commercial product,
5 that formulator would have had as his goal
6 being within 10 percent variation, correct?

7 A. It may depend where in the world
8 they were doing it, whether it's the FDA or
9 what. There's different situations so you
10 would have to narrow down the situation.
11 That's all I'm trying to say.

12 Q. You gave a deposition in this
13 case?

14 A. Absolutely.

15 Q. And you were under oath when you
16 gave it?

17 A. Of course.

18 Q. And of course you answered
19 honestly at the deposition?

20 A. Of course.

21 Q. Let's go to page 137 of the
22 deposition.

23 A. Yes. If I remember Pages 136 and
24 137, those questions were asked.

1 Q. Well, let's read it and let's see.
2 Did you give this answer at your deposition.
3 "Question: If a pharmaceutical
4 formulator as of 2002 were pursuing a commercial
5 product, that formulator would have had as a
6 goal being within 10 percent variation, correct?

7 Answer: I would think that would be
8 one of the goals, yes."

9 Did you give that answer to that
10 question under oath at your deposition?

11 A. Absolutely. But the problem with
12 that is you're taking it in isolation.

13 Q. And you were asked the question at
14 your deposition and you gave that answer under
15 oath?

16 A. Of course. But you can't take one
17 page out of the book.

18 Q. Thank you, Doctor.

19 A. Okay.

20 Q. Now, actually at the time, at the
21 relevant time, the folks that wrote the patent
22 also talk about a known level of uniformity?

23 A. Right. That's at my deposition at
24 136.

1 Q. Well, do you recall what the
2 patent says the level of uniformity was that
3 anybody of skill in the art would want to
4 pursue?

5 A. I do remember that and I can go
6 over that. But the way that was written and
7 actually --

8 Q. I just asked you if you remember.

9 A. I remember, yes.

10 Q. Do you remember that it was 10
11 percent?

12 A. We should look at the precise
13 wording, but I do remember that. I remember
14 what they wrote.

15 Q. Okay. Let's go back to Column 2
16 of the patent.

17 A. Do you want to put it up?

18 Q. I'm sorry. We're just getting it
19 up.

20 A. No problem.

21 Q. So Column 2 and let's go down to
22 about Line 40. Let's just go right after where
23 it says FDA.

24 Do you see it says currently?

1 A. Yes.

2 Q. Currently, it's as required by
3 various world regulatory authorities dosage
4 forms may not vary more than 10 percent in the
5 amount of active present. When applied to
6 dosage units based on films, this virtually
7 mandates that uniformity in film be present.

8 Do you agree with the patent's
9 characterization of the state in the art in that
10 regard?

11 A. Yes and no. Would you like me to
12 explain?

13 Q. No. That's what the patent says;
14 is that right?

15 A. Yes. But the FDA says 15 percent.
16 That's also very important to realize.

17 Q. But you're not --

18 A. The statement is correct, but the
19 FDA 15 percent. That's all I'm saying.

20 Q. Thank you, Doctor. Now, we're
21 going back to the claim. And if you need us to
22 blow it up more or you want a particular part
23 blown up, just tell me, Doctor, and we will do
24 it.

1 A. No problem.
 2 Q. But I'm assuming you can see it
 3 okay?
 4 A. I can see it. Plus I have it here
 5 in front of me.
 6 Q. Great. It says -- there is
 7 discussion of viscosity in this patent claim;
 8 is that right?
 9 A. Yes.
 10 Q. And I believe the first mention is
 11 up there by the wherein. Do you see the
 12 reference to viscosity there?
 13 A. Yes.
 14 Q. And it also references -- well,
 15 let's just talk about that. It says, Wherein
 16 said matrix has viscosity sufficient to aid in
 17 substantially maintaining nonself-aggregating
 18 uniformity of the active in the matrix. Do you
 19 see that?
 20 A. Yes.
 21 Q. Now, viscosity is essentially
 22 talking about the thickness of a substance; is
 23 that right?
 24 A. It has to do with -- how are you

1 defining thickness? What do you mean?
 2 Q. Consistency.
 3 A. Constituency?
 4 Q. As far as to water --
 5 A. Thickness this way, you mean? I
 6 think we're on the same page. It has to do
 7 with -- a syrup would be more viscose than
 8 water, for example.
 9 Q. And it says that the goal of
 10 working with this viscosity parameter is to get
 11 a nonself- aggregating uniformity of the active
 12 in the matrix. Do you see that?
 13 A. Yes.
 14 Q. You understand that
 15 nonself-aggregating means that the particles
 16 that are being put in the matrix won't clump
 17 together, for instance?
 18 A. Yes, I agree with that.
 19 Q. So you agree that this claim
 20 doesn't set any specific viscosity levels, does
 21 it?
 22 A. Well, it says the viscosity
 23 sufficient and then it would tie it back into
 24 the 10 percent that we were just talking about

1 at the end of the claim.
 2 Q. But you know there's a measurement
 3 of viscosity, right, a unit of measurement?
 4 A. Sure.
 5 Q. What is that?
 6 A. Well, it could be poise or
 7 centipoise. It depends on what system you're
 8 using.
 9 Q. And it doesn't specify
 10 centerpoise; is that right?
 11 A. I agree with you.
 12 Q. And there's nothing anywhere else
 13 in the claim that specifies a viscosity level;
 14 is that right?
 15 A. Well, again, the way I look at it
 16 is through the eyes of one of ordinary skill in
 17 the art. It's a teaching of a viscosity
 18 sufficient to do that, that ends up giving you
 19 that uniformity of 10 percent, that we
 20 discussed, later on and does the other things
 21 that are talked about in this claim.
 22 Q. And another thing that's mentioned
 23 in the claims is drying, correct?
 24 A. Yes.

1 Q. And let's just find one that
 2 references to drying. Let's go to the wherein
 3 second from the bottom about the third line
 4 down just to give you a reference, Doctor.
 5 There are other references but this is an
 6 example.
 7 It talks about the film forming matrix
 8 is capable of being dried. Do you see that?
 9 A. Yes.
 10 Q. Now, the claim -- in none of the
 11 claims
 12 you looked at specifies parameters for drying, is
 13 that correct, it does not specify?
 14 A. Not parameters. But again, you
 15 would read it in light of the specifications.
 16 Q. But in the claim -- and the claim
 17 is what we're deciding whether this is obvious
 18 or not; is that right?
 19 A. Yes. But again -- again, I'm not
 20 a lawyer. I always thought, and you correct me
 21 if I'm wrong, that you read the claims in light
 22 of the specification.
 23 Q. And my question is, there is no
 24 parameter for drying contained in this claim;

1 is that right?

2 A. Other than reading -- other than
3 one of ordinary skill in the art would have
4 read the patent and understood what's important
5 about drying and what's not important.

6 Q. One other element I want to point
7 out.

8 It's in the next wherein. It says, Wherein the
9 uniformity subsequent to casting and drying of the
10 matrix is measured by substantially poised individual
11 unit doses which do not vary by more than 10 percent
12 of said desired amount of said at least one active.

13 You've read that many times before, Doctor?

14 A. Yes, I've seen it.

15 Q. An it talks about a mearsurement
16 -- is it fair to call it kind of a 10 percent
17 variation measurement?

18 A. I think I know what you're saying
19 and I'm fine with that.

20 Q. But it doesn't specify a
21 particular way of doing the 10 percent
22 measurement in the claim, does it?

23 A. But it does in the specification.
24 They give examples.

1 Q. But it doesn't specify -- well,
2 first, let's take the claim. It doesn't
3 specify in the claim; is that right?

4 A. Again, we're going beyond my --

5 Q. Is it in the claim? That's all
6 I'm asking here.

7 A. Well, if you're just isolating it
8 to that, I think that one of ordinary skill in
9 the art would probably understand what I said
10 about the three-sigma rule, but they give
11 examples in the specifications and that's why I
12 give it --

13 Q. I'm glad you mentioned the
14 three-sigma rule. Actually, the specification
15 doesn't point out a single method of testing for
16 variability, does it?

17 A. I think they do. Let me try to
18 see if I can find this for you.

19 Q. Don't they pick out a number of
20 methods? Doctor, do you remember that?

21 A. Well, they gave specific examples
22 where if you go through the calculations you
23 get -- you can tell that they're basing it on
24 what I said. I can try to find the examples

1 for you.

2 Q. I think I will showing them to you
3 in a little bit. But right now just to
4 understand what you recall about the
5 specification of the patent, is it your
6 testimony that one specific method of testing
7 for variability is what's in -- what the patent
8 calls for? Is that your understanding?

9 A. I thought they were talking about
10 what I was going over, statistical variation.

11 Q. Do you think they talk about
12 statistical variation --

13 A. Maybe I should try to --

14 Q. Because I have limited time, I
15 will let your lawyer find the place. Is it
16 your understanding -- what did you call it,
17 sigma?

18 A. Three-sigma rule.

19 Q. That's discussed in the patent?

20 A. It's not like that, but they give
21 an example. In fact, Table 5 and Column 44, if
22 you go through that, they're talking about four
23 percent based on the average. So if you go
24 through that, I think you will end up with the

1 types of things that I'm saying.

2 And if you go through that analysis on
3 Table 5 you will see that that when you go through
4 the numbers they give you, that if you get four
5 percent, then you're going through that type of
6 analysis.

7 Q. Well, let's put it up. It doesn't
8 say anything about sigma, does it?

9 A. It doesn't use those words, no.

10 Q. And it doesn't say anything about
11 standard deviation, does it, Doctor?

12 A. It doesn't use those words, no.

13 But it does say four percent based on average.

14 Q. And we will talk about the
15 testing, Doctor. But do would you
16 agree with me

17 that the patent specification doesn't say to
18 use this sigma calculation that imposed on
19 Chen?

20 A. It gives an example. That's all I
21 can say.

22 Q. And this is an example, this Table
23 5?

24 A. That's an example. There may be

1 --

2 Q. That doesn't say anything about
3 sigma?

4 A. It doesn't use those words.

5 Q. And doesn't say anything about
6 standard deviation?

7 A. It doesn't use those words,
8 correct.

9 Q. In fact, there are lots of ways --
10 are you aware of the various ways that you can
11 test as according to the specification for
12 variability?

13 A. Well, I'm not sure I understand
14 what you're asking exactly.

15 Q. Well, let's put the patent aside
16 for just a second. There are lots of ways you
17 can measure for content uniformity; isn't that
18 right?

19 A. You mean analytical methods or
20 statistical methods?

21 Q. Any method?

22 A. Basically, what you do -- they
23 give instructions on this, you take the
24 different examples, I can try to find those for

1 you too, you dissolve a way -- the material,
2 the polymer, and then you use an analytical
3 technique to determine what the drug level is.

4 Q. Did you know that the patent uses
5 weight as a means of measuring content
6 variability?

7 A. They mentioned that, but they've
8 mentioned several methods.

9 Q. That's what I'm trying to get at.
10 They mention several methods, don't they,
11 Doctor?

12 A. Well, I think once you realize
13 when you read, it's certainly but not that you
14 would want to use. To be rigorous is a
15 chemical method. That to me is what one of
16 ordinary skill in the art --

17 Q. They mentioned a number of method,
18 Doctor?

19 A. They mentioned visual inspection,
20 they mentioned weight.

21 Q. What the patent says is that one
22 of skill in the art can use whichever method
23 they would like to use?

24 A. Why don't you take me exactly

1 where you're looking at.

2 Q. Why don't we just go here, Column
3 36.

4 A. Okay.

5 Q. It's Line 19 testing for
6 uniformity?

7 A. Yes.

8 Q. And it lists a number of ways it
9 can be checked for uniformity. You can take
10 samples of the film that you can remove and
11 test, you can do film thickness, color, assay
12 and active ingredients and overall appearance
13 may be checked?

14 A. Yes. When I do things myself, I
15 use those things as a starting point. But if
16 I've giving a number, then I'm going to use
17 something like a chemical method and they give
18 them too.

19 Q. Well, we will talk a little bit
20 more about that in a little bit. Well, let me
21 ask you this in particular -- well, can we put
22 up his slide PDX-1711, please?

23 You have testified in this case and I
24 believe this morning, Doctor, what you view as the

1 key inventive part of this patent; isn't that right?

2 A. I talked about that, yes.

3 Q. Now --

4 A. But I think there are several key
5 inventive parts.

6 Q. But you put this slide up and you
7 talked about this, that this is the important
8 part, the key inventive part of the invention,
9 isn't it?

10 A. Yes. And also drying and things
11 like that.

12 Q. Well, let's look at it. So you're
13 quoting from the patent and you say, We'll come
14 to the top one in just a second.

15 A. Sure.

16 Q. Let's take the second one first.

17 Casting dispersion must have viscosity low
18 enough to process but high enough to limit
19 migration and aggregation of active. Do you
20 see that?

21 A. Yes.

22 Q. Now, that is an inventive step in
23 your mind?

24 A. Yes.

1 Q. One that a person of ordinary
2 skill in the art would not be able to come to
3 without the assistance of this patent?
4 A. I haven't seen it in general and
5 all the things that were cited, certainly not
6 in Chen, and certainly not as we noticed, the
7 six future articles that we looked at?
8 Q. So it's clear I'm not limiting to
9 you to what's in writing in an article. I'm
10 asking whether that would not have obvious to a
11 person of ordinary skill in the art?
12 A. It clearly wasn't. Any time
13 somebody invents something, after the fact
14 these things become more simpler.
15 Q. Well, let's see. What it says is
16 casting dispersion and casting is referring
17 when you put the matrix into the cast, you're
18 actually making the film, you're casting the
19 film, right?
20 A. Yes.
21 Q. And casting dispersion must have
22 viscosity low enough to process. Do you see
23 that?
24 A. Yes.

1 Q. That means it has to have a
2 viscosity low enough so you can actually get
3 the film -- the matrix to go into the cast,
4 right? It's got to flow enough to go into the
5 cast, right?
6 A. Yes.
7 Q. Now, anybody of skill in the art
8 would know that you have to have a low enough
9 viscosity to get the matrix into the film,
10 wouldn't they, Doctor?
11 A. I think that part is true. By the
12 way, I think it's also important to realize
13 that you're taking these comments in isolation,
14 which I did.
15 But clearly as I tried to point out in my Direct,
16 you're balancing all these things with other
17 properties you want like release kinetics --
18 Q. Doctor, I'm just working for the
19 slide you put up, right?
20 A. I understand. But --
21 Q. Can I ask you more questions about
22 it?
23 A. Of course.
24 Q. And the second half says, But high

1 enough to limit migration and aggregation of
2 active. Do you see that?
3 A. Yes.
4 Q. So Part 2 of this inventive
5 concept is this viscosity, the thickness, has to
6 be high enough to limit the particles from
7 moving around?
8 A. Yup.
9 Q. And preventing them from
10 aggregating, right?
11 A. Yes.
12 Q. Doctor, wouldn't somebody of skill
13 in the art have understood that the matrix has
14 to be thick enough to prevent particles from
15 flowing?
16 A. After the fact it sounds
17 straightforward, but it's not. People don't do
18 it.
19 Q. I'm talking about at the time
20 somebody of skill in the art -- you have this
21 mixture that you are going to put into a cast
22 and you know there are particles in that
23 mixture.
24 It would take an inventive concept to

1 know that you just want it to be thick so that the
2 particles won't flow?
3 A. Like I said to you, when we first
4 started doing it ourselves when I asked my
5 students --
6 Q. That wasn't my question.
7 A. Well, it is, because --
8 Q. You didn't answer my question.
9 MR. BRAHMA: Your Honor, is
10 Mr. Lombardi going to actually let Dr. Langer
11 answer the question?
12 THE COURT: Sit down. He's
13 fine.
14 THE WITNESS: As I said, he
15 thought it was like breaking glass uniformly. I
16 don't think it was very easy to do, and nobody
17 did it.
18 BY MR. LOMBARDI:
19 Q. What the patent doesn't do is give
20 direction on the exact viscosity that anybody of
21 skill in the art should use to achieve low
22 enough viscosity on the one end and high enough
23 on the other?
24 A. Is that a question or --

1 Q. That's a question.

2 A. It gives you ranges, but those
3 ranges are broad.

4 Q. Huge, right?

5 A. Huge is a relative word.

6 Q. Well, actually, Doctor, what you
7 think is that while you say that this is
8 inventive, you believe that a person of
9 ordinary skill in the art just given this
10 information would be able to figure out what to
11 do; isn't that right?

12 A. I think once you understand that
13 and you understand something about the drying
14 conditions and the particle size, then you have
15 a teaching by which you can do a routine
16 experimentation. Once you're taught the trick,
17 so to speak, of locking in and drying
18 correctly, I think one could, yes.

19 Q. When you say locking in, by
20 locking in, you mean locking the particles in
21 position within the matrix?

22 A. That's part of what you're doing.

23 Q. I'm just asking what you mean when
24 you said lock in. And that's what you're

1 referring to; isn't it?

2 A. Locking in, in such a way that
3 you're controlling, that they really can't
4 migrate anymore and that you can dry it
5 appropriately.

6 Q. Doctor, there is actually
7 significant information in the art at all times
8 prior to 2001 -- I shouldn't say all times, but
9 prior to 2001 concerning viscosity and the use
10 of viscosity to affect the flow of particles;
11 isn't that right?

12 A. There certainly are articles that
13 talk about some of those things, yes.

14 Q. So it was known in the art back in
15 2002 and prior that when you have a suspension
16 like this or you have particles within a matrix
17 that viscosity can affect the movement of those
18 particles. That was known, wasn't it?

19 A. In certain context, but not when
20 you combine the many different things that you
21 had to do to get the film to work.

22 Q. Actually, the claims just talk
23 about viscosity, is that right, not all of
24 these other --

1 A. It talks about the entire
2 combination. You can't isolate different
3 elements. You have to put them all together.

4 Q. Would you agree with me, doctor,
5 that it was well known in the art in 2002 and
6 before how to produce a stable suspension of
7 particles?

8 A. I'd have to see the situation,
9 what you mean by stable and under what
10 conditions.

11 Q. By stable I mean particles that
12 don't move much in the matrix.

13 A. I would have to see the situation.

14 Q. You talked about the Lachman
15 reference, is that right, this morning?

16 A. Yes.

17 Q. Isn't it true that the Lachman
18 reference --

19 A. Well, actually I'm not sure we
20 did.

21 Q. You at least put it up on the
22 screen, I think?

23 A. I did -- no, it was put up on the
24 screen.

1 Q. If I missed that, then I
2 apologize.

3 A. To be correct, I think it was put
4 up on the screen and not discussed.

5 Q. Lachman is a source that's in the
6 prior art; is that right?

7 A. Yes.

8 Q. And you would agree with Lachman
9 that when you have a suspension that has
10 particles in it and a matrix, that those
11 particles can fall in the matrix and aggregate
12 depending on various factors; is that right?

13 That was taught by Lachman; isn't that right?

14 A. Do you want to put Lachman up so
15 we can answer the question?

16 Q. Can you answer the question as I
17 put it?

18 A. I want to take a look at Lachman
19 to make sure we're on the same page.

20 Q. Well, let me ask you generally, it
21 was known prior to 2002 that you can affect
22 particles and whether they're mobile or not
23 within a matrix
24 by -- you can affect that by playing with the

1 viscosity?

2 A. Are you talking about vertically
3 or horizontally or --

4 Q. Either way.

5 A. Again, I would have to see exactly
6 what you're referring and what you were trying
7 to do. I think you're oversimplifying it
8 tremendously.

9 Q. Would you agree that it was known
10 in the art that the parameter most powerful in
11 changing the velocity of the settling of a
12 particle is a diameter or radius and the
13 formulators are best able to control that and
14 the viscosity of the medium.

15 A. So you're talking about settling
16 vertically now?

17 Q. Yes.

18 A. So we're not talking about
19 horizontal movement or any of the other seven
20 or eight parameters that I talked about on my
21 Direct. So you're just talking about settling?

22 Q. Yes.

23 A. Can you read the statement again.

24 Q. Formulators are able to control

1 the viscosity and thereby have an
2 effect on the
3 settling of the particles.

4 A. I think that that's probably fair
5 in isolation. Again, I want to see it in
6 context.

7 Q. In fact, Stokes law you talked
8 about this morning, I think that goes back to
9 1850s or thereabouts?

10 A. That was one of the eight
11 different forces.

12 Q. And Stokes law is actually
13 something that is discussed for several columns
14 in the patent; isn't that right?

15 A. Correct.

16 Q. And that's to discuss the
17 positioning and the migration and things like
18 that of the particles within the matrix.

19 That's why they're talking about in the patent,
20 right?

21 A. Vertically.

22 Q. Right.

23 A. But horizontally, you don't want
24 to ignore that either. That's critical.

1 Q. But I'm talking about Stokes law
2 right and all the elements of Stokes law were
3 well known at the time, meaning 2002 or before;
4 isn't that right?

5 A. I guess I'm not sure exactly what
6 you mean by when you're saying all the elements
7 were well understood.

8 Q. I mean Stokes law, is it fair to
9 call them variables that go into Stokes law?

10 A. Sure.

11 Q. That was all well known in 2002
12 and before; isn't that right?

13 A. You mean the equation of Stokes
14 law?

15 Q. Yes.

16 A. The equation was understood.
17 People are still studying exactly how accurate
18 it is today.

19 Q. And part of the equation was the
20 viscosity of the suspension; isn't that right?

21 A. That's one parameter, but there's
22 other things in the law.

23 Q. There's settling velocity, there's
24 density of particles, there's density of the

1 liquid, there's the radius of particulate, but
2 those are the main elements of the Stokes law?

3 A. Those are amongst them, yes.

4 Q. And Stokes law is used by
5 scientists and was used by scientists before
6 2002 to help determine the falling of particles,
7 for instance, in a suspension, right?

8 A. So again, to look at vertical
9 falling in a suspension, people looked at those
10 kinds of things.

11 Q. Okay. So before I want to move
12 onto a couple of other things here --

13 A. Sure.

14 Q. -- you went through a series of
15 articles.

16 I just want to give you a reference, Doctor. It's
17 PDX1712. And this is just to remind you, Doctor, of
18 the testimony that you gave.

19 This was a series of what was six
20 articles, these are the articles that were after
21 2002, and you described what you thought their
22 relevance was this morning; is that right?

23 A. I think that's fair, yes.

24 Q. Now, these articles did you choose

1 these articles?

2 A. I chose some, yes.

3 Q. Did you choose all of them?

4 A. Well, I was involved in choosing
5 all of them, yes.

6 Q. Did somebody -- did the lawyers
7 give you articles that went on this list?

8 A. I can't recall all of them. I had
9 one of my associates do a literature search and
10 the lawyers also gave us some. I don't recall
11 which ones were which.

12 Q. Were there some selectivity in
13 putting articles on this list?

14 A. Not really. Let me put it this
15 way: I didn't find any articles from the
16 literature that said anything other than what I
17 am showing you here.

18 Q. Just so we're clear, you're not
19 suggesting that in this post-2002 time frame
20 there's not art showing that people could make
21 a film that had uniform distribution of
22 particles, are you?

23 A. Well, obviously once Yang did
24 that, others did. But keep in mind, there

1 wasn't a product that was developed or approved
2 by FDA until 2009. And article after article
3 including one of your own witnesses keep saying
4 this is a heck of a difficult problem.

5 Q. Let's talk about the article by
6 one of our own witnesses. That's the Morales
7 McConville article?

8 A. Yes.

9 Q. Did you read the entire article?

10 A. I did. I don't have it committed
11 to memory.

12 Q. How long is the article? Is it a
13 long article or short article?

14 A. A medium article. If it was
15 somewhere between 10 and 20 pages. I could be
16 wrong. Do you want me to look that up for you?

17 Q. It's right here. You can pull it
18 up. It's so PTX213. It's about 12 pages.

19 A. That was my recollection.

20 Q. What Dr. McConville and his
21 coauthor, what they did -- the portion you're
22 talking was about one paragraph out of that
23 article; is that right?

24 A. Yes -- well, there may have been

1 other mentions too, but I think what I
2 highlighted was some of that.

3 Q. And that one paragraph is at page
4 191 I believe. And it's the one on the
5 left-hand column. The paragraph says, Since the
6 early development -- and you can see what
7 you're referring to I think was the Yang quotes;
8 is that right?

9 A. Well, I think the whole paragraph
10 is useful when you read it in terms of
11 addressing units under the points that you were
12 making before.

13 Q. What you note, Doctor, is that
14 what's noted here is basically cribbing from the
15 '514 patent, isn't it?

16 A. What do you mean by cribbing?

17 Q. It's paraphrasing what was in the
18 '514 patent?

19 A. Again, as a scientist this is a
20 review article. What review articles do is
21 analyze the literature critically. And to use
22 your words, they rephrase certain things from
23 different patents.

24 They are also talking Schmidt and again pointing out

1 that this -- the quote that I made, they say it
2 higher up. Content uniformity, in contrast to what
3 you're trying to explain to me content uniformity has
4 been a major challenge for the pharmaceutical
5 scientists.

6 Q. Schmidt was also from the '514
7 patent, did you remember that?

8 A. Of course. I pointed that out.

9 Q. My question to you was just isn't
10 it true that this is summarizing information
11 from the '514 patent?

12 A. So the answer is yes. But as I
13 went over in my Direct, this is a review
14 article. What a review article does is exactly
15 what I just said. In other words, it summarizes
16 information from other articles and gives a
17 critical analysis of it and then it's reviewed
18 by people in the field to see if they think
19 that they did a fair job.

20 Q. What this article doesn't do, it
21 doesn't analyze the claims of the '514 patent?

22 A. Of course it doesn't. It's a
23 review article.

24 Q. And I think you said at one point,

1 maybe I misunderstood you, it doesn't
 2 complement the '514 patent; is that right?
 3 A. This particular one?
 4 Q. Yes.
 5 A. This particular article doesn't --
 6 it just states what it states.
 7 Q. Right.
 8 A. It says this is a big problem and
 9 that Yang et al. Went on to overcome it.
 10 Q. He quotes that background but what
 11 he doesn't -- there's no discussion of the Chen
 12 reference?
 13 A. I don't see any reason why there
 14 would be.
 15 Q. Is there any discussion of the
 16 Chen reference, Doctor?
 17 A. Absolutely not.
 18 Q. Is there any discussion of the
 19 Bess reference?
 20 A. No, because --
 21 Q. Is there any comparison of the
 22 claims of the '514 patent to the prior art?
 23 A. No.
 24 Q. Thank you. And that's actually

1 true of all of the six that you put up there on
 2 the screen, none of them analyzed Bess or Chen;
 3 is that right?
 4 A. To me what these people do is that
 5 they are trying to pick the closest things
 6 possible. I don't find Bess or Chen very close
 7 to the '514 patent myself. I don't think one
 8 of ordinary skill in the art would either so
 9 that's why I assume that they weren't put up
 10 there.
 11 Q. My question was were Bess and Chen
 12 considered in any of these references that you
 13 put up on the screen?
 14 A. Not to my knowledge. But --
 15 Q. And there was no analysis of
 16 whether you -- what you deemed to be the
 17 inventive thought, is there any analysis in any
 18 of these references about whether that was
 19 truly an inventive thought?
 20 A. I would certainly say yes. When
 21 you
 22 read --
 23 Q. Let's look at McConville. There's
 24 nothing in McConville that says that; isn't

1 that right?
 2 A. McConville I cited to show there's
 3 been a major challenge and they attribute Yang
 4 to solving that challenge.
 5 Q. And the Perumal thesis just says
 6 the same thing. It's the same kind of
 7 information taking from the '514 patent, isn't
 8 it?
 9 A. Well, no. The Perumal thesis, if
 10 you go to the table, they give a detailed
 11 analysis of all kinds of articles that had been
 12 discussing content uniformity. And if you go
 13 to the table and look at all different kinds of
 14 details and they did experiments themselves, so
 15 they go far, far beyond what you said.
 16 Q. Let's look at what you put up on
 17 the screen. So we have PTX1713. And it just
 18 says, Films suffered from aggregation or
 19 conglomeration of particles, and it talks about
 20 uniformity, and as you say, it's citing
 21 specifically just to the '514 patent, right?
 22 A. At that particular place, but I
 23 also went over the table that analyzed a lot of
 24 literature and I went over their experiments

1 which couldn't get content uniformity either.
 2 You can't cherry pick.
 3 Q. Well, we can talk about cherry
 4 pick later. Let's go to PTX1715. And all that
 5 Noag(ph) is doing here is stating that water
 6 soluble films can have these aggregation or
 7 conglomeration of particles. That's what it's
 8 saying.
 9 A. It's pointing out the problems
 10 again.
 11 Q. And tablets have been around for
 12 centuries.
 13 A. Tablets have been around for a
 14 long time but we're not talking about tablets.
 15 Q. We're still studying problems with
 16 tablets today, aren't we?
 17 A. Sometimes.
 18 Q. People are still writing articles
 19 about tablets today, aren't they?
 20 A. Of course, but not about issues
 21 like that.
 22 Q. Now, Doctor, let me move along
 23 here to another topic. Let's talk about Chen.
 24 You talked about Chen for quite a

1 while during your testimony. You were on the same
 2 page of the Chen patent application?
 3 A. I remember Chen, yes.
 4 Q. I thought you would. And Chen,
 5 you talked about some of the things that Chen
 6 did in the course of that application, right?
 7 A. I'm not sure I know what you mean.
 8 Q. There's no question that Chen is
 9 making a film; is that right?
 10 A. Chen is making a film, yes.
 11 Q. For the delivery of active
 12 ingredients; is that right?
 13 A. In some of the examples, yes.
 14 Q. And making it using polymers?
 15 A. Yes.
 16 Q. And taste modifying agents?
 17 A. In some cases, yes.
 18 Q. And at least one of the
 19 embodiments that they talk about is actually an
 20 opioid?
 21 A. Yes.
 22 Q. And it's a cast film that's being
 23 used there?
 24 A. Yes.

1 Q. Now, the concern in Chen
 2 throughout, there is a concern with having a
 3 formulation that is actually uniform; isn't
 4 that true?
 5 A. Where do you see that?
 6 Q. Well, you disagree I take it?
 7 A. Well, I'm willing to hear what you
 8 have to say. I didn't see that so I'm willing
 9 to be educated.
 10 Q. Let's start by looking at your
 11 chart 1720.
 12 A. Okay.
 13 Q. This is one of the ones you show.
 14 A. Right.
 15 Q. And you agree that Chen is talking
 16 about homogeneity in those first two steps,
 17 right?
 18 A. I don't even want to go overboard
 19 on that. What I said in my Direct is that he's
 20 talking about it in Step 1. And in three of
 21 the four statements that I showed, I don't
 22 think he discussed it in Step 2. And the one
 23 statement that I discussed, it's unclear
 24 depending how you interpret it whether he's

1 discussing it in Step 2 or not. That's what I
 2 said. We can go back to those four statements if
 3 you would like.
 4 Q. But you can see that there were
 5 discussions of homogeneity. And were those
 6 discussions at least consistent, doctor, with
 7 the idea of making a uniform film?
 8 A. First of all, the discussions of
 9 homogeneity by and large are only about making
 10 the polymer homogeneous, not the drug, not the
 11 active.
 12 Q. But my question to you was that's
 13 consistent with making a uniform film, isn't it?
 14 A. I'm not -- I don't know that it
 15 is. If you want to make a -- you're only
 16 talking about dissolving a polymer in a
 17 solution.
 18 Q. If you want to make a homogeneous
 19 film, you need to have homogeneity in Steps 1
 20 and 2, don't you?
 21 A. You need to have homogeneity once
 22 you add the active.
 23 Q. Well, is it consistent when
 24 getting homogeneity when you put the active in

1 to have homogeneity in Steps 1 and 2?
 2 A. I don't know how to answer it.
 3 It's not inconsistent.
 4 Q. That's all my question was.
 5 A. It's not inconsistent.
 6 Q. Let's go back to the whole slide.
 7 You said there's nothing about homogeneity in
 8 Steps 3 and 4.
 9 I want to ask you in Step Five, isn't it
 10 clear that what Chen wants is to have individual
 11 dosage units that are the same dosage?
 12 A. I don't know. Where do you see
 13 that?
 14 Q. Let's look at page 16 of Chen.
 15 A. Okay. Where is that?
 16 Q. It's JTX187.
 17 A. Okay.
 18 Q. And up at the top it says, For
 19 example, the cast --
 20 A. Where are you?
 21 Q. At the top where --
 22 A. Oh, I see. For example, the cast
 23 film can be die cut?
 24 Q. Yes. So this is talking about

1 cutting the film after it's been cast, right?
 2 A. Yes.
 3 Q. And it may be cut into a size that
 4 contains, for example, a single dosage unit,
 5 right?
 6 A. Yes.
 7 Q. So Chen is interested at least in
 8 making dosage units that have uniformity, isn't
 9 he?
 10 A. Where do you see that? Where does
 11 he say uniformity?
 12 Q. Well, he wants to make a size that
 13 contains a single dosage unit, right?
 14 A. Right. But where does that
 15 discuss uniformity or what the uniformity
 16 should be?
 17 Q. Well, you don't see the word
 18 uniformity, right.
 19 A. I don't even see anything that
 20 even indicates it.
 21 Q. So you think he just wants cut a
 22 size that would end up with multiple different
 23 uniformities?
 24 Is that what somebody with skill in the art would do

1 in this area?
 2 A. Well, first of all, it's a she.
 3 And secondly, you can't tell -- what Chen is
 4 trying to do in my opinion as I discussed
 5 earlier is trying to establish a principal of a
 6 system that has --
 7 Q. So you can't tell whether Chen
 8 here assumed a person of skill in the art would
 9 be interested in developing a film that has
 10 uniformity from dosage unit to dosage unit? A
 11 person of skill in the art you can't tell
 12 whether they would be interested in that during
 13 this time period?
 14 A. Two or three points, she might
 15 well be but she never talks about that. Just
 16 like I was interested when I mentioned early on
 17 in my Direct about trying to come up with the
 18 dosage form and release an angiogenic
 19 inhibitor. I was far more concerned that I
 20 could release it for a period of time than I
 21 was that it had a certain reproducibility.
 22 Q. And this it says for example, a
 23 dosage unit may include a film size with to a
 24 particular surface area that contains a dosage

1 of active agent in the range of 20 to 250 mg.
 2 You read that as saying they're only interested
 3 in making one single dose, not trying to get
 4 uniformity?
 5 A. I don't think you can tell from
 6 that. And I don't think you can be mind reader
 7 of what she's interested in or not.
 8 Q. I'm talking about what of one
 9 skill in the art would --
 10 A. I agree.
 11 Q. The size of the film may be varied
 12 according to dosage required. The dosage
 13 contained in each square centimeter is selected
 14 according to the active ingredient. When a
 15 person of ordinary skill in the art is
 16 developing a film system at this point in time
 17 would be interested in making sure that the
 18 dosages that they cut out the film have the same
 19 active.
 20 A. It depends on the situation. You
 21 have to look at the situation they're trying to
 22 do and what their goals were.
 23 Q. Now, I think you mentioned -- if
 24 we go back to page 15 for just a second.

1 A. 15 of Chen?
 2 Q. Same document. And I'm going to
 3 put it up on the screen. I think this is
 4 something you commented on earlier, the
 5 paragraph at the bottom of that page, doctor.
 6 You can see again the reference to uniformity.
 7 Do you see that?
 8 A. Where are you?
 9 Q. It starts at the top, in an
 10 embodiment of the invention, the solvent
 11 casting method involved a natural or synthetic
 12 hydrocolloid that is completely dissolved or
 13 dispersed in water, et cetera. In addition to
 14 the active agent and hydrocolloid, any of the
 15 ingredients listed above may be added and
 16 dispersed or dissolved uniformly in the
 17 hydrocolloid solution. Do you see that?
 18 A. Yes, that's one of the things we
 19 discussed before. I remember you brought that
 20 up on your Cross.
 21 Q. And you can see is it really
 22 possible to read as indicating that that the
 23 active ingredient is dissolved uniformly. It's
 24 uniformly throughout that particular solution,

1 right?

2 A. I said either way. But even if
3 you took the case that you want to put forth,
4 then that is Step 2. It doesn't deal with
5 Steps 3, 4 and 5 in my flowchart.

6 Q. But you need to do this. You need
7 to have that homogeneous mixture if you're
8 going to make a uniform --

9 A. Homogeneous mixture of the drug.

10 Q. Correct?

11 A. That would be critical in my
12 opinion that a homogeneous mixture of the drug
13 at Step 2.

14 Q. Okay. So --

15 A. Not at the other steps.

16 Q. And it goes on to say that the
17 homogeneous mixture, it talks specifically
18 about the viscosity; isn't that right?

19 A. They mention the viscosity. But
20 of course as you read the whole patent, what
21 you see is the viscosity, the reason they're
22 interested in it has to do with mucoadhesive
23 property. It's not --

24 Q. But I'm just talking about right

1 here it's talk the viscosity, right?

2 A. Oh, absolutely.

3 Q. And it goes on to say that it
4 makes this dosage and it says, the
5 manufacturing process for forming the dosage
6 unit is illustrated in Figure 2. Doesn't that
7 indicate to you that they're making a dosage
8 unit. Meaning, a unit that has the desired
9 dose on it for administration to a person?

10 A. I don't understand the question.

11 Q. Okay.

12 A. It says what it says.

13 Q. Well, actually you do know that as
14 part of Chen's work, Chen did actually give
15 some of the film that she made to humans; isn't
16 that right?

17 A. There was a human pharmacokinetic
18 study, is that's what you're asking. I don't
19 know if she did it herself or what.

20 Q. But it's reported in the patent
21 that the drug was given to humans; isn't that
22 right?

23 A. That's correct.

24 Q. That means that you're making more

1 than one dosage form?

2 A. Yes, I agree with that.

3 Q. And certainly, if you're a person
4 of skill in the art, you would want in your
5 manufacturing process to be making something
6 that has a uniform dosage; isn't that right?

7 A. I think when you -- my experience
8 when you do a very simple clinical trial, of
9 course you would like things as close as
10 possible. But the goals are much more lenient
11 when you do six patients. And this wasn't even
12 an FDA approved trial. It may have been done in
13 a different country. I don't know but. The
14 leniency when you're trying to do an early test
15 on humans is enormous. It's not anywhere near
16 15 percent. It certainly doesn't have to be.
17 So you can't conclude there what you're trying
18 to say, I believe.

19 Q. I want to look quickly at Figure
20 5, Doctor, if we could and maybe we will take
21 one of your charts. That might be the easiest
22 way to do it.

23 A. Sure.

24 Q. I think it would be 1724 or so.

1 A. Okay.

2 Q. We will just use this. Do you see
3 it?

4 A. Yes.

5 Q. You talked about this, this
6 morning. The base of this is Figure 5 from
7 Chen; is that right?

8 A. That's correct.

9 Q. And so what we see here is in Chen
10 you've already taken one of the four actives
11 that Chen was testing off the chart by the time
12 you got here, right?

13 A. Because it hadn't reached even by
14 any standard what --

15 Q. Right. I'm just trying to make
16 sure for the record it's clear. We're not
17 looking at the actual chart. You've taken
18 something off?

19 A. That's fair, yes.

20 Q. The one that you left behind, what
21 you're getting is results that are plateauing
22 around the 100 percent mark; is that right?

23 A. Let me just say we're making

24 assumptions that it appears to plateau. I

1 didn't do statistics on that, but I'm not
 2 disagreeing with you.
 3 Q. And doctor, when you do these bars
 4 that extend on either side, there should be
 5 bars for each one of the doses that you're
 6 testing?
 7 A. Correct.
 8 Q. And so theoretically, we should be
 9 able to find eight of those as the Judge called
 10 it, nails? They look like their nails to be
 11 hammered down?
 12 A. I understand your question.
 13 Q. So because some of these dosage
 14 forms are overlapping we can't see all of the
 15 horizontal lines that make up these bars; is
 16 that right?
 17 A. You can't see it on this, no.
 18 Q. And it looks like --
 19 A. That's part of what I said when I
 20 say we have to make certain assumptions early
 21 on.
 22 Q. Understood. If you look at this,
 23 there is one set of those bars that is higher
 24 than the others, isn't it?

1 A. Again, you mean the one at 8
 2 minutes? Is that what --
 3 Q. This is what I mean, if you take
 4 the one going across -- there's one that seems
 5 to be above the others going all the way
 6 through, right?
 7 A. Possibly. I have to go back to my
 8 initial notes. I'm not sure it's the same
 9 point. In fact, I don't think it is.
 10 Q. But at any rate, if you say, for
 11 instance, at the 10 if you took that top bar
 12 out, that would be associated with one of the
 13 dosages, right?
 14 A. I don't understand the question.
 15 Q. So we talked about how those bars,
 16 you're going to have bars with two horizontal
 17 lines surrounding each of the dosage forms,
 18 right?
 19 A. Okay. I think I understand what
 20 you're saying.
 21 Q. And you agree with that, right?
 22 A. You're saying from each point
 23 you're going to have a bar with -- and there's
 24 going to look like this?

1 Q. Yes.
 2 A. I think we're on the same page.
 3 Q. And you agree with me that's how
 4 normally it would be portrayed?
 5 A. Yes.
 6 Q. Now, there's one if you look over
 7 at 10, it might be close to 110 percent. But
 8 certainly all the other bars are below the 110
 9 percent; isn't that right?
 10 A. Where are you?
 11 Q. If you can --
 12 A. You're talking about the standard
 13 deviation?
 14 Q. Yes, right there.
 15 A. So not the --
 16 Q. There's a top horizontal bar. Do
 17 you see that?
 18 A. Yes.
 19 Q. So that's one of the dosage forms,
 20 right, and that's kind of close to 110 percent
 21 if you eyeball it?
 22 A. If you're talking about standard
 23 deviations, not the variation that we're talking
 24 about.

1 Q. Right?
 2 A. If you're talking about standard
 3 deviation.
 4 Q. Yes?
 5 A. Standard deviation in that case
 6 looks to be about 110 percent.
 7 Q. And the rest of the bars are less
 8 than 110 percent in that example?
 9 A. For the standard deviations.
 10 Q. Right?
 11 A. For standard deviations you're
 12 saying.
 13 Q. Correct?
 14 A. I just want to make sure we're on
 15 the same page.
 16 Q. Yes?
 17 A. Well, actually it looks to me like
 18 two of them are above 110 percent.
 19 Q. Let's just start with No. 10.
 20 A. To me for standard deviations, 10
 21 looks to be just below it. Eight minutes looks
 22 above it. I would say seven minutes looks
 23 above it. I'm having trouble judging six
 24 minutes. They're basically touching it to me

1 at four, five and six minutes.
 2 Q. For each minute you found one bar
 3 that was either touching or slightly above or
 4 close to that 110 percent mark; isn't that
 5 right?
 6 A. On standard deviations.
 7 Q. Right?
 8 A. On standard deviations, I can't
 9 tell right now without my notes in front me
 10 whether it's one bar or more.
 11 Q. Now, doctor, at least you can say
 12 on the -- strike the question. I will move
 13 forward.
 14 A. Sure.
 15 Q. Doctor, in a patent there were a
 16 few examples were there was testing done on
 17 content uniformity; am I right?
 18 A. Which patent are you talking
 19 about?
 20 Q. The; 514 the patent-in-suit that
 21 we're talking about.
 22 A. Okay. I will go to that.
 23 Q. I will put it up on the screen.
 24 So there's an example here in Column 47. Just

1 to give you a frame of reference, doctor, I
 2 will go back to Column 46 so you can see the
 3 bottom. That's not going to be a particular
 4 issue here, but so you can see where we are.
 5 This is talking about Example X to AA. Do you
 6 see that?
 7 A. Examples X to AA in Column 46,
 8 yes.
 9 Q. I'm just giving you a frame of
 10 reference. Then we go over to Column 47 and we
 11 talk further about that, correct?
 12 A. Yes, that's are part of examples X
 13 to AA.
 14 Q. And they talk about the results in
 15 the last paragraph at the bottom of the
 16 left-hand side. Do you see that generally?
 17 A. I'm just trying to make sure we
 18 are on the same part.
 19 Q. I will give you a specific line
 20 reference, doctor, I'm looking at. Let's look
 21 at Line 56.
 22 A. Okay.
 23 Q. It says the dried film was .005
 24 inches thick by 5 ml and was cut into a certain

1 size pieces weighing 70 mg plus or minus 0.7 mg,
 2 right?
 3 A. Yes.
 4 Q. And then it says demonstrating a
 5 uniformity of a composition of a film. Do you
 6 see that?
 7 A. Yes.
 8 Q. So this weighing of the pieces is
 9 what demonstrates the uniformity of the
 10 composition of the film in this example?
 11 A. In this example, that's what
 12 they're using, yes.
 13 Q. So you would agree with me, we
 14 talked about this earlier, but weighing the film
 15 is a way of determining composition and one
 16 that people of skill in the art would be
 17 familiar with; is that right?
 18 A. They would. But personally, when
 19 I read it I think one of ordinary skill in the
 20 art would do everything including chemical
 21 composition, but this is certainly an
 22 indication of that.
 23 Q. And then is what they did in the
 24 patent?

1 A. This example in this particular
 2 instance this is what they did, but I don't
 3 view that as exclusive.
 4 Q. And you talked about the Bess,
 5 B-e-s-s, reference, right?
 6 A. Yes.
 7 Q. That's at JTX184. I want to go to
 8 that.
 9 And Bess, it's another example of making a film with
 10 an active ingredient; is that right? I'm talking
 11 about in a general sense, Doctor?
 12 A. What do you mean in a general
 13 sense.
 14 Q. I'm just trying to give a frame of
 15 reference to the Court of what Bess involves.
 16 It involves the technology of making films with
 17 active ingredients for administration to
 18 humans; is that right?
 19 A. Yes.
 20 Q. In Bess -- let's see if we can
 21 find an example. Let's go to Column 12 where
 22 the examples begin.
 23 A. Okay.
 24 Q. It's on the screen, not in your

1 slide.

2 A. Okay.

3 Q. So this is just the example

4 section and if you want it in front of you,

5 it's JTX184.

6 A. Yes, I have it.

7 Q. So you recognize this as Bess

8 actually formulating a film; is that right?

9 A. Yes.

10 Q. And he talks about making various

11 preparations mixing them together, right?

12 A. Yes, I talked about that on my

13 Direct.

14 Q. And there's one spot where there's

15 mixing. Do you see that in C?

16 A. Yes.

17 Q. And then there's a combination in

18 D of some more elements?

19 A. Yes.

20 Q. And then in E there's more

21 thorough mixing?

22 A. What do you mean by more thorough

23 mixing?

24 Q. Well, it's more mixing, but they

1 call it thorough mixing; is that right?

2 A. That's what they say, yes.

3 Q. And then in F, they talk about

4 putting a dextromethorphan. That's an active

5 ingredient; is that right?

6 A. Yes.

7 Q. So then they added that in with

8 mixing. Do you see that?

9 A. You mean the first sentence of F?

10 Q. Yes, that's correct. So all that

11 mixing, Doctor, is it at least consistent --

12 it's not inconsistent with making a uniform

13 film, right?

14 A. I think it goes to what we said

15 before, you can be up to Step 2 in my flowchart

16 and it's not inconsistent with that. It's not

17 necessarily consistent with it either.

18 Q. Okay. Let's go to the next

19 paragraph. And now it talks about preparation

20 F. They are actually ready to put it into the

21 mold, right?

22 A. Let me take a look. Preparation

23 F, yes.

24 Q. They've got it all mixed together

1 and they're going to pour on the mold and cast

2 the film et cetera. Do you see that?

3 A. Yes.

4 Q. You can see if you go down it was

5 dried under warm air, so that drying element is

6 there again?

7 A. Yes. But unlike the '514 they pay

8 no attention to really the key issues about

9 drying. That's just a very general statement.

10 Q. And look at the very end of that

11 paragraph where it says a weight -- it gives

12 the weight, doesn't it?

13 A. Yes.

14 Q. Weight plus or minus 3mg; is that

15 right?

16 A. Yes.

17 Q. That's within 10 percent?

18 A. The weight -- now, we're talking

19 about a standard deviation or --

20 Q. No. I'm talking about -- you just

21 looked at the weight in the patent of the '514?

22 A. Right.

23 Q. They said that determined content

24 uniformity, right?

1 A. Well, let's go over the exact

2 numbers.

3 Q. Doctor?

4 A. Yes.

5 Q. The weight reported here is 70 mg

6 plus or minus 3, isn't it?

7 A. If that's a standard deviation,

8 then you use that three-sigma rule and you will

9 be up to 70 minus 9.

10 Q. '514 didn't say anything about

11 using the standard deviation in the example we

12 talked about it, did it?

13 A. Let me go back to the example.

14 Q. We will let the record stand on

15 whether it's there or not there.

16 A. Okay. I'm fine with that.

17 Q. This says a weight of 70 plus or

18 minus 3mg, right?

19 A. Right.

20 Q. That indicates a variation of less

21 than 10 percent?

22 A. I don't agree with that.

23 Q. That's exactly the kind of

24 measurement they used in the patent?

1 A. But that's not standard deviation.
 2 Q. It doesn't say standard deviation
 3 there?
 4 A. Well, it doesn't say anything.
 5 Q. Well, let's go back to the patent
 6 and Column 47 just to wrap this up, Doctor. A
 7 weight of 70 plus or minus 3, do you see that?
 8 A. Yes.
 9 Q. Let's go back to Column 47.
 10 A. Where are you exactly?
 11 Q. I'm getting there. It's the '514
 12 patent.
 13 A. Okay. It's 70 mix plus or minus
 14 0.7.
 15 Q. Let me get it up on the screen.
 16 It says pieces weighing 70 mg plus or minus 0.7
 17 mg, no more information, no less information
 18 provided in Bess.
 19 A. Well, that's a big difference.
 20 One is way less than 10 percent. And that's
 21 more than 10 percent if you use the three-sigma
 22 rule which I expect people to do. But beyond
 23 that, this is just one test that they are
 24 giving you as an indication.

1 Q. That's what the people did in the
 2 patent in this example, right?
 3 A. In this one particular case.
 4 Q. No sigma conversation here?
 5 A. You can do that.
 6 Q. Nothing about sigma?
 7 A. It's still less than 10 percent.
 8 Q. Nothing about sigma, sir? Can you
 9 answer my question.
 10 A. It's --
 11 Q. I would just like you to answer.
 12 A. In that particular statement,
 13 there's no mention of sigma.
 14 Q. Let's go back to Bess.
 15 A. Bess' variation is quite a bit
 16 higher. If you do standard deviation, one will
 17 be 1 percent and the other will be about 3 or 4
 18 percent.
 19 Q. Thank you, doctor. But that's not
 20 in the patent that we just looked at, right?
 21 A. Well, you're looking at isolated
 22 places, sir.
 23 Q. And it's not in Bess right there,
 24 is it?

1 A. You're looking at isolated places.
 2 You have to look at the patent as a whole.
 3 Q. I'm just asking for an answer to
 4 my question?
 5 A. I'm answering it. I'm agreeing
 6 with you. But I'm saying you're looking at
 7 isolated places and that's not what one of
 8 ordinary skill in the art does it.
 9 Q. Thank you, Doctor. I'm running
 10 out my self-imposed time limit here.
 11 A. No worries.
 12 Q. Let's wrap this up. We were
 13 talking about earlier, Judge --
 14 MR. LOMBARDI: Not Judge. I
 15 apologize.
 16 BY MR. LOMBARDI:
 17 Q. Doctor, we were talking about
 18 viscosity earlier and you said that a person --
 19 let me just ask you and make sure I'm not
 20 mischaracterizing. I want to make a statement.
 21 I want to make sure I'm not mischaracterizing
 22 what you said.
 23 A. Of course.
 24 Q. A person of skill in the art of

1 2002 would not have had any idea that
 2 increasing viscosity could reduce the
 3 aggregation of particles in a matrix?
 4 A. I don't think I said it quite like
 5 that.
 6 We can read back exactly what I said. But my
 7 statement would be that they would certainly not have
 8 been led to do that given all the other
 9 considerations that they have to do and make when
 10 they're developing a novel dosage form that had never
 11 been developed before.
 12 Q. Isn't it true, doctor, that at the
 13 time the '514 patent filed in 2002 persons of
 14 skill in the art were moving viscosity,
 15 changing viscosity in order to prevent
 16 aggregation from occurring in a film
 17 formulation?
 18 A. Where have you seen that?
 19 Q. I'm just asking you.
 20 A. I don't think so.
 21 Q. Well, let's look at the '514
 22 patent.
 23 A. Okay.
 24 Q. Let's go to Column 2.

1 A. Okay.

2 Q. Down there at the bottom you

3 mentioned Horstmann and Zerbe. They were all

4 on your slides. Do you remember that?

5 A. Correct.

6 Q. And it says, Horstmann and Zerbe

7 incorporated additional ingredients, i.e. gel

8 formers and polyhydric alcohol respectively,

9 why, to increase the viscosity of the film prior

10 to drying in an effort to reduce aggregation of

11 the components?

12 A. Right. One of them doesn't even

13 have a drug in it so it's a question of what

14 they really trying to say.

15 Q. This is the '514 patent?

16 A. I agree.

17 Q. And you've read Zerbe and

18 Horstmann?

19 A. Yes.

20 Q. And you agree with the patent

21 applicants, the inventors' description of

22 Horstmann and Zerbe, don't you?

23 A. Well, I think that through their

24 eyes because they were concerned with this

1 issue -- maybe you have read it, but my

2 interpretation when you really read those two

3 patents is they were concerned about at most

4 keeping various components, not necessarily the

5 drug away from each other.

6 If there are particular quotes that

7 you want to take me to in those patents, I'm happy to

8 look at them, but I don't think you will find them.

9 Q. My question is, just simply do you

10 agree with the characterization of Horstmann

11 and Zerbe that appears in the patent?

12 A. I think it's one way to look at

13 it. As I read those patents, it's looking at

14 it through the eyes of somebody who was

15 concerned about these issues. As I said, if

16 you go back and look at Horstmann and Zerbe,

17 I'm happy to look at those with you but I don't

18 think you will find exactly what you're saying.

19 Q. Let's go to your deposition.

20 A. Sure.

21 Q. Let's go to page 151 of your

22 deposition.

23 A. Okay.

24 Q. And up toward the top the question

1 starts and you say yes. My question to you,

2 Doctor, is did you give this answer to this

3 question under oath at your deposition:

4 "Question: I believe you agree with the

5 statement that the '003 Horstmann patent does

6 teach adding ingredients to increase the

7 viscosity in an effort to reduce aggregation of

8 the components of the film?

9 Answer: Yes, I'm not disagreeing with

10 that. I'm just trying to give you a complete

11 picture, but I agree with that statement. I

12 think the way the patent characterizes

13 everything is correct."

14 Is that the answer you gave to that

15 question at your deposition.

16 A. I think that's what I'm saying

17 now. I'm just trying to give you the complete

18 picture.

19 Q. And if we go back, doctor, what it

20 shows is that at a minimum in Horstmann and

21 Zerbe there was a recognition that increasing

22 the viscosity of the film to affect and reduce

23 the aggregation of the components was something

24 that a person of ordinary skill in the art

1 knew; isn't that right?

2 A. I think that an

3 oversimplification. You have to go to those

4 patents and look at specific statements. And

5 those components don't necessarily have to be

6 the drugs, sir.

7 Q. I'm just relying on the people who

8 wrote the patent?

9 A. I agree with you. That's what I'm

10 trying to say, you have to look at the specific

11 statements.

12 Q. And you know that the people that

13 wrote the patent thought that the method that

14 Horstmann and Zerbe used could have been

15 improved upon, right?

16 A. Absolutely.

17 Q. And that's why they filed their

18 patent. It was something they improved upon,

19 they thought, right?

20 A. Well --

21 Q. Well, I don't mean to ask you the

22 intention of the patent people. But they said

23 in the specification here that they thought it

24 could be improved, right?

1 A. I'm not sure I understand what you
2 mean by improved.

3 Q. Well, I think I already covered
4 the point. But my only point here, sir, is
5 their recognition of the inventive concept that
6 affecting the viscosity of the film prior to
7 drying can be used to reduce aggregation?

8 A. Of certain components.

9 Q. Okay.

10 MR. LOMBARDI: No further
11 questions, Your Honor.

12 THE COURT: All right. Thank
13 you. Any Redirect?

14 MR. BRAHMA: Yes, Your Honor.

15 - - -

16 BY MR. BRAHMA:

17 Q. Dr. Langer, I would like to ask
18 you a few different questions about some of the
19 things that Mr. Lombardi asked you about. I
20 will try to be brief but I'm not making any
21 promises.

22 If we go to the patent JTX2, I will
23 start with the last thing he asked you about so if we
24 can pull that up, Column 2 at the bottom.

1 A. Yes.

2 Q. So he asked you about this
3 statement about Horstmann and Zerbe that talks
4 about using gel formers and polyhydric alcohol
5 to increase the viscosity of the film prior to
6 drying in an effort to reduce aggregation of
7 the components?

8 A. Yes.

9 Q. Did either Horstmann and Zerbe
10 show a film that actually achieved content
11 uniformity?

12 A. No. There was no discussion of
13 that there.

14 Q. And do you know whether Horstmann
15 or Zerbe led to any approved drug product?

16 A. I don't believe they did.

17 Q. And going up a little bit in that
18 same column where it talks about the 10 percent
19 uniformity requirement?

20 A. Yes.

21 Q. So this is the sentence starting,
22 For this reason dosage forms formed by
23 processes such as Fuchs would not likely meet
24 the stringent standards of governmental and

1 regulatory agencies such as the U.S. FDA
2 related to the variation of active in dosage
3 forms. Currently, as required by various world
4 regulatory authorities, dosage forms may not
5 vary more than 10 percent in the amount of
6 active present.

7 I know Mr. Lombardi asked you
8 questions about this but he did not allow you to
9 respond. So I would like to ask you what would a
10 person of ordinary skill in the art have interpreted
11 those sentences to mean?

12 A. Well, they would interpret the
13 first sentence that for certain dosage forms --
14 again, these cast films had not been approved
15 yet until another seven years, so they would
16 certainly be concerned about whether Fuchs or
17 the other ones would meet what would be
18 presumed standards. These would be what I call
19 an other category.

20 The second sentence is a little bit
21 complex, but as I looked into this, the FDA has a
22 variation of 15 percent, not 10 percent. Some other
23 regulatory authorities may have lower ones, but the
24 way I look at that sentence, given what I know the

1 FDA has, is that certain world regulatory authorities
2 will not allow it to be more than 10 percent, but the
3 FDA would and there's would be 15 percent; and that's
4 true. That's a fact. Anybody can look that up.

5 And that's what I was trying to say.
6 You're right. I didn't get a chance to complete the
7 answer.

8 Q. On that note, Dr. Dyar(ph) and Mr.
9 Lombardi suggested that you might be able to
10 tweak viscosity here and there to increase the
11 uniformity. First of all, would a person of
12 ordinary skill in the art know to do that from
13 the prior art?

14 A. I just don't see how they would
15 know how to do it from the prior art. Like I
16 said, all six references that I cited kept
17 saying well after the 2002 patent, just how
18 difficult and complex this was.

19 In addition as I was also saying to
20 Mr. Lombardi, it's not just tweaking it, because you
21 can't just change one thing. If you change the
22 viscosity, that may help you on certain things. But
23 you really in any of these cases balancing all
24 different kinds of properties. You're balancing

1 release kinetics, you're balancing other kinds of
2 things. You can't just change one thing in
3 isolation. If it was just a one-variable thing, that
4 would be one thing, but it's not.

5 Q. I'd like to ask you a portion of
6 the patent that Mr. Lombardi pointed you to
7 talking about testing for uniformity. It's
8 Column 36 starting at Line 19.

9 A. Okay.

10 Q. Right under the heading Testing
11 Films for Uniformity, and the first sentence
12 says, It may be desirable to test the films of
13 the present invention for chemical and physical
14 uniformity during the film manufacturing
15 process. Do you see that?

16 A. Yes.

17 Q. Does physical uniformity relate to
18 drug content uniformity?

19 A. Well, it's possible. It could be
20 -- yes, physical uniformity could be a
21 surrogate for it.

22 Q. Are there other things that are
23 also encompassed within the term physical
24 uniformity?

1 A. Yes, I would think so.

2 Q. The tests that are described below
3 of film thickness, color, overall appearance,
4 do all of those tests relate to drug content
5 uniformity?

6 A. No, they would not. That would
7 probably be under more of a category of physical
8 uniformity.

9 Q. Now, in Mr. Lombardi's
10 questioning, he asked several times about the
11 three-sigma rule. The '514 patent, did that
12 invent the three-sigma rule?

13 A. No.

14 Q. And you didn't invent the
15 three-sigma rule, right?

16 A. As far as I know.

17 Q. So where did the three-sigma rule
18 come from?

19 A. That's just standard in
20 pharmaceutical practice.

21 Q. Is that a standard principle of
22 statistics?

23 A. Yes. That's what I was showing on
24 the one graph.

1 Q. Does that rule apply whenever
2 someone is using a mean and a standard
3 deviation?

4 A. Yes.

5 Q. So if data is reported in mean and
6 standard deviation format, would a person of
7 ordinary skill in the art know to apply the
8 three-sigma rule?

9 A. Sure.

10 Q. Now, let's go to the data in Bess
11 that

12 Mr. Lombardi was pointing to you. It's JTX184, and
13 the weight test results that he was pointing you to
14 are in Column 13.

15 A. Okay.

16 Q. Starting at Line 1 going through
17 Line 7.

18 A. Okay.

19 Q. So it ends there with the weight
20 results of 70 plus minus 3mg, right?

21 A. Yes.

22 Q. So in that measurement, is 70 the
23 mean?

24 A. Yes.

1 Q. Is 3 the standard deviation?

2 A. I believe so. It's not specified,
3 but I would think so.

4 Q. And if you applied the three-sigma
5 rule to that data, what would the range of
6 weight measurements be?

7 A. 70 plus or minus 9. That's what I
8 was saying to Mr. Lombardi.

9 Q. Does that range of plus or minus
10 9, is that greater than 10 percent?

11 A. Sure. 70 plus or minus 7 would be
12 10 percent.

13 Q. I'd like to take you to Figure 5
14 of the Chen reference. And Chen is JTX187.

15 A. Okay.

16 Q. And Mr. Lombardi asked you about
17 the time points at Time 10.

18 A. Right.

19 Q. Is that the only data that a
20 person of ordinary skill in the art would look
21 at in determining whether the Chen films had
22 drug content uniformity?

23 A. I would think they would look at
24 all the data, if they were going to use this

1 approach at all. Like I said, this approach to
2 me for both sides involves a lot of assumptions.
3 But again, I was trying to pick what I thought
4 were some favorable assumptions in doing an
5 analysis. But somebody of ordinary skill in
6 the art if they were going to do this, they
7 would look at everything.

8 Q. If one was to apply the
9 assumptions that were most favorable to Dr.
10 Dyar, would they still have to look at the data
11 for all of the time points that are steady
12 state?

13 A. I would say they probably look at
14 all the time points at steady state and all the
15 time points that are not steady state. If you
16 have a variation and you're really saying that
17 it's reproducible, then I wouldn't think that
18 the points that are even below that plateau you
19 wouldn't ignore them, and some of those have
20 huge standard deviations, so you would consider
21 all the data.

22 I was trying to take the position that
23 Dr. Dyar was, but somebody would actually take all of
24 the data.

1 Q. In terms of the claims of the '514
2 patent, when they apply this 10 percent
3 uniformity requirement, that's saying that none
4 of the samples that you take of the film you
5 make can be outside of that 10 percent range,
6 right?

7 A. Well they do -- the USP -- I mean,
8 that's true. But they basically have tests
9 where you might do 20 samples and see what
10 happens, something like that. There's specific
11 guidance from the USP on them.

12 Q. If I can move to Stokes law really
13 quickly. This is slide DVX 3.017 from Dr. Dyer's
14 presentation. I will just use the version that
15 he had put up that explains what the different
16 variables are. You mentioned a lot of these
17 variables were changing and I wanted to ask you
18 about that.

19 During the drying process, where it says
20 density of liquid, that's the density of the film
21 dispersion, the dispersion that's being cast; is that
22 right?

23 A. Yes.

24 Q. Does that density of liquid change

1 as the film is being dried?

2 A. Yes. And that's what I was trying
3 to say on my Direct a little bit more too, the
4 density of the liquid changes upon being dried,
5 the viscosity of the liquid changes upon being
6 dried. This is a far more complex thing than
7 just plugging it in because it's a variable
8 over time. Not to mention that it's only one
9 of many things that's happening.

10 Q. Did any of the prior art
11 references that you saw, either the ones that
12 Dr. Dyar is actually relying on or anything
13 else you saw in your investigation talk about
14 how the density or viscosity of the casting
15 dispersion would change in a matter of time
16 during the drying process?

17 A. I didn't see anything about that
18 at all.

19 Q. So is it fair to say then that
20 even the application of Stokes law to the film
21 casting process and drying process was not
22 shown in the prior art?

23 A. I think it's not shown in the
24 prior art, but I still think it's a huge

1 oversimplification because it's one of eight
2 things going on.

3 Q. Last small point, Mr. Lombardi
4 asked you about the discussion of suspensions
5 in Lachman, and that's on PDX 1729.

6 A. Okay.

7 Q. And he suggested that in the
8 context of suspensions, those of ordinary skill
9 in the art knew how to use viscosity to keep
10 active from settling.
11 Do you remember that question?

12 A. Yes.

13 Q. What is a suspension? Can you
14 give me an example of a pharmaceutical
15 suspension?

16 A. A pharmaceutical suspension in
17 contrast to a pharmaceutical film, something
18 like Milk of Magnesia, you shake it up. It's a
19 two-part system and you shake it up before you
20 use it.

21 Q. So that suspension like Milk of
22 Magnesia, is that dried?

23 A. No. It's a -- no, you take it as
24 a suspension.

1 **Q. Why does that bottle tell the**
 2 **person taking the Milk of Magnesia to shake it**
 3 **up?**
 4 **A. Because it settles and isn't**
 5 **uniform. So you shake things up so that you**
 6 **hopefully get a fairly uniform dose right**
 7 **before you take it. It's a very different**
 8 **situation than a film.**
 9 **Q. And finally, Mr. Lombardi asked**
 10 **you about the post-2002 articles and why they**
 11 **don't refer to Bess or Chen and I'm not sure**
 12 **that your response to that could be completed.**
 13 **So I will you again, why wouldn't the**
 14 **post-2002 articles and references that we talked**
 15 **about earlier, why didn't they refer to either the**
 16 **Bess patent or the Chen reference?**
 17 **MR. LOMBARDI: I will object,**
 18 **Your Honor. There's no foundation for**
 19 **this witness to testify as to what**
 20 **particular inventors in those patents**
 21 **thought and did.**
 22 **THE COURT: Why don't you**
 23 **rephrase the question a little**
 24 **differently so he can answer it.**

1 **MR. BRAHMA: Okay.**
 2 **BY MR. BRAHMA:**
 3 **Q. The Bess or the Chen reference,**
 4 **were either of them directed to the problem of**
 5 **drug content uniformity?**
 6 **A. No, they weren't. They both had**
 7 **different goals.**
 8 **Q. Did either the Bess or the Chen**
 9 **reference state that they had achieved films**
 10 **that meant any drug content uniformity**
 11 **requirement?**
 12 **A. Not at all. They just didn't**
 13 **address it one way or the other.**
 14 **Q. Would you have expected either the**
 15 **Bess patent or the Chen reference to have**
 16 **turned up in a literature search that was done**
 17 **post-2002?**
 18 **A. I wouldn't, because when you do**
 19 **literature searches, and we do them all the**
 20 **time, you look for things that are directly**
 21 **relevant to your art.**
 22 **That's why when we did that, we turned up references**
 23 **Perumal and others that really dealt head-on with**
 24 **this issue, not ones that are very peripheral to it**

1 **at best.**
 2 **Q. And in the course of the**
 3 **literature searches that were done, for**
 4 **example, in Perumal, would you characterize**
 5 **those references as being more on point with**
 6 **respect to the issue of drug content uniformity**
 7 **than other Bess or Chen?**
 8 **A. Well, of course. That's what they**
 9 **were directly about. That was their whole**
 10 **point.**
 11 **Q. The other articles?**
 12 **A. Well, certainly Perumal. It**
 13 **depends which article we're talking about.**
 14 **MR. BRAHMA: I have no**
 15 **further questions.**
 16 **THE COURT: Dr. Langer, you**
 17 **may step down.**
 18 **MR. LOMBARDI: Your Honor, I**
 19 **have just two that will be very brief.**
 20 **THE COURT: Are they things**
 21 **that came up during Mr. Brahma's**
 22 **Redirect?**
 23 **MR. LOMBARDI: Yes, Your**
 24 **Honor.**

1 **THE COURT: All right. I**
 2 **will give you a chance.**
 3 **MR. LOMBARDI: Thank you,**
 4 **Your Honor.**
 5 **- - -**
 6 **BY MR. LOMBARDI:**
 7 **Q. You talked about suspension and**
 8 **Lachman and how that's a special area of art; is**
 9 **that right?**
 10 **A. I don't think I said it was**
 11 **special. I just said it was different.**
 12 **Q. Different from the patent; is that**
 13 **what you meant?**
 14 **A. Well, a suspension is just a**
 15 **different dosage form compared to a thin cast**
 16 **film.**
 17 **Q. But actually, the patent talks**
 18 **about what they're working with being a**
 19 **suspension all throughout the patent, doesn't**
 20 **it?**
 21 **A. But they're totally -- it's like**
 22 **apples and oranges. One is a dosage form that**
 23 **you shake before you use it and the other is**
 24 **sort of a means to an to try to create this cast**

1 film.

2 Q. I will show you two things. Let's

3 go to Column 24 of the '514 patent.

4 A. Sure, whatever you like.

5 Q. Let's go to Line 42. And you see

6 there it says a stable suspension is an

7 important characteristic for the manufacture of

8 a premix composition, and it goes on from

9 there, right?

10 A. Yes.

11 Q. And that's in the patent. Do you

12 remember that from being in the patent?

13 A. I can see it there and I remember

14 it.

15 Q. And Lachman there's no doubt

16 provides exhaustive information about

17 suspensions; is that right?

18 A. Well, it's a totally different

19 situation, but I'm not sure what you're asking.

20 But he talks about suspension, yes. But that's

21 the final product this is a step in.

22 Q. And last thing, doctor, you talked

23 about the 10 percent I will call it rule on the

24 FDA and I'm not trying to characterize --

1 A. Sure.

2 Q. It's true, isn't it, that if a

3 pharmaceutical formulator as of 2002 were

4 pursuing a commercial product, that formulator

5 would have had as a goal being within 10

6 percent variation; isn't that true?

7 A. I think it depends on the

8 situation. We talked about that before. We

9 talked about my testimony before. I'm not sure

10 if you're repeating what we said.

11 Q. I think you're right and I didn't

12 remember I asked you about --

13 A. You did. I talked to you about

14 136 and 137 in my deposition.

15 Q. Thank you very much, doctor.

16 MR. LOMBARDI: That's all the

17 questions I have.

18 THE COURT: All right.

19 Dr. Langer, you may step down.

20 THE WITNESS: Thank you.

21 THE COURT: All right.

22 MR. LADOW: We're calling

23 Professor Robert Prud'homme, Your

24 Honor.

1 THE COURT: Okay.

2 THE WITNESS: My name is

3 Robert Krass(ph) Prud'homme,

4 P-r-u-d-h-o-m-m-e.

5 - - -

6 ...ROBERT PRUD'HOMME, having

7 been duly sworn, was examined

8 and testified as follows:

9 - - -

10 BY MR. LADOW:

11 Q. Good afternoon, Dr. Prud'homme.

12 A. Good afternoon.

13 Q. The court already has your CV as

14 JTX10. Could you give the Court a little bit

15 of background about how your experience relates

16 to what we've been talking about in the case

17 today?

18 A. I'm a professor at Princeton

19 University. I've been the president of the

20 U.S. Society of Rheology which deals with

21 polymer flow and rheological properties. I've

22 been the Chair of Dow's Technical Advisory

23 Board on Material Science that gives Dow advise

24 on materials they make including polyoxides and

1 other materials with pharmaceutical

2 applications.

3 I'm currently on their Technical

4 Advisory Board for Formulations so I'm involved in

5 their guiding, their formulations research which

6 includes pharmaceuticals. We have had research

7 supported by and I've been a consultant for major

8 pharmaceutical companies throughout most of my

9 career.

10 A. Thank you.

11 Q. And what area in particular is

12 your expertise?

13 A. My expertise is in polymers and

14 now especially polymers applied to drug

15 delivery.

16 MR. LADOW: We would offer

17 Dr. Prud'homme as qualified as an

18 expert in polymer science in the

19 development of pharmaceutical

20 formulations, Your Honor.

21 THE COURT: All right. You may

22 proceed.

23 BY MR. LADOW:

24 Q. Dr. Prud'homme, you've offered

1 opinions on the '150 patent in this case?
 2 A. Yes, I have.
 3 Q. Are you familiar with that patent?
 4 A. Yes.
 5 Q. I want to go to PDX1803. And if
 6 you could explain what your understanding is of
 7 the polymer profiles that's provided by the
 8 patent?
 9 A. So this is a general overview of
 10 the focus of what the patent teaches about
 11 polymers and the polymer profile. You see it's
 12 talking about the properties when once
 13 balancing fast the solution
 14 of resistance, and it states to obtain these
 15 performance characteristics when one is between 50 to
 16 75 percent and preferably greater than 60 percent of
 17 a low intermediate molecular weight PEO and a small
 18 amount of a higher molecular weight intermediate PEO.
 19 Q. Thank you. Does the term
 20 intermediate molecular weight appear in the
 21 patent?
 22 A. This is a term that I come up
 23 with, Your Honor. In this case, we will talk a
 24 lot about PEOs today and polymers. There are

1 very high molecular weight polyethylene oxide
 2 which were the matter of most of the older art.
 3 And there are very low molecular weight
 4 polyethylene glycol which are generally called
 5 PEGs, so those PEGS have the same molecular
 6 structure but are generally 20,000 of weight
 7 and lower.
 8 The polyethylene oxides of the most of
 9 the prior art is millions of molecular weight higher
 10 and this patent focuses on and directs a person to
 11 this intermediate molecular weight range between
 12 100,000 and 900,000, and that's really the teaching
 13 of this patent. So I call those intermediates.
 14 There's going to be a low intermediate between
 15 100,000 and 300,000 and a high intermediate between
 16 600,000 and 900,000.
 17 Q. All right. And you heard Dr.
 18 Amiji's testimony today in regard to
 19 indefiniteness and obviousness?
 20 A. Yes, I did.
 21 Q. Let's turn to the indefiniteness
 22 issue first. Did you agree with his testimony
 23 that the '150 patent was indefinite?
 24 A. No.

1 Q. Let's go to PDX1824. Dr.
 2 Prud'homme, do you understand this is the
 3 standard for showing indefiniteness in a patent
 4 case?
 5 A. Yes, I do.
 6 Q. And the scope of the claim, a
 7 person of ordinary skill would understand the
 8 scope of the claim with reasonable certainty?
 9 A. Yes.
 10 Q. Is that the standard that you
 11 applied in your analysis?
 12 A. Yes, it is.
 13 Q. In regard to the person of
 14 ordinary skill, you heard Dr. Amiji about the
 15 level of skill of that person. Do you have any
 16 material disagreement with that?
 17 A. No material disagreements.
 18 Q. Let's go to PDX1825. Do you
 19 recognize this is the Court's claim construction
 20 of this case, a portion of it in regards to the
 21 '150 patent?
 22 A. Yes, I do.
 23 Q. Did you apply this construction in
 24 looking at the indefiniteness issue?

1 A. Yes, I did.
 2 Q. Now, Dr. Amiji as you heard
 3 testified that the person of ordinary skill in
 4 the art would not have been able to determine
 5 the scope of the asserted claims with
 6 reasonable certainty.
 7 And to address that, let me ask you, Dr.
 8 Prud'homme, based on the claim and the specification
 9 and the file history of the patent, you reviewed
 10 those?
 11 A. I have reviewed those.
 12 Q. And based on the claim and
 13 specification and the file history of the
 14 patent, do you have an opinion as to how a
 15 person of ordinary skill in the art would
 16 understand the average molecular weight in the
 17 claim?
 18 A. Yes, I do.
 19 Q. Can you explain that?
 20 A. Yes. So the viscosity average
 21 molecular weight or the average molecular
 22 weight, which Your Honor put in the claim
 23 construction and I think is appropriate when
 24 it's talking about averages, and the average

1 which Dr. Conville(ph) talked about yesterday,
2 which Dr. Amiji talked about, is a viscosity
3 average. So I believe that's the appropriate
4 average to be describing these low and high
5 intermediate molecular weights.

6 Q. Thank you. Let's go to PDX1826.
7 What is the significance of this portion of the
8 specification for your analysis?

9 A. So this is from Table 21 and it's
10 describing the PEOs obtained from Dow Chemical
11 Company.

12 Q. Let's go to PDX1827.

13 A. This is a from the file history of
14 a book offered by Flick that was part of the
15 file history and it's talking about the Union
16 Carbide polyox. Union Carbide was purchased by
17 Dow so it's Dow's the polyoxes now. And
18 polyoxes are sold or specified by a grade and
19 it's really characterized in three ways.

20 There's a name, a grade like N10 and
21 that's also another designation of the approximate
22 molecular weight which is another designation to this
23 and then a viscosity range. So they're characterized
24 by these three things and it defines the viscosity

1 average molecular weight.

2 Q. In sum how does this reference in
3 the file history, the Flick reference and the
4 discussion about polyox bear on your
5 understanding of how a person of ordinary skill
6 in the art would understand the claims?

7 A. I think it directs us to a
8 viscosity is a way to measure molecular weight
9 and, therefore, the viscosity average molecular
10 weight defines the molecular weight which is
11 specified in the patent.

12 Q. Now, there's different ways of
13 talking about average molecular weight in
14 various context; is that right?

15 A. Yes.

16 Q. Did you hear Dr. Amiji talking
17 about that earlier today?

18 A. Yes, I did.

19 Q. Let's call up DDX4.011 -- no,
20 let's try DDX4.010. I'm sorry. The one I want
21 is DDX4.013.

22 Do you recall this slide that Dr. Amiji testified
23 about earlier?

24 A. Yes, I do.

1 Q. Now, is the viscosity average
2 molecular weight that's on this slide is that
3 nomenclature of what you're talking about when
4 you say viscosity average molecular weight?

5 A. Yes, that's a nomenclature I'm
6 talking about.

7 Q. And there are other labels or
8 measurements for average molecular weight,
9 there are number average, weight average, z
10 average. Do you see that?

11 A. Yes.

12 Q. Can you explain to us what the
13 difference is between those and let's take them
14 one by one and I will you about each of them
15 separately.

16 So with number average molecular weight,
17 would one of ordinary skill in the art reading the
18 claims of the '150 patent have any reason to read
19 those claims as referring to number average molecular
20 weight?

21 A. No. The number average overweighs
22 the importance of a low molecular weight
23 species and that would not be the average
24 anyone would use.

1 Q. Let's go to the Z average
2 molecular weight. Is there any reason why a
3 person of ordinary skill in the art would look
4 at the claims in the '150 patent and understand
5 them to be referring to a Z average molecular
6 weight?

7 A. No. This average overestimates
8 over -- puts an emphasis on the ultra high
9 molecular weight so that wouldn't be used to
10 specify or characterize the polymers that we're
11 talking about.

12 Q. And this is something that is
13 well-known to a person of ordinary skill?

14 A. Yes.

15 Q. And this is the equation that
16 allows you to calculate these numbers and you
17 know it's going to askew one way or the other?

18 A. That's right. There's no
19 instrument to measure MZ and for
20 these sorts of
21 polymers MN is not measurable for these high
22 molecular polymers. Therefore, those values
23 can only be mathematically calculated. The
24 viscosity average can be experimentally

1 measured with high precision and that's the
2 appropriate measure.

3 Q. When you said, for example, the
4 number average, they can't be measured, what
5 you mean is they can't do a physical
6 experiment?

7 A. There's no experimental apparatus
8 to measure that for these types of molecules.

9 Q. And then the only way you can do
10 it is through GPC for MN?

11 A. One must do GPC and then take that
12 distribution and do the mathematical analysis of
13 that distribution which Dr. Malus(ph) has done.

14 Q. And with respect to weight average
15 molecular weight, is there any reason why a
16 person of ordinary skill in the art would read
17 the claims as necessarily referring to a weight
18 average molecular weight?

19 A. I don't believe so. The weight
20 average molecular weight is very close to the
21 number average. You can see they vary by
22 something like 10 percent for this type of
23 polymer. But the direct and precise
24 experimental technique would be a viscosity

1 average molecular weight. Therefore, I think
2 that's the appropriate one to calculate when
3 one is asking questions about the distribution.

4 Q. In terms of the viscosity average
5 molecular weight, you said you
6 think a person of
7 ordinary skill would apply the claims of the
8 '150 patent.

9 Can you explain to the Court to what
10 extent that is a well-known measurement and why it
11 might be used in the context of the polymers that
12 we're talking about here?

13 A. The viscosity average molecular
14 weight has been around since at least 80 years
15 of some of the early work by the early polymer
16 scientists. It is in the Dow brochure that
17 date from the '80s. They describe calculating
18 intrinsic viscosity and how that's related to
19 the weight average -- or sorry.
20 The intrinsic, how that's related to this viscosity
21 average. So that is demonstrated back in the older
22 Dow brochures. So the concept of viscosity average
23 molecular weight has been around for a very long
24 time.

1 Q. I think we will come back to this
2 slide, but I would like to move for a moment to
3 -- let's try to put back DDX4.011.

4 So, Dr. Prud'homme, do you recognize
5 this as the Dow brochure that Dr. Amiji was referring
6 to?

7 A. Yes, this is the more modern Dow
8 brochure.

9 Q. And it has different grades of
10 polyox, we saw that, and the approximate
11 molecular weight. Can we get maybe the exhibit
12 itself? I think it's JTX30. That's worse so
13 let's go back to the other one.

14 So there's been a lot of testimony,
15 Dr. Prud'homme, and you've been here listening to it
16 in relationship to polyoxide. What is it really and
17 how is it measured? What does it mean, that it's an
18 approximate molecular weight and that's what I would
19 like to ask you a few questions about.

20 A. So it had an approximate molecular
21 weight. You can see they break it down by
22 100,000; 200,000 and 300,000 so for their
23 customers they broke it down to these nice
24 units and chunks and they can buy those of that

1 approximate molecular weight. That doesn't
2 actually represent the exact molecular weight
3 at any particular lot that they sent out.

4 So the precise value of what is the
5 weight average molecular weight of a particular
6 sample has to be determined by it says here a
7 rheological measurement. Rheology is the science of
8 flow and solutions. So you take a dilute solution
9 and measure the dilute solution from which one
10 measures the intrinsic viscosity so that's the
11 rheological measurement one would use to precisely
12 get the weight average molecular weight.

13 Also, there is reference in this
14 brochure to a way in which Dow releases samples or
15 deliver samples to customers and --

16 Q. She's doing that. Doctor, please
17 go ahead. I'm sorry.

18 A. So I'm trying to describe three
19 things, there's a name, WSR80. There's an
20 approximate molecular weight. And then for a
21 particular example, there would be a precise
22 molecular weight determined from this intrinsic
23 viscosity measurement. It's also a very crude
24 measure which will be the viscosity of a 5

1 percent solution.

2 So that's a way in which a customer when
3 they deliver a sample can quickly see is this in the
4 right ballpark, is representative of this sample I
5 bought. And you will see the viscosity measures for
6 the second pair WSR N80. It goes from 55 to 90, so
7 clearly so it's not just a 200,000 molecular weight
8 which is for every sample sent out. There's a range
9 of molecular weights. And this range of viscosities
10 is their release of criteria for customers to accept
11 it.

12 The particular precise molecular
13 weight of that particular sample would be determined
14 by the viscosity average molecular weight.

15 Q. So this is JTX30. Dr. Prud'homme,
16 unpack that a little bit. It's a lot of there.

17 You heard Dr. Amiji testify that the
18 viscosity ranges that are talked about on the right
19 side of the slide there, of the chart that we have
20 up, the 5 percent solution, et cetera, I believe that
21 Dr. Amiji said that these rheological tests were done
22 and that was correlated somehow with the approximate
23 molecular weight that resulted in the table where you
24 have 100,000; 200,000. Did you hear that testimony?

1 A. I heard that testimony.

2 Q. Is that how it works?

3 A. No, that's incorrect. That 5
4 percent solution viscosity says that that
5 sample is a WSR N80 for the person who's
6 receiving it. I've been a consultant with
7 Colgate, for example, and they would receive
8 polymer samples and they would run this test and
9 say, okay, does it fall in the 55 to 90
10 centipoise range of this experiment. And if it
11 did, then they would accept that sample as being
12 this WSR N80 that they purchased from Dow. So
13 this is really a qualification measurement
14 rather than being used to measure a precise
15 molecular weight of that sample.

16 Q. Where did the approximate
17 molecular weight come from?

18 A. Historical, at some point it was
19 measured and defined this product line. So
20 it's retained as a way to identify for
21 customers what the approximate molecular weight
22 range for these samples that they want to buy.

23 Q. Now, Dr. Amiji also talked about
24 that in Dr. Yau's analysis the viscosity

1 average molecular weight was a lower number
2 around 100,000 as compared to the approximate
3 200,000 of the N80, and there's been some
4 discussion about how can that be. Can you
5 comment on that?

6 A. As I said, the approximate
7 molecular weight range is 200,000, is a number
8 that goes back 40 years. So within that
9 designation WSR N80, 200,000 going back 40
10 years, they sold products which satisfied the
11 release characteristics of their customers of
12 55 to 90 centipoise. So this material that Dr.

13 Yau did a precise measurement of would satisfy
14 that viscosity range release criteria.

15 But there's nothing inconsistent with
16 this approximate or nominal molecular weight range
17 specified by Dow, 200,000 and the actual precise
18 viscosity average molecular weight reported by
19 Dr. Yau. Dow will not release any of their viscosity
20 molecular weight average results on individual
21 samples to customers.

22 Q. Dr. Amiji, I believe, was also
23 asked on Direct Examination how would the
24 person of skill going about knowing if a

1 particular polymer sample fell within the range
2 of the claims. Do you recall that?

3 A. Say that again, please.

4 Q. That Dr. Amiji was asked on Direct
5 Examination, how would a person of skill
6 understand whether a particular polymer sample,
7 the molecular weight of that sample fell within
8 the requirements of the claims of the '150
9 patent. Do you recall that?

10 A. Yes, I do.

11 Q. Let me ask you that same question.
12 How do you think a person of skill would go
13 about understanding how to perform that
14 analysis?

15 A. As I understood Dr. Amiji's answer
16 would be he would take this approximate
17 molecular weight value off the bottle and say
18 this is what the molecular weight of that
19 sample is. I believe a person of skill in the
20 art at the time of the invention would realize
21 that one needs a precise number if one is going
22 to try to defend the patent or decide whether
23 there's infringement.

24 So one would use a precise measure of

1 the molecular weight, the viscosity average molecular
2 weight, to determine the exact characteristics of a
3 sample.

4 Q. How would a person of skill go
5 about doing that?

6 A. At the time of the invention, the
7 technique that would be used then and today
8 would be gel permeation chromatography. One
9 needs to look at the entire distribution to know
10 whether there's a component which is in this
11 high intermediate molecular weight and low
12 intermediate molecular weight range. One can't
13 determine whether there's multiple bottles or
14 one bottle. One needs to look at the product
15 and say does this infringe. And one does that
16 by looking at the distribution to see if it
17 satisfies the claim construction which Your
18 Honor defined.

19 Q. And so if you're going to -- if
20 you have to do GPC, do you have to understand
21 the molecular weight distribution?

22 A. That's right. If I'm trying to
23 find out whether there are individual steps
24 that fall under the claims of this patent, I

1 believe one needs to look --

2 MR. SMEREC: Your Honor, we will
3 object to the extent that we're in the
4 invalidity case. The infringement
5 case has closed.

6 THE COURT: I was wondering about
7 that.

8 MR. LADOW: Well, Your Honor, it
9 seems that there is this crossover
10 between their infringement case and
11 their indefiniteness case. And part
12 of that indefiniteness case is you
13 heard on Direct of Dr. Amiji, well,
14 we just don't know what it means, the
15 person of skill wouldn't know what to
16 do, when it comes time to look at
17 infringement, you have all of these
18 molecular weight values and the patent
19 doesn't say what it is. And part of
20 that crosses over between those two
21 and that's why I'm asking

22 Dr. Prud'homme these questions.

23 THE COURT: Well, I will allow it.
24 but I will not allow it to be part of

1 the infringement or noninfringement
2 argument. But for this part, go
3 ahead.

4 MR. SMEREC: Thank you, Your
5 Honor.

6 MR. LADOW: Understood, Your
7 Honor.

8 BY MR. LADOW:

9 Q. Going back to where we were, you
10 need GPC to do molecular weight distribution, I
11 think you said?

12 A. Yes.

13 Q. If you wanted to determine whether
14 you had a polymer sample, a person of ordinary
15 skill that met the requirements of the claims
16 and if you understood the claims, what would
17 you do with GPC in order to determine whether
18 your sample met the requirements of the claims?

19 A. I would do GPC. I would look,
20 therefore, at the distribution of
21 polymers and
22 then the claim construction is are there two
23 different sets of polymers that have this
24 average molecular weight specification.

1 Therefore, I would analyze it according to that
2 criteria and say are there two different sets
3 which would satisfy this lower intermediate and
4 higher molecular intermediate specification.

5 Q. You also heard testimony that GPC
6 is not like going to the drugstore, but it's
7 not as readily available to the consumer. But
8 is it well-established and available in the
9 pharmaceutical analytical space?

10 A. It's a standard analytical
11 procedure, yes.

12 Q. And if you're trying to analyze
13 whether a sample falls within a claim that you
14 do GPC, what steps would you take after that in
15 order to determine whether a person of the
16 ordinary skill was trying to determine whether
17 his sample falls within the claim? What would
18 they do next?

19 MR. SMEREC: Your Honor, I believe
20 it's outside the scope of what was
21 offered on the invalidity case and
22 really is an attempt to use
23 infringement.

24 THE COURT: Well, I will not use

1 it for that purpose so I will overrule
 2 it.
 3 THE WITNESS: Can you state the
 4 question again?
 5 BY MR. LADOW:
 6 Q. Yes. So you need a molecular
 7 weight, you have a molecular weight
 8 distribution, you have to analyze it, you've
 9 done GPC, and now, you're going to try to see
 10 whether the samples you have meet the
 11 requirements of the claims of the '150 patent.
 12 What are you going to do next?
 13 A. What I would do looking at the
 14 claims of the '150 patent I'm directed towards
 15 is there this higher molecular weight component
 16 and is it more than a stray amount. Therefore,
 17 I would will draw it at that 600,000 molecular
 18 weight boundary which is the lower boundary of
 19 the weight and say, is there a stray amount or
 20 not, if I was concerned about that.
 21 And then I would do the averaging of the
 22 components that were in the higher molecular weight
 23 distribution and averaging of the components that
 24 were in the low molecular weight distribution and I

1 would see what that average is as Dr. Yau and Dr.
 2 Lathis(ph) has done.
 3 Q. And you were asked about
 4 partitioning at your deposition; is that right?
 5 A. Yes.
 6 Q. And you --
 7 MR. SMEREK: Your Honor --
 8 THE COURT: Mr. Ladow, I don't
 9 understand how this deals with
 10 indefiniteness.
 11 MR. LADOW: I will move on, but
 12 it's because they have asked as I said
 13 Dr. Amiji if a person of -- on
 14 indefiniteness, not on infringement,
 15 Your Honor. If a person of ordinary
 16 skill has a sample, how do they
 17 understand what to do with it. And
 18 Dr. Amiji said, well, the person of
 19 ordinary skill can understand the
 20 claims and can't understand how --
 21 THE COURT: Well, that's the
 22 question, can they understand the
 23 claims. That's what we're talking
 24 about what do the claims mean. Once

1 we figure that out, I think the record
 2 will be sufficient as to whether or
 3 not they can. But I don't think
 4 that's what you're asking about.
 5 MR. LADOW: I will move on. Thank
 6 you, Your Honor.
 7 THE COURT: Why don't we take our
 8 lunch break and we can come back in an
 9 hour and continue with Dr. Prud'homme
 10 and whatever else we have.
 11 Is there anything you want to
 12 talk about before we take lunch break?
 13 MR. LADOW: No, Your Honor.
 14 (Luncheon recess taken.)
 15 - - -
 16 - AFTERNOON SESSION -
 17 THE COURT: All right. Please be
 18 seated. Dr. Prud'homme can come back.
 19 MR. LADOW: Your Honor, should I
 20 approach now with these or wait until after his
 21 testimony?
 22 THE COURT: I don't know what they
 23 are, but, sure, bring it ON up.
 24 MR. LADOW: It just relates to Dr.

1 Prud'homme.
 2 (Binders handed to the Court.)
 3 MR. LADOW: Shall I begin, your
 4 Honor?
 5 THE COURT: Yes.
 6 MR. LADOW: Thank you.
 7 Could we go back to DDX-4.013? I
 8 just want to make sure the record is clear on
 9 one thing. I may have misheard Dr. Prud'homme.
 10 BY MR. LADOW:
 11 Q. Dr. Prud'homme, viscosity average
 12 molecular weight is typically closest to which
 13 of the other molecular weight averages that are
 14 there?
 15 A. To weight average molecular
 16 weight.
 17 Q. And those two typically tend to be
 18 fairly close?
 19 A. For this class of polymers, within
 20 something like ten percent, yes, they're
 21 relatively close.
 22 Q. And viscosity average molecular
 23 weight is usually not close in these types if
 24 polymers to number average or Z average, the

1 release that you stated earlier?
 2 A. It is not.
 3 Q. Okay. So to conclude in regard to
 4 indefiniteness, Dr. Prud'homme, based on
 5 materials that you have looked at and looking at
 6 the claims and the specification, the file
 7 history, what's your conclusion as to whether a
 8 person of ordinary skill in the art in 2003
 9 would have been able to understand the claims of
 10 the '150 patent with reasonable certainty?
 11 A. I think they would have understood
 12 them with reasonable certainty, yes.
 13 Q. Thank you.
 14 We're going to move on to the
 15 priority issue.
 16 MR. LADOW: If we could call up
 17 DDX-4.018.
 18 BY MR. LADOW:
 19 Q. Dr. Prud'homme, do you recall that
 20 this slide was used during Dr. Amiji's
 21 presentation?
 22 A. Yes, it was.
 23 Q. And it related to the priority
 24 discussion?

1 A. Yes.
 2 Q. And that you understand that we're
 3 talking about in part, U.S. Application 902,
 4 which is JTX-0249?
 5 A. Yes.
 6 Q. And then the question is whether
 7 or not the priority of the '150 patent goes back
 8 to May 28, 2003, based on the contents of the
 9 902 application; is that right?
 10 A. Yes.
 11 Q. And that Dr. Amiji testified that
 12 he located, or he identified three elements that
 13 he was looking for in that application, and he
 14 said the first two were there that he's got
 15 checked off on the slide, but he didn't think
 16 the third one was there.
 17 Did you hear that testimony?
 18 A. Yes, I did.
 19 Q. Did you agree with that testimony?
 20 A. No, I don't.
 21 Q. We're going to turn to the 902
 22 application, but before we do that, could you
 23 just give us a high level view as to the nature
 24 of your disagreement with the conclusion that

1 the 902 application doesn't set forth this third
 2 requirement, which, as I understand it from Dr.
 3 Amiji's testimony, is that the low molecular
 4 weight PEO is 60 percent or more of the PEO and
 5 HCP combination where the PEO has both a lower
 6 and a higher, consists of lower and higher sets
 7 as described in the claim?
 8 A. I think that as Dr. Amiji and I
 9 agree, that the 902 sets forth polymer
 10 components as being PEO and hydroxy cellulose
 11 that describes a low and high molecular weight
 12 PEO component, and I believe the specifications
 13 clearly lay out that this low molecular weight
 14 PEO component should be 60 percent or greater of
 15 the total polymer component. So I think that's
 16 clearly laid out.
 17 Q. All right. Why don't we go to
 18 that. Let's call up JTX-249 at page 30, and see
 19 if we can blow this up.
 20 So, Dr. Prud'homme, do you
 21 understand that this is page 30 of the 902
 22 application?
 23 A. Yes, I do.
 24 Q. And you studied the 902

1 application to see whether or not this, these
 2 elements were present?
 3 A. Yes.
 4 Q. And is there anything that you
 5 think is significant on this issue in the first
 6 paragraph here?
 7 A. Yes. So as being highlighted in
 8 the first paragraph, that it describes POE in
 9 desirably from about 20 to 100 percent by weight
 10 on the polymer component. So it's defining the
 11 polymer component and saying PEO is part of
 12 that.
 13 And then it says, the hydrophilic
 14 cellulose polymer range is from zero percent to
 15 80 percent, and so that's defining a second
 16 polymer which may be a part of the polymer
 17 component.
 18 Q. All right.
 19 A. And it gives a range zero to
 20 80 percent.
 21 Q. Thank you.
 22 And is there something in the last
 23 paragraph you wanted to point us to?
 24 A. Yes. So in the last paragraph, it

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1 says, in some embodiments, it may be desirable
2 to combine a high molecular weight component
3 with a low molecular weight PEO component.
4 Once again, it's identifying that the polymers
5 in the system are, defines this term polymer
6 component.

7 Q. All right. Can we go to the next
8 page of the 902 application, so that's JTX-209
9 at 31.

10 A. Yes.

11 Q. And we've abstracted out two
12 paragraphs here, and why don't we talk about the
13 first paragraph first.

14 A. All right. So they are talking
15 about desirable characteristics, and they say,
16 these can be achieved by combining small amounts
17 of high molecular weight PEOs with larger
18 amounts of low molecular weight PEOs. So there
19 it's describing these two PEO components. And
20 desirably, such competitions contain about
21 60 percent or greater levels of the lower
22 molecular weight PEO in the PEO-blend polymer
23 component. It's talking about the blend polymer
24 component and polymer component has been defined

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1 as PEO plus 8 PMC or HPC, if it is, in fact,
2 there.

3 So I think it's connecting this
4 term that polymer component means all the
5 polymers in the system. And it's saying that a
6 desirable formulation is one that has 60 percent
7 or greater levels. So I think this speaks
8 directly to claim 1.

9 Q. All right. Why don't we go to
10 this bottom paragraph and tell us how that bears
11 on this priority issue.

12 A. The adjacent paragraph says that
13 that film compositions may include about
14 50 percent to 75 percent low molecular weight
15 PEO optionally combined with a small amount of a
16 higher molecular weight PEO, with the remainder
17 of the polymer component containing a
18 hydrophilic cellulosic polymer. So, again, it
19 is identifying the polymer component comprises
20 or may comprise PEO plus HPMC, or plus
21 cellulosic.

22 Q. And let me ask you a couple
23 questions about this paragraph. So when it
24 talks about the 50 to 75 percent of the low

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1 molecular weight PEO, do you understand this to
2 be saying that that 50 to 75 percent low
3 molecular weight PEO is in the polymer
4 component?

5 A. Yes.

6 Q. And would you understand, do you
7 think a person of ordinary skill would
8 understand the phrase, 50 to 75 percent low
9 molecular weight PEO that we see there as
10 including 60 percent or more PEO?

11 A. Absolutely.

12 Q. Let's go on to JTX-249 at page
13 83. It's page 83 of the 209 application.

14 And was there something in this
15 passage that you wanted to highlight?

16 A. So again they're talking about
17 desirable characteristics and polymer components
18 containing about 50 percent or higher levels of
19 PEO, so again they're talking about polymer
20 components.

21 And specifically, in those films
22 containing combinations of varied molecular
23 weight PEOs, those with about 60 percent or
24 higher of the lower molecular weight PEO and it

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1 gives a molecular weight range for that,
2 dissolved faster. It's defining the 60 percent
3 or higher and is including the polymer
4 components, which has always included both PEO
5 and HPMC if that's in the formulation.

6 Q. Thank you.

7 Why don't we go back to the last
8 page we were on, which is page 31 of the
9 application.

10 You now, Dr. Prud'homme, these
11 passages in the 902 application that you've been
12 covering, are they also found in the same
13 language in the '150 patent itself?

14 A. Exactly.

15 Q. And is that shown here on, in what
16 we see is the bottom right from the patent?

17 A. Yes. The top left is what we've
18 been discussing out of the 902. The bottom
19 right is the corresponding section out of the
20 '150 patent that shows are identical.

21 So the inventors, I believe, had
22 described the scope of the invention, had that
23 technology, and therefore included it now in the
24 claims of the '150 the.

1 Q. And this is an illustrative
 2 section where it's the same in the '150 patent,
 3 and that's true for the other passages that we
 4 saw in the 902 application?
 5 A. Yes. Both specifications are
 6 essentially identical.
 7 Q. So having gone through this
 8 analysis of the 902 application, Dr. Prud'homme,
 9 is it your opinion that a person of ordinary
 10 skill in the art in 2003 would understand that
 11 the inventors of the '150 patent as of that date
 12 were in possession of an invention that
 13 corresponded to the claims of the '150 patent,
 14 including that 60 percent or more of the polymer
 15 component would consist of the low molecular
 16 weight of PEO where you could also have HPMC as
 17 one of the polymer components?
 18 A. Yes, I do.
 19 MR. LADOW: Thank you. Thank you,
 20 Dr. Prud'homme. No further questions.
 21 THE COURT: All right.
 22 Cross-examination.
 23 MR. LADOW: Oh, I'm sorry your
 24 Honor. I do have one other question.

1 claims, they still contained -- they've taken
 2 the content of the 902 application.
 3 Q. And the Yang reference was
 4 published in 2005; is that correct?
 5 A. Yes.
 6 Q. And --
 7 A. That's after the 2003 date of the
 8 902 patent.
 9 Q. Thank you, sir?
 10 A. Application. Sorry.
 11 MR. LADOW: To revisit having
 12 concluded the examination, thank you, Dr.
 13 Prud'homme.
 14 THE COURT: All right. Thank you,
 15 Mr. Ladow.
 16 Mr. Smerek?
 17 MR. SMEREK: Thank you, your
 18 Honor. CROSS-EXAMINATION
 19 BY MR. SMEREK:
 20 Q. Good afternoon, Dr. Prud'homme.
 21 A. Good afternoon.
 22 Q. I want to focus on your opinions
 23 on indefiniteness first.
 24 You would agree with me that there

1 THE COURT: All right.
 2 MR. LADOW: Sorry, counsel.
 3 THE COURT: Direct examination.
 4 MR. LADOW: My apologies.
 5 THE COURT: No problem.
 6 MR. LADOW: Could we go for a
 7 moment to PDX- 1822.
 8 BY MR. LADOW:
 9 Q. So is it the case that if your
 10 understanding is the 902 application is the
 11 priority date of the '150 patent, that the '150
 12 patent has a priority date of 2003?
 13 A. Yes, it is.
 14 Q. And if that's the case, would the
 15 Yang reference that you heard Dr. Amiji talk
 16 about be prior art for the '150 patent?
 17 A. It would not.
 18 Q. And why is that?
 19 A. Because in the, the 902 disclosure
 20 has all of the elements that are common to the
 21 '150 patent. It proves the inventors had the
 22 scope of the invention, understood the invention
 23 at the time of May 28, 2003, and therefore when
 24 they filed the '150 patent and added those

1 are multiple ways to characterize molecular
 2 weight known in the art; is that correct?
 3 A. By characterize, do you mean
 4 experimentally, or do you mean to represent the
 5 results of experiments?
 6 Q. I mean just in general, there are
 7 multiple different methods to characterize
 8 molecular weight; is that correct?
 9 A. There are various experiments that
 10 allow one to measure and characterize molecular
 11 weights. There are various ways of reporting
 12 information on distributions to provide
 13 information about molecular weights, yes.
 14 Q. And we have not even today talked
 15 about all of the various ways to calculate or
 16 experimentally determine molecular weight; is
 17 that correct?
 18 A. We have not talked about them all.
 19 That's correct.
 20 Q. And you've been here for the
 21 testimony. You were here yesterday as well; is
 22 that correct?
 23 A. I was here yesterday, yes.
 24 Q. And there has been a lot of

1 testimony about the various ways to calculate
2 experimentally or characterize and determine
3 molecular weights of different polymer samples;
4 is that correct?

5 A. There hasn't been much discussion
6 of experimental techniques. There was
7 discussion of GPC and to analyze the
8 distribution once one obtains it. And there has
9 been discussion about intrinsic viscosity
10 measurements.

11 Q. And intrinsic viscosity, that's
12 the rheological measurements that there has been
13 testimony about?

14 A. That's the rheological measurement
15 or viscosity measurement.

16 Q. And so you would agree with me
17 there are many other ways to characterize or
18 experimentally determine molecular weight?

19 A. There are a finite number of ways.

20 Q. But we have not talked about them
21 all?

22 A. We have not talked about them all.

23 Q. The ones we have talked about,
24 we've heard testimony about numbered, number

1 Peak molecular weight?

2 A. Your expert yesterday, he was
3 questioned, he picked the peak value.

4 Q. Okay. And all of these different
5 methods that we've talked about and others that
6 we have not, they all result in different, a
7 different answer for the molecular weight of a
8 particular sample; is that correct?

9 A. Different analyses will give, for
10 a single distribution will give you different
11 averages, correct.

12 Q. Different average molecular
13 weights?

14 A. Yes.

15 Q. And the patent doesn't expressly
16 identify any specific method to determine
17 molecular weight; is that correct?

18 A. As I've testified, I believe that
19 the patent, because it goes back to the train
20 from Dow materials, Dow specifies materials as
21 viscosity molecular weights and that's the
22 common thing to do. That would be I would say
23 almost universal in my understanding of how to
24 report average molecular weights.

1 average molecular weight; is that correct?

2 A. We have talked about that.

3 Q. And weight average molecular
4 weight?

5 A. We have talked about that.

6 Q. And the average molecular weight?

7 A. Yes.

8 Q. And the viscosity average
9 molecular weight?

10 A. Yes.

11 Q. And there's also peak average,
12 peak molecular weight. That's another way to
13 characterize molecular weight?

14 A. I'm not familiar with people
15 describing peak average molecular weight. I've
16 never seen that used.

17 Q. And, I'm sorry. Peak molecular
18 weight. Not peak average, but just peak
19 molecular weight.

20 A. I'm not familiar with that being a
21 standard term in the polymer science community
22 to determine, to describe molecular weight
23 distributions or polymer averages.

24 Q. Are you aware of that at all?

1 Q. Thank you.

2 But I just want to be clear. The
3 patent itself doesn't specify any specific
4 molecular weight to use?

5 A. I said I think it's because it's
6 so universally accepted, it's implicit.

7 Q. And the patent does not actually
8 say viscosity average molecular weight; is that
9 correct?

10 A. As I just said, I believe it's
11 implicit.

12 Q. And I'm just, if you just answer
13 my question: Does the patent specifically
14 reference viscosity average molecular weight?

15 A. It does not because it's implicit
16 in the, in molecular weight of these sorts of
17 polymers that would be a viscosity average
18 molecular weight.

19 Q. Thank you.

20 And I would like to go there
21 because I understand that it's your testimony
22 and your opinion that a person of skill in the
23 art would know, looking at the patent, that
24 the patent would be discussing viscosity

1 molecular -- viscosity average molecular weight
2 as would be described by the manufacturer; is
3 that correct?

4 A. As would be commonly understood by
5 a person of ordinary skill in the art, yes.

6 Q. And let's go ahead. And I think
7 you got that from the references in the patent,
8 you said?

9 A. Well, also just my general
10 understanding of this field over my career.

11 Q. And I'm not talking about
12 specifically your testimony about what the
13 patent specification describes for molecular
14 weight. It's your opinion that the patent
15 describes viscosity average molecular weight; is
16 that correct?

17 A. What I'm saying is, I believe
18 because it uses the Dow material, Dow material
19 is described in terms of the molecular weight,
20 it would guide one in that direction, but I
21 think that one would end up always in that
22 direction anyway.

23 Q. So just so I'm clear, the answer
24 to my question is that it's your testimony that

1 the patent specification would teach a person of
2 skill in the art to use viscosity average
3 molecular weight as demonstrated by what was
4 reported by Dow?

5 A. Not quite.

6 Q. Okay.

7 A. I --

8 MR. SMEREK: Well, can we look at
9 the patent specification? If I could see Table
10 21, please.

11 BY MR. SMEREK:

12 Q. So now we're showing you Tables 21
13 and 22 from the '150 patent. You've seen these
14 before; is that correct?

15 A. I have seen these before, correct.

16 Q. Okay. And focusing on Table 21,
17 there's a footnote at the bottom of the table,
18 and it says, available from the Dow Chemical
19 Company. And that's a footnote referring to the
20 PEO in Table 21; is that correct?

21 A. Yes, it is.

22 Q. And that's the basis for your
23 testimony that the specification would teach a
24 person of skill in the art that average

1 viscosity molecular weight is what one would
2 look to; is that correct?

3 A. I said that's part of what would
4 direct one to consider how Dow reports their,
5 their viscosity values.

6 Q. And there's nothing else in the
7 patent specification or the patent claims that
8 talk about molecular, the average molecular
9 weight; is that correct?

10 A. Not the average. It gives ranges
11 for the average molecular weight.

12 Q. And there's nothing else in the
13 patent specification except for this footnote
14 here that would tell a person of skill in the
15 art how to compute, calculate, determine average
16 molecular weight as used in the patent; is that
17 correct?

18 A. No. I believe that it would be
19 implicit in this whole field that if I want to
20 report an average molecular weight, it would be
21 a viscosity average.

22 Q. And then looking at what was
23 actually reported or used here in Table 22,
24 Table 22 reports different compositions; is that

1 correct?

2 A. Yes.

3 Q. And it uses or identifies
4 different molecular weights for each of those
5 different compositions; is that correct?

6 A. Yes. Those are the nominal values
7 on the bottles that were used in the experiment,
8 yes.

9 Q. Okay. So the patent, when it's
10 talking about molecular weight in Table 22, is
11 using the molecular weight as you said, the
12 values provided by the manufacturer on the
13 bottles; is that correct?

14 A. Correct.

15 Q. Okay. Now, it's your testimony
16 that you can't rely on the viscosity average
17 molecular weight as reported by the
18 manufacturer; is that correct?

19 A. I didn't say that. What I said
20 was, these values, these nominal values give you
21 guidance as to the approximate molecular weight
22 of that sample, but one would need to measure
23 that if one is asking questions, do I infringe
24 or not. So this would be general guidance as to

1 what the ranges one might expect when one is
 2 doing this design and experiments.
 3 Q. And I just want to understand. If
 4 I'm a person of skill in the art and I see
 5 reported in the patent, Table 21, that I can
 6 look to Dow and I see reported in Table 22 the,
 7 what you would agree is the range of weights
 8 reported by Dow, and now you are telling me that
 9 I can't use that, I have to use a viscosity
 10 average molecular weight that's calculated
 11 somewhere else, how is the person of skill in
 12 the art to know what the average molecular
 13 weight would be in order to fall within the
 14 claims of the patent?
 15 A. I think you might have
 16 inadvertently used a phrase there where you said
 17 Dow reports a range of molecular rates, and
 18 that's the whole point, is they don't tell you
 19 what range a molecular weight is between the
 20 200,000 or the 300 or the 900,000 sample.
 21 They're telling you, this is our placeholder,
 22 this is approximately what it will be. If one
 23 has to ask the precise question what is that,
 24 one needs to measure it.

1 If one needs to say, are there two
 2 sets which have these two different properties
 3 on a sample, one would have to take that set
 4 apart, do the distribution, and look at it and
 5 measure it.
 6 Q. And I'm sorry. I perhaps was not
 7 clear in my question. If you look at Table 22,
 8 it identifies one, two, three, four different
 9 sets, types of molecular weight PEO; is that
 10 correct? It identifies 100,000 dalton molecular
 11 weight; is that correct?
 12 A. Yes.
 13 Q. And 200,000 PEO molecular weight?
 14 200,000 daltons?
 15 A. Yes.
 16 Q. And 300,000 daltons for a PEO
 17 molecular weight?
 18 A. Yes.
 19 Q. And 900,000 daltons?
 20 A. And I think the way you
 21 characterize these as types is the appropriate
 22 way to characterize it.
 23 Q. They're grades of PEOs.
 24 A. Grades or types.

1 Q. From Dow?
 2 A. Yes.
 3 Q. And they reflect those identified
 4 molecular weights as they're sold by Dow; is
 5 that correct?
 6 A. No. The point I just make --
 7 Q. You said no. I just want to
 8 understand. Are those the molecular weights for
 9 the grades that Dow, that Dow reports?
 10 A. No.
 11 Q. So those -- that's fine.
 12 A. May I answer?
 13 Q. Well, you said no, and that's
 14 enough.
 15 A. No. I don't feel that fairly
 16 characterizes my opinion when you ask me a
 17 question.
 18 Q. Well, let's go ahead and bring up
 19 the Dow chart, the Dow brochure, which I believe
 20 is, let's see -- thank you.
 21 And we're looking at the Dow
 22 brochure. And can I get the bottom as well?
 23 You've seen this; is that correct?
 24 A. Yes, I have.

1 Q. And this is the Dow brochure that
 2 we've talked about and they give a molecular
 3 weight; is that correct? An approximate
 4 molecular weight for the various different
 5 grades that a POSA could buy, a person of skill
 6 in the art; correct?
 7 A. An approximate molecular weight,
 8 and I --
 9 Q. Approximate molecular weight.
 10 That's what they say at the top?
 11 A. Yes.
 12 Q. And you can buy them in grades,
 13 including 100,000, 200,000, 300,000. We saw
 14 those in the patent; is that correct?
 15 A. Yes.
 16 Q. And 900,000. We saw that in the
 17 patent?
 18 A. Yes.
 19 Q. So Table 22 in the patent, you
 20 would agree, correlates to the grades that you
 21 can buy from Dow. A person of skill in the art
 22 looking at the patent would know that they could
 23 go to Dow and they could buy these grades that
 24 are -- that are disclosed in Table 22 from Dow;

1 is that correct?

2 A. Correct.

3 Q. And you're saying that they, they
4 couldn't, the person of skill in the art
5 couldn't rely on those grades as identified in
6 Table 22 in determining whether or not they,
7 they infringe the patent?

8 A. I didn't say that.

9 Q. All right. And down here it's
10 correct that Dow reports that these grades are
11 based on rheological measurements; is that
12 correct?

13 A. Yes.

14 Q. And that they're going to vary
15 from other methods that we've discussed for
16 describing molecular weight, including gel
17 permeation chromatography, or GPC; is that
18 correct?

19 A. If you look at the phrase, may not
20 be directly comparable, they're giving
21 themselves some caveat or some room to say that
22 the nominal approximate values are not what one
23 might get from other more precise measurements.
24 And, in fact, for a particular set of, let's

1 say, type 200,000, if one does the accurate
2 molecular weight measurement, one will get a
3 value which is not exactly 200,000.

4 Q. And that accurate weight
5 measurement is a GPC analysis, in your view?

6 A. If one is asking the question
7 about the entire distribution, one can do an
8 intrinsic viscosity experiment, which is done by
9 a rheological measurement, diluting solutions,
10 floating them through a capillary, measuring
11 time to get one number.

12 Q. You were here during the whole
13 part of the trial yesterday and today; is that
14 correct?

15 A. I have been here, yes.

16 Q. You didn't hear any testimony from
17 any of the experts about anybody doing any kind
18 of rheological measurements on any samples; is
19 that correct?

20 A. I --

21 Q. Just, if you -- if you heard it or
22 didn't hear it, I didn't hear anything and I
23 just want to know if I missed something.

24 A. Okay. Based on rheological

1 measurements, what Dr Yau did was a GPC
2 separation and then analyzed each fragment.

3 Q. Thank you.

4 A. Based on rheological measurements,
5 which correlates the intrinsic viscosity to the
6 molecular weight.

7 Q. You didn't hear anybody actually
8 did rheological measurements on a sample of Dow
9 N80; is that correct?

10 A. I did not see intrinsic viscosity
11 measurements that anyone has done, that is a
12 single experimental intrinsic viscosity
13 measurement done --

14 Q. Thank you.

15 A. -- on any sample.

16 Q. I now want to move over into the
17 priority date argument. And I guess just the
18 first question: You offered no opinion in
19 your -- you addressed Yang in your expert report
20 by contending that that reference was not prior
21 art; is that correct?

22 A. That's -- yes.

23 Q. And you offered no opinion in your
24 expert report that if Yang was determined to be

1 prior art, because the priority date shifted,
2 you offered no evidence in your expert report
3 that it, that it wouldn't render the claims, the
4 asserted claims of the patent obvious; is that
5 correct?

6 A. I offered no opinion because it
7 was no prior art.

8 Q. Thank you.

9 If we could go ahead and look at
10 JTX-249. And if we could jump to, I think the
11 page you were looking at was 31 that you said
12 had the description of the 60 percent
13 limitation.

14 And if we could look -- do you
15 remember, it was the top, top paragraph and top
16 two paragraphs and the bottom paragraph, I
17 think.

18 Now, let me just stay here for a
19 moment. And I think you mentioned 60 percent,
20 and you said that in your view, we see
21 60 percent, and you mentioned, you said
22 60 percent was between 50 percent and
23 75 percent; is that correct?

24 A. It is.

1 Q. And that was the basis of your
2 opinion, or at least part of your opinion as to
3 why Yang was not prior art, because 60 percent
4 clearly fell inside of 50 to 75 percent?

5 A. We looked at several of these
6 sections of the specification. I believe that
7 they clearly lay out that the low molecular
8 weight PEO is to be 60 percent or greater of the
9 total polymer component, yes.

10 Q. Well, this does not say 60 percent
11 or greater, does it? 50 to 75? Well, let me --

12 A. I'm looking above. 60 percent or
13 greater levels of the PEO blend. That's the
14 total polymer component. I believe that clearly
15 says it, yes.

16 Q. Thank you.
17 So let's look up at the first
18 paragraph. That's where you were looking?

19 A. Yes.

20 Q. It says 60 percent or greater
21 levels, okay, of the lower molecular weight PEO,
22 so we have that. And then we say, in the PEO
23 blend polymer component. So there it's looking
24 at 60 percent of the low molecular weight PEO in

1 you would agree that 50 percent to 75 percent
2 does not fully describe the range of 60 percent
3 or greater; is that right?

4 A. No. I believe it does. And --

5 Q. Well, so let me explore that.

6 So if I had 80 percent low
7 molecular weight PEO, would, in your opinion,
8 your expert opinion, would 80 percent low
9 molecular weight fall within the claim of
10 60 percent or greater that we see in the
11 patent?

12 A. I believe that second paragraph --

13 Q. I'm sorry. Right now I'm talking
14 about the patent. Would the limitation of
15 60 percent or greater, would 80 percent low
16 molecular PEO fall within the limitation of
17 60 percent or greater?

18 A. If it satisfied all three of those
19 elements of the, of the patent claims.

20 Q. Thank you.

21 A. Both PEO, possibly HPMC, high and
22 low molecular weight set and 60 percent or
23 greater, it would fall within the claims I
24 believe.

1 the blend of low and high molecular weight PEO;
2 is that correct?

3 A. I interpret polymer component as I
4 showed in several places to mean whatever
5 polymers are there.

6 Q. Okay. But in this particular
7 sentence, it's only disclosing the PEO blend; is
8 that correct?

9 A. They -- this experiment is on the
10 PEO.

11 Q. Okay.

12 A. Part of the polymer.

13 Q. And so if I could look at the next
14 paragraph, it says, to balance the properties of
15 adhesion, and goes on. And then it says, film
16 compositions may include 50 to 75 percent low
17 molecular weight.

18 Now, let's just stop there. The
19 asserted claims are 60 percent or greater of the
20 overall polymer component is low molecular
21 weight; is that correct?

22 A. Yes.

23 Q. And you would agree that
24 60 percent or greater, that's the claim term --

1 Q. So if we had 80 percent low PEO
2 and we also had in your view the high molecular
3 weight PEO component and the HPC component, that
4 would satisfy 1 and 2, the other two parts of
5 this claim, you would agree that 80 percent
6 would be covered; is that correct?

7 A. If all three of those elements are
8 in place, yes, I believe it would.

9 Q. Thank you.

10 And so now --

11 THE COURT: Mr. Smerek --

12 MR. SMEREK: Sorry.

13 THE COURT: Just try not to start
14 talking while he's actually -- you know, I know
15 what you are trying to do and I understand it,
16 but let him finish the sentence first.

17 MR. SMEREK: Thank you, your
18 Honor.

19 BY MR. SMEREK:

20 Q. And if --

21 THE WITNESS: Thank you.

22 BY MR. SMEREK:

23 Q. And if we now look at the second
24 paragraph, 50 percent to 75 percent low

1 molecular weight.
 2 And would you agree with me that a
 3 low molecular weight PEO of 80 percent would not
 4 be described by the range of 50 percent to
 5 75 percent low molecular weight PEO?

6 A. As we write patents in my group,
 7 what you do is you first set out to do research,
 8 and you come up with a design of experiments
 9 like they have in Table 22. Then one does those
 10 experiments. Then one starts writing the patent
 11 to decide, here's what we've learned, here's
 12 what we're going to teach.

13 And then one says, now within what
 14 we've learned and what we are going to teach,
 15 what do we want to claim, and what are the
 16 claims of the patent.

17 So here they're describing what
 18 they have learned, and I think that 60 percent
 19 or greater. And then this next one is for
 20 adhesion prevention, fast dissolution rate, tear
 21 resistance, 50 to 75 percent works well, and
 22 optionally a higher molecular weight polymer.
 23 So they're laying out what they've learned. And
 24 then they took all of their learnings, which is

1 MR. LADOW: Nothing further, your
 2 Honor.

3 THE COURT: All right. Professor
 4 Prud'homme, you may step down. Thank you.

5 THE WITNESS: Thank you very much.
 6 (Witness excused.)

7 MR. LADOW: Your Honor, we had
 8 originally planned for two other witnesses, but
 9 in the interests of time, plaintiffs are not
 10 going to put on their commercial success
 11 witness, and if I understand correctly,
 12 defendants are not putting on theirs since
 13 there's nothing to rebut.

14 THE COURT: So does that mean that
 15 you're not calling Professor Bell, or Dr. Bell,
 16 and they're not calling Ms. Lawton?

17 MR. LOMBARDI: Your Honor, we were
 18 presented with this literally five minutes
 19 before we came in. I wondered if your Honor can
 20 give us a minute to --

21 THE COURT: I can certainly give
 22 you a minute. In other words, Mr. Ladow, you're
 23 not calling Dr. Bell?

24 MR. LADOW: That was the

1 in all of the specifications, and said, here's
 2 what we're going to put in our claims that we
 3 can defend.

4 And I think they have clearly
 5 shown that the 60 percent or greater levels was
 6 something they decided, this is what we wanted,
 7 this is what we can prove infringement, and
 8 therefore this is our claim.

9 So the claim is more specific and
 10 narrower than all the teaching specification.
 11 But I believe this teaching and specification
 12 covers what is eventually claimed.

13 Q. And I had a very simple question,
 14 and it was just: Can we agree that low
 15 molecular weight of 80 percent would not fall
 16 within the range described by 50 percent to
 17 75 percent low molecular weight?

18 A. It would be above 50 to
 19 75 percent.

20 Q. And -- thank you.

21 MR. SMEREK: Nothing further, your
 22 Honor.

23 THE COURT: All right. Any
 24 redirect here?

1 intention, your Honor.

2 THE COURT: Well, okay. I mean,
 3 now we're turning that intention into a reality.
 4 Right?

5 MR. LADOW: Yes, your Honor.

6 THE COURT: Okay. All right. So
 7 they're not calling him.

8 And maybe or maybe not, but I will
 9 certainly give the defendants a chance to think
 10 about it, though it's hard to figure out --
 11 well, in any event, I will give them a chance to
 12 think about it.

13 Do you have any more people you
 14 want to call today or is that it for you?

15 MR. LADOW: That would be it for
 16 today, your Honor, and the rest would be in
 17 December.

18 THE COURT: Okay. Well, do you
 19 want to take a little recess and I will let you
 20 all talk about it?

21 MR. LOMBARDI: That would be fine.

22 THE COURT: Take as much time as
 23 you need. Since we're not going to be doing
 24 much more today under any circumstance, why

1 don't we just take a 15-minute break.
 2 MR. LOMBARDI: Thank you, your
 3 Honor.
 4 (Short recess taken.)
 5 - - -
 6 (Proceedings resumed after the
 7 recess.)
 8 THE COURT: All right. Please be
 9 seated. So what's the status now?
 10 MR. LOMBARDI: Well, your Honor,
 11 the bottom line is, we believe we should go
 12 ahead and present a streamlined version of this
 13 witness. I can explain to you why.
 14 There is a difference in
 15 understanding between the parties on what the
 16 commercial success evidence has been so far and
 17 what witnesses --
 18 THE COURT: I would have said
 19 right now there's no commercial success.
 20 MR. LOMBARDI: I'm sorry. I
 21 should have said secondary considerations,
 22 your Honor. That was a misstatement on my
 23 part.
 24 THE COURT: Okay.

1 MR. LOMBARDI: But with secondary
 2 considerations, there have been witnesses who,
 3 as you know, have testified to things that we
 4 believe they shouldn't have testified to. We
 5 don't know what the status of that is going to
 6 be.
 7 We have offered to do things like
 8 to defer this witness until December and reserve
 9 our right depending on things that happen in our
 10 review of the record, but we weren't able to
 11 reach agreement on that.
 12 So I think what we need to do,
 13 because she does respond, she does provide
 14 evidence that we can argue from on things like
 15 long-felt need and --
 16 THE COURT: Is it an economist?
 17 MR. LOMBARDI: She's going to talk
 18 about the market and what was in the market
 19 before the film and what happened when it went
 20 to the film.
 21 And so that gives us -- I agree,
 22 your Honor, it's obviously not an economist on
 23 the other side that she'll be rebutting at this
 24 point, but there's still --

1 THE COURT: Okay.
 2 MR. LOMBARDI: -- evidence out
 3 that there bears some relevance.
 4 THE COURT: Mr. Ladow, what do you
 5 have to say? I mean, you don't actually have to
 6 say anything.
 7 Well, so they want to put on a
 8 witness. Do you oppose that?
 9 MR. LADOW: Absolutely, your
 10 Honor.
 11 THE COURT: Okay. That's what I
 12 wanted you to say. So why?
 13 MR. LADOW: We have the two
 14 doctors, as you know. They were the opposing
 15 experts in terms of the field that they were
 16 covering.
 17 THE COURT: Yes.
 18 MR. LADOW: The commercial success
 19 witness that they're talking about, Ms. Lawton,
 20 she's entirely a rebuttal witness to our
 21 commercial success witness, Dr. Bell. That's
 22 all she did. Her report said, I am rebutting
 23 Dr. Bell's commercial success testimony. It's
 24 market, economic kinds of information, and it

1 just has nothing to do with the doctor
 2 testimony.
 3 And so there is no commercial --
 4 we're not putting on Dr. Bell. There's no
 5 commercial success case to rebut. There can be
 6 other secondary considerations in the case in
 7 addition to commercial success, but there is no
 8 commercial success case here to rebut, and
 9 therefore that witness shouldn't go on.
 10 THE COURT: Mr. Lombardi, you're
 11 saying you want to call this person, this
 12 witness, this expert, not to address commercial
 13 success, but to address, you said, long-felt
 14 need?
 15 MR. LOMBARDI: Long-felt need and
 16 just the general pattern, the general progress
 17 of this product in the market.
 18 They have tried -- so for
 19 instance, today, we had arguments about, and
 20 your Honor deferred ruling about Dr. Langer
 21 using -- he put in some documents today from
 22 which they want to argue secondary
 23 considerations of obviousness, and we offered
 24 actually just to drop all secondary

1 considerations and then we wouldn't be having
2 this discussion.

3 But our concern is that if we
4 don't put this witness on, that we may be in a
5 position where we don't have evidence we need to
6 rebut any arguments about long-felt need, and so
7 forth.

8 And so --

9 THE COURT: Okay. So here's what
10 I propose to do unless, Mr. Ladow, there's
11 something else you want to say right now.

12 MR. LADOW: I suppose it depends
13 on what your Honor says.

14 THE COURT: Your right to say
15 something evaporates once I say something.
16 There's nothing you want to say?

17 MR. LADOW: No, your Honor.

18 THE COURT: Okay. Well, I am
19 dubious that this witness has any relevant
20 information, but I really can't tell that
21 without hearing what the witness has to say.

22 So I assume she's here, they're
23 ready to go, you're ready to cross-examine her.
24 So I'm thinking let's have her called, have her

1 testify. You can cross-examine her, and if it
2 turns out that she has no relevant information,
3 you know, I wasn't planning on doing anything
4 else this afternoon anyhow.

5 MS. BOURKE: Can I add to
6 Mr. Ladow's comment?

7 THE COURT: Okay.

8 MS. BOURKE: Ms. Lawton put in a
9 rebuttal report to Dr. Bell. But for Dr. Bell's
10 report, Ms. Lawton wouldn't have put in a
11 report.

12 I can read to your Honor the
13 assignment that she had.

14 THE COURT: Well, why don't you
15 pass it up. Well, no. Put it on the record.
16 Sorry. Go ahead, Ms. Bourke.

17 MS. BOURKE: Sure. She said, I
18 have been retained to analyze and provide my
19 opinions regarding plaintiff Reckitt's claims
20 that the alleged commercial success of Reckitt's
21 Suboxone sublingual film is attributable to the
22 '832 and the '514 patent as set forth in the
23 expert report of Gregory K. Bell, PAC, dated
24 April 10, 2015. Her report goes in in May.

1 She says, My analysis in response
2 to Dr. Bell's report is divided into two main
3 compounds. Then she goes on.

4 She's a rebuttal witness to Dr.
5 Bell, and but for Dr. Bell, she wouldn't be here
6 today. And if we have withdrawn Dr. Bell, then
7 Ms. Lawton doesn't have a basis to testify.

8 THE COURT: All right. I
9 understand what you're saying.

10 Mr. Lombardi?

11 MR. LOMBARDI: Yes.

12 THE COURT: What do you have to
13 say to that?

14 MR. LOMBARDI: Well, the fact that
15 she got into the case in the first place as a
16 rebuttal to one of their witnesses doesn't
17 dictate whether what she says has some
18 relevance.

19 So we heard Dr. --

20 THE COURT: Well, but I mean,
21 she's a rebuttal witness on commercial success,
22 and if it seems to be agreed that commercial
23 success is not in the case anymore; right?

24 MR. LOMBARDI: They are dropping

1 commercial success, but, for instance, we heard
2 from Dr. Wollschlaeger, I believe I have that
3 right, who talked at length about the switch
4 from tablets to the film. He talked about that
5 from a medical perspective. She can shed light
6 on that from an economic perspective. And the
7 fact that they've withdrawn somebody who can
8 talk about the economic part doesn't mean that
9 she's not relevant to the economic part.

10 So, Judge, we're in a position
11 right now where we have to decide for the whole
12 case, because we're coming back in December,
13 whether to put this witness on.

14 We asked for --

15 THE COURT: I mean, I understand,
16 more or less, that this is a good time to
17 decide, and that nothing -- my impression is
18 nothing that's going to happen after this is
19 going to change whether she has relevant
20 testimony or not.

21 MR. LOMBARDI: We tried to get
22 that agreement. We asked if there would be an
23 agreement there would be no further secondary
24 testimony, no surprises, nothing like that, and

1 we couldn't get an agreement to that.
 2 So here we are in a position where
 3 we can't nail down -- we actually don't now what
 4 the record says right now. We have a
 5 recollection, but we have not had a chance to
 6 look at it. So we can't nail down exactly what
 7 has happened now. We don't know what will
 8 happen in the future, and if what happened the
 9 last two days is any indication, there could be
 10 surprises in the future. And we're being told
 11 that you should have to give up this witness
 12 just because we have given up a witness that
 13 we -- that we don't want to call.

14 So I guess I would suggest this,
 15 your Honor. I think, I understand that there
 16 may be a dispute about whether it's ultimately
 17 relevant, and I think I'm not trying to
 18 foreclose that at all. I mean, I understand
 19 that if you were to take this testimony, there
 20 would be argument about that.

21 But I think we ought to go forward
 22 with it, or -- and I think that's the most
 23 efficient way of doing it. But if we are not
 24 going to do that, to foreclose us completely I

1 think would be prejudicial to us, because we
 2 don't know what's going to happen in December.

3 And so, at a minimum, we should be
 4 able to reserve the right to bring her back in
 5 December. And we tried to get that agreement,
 6 too, and we couldn't get that agreement.

7 So I think the efficient use of
 8 time probably, assuming your Honor has the time
 9 for it this afternoon, is just to get it done
 10 and get it out there, and then we can argue
 11 about its significance later. But the one thing
 12 I think that would be prejudicial is just to say
 13 that we can't do it at all at this point.

14 THE COURT: Well, and there's no
 15 reason why I have to say that at this point,
 16 because we have December.

17 All right. Well, so here's what I
 18 think. I recognize the strength, or at least
 19 what seems to me the strength in what Ms. Bourke
 20 said, and maybe that means -- and maybe that
 21 means I shouldn't be allowing this testimony at
 22 all. But since we're here, we have the time,
 23 and we have time between now and December when
 24 you can argue about whether whatever it is I'm

1 about to hear means anything, why don't we go
 2 ahead and you put on the witness for whatever it
 3 is that you think she has to offer and, you
 4 know, we'll add to the list of things we have to
 5 resolve later. We're here, and it just seems
 6 like an efficient use of time.

7 MS. BOURKE: Your Honor, can I
 8 just take one more stab at this, if I may?

9 THE COURT: Okay.

10 MS. BOURKE: May I hand up the
 11 table of contents to her expert report because
 12 she can't testify outside the bounds of the
 13 opinion that she has provided in her expert
 14 report.

15 THE COURT: I do understand that
 16 generally, yes.

17 MS. BOURKE: So maybe if you took
 18 a look at what her stated opinions are.

19 THE COURT: Okay. Okay.

20 (Ms. Bourke handed documents to
 21 the Court.)

22 (Pause.)

23 MS. BOURKE: Perhaps I gave you
 24 the pages out of order. I apologize.

1 THE COURT: That's all right.
 2 I've figured it out.

3 (Pause.)

4 THE COURT: I take it plaintiff --
 5 what secondary considerations is the plaintiff
 6 arguing in this case?

7 MR. LADOW: So, your Honor, for
 8 example, I believe in the expert report of one
 9 of the experts who is going to testify in
 10 December in connection with another patent that
 11 we have not done here today, there's some -- a
 12 reference to copying, so that would be a kind of
 13 secondary consideration.

14 THE COURT: Well, so I've heard,
 15 or I thought I've heard here one time or another
 16 copying, praise, long-felt need?

17 MR. LADOW: Yes. So what we --

18 THE COURT: What I'm trying to do
 19 is get what the maximum universe of secondary
 20 considerations that you either have, that you
 21 have, or will in the future put on.

22 MR. LADOW: Well, one of them is
 23 not going to be commercial success.

24 THE COURT: No. I understand

1 that, too.
2 MR. LADOW: And so in regard to
3 what we're going to put on in the whole, yes,
4 it's possible there could be some on copying.
5 There could be some on long-felt need, but I'm
6 just kind of going through categories.

7 THE COURT: Well, that's what I'm
8 trying to --

9 MR. LADOW: And --

10 THE COURT: So --

11 MR. LADOW: May I, your Honor?

12 THE COURT: Yes. Go ahead.

13 MR. LADOW: Yes. For example, one
14 of the things that counsel referenced was that
15 Dr. Langer today, that Dr. Langer today talked
16 about those post 2002 articles, post 2003
17 articles. And those articles were discussed
18 by his opposing expert, Dr. Dyar, in his
19 testimony. And Dr. Langer said it looked like
20 that was a recognition that this problem had
21 been solved.

22 And so we can't -- and, you know,
23 there's also unexpected results could be a
24 secondary consideration.

1 So what we said to defendants is,
2 we can't give up the right to argue any
3 secondary consideration, but what we're clearly
4 doing is we're not presenting commercial
5 success, and therefore the reciprocal evidence
6 doesn't come in.

7 We have the two doctors. They
8 opposed each other. It does not make any sense
9 for Ms. Lawton to oppose Dr. Wollschlaeger.

10 He's a medical doctor. She's a damages expert.
11 The other category, your Honor, is
12 typically praise, long-felt need, failure of
13 others, copying and unexpected results are the
14 typical -- and commercial success are the
15 typical categories.

16 THE COURT: All right.

17 MR. LADOW: And what Ms. Lawton is
18 really talking about is her view of the internal
19 company history and about the marketing and
20 price and trying to argue that that was a drive,
21 as I said in my opening.

22 THE COURT: Right.

23 MR. LADOW: And the person who,
24 that raised those issues was Dr. Bell's report,

1 that she responded to. So it's not sort of just
2 an incidental fact that she got into the case
3 that way. That's her only reason for existence
4 in the case.

5 THE COURT: Well, so I'm either
6 going to do one of two things. I'm either going
7 to hear Ms. Lawton right now, or I'm certainly
8 going to say that the defendants can call her,
9 if appropriate, in December.

10 Which one of those do you want to
11 do?

12 MR. LADOW: December, your Honor.

13 MS. BOURKE: Yes. I think it
14 might be better to have the latter, because
15 there are a bunch of highly confidential,
16 outside attorneys' eyes only slides that she has
17 presented, and therefore it's going to raise all
18 sorts of issues about how we're going to publish
19 or not publish, and what we're going to do with
20 those, which we have not resolved with the
21 defendants yet. So if you reserve, we may be
22 able to negotiate that without taking up the
23 Court's time right now.

24 THE COURT: And, Mr. Lombardi, is

1 it much of a problem for you to reserve her?

2 MR. LOMBARDI: Well, there is
3 always the expense, Judge, because --

4 THE COURT: Yes. It seems like
5 there's a lot of expense going on here.

6 MR. LOMBARDI: There is. There's
7 no doubt about that. But it's another component
8 of it. She would have to come back and get
9 ready and appear, and she is here and ready to
10 go. And we have actually been able to hone it
11 down, we think, so that it will not be a lengthy
12 amount of testimony. So from our point of view,
13 efficiency would say to do it today.

14
15 THE COURT: What did we save for
16 this day, December 18th? We saved infringement
17 of two patents and invalidity of one patent;
18 right?

19 MR. LADOW: Yes, your Honor. It's
20 infringement and invalidity of the '832 patent
21 and infringement only of the '514, since we
22 heard validity on the '514 during the last
23 couple days.

24 THE COURT: Okay.

1 MR. BROWN: In addition, there's
2 infringement of the '150 on Par.

3 THE COURT: I'm doing that on a
4 different day.

5 MR. BROWN: I'm sorry.

6 THE COURT: So I'm not too worried
7 about that. But thank you, Mr. Brown.
8 So if it turns out, Mr. Ladow,
9 that everything Ms. Lawton has to say is
10 irrelevant, is there some prejudice here to
11 you?

12 MR. LADOW: Yes. I think so, your
13 Honor. There's -- having made a decision to not
14 put forward commercial success, and since,
15 respectfully, I don't think that they really
16 should be able to do that, I think that it
17 colors the situation to hear it in a one-sided
18 way. And in addition to that, we have these
19 confidential -- she's really, you know, sort of
20 just reading a lot of documents, not offering an
21 expert economic opinion, and she's sort of
22 doing a narrative history of 30 years at the
23 company, and marketing practices. And I think
24 it is potentially prejudicial, and there's also

1 the confidentiality issue that we mentioned
2 before.

3 And there's no prejudice to them,
4 putting aside a modicum of cost in the overall
5 scheme of things, waiting until December to see
6 if it's actually relevant, relevant to anything
7 that happens in the case.

8 And I just wanted to add to that
9 that when counsel was talking about, well, we
10 don't know what's going to happen in December,
11 well, we do know what is going to happen in
12 December. We're going to put on the
13 infringement and invalidity cases we just talked
14 about. We're not going to put on any more
15 doctors. We're not going to put on any more
16 economists. So the things that she would be
17 addressing, you know, we're not putting on in
18 December. That could be resolved then and she
19 could be available then, as you said. So we
20 would respectfully suggest that that is the best
21 course.

22 THE COURT: All right. I think
23 actually, the -- I'm thinking that the better
24 course here actually, Mr. Lombardi, is not to do

1 any more today.

2 I am just thinking about what I've
3 heard so far and what I might hear from doctors
4 or professors who are not economists in the
5 future. I am really finding it hard to believe
6 that a person, an economist, who has written a
7 commercial success report, I'm thinking it's
8 real unlikely that she has much to add on any of
9 these secondary considerations.

10 I'm not saying that she doesn't,
11 so I will give you a chance in December, and it
12 may be the case -- so that's what I'm going to
13 do. I'm not going to hear her testimony today.
14 And what I've just said is without prejudice to
15 your presenting her in December.

16 So what I would like to do is hand
17 back the three pages that I got from Ms. Bourke.
18 And does that mean that in terms of testimony,
19 we are through for today?

20 MR. LOMBARDI: I believe so, your
21 Honor.

22 THE COURT: All right. One of my
23 staff mentioned that at some point, somebody was
24 talking about a deposition of Myers. Does

1 anyone know what we're talking about here?

2 MR. SMEREK: Myers was played
3 yesterday. There was another deposition that I
4 believe plaintiffs were going to play today, but
5 that has been withdrawn, their withdrawal of the
6 commercial success.

7 THE COURT: Oh, all right. So
8 let's just talk about December for a minute.

9 My thought had been that we were
10 going to do infringement for Par starting on
11 December 17th, the day that had been scheduled,
12 and we would just do that until whenever it
13 ends. Having seen how long we spent on
14 infringement in this case, I'm wondering, do you
15 have a sense whether, how much time we're going
16 to need for this? I'm wondering whether we
17 actually need -- how much of the day do you
18 think we're likely to need for this?

19 MR. LADOW: Your Honor, if I could
20 give you a little information that may help with
21 that. I think it's -- I think counsel would
22 agree that the infringement case against Par on
23 the '150 patent, so not the other two patents,
24 but on the '150 patent, much of that case is

1 much the same as what you heard today because of
2 the particular polymers.

3 THE COURT: You mean we're going
4 to have a graph with a line drawn through it?

5 MR. LADOW: The very one.

6 THE COURT: Okay.

7 MR. LADOW: And so while they have
8 their own formulation that comes into play at a
9 certain part in that analysis when you look at
10 the percent, the other part of it, you know,
11 is --

12 THE COURT: Okay. I get that.

13 MR. LADOW: Yes. And -- well, so
14 what I'm saying is, is that depending on how the
15 Court wants to deal with that, we don't
16 necessarily have to put on all of that same
17 testimony again. It wouldn't mean that the
18 people wouldn't be available to be examined by
19 counsel.

20 THE COURT: Well, that's something
21 you can work out with Mr. Brown. I mean, you
22 can talk to each other and decide what you want
23 to do about that. You know, Par deserves their
24 day in court, so whatever they want to do is

1 would -- putting aside whatever discussions we
2 may have about working anything else out, we
3 would propose that, yes.

4 MR. BROWN: Your Honor, in
5 discussions with Watson, what I think we would
6 propose is that the infringement cases, rather
7 than breaking, having like a special time for
8 Par and then go into basically the same case
9 against Watson, I think you are going to find
10 similar repetition you would see versus the '150
11 patent. We think it would be much more
12 efficient and easier for the Court to have the
13 infringement cases go forward.

14 THE COURT: In other words, what
15 you are saying is, what when I originally
16 separated them, merge them back together?

17 MR. BROWN: Exactly.

18 MR. NUTTER: It has become that,
19 your Honor.

20 THE COURT: I'm perfectly fine
21 with that.

22 MR. LADOW: I think that that
23 would probably make sense, too, your Honor.

24 THE COURT: All right. Well, I

1 fine by me.

2 Well, I guess what I'm wondering
3 is, do you think, since we've -- do you think
4 you can do the rest of this trial in the seven
5 hours that you're allotted December 18th?

6 MR. LADOW: I think, your Honor,
7 if we could potentially use some of the 17th
8 and then not have the potential of trying to
9 keep anybody later, particularly on that
10 Friday.

11 THE COURT: Yes, yes, yes. It's
12 not the best time.

13 MR. LADOW: So I think that from
14 our point of view, if we could bridge between
15 the days and just continue after Par, if that is
16 how the Court wants to do it.

17 THE COURT: Well, no. I'm
18 perfectly happy to do that. Basically, do Par
19 for however long Par takes on the 17th.
20 Assuming that it does not take until
21 5:00 o'clock, then just start wherever it
22 is we would start and carry on over into the
23 18th.

24 MR. LADOW: That's what we

1 don't know how -- I am perfectly happy to do
2 that.

3 Maybe you can just talk amongst
4 yourselves, make sure you've got the details and
5 schedules, and I don't know what else.

6 MR. LADOW: I think since the
7 Court seems to have some flexibility on it, if
8 counsel can get together and come to an
9 agreement and make a proposal that we could
10 present for your consideration.

11 THE COURT: Yes. You don't really
12 have to present it for my consideration unless
13 you've got something really odd and go -- you
14 know. I mean, I'm just going to show up on the
15 17th, and whatever it is you're ready to do, I'm
16 ready. You know, it's like -- well, whatever
17 you want to do is fine.

18 MR. LADOW: Understood.

19 THE COURT: And as long as you're
20 agreed amongst yourselves as to what it is. If
21 you have a dispute as to what it is you're
22 doing, then I'd like to know about it in
23 advance. Okay?

24 MR. LADOW: Thank you, your Honor.

1 THE COURT: All right?

2 MR. NUTTER: Yes, your Honor.

3 MR. BROWN: Yes, your Honor.

4 THE COURT: All right. So what

5 I'm wondering though is one of the things, what

6 I've heard in the last few days is kind of fresh

7 in my mind right now. It's not going to be

8 fresh in my mind in December.

9 And I was wondering, it would be

10 helpful to me, assuming that it's not a bad idea

11 for some reason or other, to maybe get in fairly

12 short order what I was thinking was some sort of

13 proposed findings of fact for the infringement

14 of the, I guess the '150, and the invalidity of

15 the '150 and the 541, or whatever the other one

16 is that we've been doing.

17 And where I sort of imagined, you

18 know, I was thinking -- actually, what I was

19 thinking, and it's just a suggestion is,

20 essentially, five double-spaced pages on each of

21 those three issues, infringement, invalidity of

22 the one patent, invalidity of the other patent,

23 just proposed findings of fact, no legal

24 conclusions, no legal arguments.

1 You know, I kind of -- this is

2 kind of like Mr. Lombardi was saying. He

3 doesn't know exactly -- he would like to review

4 the record and see what it was that was proved

5 on secondary considerations so far.

6 I would kind of like you all to

7 get the record, which I assume is probably

8 available real soon, am I right? Okay.

9 THE COURT REPORTER: Yes.

10 THE COURT: And tell me what, you

11 know, what it is you think that you proved, and

12 then I wasn't really going to do much with this

13 other than internally digest it while it's still

14 fresh in my mind.

15 Do you understand what I'm

16 suggesting?

17 MR. LADOW: I believe so. I take

18 it it would just be regular proposed findings OF

19 fact with record cites, et cetera?

20 THE COURT: Right. Is that

21 something that you're agreeable to doing?

22 MR. NUTTER: I believe so, your

23 Honor, speaking on behalf of both defendants.

24 THE COURT: All right. Is it

1 something that could be done -- you know, we are

2 talking about less than two days of trial. And

3 obviously, you know, part of the reason for

4 saying five pages per sort of issue is whatever

5 level of detail that allows you, that's about as

6 much detail as I can absorb. I mean, I'm sure

7 you could write 15 pages on each of these

8 issues, but that's not actually -- that's not

9 going to be helpful.

10 So how long do you think would be

11 a reasonable -- I was thinking maybe this is

12 something you could do by sometime next week?

13 MR. LADOW: Perhaps the end of

14 next week?

15 THE COURT: Yes.

16 MR. LADOW: Or two weeks, your

17 Honor, maybe?

18 THE COURT: I'm sorry?

19 MR. LADOW: Perhaps two weeks?

20 MR. NUTTER: Two weeks, I think.

21 THE COURT: Two weeks? Okay. All

22 right.

23 And this is not to say that there

24 might not be some kind of legal briefing on

1 these things after we do the other trial, but I

2 am cognizant that at least, to some degree,

3 you're going to be preparing for this next trial

4 in the meantime.

5 And I forget. Do I have a

6 pretrial conference on the Par part of this?

7 MR. LADOW: Yes, your Honor. I

8 believe it's on that Monday.

9 MR. FINEMAN: Yes, your Honor.

10 MS. BOURKE: You do, your Honor.

11 It is on the Monday of that week. The 14th, I

12 think it is.

13 THE COURT: Okay.

14 MR. NUTTER: Would you like Watson

15 to attend if it's going to be intertwined, your

16 Honor?

17 THE COURT: I think you'd attend

18 whether I wanted you to or not, so, yes, you

19 might as well attend.

20 And, in fact, I will leave it

21 to you all to figure out whether the full

22 pretrial -- I mean, because I guess you probably

23 have not started the exchanges yet.

24 What is appropriate given that

1 I've already heard -- you know, I leave it to
2 you to figure out exactly what you want to do in
3 terms of a pretrial conference. It does not
4 have to be the full thing if that does not
5 really make sense.

6 But is that something, Mr. Brown
7 and Mr. Ladow, you can just figure out what
8 makes sense to do?

9 MR. BROWN: I think we can, I
10 think we can work out the minimally effective
11 amount of pretrial --

12 THE COURT: I like that phrase,
13 minimally effective. That's good.

14 MR. LADOW: We're going to try to
15 work out the maximally effective.

16 THE COURT: I guess there's
17 something to be said for that, too.

18 Okay. All right. And then I
19 guess the other thing is, do you want to, in
20 light of the reservation here, do you want to
21 submit some more paper on these six exhibits
22 that the defendant objected to?

23 MR. LOMBARDI: Sure, your Honor.
24 We're happy to do that. And we probably can do

1 it quicker than the two weeks, but is it better
2 to have everything come in --

3 THE COURT: It's probably to have
4 everything, you know, yes. It's probably better
5 to have it come in at the same time.

6 MR. LOMBARDI: Okay.

7 THE COURT: But the only thing is,
8 since that's kind of a legal thing, whereas I
9 imagine on the findings of fact, you would just
10 submit them simultaneously, legal thing, it's
11 usually better to have one side go first so the
12 other side can respond to the particular
13 arguments. And I'm trying to think who it makes
14 sense to have go first.

15 MR. LADOW: Well, I certainly
16 think, your Honor, that it would be the
17 defendants that should go first because they've
18 made a motion in limine already. It was
19 rejected. You've heard the testimony. If they
20 continue to present an objection to it, we would
21 need to know what the grounds are.

22 THE COURT: What do you say there?

23 MR. LOMBARDI: No problem.

24 MR. BROWN: That's fine.

1 MR. LOMBARDI: No problem.

2 THE COURT: Okay. When would you
3 like to submit it?

4 MR. LOMBARDI: I would think a
5 week we could do it.

6 THE COURT: All right. And I
7 don't think -- I'm not necessarily -- would you
8 rather submit a brief or a letter?

9 MR. LOMBARDI: And that makes no
10 difference to me, your Honor. Whatever would be
11 easier for you.

12 THE COURT: Do you have a --

13 MR. LADOW: A letter is fine, your
14 Honor.

15 THE COURT: How many pages of
16 single-spaced letter do you think you need?

17 MR. LOMBARDI: I wouldn't think it
18 would be more than five for sure, Judge, but it
19 would probably be less than that. I'm just
20 trying --

21 THE COURT: Okay. So I will give
22 you six pages.

23 MR. LOMBARDI: Okay.

24 THE COURT: If you write less,

1 that will be nice, but six would be fine. And I
2 will give you the chance to write up to six in
3 response.

4 And so you said a week. Today is
5 Wednesday. So next week?

6 MR. LOMBARDI: Yes.

7 THE COURT: And then -- okay.
8 Well, you'll be working. We're on holiday.

9 But, yes. Why don't you just file
10 something next Wednesday. And, Mr. Ladow, you
11 can file something the following Wednesday.

12 MR. LADOW: Yes, your Honor.

13 THE COURT: All right. And so I
14 guess in the two weeks for the proposed findings
15 of fact, that would then coincide with when
16 you're filing that other. Everything would then
17 be due a week -- I forget. I already lost
18 track. When did we say that your findings of
19 fact was going to be? That was two weeks, too.
20 Right?

21 MR. LADOW: Yes.

22 THE COURT: The 18th. Is that all
23 right? I'm not putting too much of a strain on
24 you since you'll be writing both of these things

1 at once?

2 MR. LADOW: I think that's fine,
3 your Honor.

4 THE COURT: Okay. All right. Is
5 there anything else you want to discuss while
6 we're here today?

7 MR. NUTTER: Just a clarification
8 regarding the findings of fact requested by the
9 Court. And I understand it is five pages per
10 issue, three issues begin infringement of the
11 '150 patent, alleged infringement by Watson, the
12 invalidity of the '150 patent, and the
13 invalidity of the 154 patent.

14 THE COURT: Right.

15 MR. NUTTER: Now, as you know, in
16 addition, they've identified six secondary
17 considerations.

18 THE COURT: Well --

19 MR. NUTTER: Can we have five
20 pages on just -- can you make secondary
21 considerations a fourth topic, or should we
22 weave those into the --

23 THE COURT: Why don't you weave
24 them into the nonobviousness part of your, or

1 obviousness, whatever your position is. I've
2 already said that secondary considerations that
3 have been done so far is pretty light.

4 MR. NUTTER: Thank you.

5 MR. LADOW: Your Honor, if I may
6 on that, I think it -- well, there may be some
7 that, you know, are in December, as we talked
8 about.

9 THE COURT: Well, no, that's true.
10 So if you think you've done something, put them
11 in yours. If you think they have not done
12 something -- I mean, obviously, all you can
13 comment on is the things they've actually talked
14 about, but if you want to say, you know -- I
15 mean, there's a limit because there may be more
16 of these later on.

17 MR. NUTTER: Correct.

18 MR. BROWN: Your Honor, I think
19 that's exactly the issue, which is this trial,
20 but for perhaps copying, the copying issue. But
21 this trial, our understanding, was to be the
22 presentation of all secondary considerations for
23 all patents.

24 And so we think it would be very

1 helpful, we want to remove the mystery out of
2 this record that they think is a secondary
3 consideration supporting the '832 patent that's
4 going to be litigated in December so we know
5 what we have to do. You know, whether we have
6 to bring Lawton back.

7 THE COURT: I thought you were
8 going to read the record and figure that out for
9 yourself.

10 MR. LOMBARDI: Just frankly, your
11 Honor, part of the issue is, when you asked
12 counsel what secondary considerations were being
13 provided, we've been trying to figure that out
14 as well, and the problem we have is in a normal
15 case we'd be done with the '832 patent before we
16 had to make a call on what we're going to, what
17 we're going to be doing in rebuttal.

18 And so our understanding was they
19 were supposed to be done the secondary
20 considerations from now, and so --

21 THE COURT: Well, of course, now
22 continues on to December 18th. Right?

23 MR. LOMBARDI: No. We thought
24 secondary considerations for everything was --

1 MR. LADOW: Your Honor -- I didn't
2 mean to interrupt you. Go ahead.

3 MR. LOMBARDI: That was our
4 understanding, that this two days was the
5 time for secondary considerations overall was
6 how we --

7 THE COURT: This is an
8 understanding that the parties have sort of
9 reached bilaterally?

10 MR. LADOW: Absolutely not, your
11 Honor. I mean --

12 THE COURT: Hold on a second.
13 I mean, this wasn't something that
14 I was involved in. Right, Mr. Lombardi? This
15 was basically Mr. Brown, the --

16 MR. BROWN: Our understanding was
17 that all that was being moved was because of Dr.
18 Davies situation. He was being moved, and our
19 witness on the '832 invalidity that had a
20 response to Dr. Davies was also being moved.
21 Neither one of those individuals, to my
22 knowledge -- and correct me if I'm wrong -- but
23 I don't believe those individuals are addressing
24 secondary considerations other than perhaps a

1 mention of copying in there somehow. Other than
2 that, I don't think there's any secondary
3 considerations.

4 THE COURT: Okay. So actually, I
5 guess I thought that was my understanding, too,
6 is, we were accommodating Dr. Davies.

7 We -- part of what you worked out
8 was then Dr. McConville, who I guess opposes Dr.
9 Davies on something, whatever Dr. Davies is
10 about. But they were being moved back. Is that
11 a wrong understanding?

12 MR. LADOW: No. That's absolutely
13 correct, your Honor. The only thing that I'm
14 saying is, is that let's say that there is
15 something in Dr. Davies' expert report about
16 copying, or maybe there's something about
17 unexpected results. But I didn't want to be in
18 a position today to commit that encyclopedically
19 and comprehensively, there were no secondary
20 considerations in what could happen in December.
21 I didn't think it was fair to us.

22 THE COURT: All right. Doesn't
23 that mostly resolve your problem, is the only
24 witness they're going to be presenting is Dr.

1 Davies, and presumably, he has written multiple
2 reports and? I have to say, I've seen him a few
3 times. Usually, he does testing. Is he doing
4 something different in this case?

5 MR. BROWN: Yes, your Honor. He's
6 not doing testing in this case.

7 THE COURT: All right. Okay. All
8 right. Well, in any event, he has written some
9 reports.

10 So by asking, by asking you to
11 submit this, I'm not trying to foreclose anybody
12 from doing whatever might arise on the third day
13 of trial, and I'm not going to decide anything
14 based on these. That's really like fixed in my
15 mind what it is you think you have proved so
16 far.

17 So things that have not happened
18 yet, you don't had a to address. And what's
19 more is, if you don't say something now, I'm not
20 going to consider it as a waiver of saying it
21 later on. So to the extent that defendants
22 don't want to use their five pages addressing
23 secondary considerations, you don't have to do
24 that. Okay?

1 And maybe -- well, does it make
2 sense actually, because the secondary
3 considerations, they actually could be short of
4 discretely just severed.

5 Do you want to just spend the five
6 pages addressing obviousness and indefiniteness
7 where the obviousness doesn't include secondary
8 considerations even though I understand the
9 Federal Circuit says I must consider them, but
10 just the straight obviousness analysis, or I
11 guess on the one, the priority date analysis,
12 really.

13 MR. LADOW: Well, it's really
14 whatever you want, your Honor, but we could
15 just -- we could just defer that until December
16 because we're going to have to do post-trial
17 briefing anyway.

18 THE COURT: You're talking about
19 deferring the secondary considerations? Maybe
20 that makes sense since they're somewhat out of
21 flux there.

22 MR. LADOW: And obviously in the
23 trial that we've had the last couple days, the
24 secondary consideration-type witnesses or even

1 the portion of the witnesses who have talked
2 about anything that might be construed as
3 secondary considerations has been a very small
4 fraction of the overall --

5 THE COURT: Yes, I would say
6 that's true.

7 MR. NUTTER: Conceptually, I think
8 that's fine, at least for both defendants. I
9 mean, the concern we have on our end is it has
10 been difficult to pinpoint the secondary
11 consideration that we actually intend to rely
12 on. We were hoping your offered submissions
13 would help us in that regard, but we understand
14 that the Court does not want unnecessary paper,
15 so we're --

16 THE COURT: Okay. Why don't we do
17 that. Leave the secondary considerations out.

18 You know, I do understand that there was
19 some dispute between Dr. Wollschlaeger and Dr.
20 O'Brien. It was probably teed up a bit, but
21 they were actually talking in fairly
22 understandable fashion. It might stay in my
23 head longer, so I'm perfectly happy to just put
24 that off until later.

1 **But I would like to -- so I'd like**
2 **the three submissions, and basically, the two**
3 **that are about invalidity won't include**
4 **secondary considerations. Okay?**

5 **Anything else?**

6 **MR. LOMBARDI: Not for us, your**
7 **Honor.**

8 **MR. LADOW: Not for plaintiffs,**
9 **your Honor. Thank you.**

10 **THE COURT: Okay. Well, thank you**
11 **all.**

12 **You know, it's always good -- you**
13 **know, it's probably never a good idea to say**
14 **anything nice until the trial is over because,**
15 **you know, it would be like Villanova naming**
16 **their sports thing the John DuPont Pavilion.**
17 **Something could happen.**

18 **But I do want to compliment you**
19 **all, because you have seemed to be very**
20 **professional in working together to get this**
21 **difficult case tried efficiently, and I**
22 **appreciate that. All right? We'll be in**
23 **recess.**

24 **(Court recessed at 4:08 p.m.)**

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