- VOLUME 1 -

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

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| RECKITT BENCKISER PHARMACEUTICALS INC., RB PHARMACEUTICALS LIMITED, and MONSOL RX, LLC, | : | CIVIL ACTION |
| 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.

- - -

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PROCEEDINGS

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

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

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

Plaintiff, are you ready?

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

THE COURT: And defendants, you're ready?

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

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

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

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

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

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

Buprenorphine is an opioid that



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

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

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

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



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

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

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



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

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

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

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

To just briefly introduce the

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

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

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



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

THE COURT: All right.

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

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

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



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

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

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



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

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

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

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

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

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

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

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

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



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

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

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

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



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

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

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



and efficacious.

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

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

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

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

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

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



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

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

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

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



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

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

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

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



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

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

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

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

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

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

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



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

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

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

And the -- he will also testify



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

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

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



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

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

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

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

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

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

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



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

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

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

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



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

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

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



art, but they wouldn't be applied here.

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

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

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

properties.

Now, your Honor, there are many, many polymers that can be used in these films. At least 30, I think, are listed in one of the patents. And PEO, polyethylene oxide, is just one of them. And then even when you talk about PEO, it's not, it's not like you just buy a single one. There's -- there's a very broad spectrum, a broad range of PEOs that are available, you know, from very low molecular weight. The lowest molecular weight ones are referred to as PEGs, the ones that are below 20,000 or so referred to as PEGs, that can go all the way up to eight million or more.

Before the '150 patent, no one ever taught combining intermediate weight PEOs, and what I'm talking about there is, PEOs averaging between about a hundred thousand to 900,000, that intermediate range in the claims, so not less than 100,00 and not more than 100,00, not up like at three or five million.

So no one ever taught combining intermediate weight PEOs that I just described where, and then on top of that, the low



molecular weight range of the 100 to 300,000 was 60 percent or more of the polymer component, all of those combinations.

This approach to balancing film properties like mucoadhesion, tear resistance and dissolution, simply was not in the prior art, and you are going to hear the defendants point to a lot of pieces of prior art, but it's just not there.

There is art like the Schiraldi reference that you will hear about that has very, very high and very, very low PEO, which was a typical approach at the time.

And then there's some that is mainly the PEG, or the very low. That's like the Keith reference. And then there are other references that simply don't say anything about the relationship of PEO molecular weight to film properties, and examples of those would be the Chen and Fuller references.

And then there are other references that involve dosage forms that wouldn't teach one of ordinary skill in the art what to use in a film. So an example of those



are Apacella, which relates to tablets, Fuller, which was directed to a study about tablets even though they made some film, but to study tablets. And there's also a reference called Verma, which relates to coating films on capsules.

So defendants also point to a reference called Yang, so that name may be familiar because we saw it before. In fact, Yang is one of the MonoSol inventors. And Yang, the Yang reference is actually the parent application of the '150 patent.

And Dr. Prud'homme will explain that the '150 patent has a priority date of May 28, 2003, based on the filing of the 902 application that led to the '150 patent. And Yang has a filing date in 2005, which means that it wouldn't be prior art.

More specifically, your Honor, the defendants contend that the 902 application filed, as I said, in 2003, does not disclose all three of the following: The 60 percent or more of the low molecular weight of the polymer component, some of the high, and then also



having some cellulosic. So they contend that that is not disclosed and the somehow the priority does not go back to this 902 application. But Dr. Prud'homme will explain and take you through that, that, in fact, the 902 application expressly discloses those claimed elements so that priority clearly goes back to 2003.

Now, finally, a person of ordinary skill, your Honor, would have no reasonable expectation of success to arrive at the invention of the '150 patent, and Dr. Prud'homme is going to address this further.

Basically, there would be such a large number of variables that the person of ordinary skill would be confronted with, polymers to choose from, the mixtures of the various polymers, the concentrations to use, that as Dr. Prud'homme will explain, this would take so much experimentation, it would actually take years just doing the math to come up with that, and so there would be no reasonable expectation of success.

And what you'll, what you'll hear

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

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

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



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

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

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



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

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

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

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



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

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

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

Thank you, your Honor.

THE COURT: All right. Thank you, Mr. Ladow.

Defendants?

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

THE COURT: I think one would be enough.

MS. BOURKE: Just one?

THE COURT: Yes.

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

THE COURT: You can hand up more than one.

(Binders to the Court.)

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

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



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

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

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

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



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

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

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



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

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

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

tablet for reasons related to child safety. That failed, but it shows what their intention was here and what they were up to.

Now, in fact, the film is the same as the tablet in all material respects. Obviously, the delivery form is business, but in the material respects, Judge, they have the same actives. They have the same buffers. They're administered the same way, under the tongue, and they treat the same thing, the opioid dependence. So, really, it's an attempt to extend their exclusivity over Suboxone tablets, over Suboxone generally from the tablets into the films.

Now, Judge, I just put this slide up briefly just for context, and counsel came up with some category in which Suboxone was the first to get FDA approval. We're not here to talk about FDA approval. We're here to talk about the patents, and the idea that we're working on is, in some of these patents is whether it was obvious to come up with this kind of film, and this kind of film has been out on the market.



You may have seen the Listerine little packs that you can buy in convenience -- there are Listerine little packs that are available commercially right now that you can buy in stores and you use them the same way. There are oral pharmaceuticals that have been available since 2004, and Suboxone actually was not the first oral pharmaceutical approved by the FDA. Onsolis actually was the first.

So that's the background here, Judge, and with that, I will jump to the patents that we are going to be talking about this week. I won't address issues that aren't coming up this week.

And the first one I want to talk about is the '150 patent. And this is the patent -- I know your Honor dealt with this at some length at Markman and in your Markman order, but this is the patent that basically deals with the polymer composition of the films, and with what the various components of that polymer composition are going to be.

And our position, as your Honor knows, is that we do not infringe, Watson does



not infringe the asserted claims of the '150 patent, and here's a representative claim. And, as your Honor is aware, there are portions above the lighted portion that deal with the polymer component, and PEO being in combination with an HCP. But the part we're talking about for noninfringement purposes is what I have highlighted here.

And so the question here really comes down to the PEOs. And, your Honor, if I didn't say it already, PEO you will hear frequently for polyethylene oxide. The PEO requirements here are set out in the highlighted portion, and there are two types of requirements. One is that there be two PEOs, so the language says the PEO comprises one or more low molecular weight PEOs and one or more higher molecular weight PEOs.

So we're talking about two PEOs, and then further on to define the weights for those PEOs.

As your Honor has seen from the claims, but just to review, the low molecular weight PEOs falls within that 100 to 300,000



dalton range, and the higher molecular weight PEO falls within the 600 to 900,000 dalton range.

And, your Honor, your claim construction, as I noted, you dealt with these issues, but a few of the points that were made during the claim construction that I think are going to be important to the noninfringement analysis here, your Honor recognized that it was clear from the patent that it has to be discrete sets of low average molecular weight PEOs and high average molecular weight PEOs. So discrete sets has to be at least two, one in each category.

Your Honor recognized that it needs to be a combination of low and high molecular weight PEOs.

And your Honor made an important observation, I think, at the bottom, about stray amounts of high molecular weight PEO. Your Honor observed that if there is a low molecular weight PEO that contains stray amounts of higher molecular weight PEOs, that wouldn't be sufficient to be within the terms of the claims.

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

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

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



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

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

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



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

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

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

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

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



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

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

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

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

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

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

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really high molecular weight PEO?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



prior art that's relevant.

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

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

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



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

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

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

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

On the other hand, the April 2008



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

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

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

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

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

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

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



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

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

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

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

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



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

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

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



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

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

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

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

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

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

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



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

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

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



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

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

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



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

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

Thank you very much.

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

All right. Plaintiff?

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

(Ms. Bourke handed notebooks to the Court.)

PLAINTIFFS' TESTIMONY

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

examined and testified as follows ...

DIRECT EXAMINATION

BY MS. BOURKE:

Q. Good morning, Doctor.

A. Good morning.

Q. Can you introduce yourself to the Court, please?

A. My name is Bernd Wollschlaeger. I'm a physician.

Q. And what type of physician are you?

A. I'm a board-certified family physician and addiction specialist.

Q. Do you maintain those certifications today?

A. Yes, I do, maintain those certifications.

Q. You said that you are board-certified in addiction? You're an addiction specialist; is that right?

A. That is correct.

Q. Can you explain to the Court what your practice is with respect to addiction medicine?



A. My practice is about 80 percent family medicine and 20 percent of addiction medicine, and I treat patients suffering from diseases ranging from opioid dependence to alcohol dependence.

Q. You said -- is there a broader term that is used for addiction medicine, sometimes called substance abuse?

A. It's called, according to the DSM-IV, substance use disorders treatment.

Q. Okay. Thank you.

And what percentage of the patients that you treat suffer from substance use disorder?

A. About 20 percent.

Q. And what percentage of that suffer from opiate dependence or opiate use?

A. About at least 80 percent plus.

Q. Now, you said you treat patients. Can you describe for the Court exactly what that entails?

A. Well, addiction to medicine entails screening diagnosis and treatment of substance use disorders, and the treatment in a



practice based setting, medication-assisted treatment assisted by substance abuse counseling.

Q. And how many patients do you directly treat at any given time that suffer from opiate dependence and other dependence?

A. Between 40 and 50 patients at any given time for opiate dependence, and for other dependence, it can range anywhere between 20 to 30.

Q. And for what length of time do you do that?

A. Treating them between three months, six months, to 13 to 14 years is my longest patient.

Q. All right. Thank you, Doctor.

And in addition to treating patients, do you engage in any other activities as it relates to your addiction specialist occupation?

A. Yes, I do. I'm a voluntary faculty member of different universities and teach medical students, family medicine residents, advance nurse practitioners in my



practice, and I also treat physicians on a local and national level about the treatment of substance use disorders.

Q. What percentage of your time is spent teaching as opposed to treating patients?

A. Well, most of my teaching, 90 percent is in practice teaching, and the remainder is out of my office in lectures, ten percent.

MS. BOURKE: So at this time, your Honor, we'd like to offer Dr. Wollschlaeger as an expert in addiction medicine and the treatment of opiate use disorders.

THE COURT: All right. You may proceed.

BY MS. BOURKE:

Q. So, Doctor, can you explain to the Court how you got motivated to enter the field of -- the treatment of opiate use disorders?

A. It was a personal and professional motivation. Personally because I, unfortunately, witnessed as a young boy the destruction of a family of a father's friend of mine, who the son suffered from heroin

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

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

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

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

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

A. Yes, I have.

Q. Okay. And who were they published by?

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



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

A. Yes, I have.

Q. Are these the statistics to which you refer?

A. That is correct.

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

A. In --

Q. With respect to that paper?

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

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

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

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



When did you first start treating opioid use disorders?

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

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

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

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

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

Q. And did you take advantage of that



act?

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

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

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

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

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

private physicians in an office-based setting.
Q. And what were the prescription approved narcotics that you were able to prescribe in the office-based setting?
A. Well, the FDA approved at that point in time only one medication and two formulary. The first one is also known as Silbotech (phonetic), and the other known as Suboxone.
Q. Okay. And who was the company that sought and gained approval of those two prescription narcotics?
A. That was Reckitt Benckiser Pharmaceuticals.
Q. And did you have a relationship with Reckitt?
A. Several years after I started treating patients with the Suboxone, and I joined the treatment advocate program of the company.
Q. And what's a treat advocate?
A. A treat advocate is a physician who assists in the education and training of other physicians to implement quality care



guidelines in the management of opioid dependence treatment.
Q. As a treatment advocate, do you advocate per the Suboxone or Reckitt products?
A. No. We were not advocating for the legalization of Suboxone products. We were advocating for the quality limitation, quality guideline.
Q. Can you slow down in your answers because it may be hard for the court reporter to keep up.
A. We were not advocating for the treatment of opioid dependence with Suboxone, but advocating for the implementation of quality care guidelines in the management of opioid dependence.
Q. Thank you, Doctor.
Were you compensated by Reckitt for that work?
A. Yes, we were, and we are compensated, and I am compensated with a honorarium.
Q. What's an honorarium?



A. An honorarium is compensated from the medical practice, which I'm engaged in during my time, and it ranges anywhere between 500 to $750 per presentation.
Q. Is it a significant source of your income?
A. No. It is far less than ten percent of my practice income.
Q. Let's talk a little bit about the prescription approved narcotics that Suboxone and the Subutex. First, what is the dosage form that those are in?
A. They're being utilized, or were utilized at that time as tablets.
Q. And what's the route of administration?
A. Route of administration is a sublingual, under-the-tongue form. So not to be swallowed.
Q. And they both contain buprenorphine; right?
A. They both contain buprenorphine, that's correct.
Q. And what is the function of



buprenorphine in those formulations?
A. Buprenorphine is a partial opioid agonist, meaning it stimulates the oral receptor. Therefore, mimicking an opioid effect but reducing the withdrawals and cravings for patients that's getting off of their drug of choice.
Q. How does that differ from, say, methadone that was used before?
A. Well, methadone, which, methadone, which is being used since 1972, is a direct opioid agonist, meaning it directly stimulates the opioid receptor and has a dose-dependent effect, meaning the more you give, the more effect you have, and the more adverse effects there are, unfortunately, to the point of overdose, which cannot happen with buprenorphine.
Q. That's because the buprenorphine has a ceiling effect?
A. Buprenorphine levels off at a certain dosage, about 16 milligrams, where it saturates more than 95 percent of the opioid receptors. Therefore, cannot induce any kind of

overdose related effect.
Q. So I believe you said that Suboxone tablets has an additional active ingredient, naloxone; is that correct?
A. That's correct.
Q. And what is the purpose and function of naloxone in that formulation?
A. Naloxone is an opioid antagonist blocking the effect of opioids, which was added in order to avoid abuse of the prescription narcotic. What it means is that if a patient decides to crush and dissolve the tablets, Suboxone tablet, the injected naloxone would exert an immediate effect and precipitate a withdrawal and craving, which is very uncomfortable.
Q. All right. Doctor, you have, have you prescribed Suboxone tablets to your patients?
A. Yes, I do, and, yes, I did, to the point it was available.
Q. And what, if any, feedback did you receive from your patients about the Suboxone tablets?



A. Over the course of time, I received feedback ranging from complaints about taste disturbances, dissolution time problems, of problems with the length of the time that it took to dissolve related to the life of production and the accidental swallowing of the product.
Q. Can I stop you there? What do you mean, what's this accidental swallowing and why is that significant?
A. The tablet takes a lot about three to six minutes to dissolve at least, and it's individually different, of course, can trigger saliva production. And in some patients, they complained that they had to swallow the product instead of waiting for it to dissolve because there was so much saliva produced.
Q. And why is that a bad thing?
A. Because the product is not workable, and it does not serve the effect once it's swallowed. It only affect the patient by sublingual transmission.
THE COURT: Ms. Bourke, could you move the mike a little closer?



MS. BOURKE: Certainly, your Honor. Is that better?
THE COURT: Yes.
BY MS. BOURKE:
Q. What other feedback did you get from the patient? We talked about taste. You talked about the dissolution time. Did you get any others?
A. The other problem the patients note was the friability of the tablets, meaning the tablets broke down in the bottle, and I noticed that when I was counting tablets, in order to ascertain that the patient complied with the prescribed dosage. And specifically, the last third of the remaining bottle, last third of the treatment base, I noticed broken-down tablets even to the point that powder remnants formed from the bottom of the bottle.
Q. And why is that a bad thing?
A. Because the patient could not dose the tablet appropriately. Instead of taking, for example, a full eight-milligram tablet, they had to fish -- that was a term used by one of my



patients -- fish out product that made up approximately eight milligrams and then apply it under the tongue, which was often difficult.
Q. Aside from the patient feedback that you got, as a practicing physician in the field of opiate, treatment of opiate use disorder, are you aware of any other issues that were around with respect to the tablet?
A. Yes. The availability of the tablets and the ability to dissolve the tablet in the solvent led to the theoretical potential of injection and abuse specifically, but buprenorphine as well as Suboxone. And my patients reported, and I heard it from other physicians that I communicated with, that intravenous abuse of Suboxone was rising, and also notification boards used by Suboxone users.
Q. Anything else?
A. Also the potential that bottles were accidentally discarded in garbage, or garbage containers led itself to the accessibility of products by children. This was a unique feature of the, of the tablets, that

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

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

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

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

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

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

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



option with the patient?

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

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

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

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

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

Q. Can you be specific about what



they told you about the film?

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

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

Q. What about the potential abuse issue?

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

Q. What about the risk of pediatric exposure?

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



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

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

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

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

A. Yes, I am.

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

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

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

Q. And what was your reaction to the finding?

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

Q. Thank you, Doctor.

Anything else with respect to the finding?

A. It clearly emphasizes that the dissolution time is improved.

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



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

Can you explain to the Court what that means?

A. Investigator-led means that the investigator, the principal investigator has full control of the design, the control level of the study, the analysis of the data and the publication of the data.

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

A. That's correct.

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

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

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



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

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

A. More than 90 percent.

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

THE WITNESS: Thank you.

THE COURT: All right. Cross-examination.

MR. SMEREK: Thank you, your Honor.

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

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

MS. BOURKE: Pre-admission?

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



admitted without objection.

MS. BOURKE: Okay. Thank you, your Honor.

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

CROSS-EXAMINATION

BY MR. SMEREK:

Q. Dr. Wollschlaeger, good morning.

A. Good morning to you.

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

A. Absolutely.

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

A. Yes, I did.

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

A. That is correct.

Q. And you talked about the Suboxone

tablet and Suboxone film today, and you've prescribed both in your practice; is that correct?

A. That is correct.

Q. And I'm correct that there are no differences in clinical outcomes between the use of Suboxone film and the Suboxone tablet or the generic buprenorphine naloxone tablet; is that correct?

A. There's no difference in clinical outcome between the tablet and the film. The generic tablets, I have limited experience because my patients hardly use them.

Q. Thank you.

And it's true that all patients are sensitive to out-of-pocket costs for the medications like Suboxone; is that correct?

A. That is correct.

Q. And, in fact, cost of Suboxone is a driving factor; is that correct?

A. That is not correct because there are multiple factors influencing a patient's decision, and even price cannot be often properly determined from patient to patient. So



it cannot be used as the only factor.

Q. And I'm sorry. I was perhaps unclear in my question. I'm correct that cost or price of Suboxone is a driving factor; is that correct?

A. That is correct.

Q. And when Reckitt launched the Suboxone film product, at that time the only other buprenorphine naloxone product on the market was the Suboxone tablet; is that correct?

A. That is correct.

Q. And when Reckitt launched the Suboxone film, they told doctors like yourself in the treatment advocate group that there would be significant savings for patients who switched over to the film; is that correct?

A. Well, we were informed that there were savings like there were savings with the tablets, there would be savings with the film, which would be adjusted and help the patient to cover the co-pays, which is not unusual in the industry for any product.

Q. So it's going to be affordable for patients to switch to the film; is that correct?



A. That there would be no obstacle to those patients that choose to take the film.

Q. You talked about Exhibit JTX-82. That was the Lyntzeris paper. Do you recall generally this is the paper that you were discussing?

A. That is correct.

Q. And if I could look at Section 3.4, adverse events, blow that up here on the screen.

And according to the Lyntzeris paper, just to be clear, there's no significant difference between side effects experienced by patients administered tablets or film; is that correct? Nothing reported?

A. That is correct.

Q. And if we look down a little bit further in that same adverse events, after, there are some side effects reported, but then there are problems that patients reported with the film; is that correct?

A. That is correct.

Q. And we discussed these problems a little bit at your deposition?



A. That is correct.

Q. And here, according to this, I think you said it was a well-conducted study that you relied upon. And it said, respondents reported film got stuck to the teeth. That's because the film gets sticky when it's wet; is that correct?

A. If it's not used properly, then it's being sticky.

Q. And so here, what percentage of people, what percentage of the respondents indicated that the film got stuck to their teeth?

A. 65 percent.

Q. Okay. And then we move on, and I guess there were more problems with people having it stuck to the roof of the mouth. And how many people reported that problem?

A. 30 percent.

Q. And others had it stuck to the cheek. How many reported that problem?

A. Eight percent.

Q. And then even before it got to the mouth, there were others that were having

problems just picking the film up. And how many had that problem?

A. 16 percent.

Q. And it got stuck to, you said wet fingers, and there were 14 percent here.

Now, I have to assume, when you read this, did you assume that there was some overlap in these problems, in the people having these problems?

A. Overlap as?

Q. Well, I'm looking at it, and if I add all of those percentages up, it is more than a hundred percent of the respondents are having trouble getting, getting the film under their tongue where it's supposed to be, so when I read it, I just assumed that there had to be some overlap in those percentages. And I'm just asking you, when you read this report, did you believe that there was overlap, or did you believe that nobody actually got the film under their tongue?

A. Well, there was probably and definitely an overlap of the 42 participants in this, that were counted.



Q. All right. And am I correct that if you don't get the film under the tongue so that it can dissolve like the tablet, that that could lead to problems with the correct dosage being delivered?

A. If not properly educated, that's always the premise that the patient needs to be properly educated, then these reported events occur, which almost never occurred with my patients.

Q. And so in your expert opinion, the respondents, the people who participated in this study, were not properly educated with respect to how you use the film?

A. I would assume, because I did not conduct and participate in the study, that many of those reported side effects and adverse effects are related to improper education and handling of the film strips.

Q. So here in this study, this well-done study, as you called it, the patients were having these problems with the film because they weren't properly trained by the persons who conducted the study, in your opinion?



A. I would assume that that is the conclusion.

Q. Okay. And if we could turn to page 4, Section 3 .2, just back up a little bit here. I'm sorry. Section -- yes. Thank you.

And hear it talks about patient preference; is that correct?

A. That's correct.

Q. Okay. And let's see here. The two groups reported similar subjective ratings for dose effects.

Do you see that?

A. That is correct.

Q. And those two groups, the one group is the film group and one group is the tablet group. That's how you read that?

A. Yes.

Q. Okay.

A. That's fine.

Q. And then a little bit, right after we pick up a little bit further in that sentence, so dose ratings, sedation craving and withdrawal effects, those are all, those are all



reported as similar. And then it says, ease of use, convenience and taste between the tablet and the film groups.

So similar subjective ratings in this well-controlled study that you, that you have talked about, ease of use, convenience and taste, were all seen as similarly subjective ratings between tablets and films, according to the study reports; is that right?

A. That is correct.

Q. Okay. We can go ahead and take that off.

Overall patient satisfaction. Are you aware that Reckitt internally has done studies from time to time with respect to the overall satisfaction of patients with the tablets or then subsequently with Suboxone film?

A. I've heard about internal studies, but I'm not privy to the results.

Q. All right. And so you have never -- you've never seen any results of those studies?

A. No, I did not.

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

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

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

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

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

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

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

**A. That has been reported. That's correct.**

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



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

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

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

**A. Absolutely.**

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

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

**A. That is correct.**

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

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



**Q. Thank you.**

**And you agree that if those tablets were individually wrapped, for example, in a blister back, that that issue of friability would be addressed?**

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

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

**A. That is correct.**

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

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

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



**blister pack, correct?**

**And what was your answer at that time?**

**A. That is correct.**

**Q. Thank you.**

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

**A. Portability would be addressed. That's correct.**

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

**A. Training is one of the components. The education of the patient is one of the components where the pediatric safety can be addressed.**

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

form; is that correct?
A. It is important independent of the dosage form.
Q. Thank you.
Now, when -- at what point -- you heard at some point in time that Reckitt was planning to withdraw the Suboxone tablet, and the stated reason for withdrawing the Suboxone tablet was pediatric safety; is that correct?
A. One of the stated reasons was pediatric safety.
Q. Okay. And the pediatric safety issue, I think as you talked about already a little bit today, is the potential unintended exposure of children to this drug; is that correct?
A. That is correct.
Q. And that issue was addressed in Suboxone film by packaging; is that correct? Not by the dosage form?
A. By packaging and the dosage form in the film.
Q. And if you turn -- if I could have up your deposition, page 134, please.



And so I asked you at line 22 at your deposition: So if issue of pediatric safety, in your opinion, would be related to the packaging of the film, or the packaging of the tablet, and whether or not it was similarly child-resistant; would that be fair?
And your response there was?
A. In theory, yes.
Q. All right. And then I also asked you later: If a Suboxone tablet was packaged in individual dosage form, the same as the Suboxone film, it would be as safe as the packaged Suboxone film strip. And you agreed that that was correct?
A. Can you show me that, please?
Q. Well, let me -- before we go there, let me just ask you the question. It's correct that if Suboxone tablets had simply been individually wrapped in a child-safe wrapping, that they would have the, be as safe from a pediatric exposure standpoint as Suboxone film; is that correct?
A. In theory, yes, but it wouldn't address friability.



Q. So they, it is correct that pediatric safety would be addressed, by packaging in a pediatrically safe child-resistant package; is that correct?
A. As part of pediatric safety program, yes.
Q. And you didn't do anything in your work here to familiarize yourself with the patents or the claims in the patents at suit; is that correct?
A. No. That was not the scope of my task.
Q. And there's nothing in your testimony regarding anything that you've testified about that you believe would connect any of these issues to any of the claims in the patent, is there?
A. That is correct.
Q. Thank you.
MR. SMEREK: Nothing further, your Honor.
THE COURT: All right. Is there any redirect?
MS. BOURKE: Nothing further, your



Honor.
THE COURT: All right, Doctor. You may step down.
THE WITNESS: Thank you, your Honor.
THE COURT: Thank you.
All right. So why don't we take our morning break? It will be 15 minutes. All right? We'll be in recess.
(Short recess taken.)
- - -
(Proceedings resumed after the short recess.)
THE COURT: All right. Please be seated.
Plaintiffs, call your next witness.
MR. BOLLINGER: Thank you, your Honor. If it please the Court, we call Dr. Lon Mathias to the stand.
Your Honor, we have a small set of demonstrative slides and which we'd like to hand up.
THE COURT: All right. Please do

so.

(Mr. Bollinger handed slides to the Court.)

... LON JAY MATHIAS,
having been duly sworn as a witness, was examined and testified as follows ...

MR. BOLLINGER: Your Honor, also some exhibit books. These are the actual exhibits. If I could hand those up also?

THE COURT: All right.

(Bollinger handed exhibit books to the Court.)

MR. BOLLINGER: Okay. If it please the Court.

DIRECT EXAMINATION.

BY MR. BOLLINGER:

Q. Dr. Mathias, good morning. I would like you, if you could, just recognizing that your CV has already been reviewed by the Court, if you could briefly touch upon some of your experiences that relate to this, the disputes in this case?

A. Sure. I started my career in



polymer science as an undergraduate at the University of Iowa. I moved to the University of Michigan for a Ph.D., did a post-doctoral fellowship in polymers at the University of California in San Diego.

Took a -- my first teaching position at Auburn University, teaching chemistry and polymer chemistry, and then moved to the department of polymer science at the University of Southern Mississippi in 1981.

Q. Now, we've heard about polyethylene oxide and what we've been calling PEO for short. Have you had experience working with polyethylene oxides in the past?

A. Yes, I have.

Q. Can you just briefly describe those?

A. We've used polyethylene oxides in our research projects. We've incorporated it into various polymers for both academic and commercial interest. We've also developed experiments using polyethylene oxides for our laboratory. We include PEO as an important



example of commercial polymer in the courses that we teach as well.

Q. All right. And there has also been a test called GPC, or what we call gel permeation chromatography. Just touch off some of the experiences you've used that or relied on it in the past?

A. We've used GPC throughout my career. It has been it's a technique that has been available for a long time. We've had -- in my research group we've had several different GPC instruments, and I've trained students on how to use those instruments and get data or characterization.

Q. All right.

MR. BOLLINGER: Your Honor, Dr. Mathias is, his CV, as you have seen is at JTX-008. And we'd offer Dr. Mathias as an expert in polymer chemistry and the analytical techniques for measuring polymeric properties.

THE COURT: All right. You may proceed.

BY MR. BOLLINGER:

Q. In this case, can you tell me



briefly what materials you have reviewed in pursuing the objectives of your analysis?

A. Sure. I looked at the '150 patent itself. I looked at the Court's claim construction. I looked at Watson's ANDA document, selected portions of that.

I reviewed the expert reports of Dr. McConville and doctor empty (who? (And I looked at the expert reports of Dr. Yau.

Q. And after you reviewed these materials, did you reach a conclusion about whether the -- about the question of infringement of the '150 patent?

A. Yes, I did.

Q. And what was that conclusion?

A. My conclusion is that the Watson product infringes claims 1 and 4 of the '150 patent.

Q. All right. We're going to talk a little bit in detail about the underlying premise of that conclusion, but before we do that, I'd like you, if you could, just briefly explain something about your understanding of the '150 patent or technology it embraces. And

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



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



construction. Did you have a chance to review that?
A. I did, yes.
Q. All right. I think that's on the next slide.
A. Yes.
Q. As you see, the Court has construed this. Can you briefly summarize your understanding and the way you applied this Court's construction?
A. Well, at a high level, it deals with the requirement that the, the material infringing the patent have two separate or discrete sets of polyethylene oxide PEO, that they have average molecular weights within certain ranges, and that the lower molecular weight comprise certain amount of the total polymer present in the material.
Q. All right. And before we get to the details of the analysis of that particular limitation, can you briefly describe why it's important to have two fractions of PEO, polyethylene oxide, a high and a low fraction as you understand it for this claim?



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

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



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



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



Q. So the very largest molecules come out very quickly from the column?
A. Yes.
Q. And then the very small ones take longer, progressively smaller, progressively longer?
A. Yes.
Q. All right. Thank you.
And what do you understand about the Polyox in terms of poly dispersity? Is there a characterization of the Polyox N80 that you can give us?
A. Well, Polyox N80 is a commercial polymer, and almost all commercial polymers are made in such a way that the broad molecular weight distribution, it's just inherent in the synthesis in the way that they are made. That broad distribution then leads to both low and high molecular weight, and the only way to figure out if they are in there is to do techniques such as this.
Q. All right. And you saw during the opening today counsel for defendant suggesting that a product such as Dow was a unimodal

distribution. Therefore, it had no high molecular weight product. Is that a correct way to look at it?

A. No.

Q. And why not?

A. Well, because just the shape of it, of the chromatogram doesn't tell you whether there's high and low molecular weight. You have to actually look at the values of the plot.

Q. All right. And is that possible with GPC?

A. Yes, it is.

Q. And do you know whether GPC was done on the N80 sample? I'm sorry. I'm getting ahead of myself.

I would like to, we have another slide that kind of expand on the discussion of how GPC works. Can we turn to that?

A. If we start on the upper left, we have a depiction of a mixture of polyethylene oxide of different sizes, different molecular weights. After the chromatograph separation, we see a well characterized distribution from low to high molecular weight, which are plotted in



the bottom figure going from low on the left to high on the right. That's a long molecular weight scale, so the numbers are small, but it represents several thousands on the left to several million on the right.

This is a very broad distribution consistent with this commercial source. The Y axis represents a relative amount or a mass fraction of each one of the molecular weights that is depicted on this.

Q. And this diagram at the bottom, obviously, you're using it as typical for a GPC, although I'm not sure that's, whether there is such a thing as typical.

Was GPC performed in this case on the N80 sample?

A. Yes, it was.

Q. And do you know who performed that testing?

A. That testing was done by Dr. Yau.

Q. All right. And can you just briefly describe your, the information you have about his background and his work on this case?



A. Dr. Yau has been working on GPC for longer than I have. He has been doing GPC for almost 50 years I understand. He has developed many of the new methods of analysis using GPC that provide additional information or different accuracy precision in the method. He has also authored one of the key reference books on GPC analysis, and that reference book is available in my lab. It's used by virtually everybody that does GPC.

Q. Thank you.

And can you tell me briefly, did you review the protocol that Dr. Yau used in analyzing the Watson's N80 Polyox?

A. I did, yes.

Q. And did you find it acceptable for the analysis?

A. Yes.

Q. Did you rely on it?

A. Yes.

Q. Did you look at the results that he prepared?

A. Yes.

Q. And do you rely on it for your



opinion today?

A. I did, yes.

Q. All right. So we're going to turn to the next figure, which is the diagram that I think we've seen several times this morning, which is the results of the analysis by Dr. Yau on the -- can you describe briefly what this is?

A. Well, what Dr. Yau is did is by a commercial sample of Polyox, break that into three separate portions, and then make up solution with each one of those portions.

He analyzed each portion then three times, which gave a total of nine GPC runs. All nine of those GPC runs are shown in this similar file. They overlay each other so closely that it's very difficult to separate the individual chromatograph.

Q. This --

A. This speaks very highly to the precision of the method and the care with which the analysis was done by Dr. Yau.

Q. In reviewing this data, did you reach a conclusion as to the type of

distribution just demonstrated or presented here?

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

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

A. No, it does not.

Q. And why is that?

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

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

Q. And what work are you referring to?

A. This is a paper by Dow



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

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

BY MR. BOLLINGER:

Q. Can you describe what the next slide is?

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

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



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

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

A. Of course.

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

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

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



this.

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

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

A. Yes, oftentimes.

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

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

this kind of analysis. This particular paper, and the one that follows, both deal specifically with PEO. So I thought they would be appropriate examples for this kind of case.

What these workers did is examine a broad molecular weight PEO similar to what is done here, and found that to understand the dynamic modules or the solution properties of that broad molecular weight sample, they had to analyze the material that's two separate fractions, one a high molecular weight fraction and the rest comprising the rest of the sample.

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

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

Q. And is --

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

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



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

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

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

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

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



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

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

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

A. Yes.

Q. And you provided that information?

A. To the lawyers, yes.

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

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



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

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

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

A. That's correct.

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

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

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

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

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

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

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



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

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

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

I think Dr. McConville's report or testimony and Dr. Amogees (phonetic), they agree that viscosity average, molecular weight, was the most commonly used.

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



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

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

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

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



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

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

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

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

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

ruling in construing the claim the way he did.
THE COURT: All right. I'm going to sustain the objection.
MR. BOLLINGER: Thank you.
BY MR. BOLLINGER:
Q. Let's move on to the next slide.
A. Well, before we leave that, there's actually one more piece of evidence that viscosity molecular average --
Q. Okay. What is that?
A. That's the L'Hote paper. I don't know if we can bring that up. There's a reference there that I think is very relevant.
The L'Hote paper was looking specifically at whether there was by molar or unimodal distribution, but they also made the statement -- and these are Dow researchers. They made the statement that the approximate molecular weights, and I'm paraphrasing, the approximate molecular weights and their product literature, (Viscosity average molecular weight), are what are being used in this evaluation.
Q. We'll jump back to that. I'm



sorry. Here it is. This is the paper you're talking about?
A. Yes.
Q. And we talked a little bit about that with that, those six, I'm sorry, unimodal distributions. What page is on it?
A. I think it's on the fourth or fifth page. I'm sorry. Too far down. Just a little bit -- right there, yes.
If we look halfway down that paragraph, it says, a comparison of the approximate molecular weight of standard Polyox WSR provided in product literature (viscosity-average molecular weight) to the molecular weight. The sentence goes on. But the key here is that they refer to their molecular weight as viscosity average molecular weight.
Q. Thank you.
And so based on that, you understood the claims to mean, be expressing molecular weight in what terms?
A. Viscosity average.
Q. All right. Thank you.
If we can go to the -- now, we've



answered the questions regarding the two discrete sets. Can you tell me how you determined whether the 60 percent limitation had been established?
A. Yes. The next slide actually shows the calculations used for that. But each of the dosage amounts on the left, we know the amount of PEO and the amount of HPMC in milligrams that are present in those doses. Knowing the, from the SEC curve the amount of high and low molecular weight PEO in the samples, we can divide each one of those weights by the total weight, and calculate 86 percent, approximately two percent, and 12 percent of the HPMC, and the 86 percent is clearly more than the about 60 percent required.
Q. All right.
MR. BOLLINGER: Your Honor, these calculations are at tab PTX-538 A, C, D and G of the evidence book and the underlying calculations.
BY MR. BOLLINGER:
Q. Now, one final question. The issue of whether they're stray or not, can you



tell me briefly what your understanding of what stray is and the amount of PEO at the high molecular weight satisfies or is not stray?
A. I think the next slide deals with that. Yes. This is one of the papers I referred to in which they were looking at a broad molecular weight distribution to evaluate its rheological properties, the practical solution properties. What they found was that the properties observed are mainly attributed to the influence of the high molecular weight fraction. This is seen in many analyses, many characterizations of broad molecular weight polymers, and it's one of the reasons that we sell, that we use broad molecular weight and not low molecular weight.
The broad molecular weight disproportionately affects certain key properties such as tensile strength. And one of the reasons for that depicted in the bottom slide there, that figure that's pulled out, the low molecular weight polymers in any given broad molecular weight sample cannot handle, but the high molecular weight materials, because they're

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

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

A. Yes.

Q. Go to the next slide.

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

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



infringe.

Q. Thank you.

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

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

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

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



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

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

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

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

MR. NUTTER: No objection.

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

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

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



MR. BOLLINGER: Okay.

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

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

THE COURT: All right. Cross-examination.

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

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

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

THE COURT: Okay.

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

THE COURT: All right.

CROSS-EXAMINATION

BY MR. NUTTER:

Q. Good morning, Dr. Mathias.

A. Good morning.

Q. I'd like to ask you a few questions about your trial testimony today. But

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

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

BY MR. NUTTER:

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

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

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

A. Yes.

Q. Now, I'd like you --

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

BY MR. NUTTER:

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



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

A. Yes.

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

A. That's correct.

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

A. I do not.

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

A. I am not.

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

A. That's correct.

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

A. I have not.

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

A. No, I have not.



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

A. I would disagree with that.

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

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

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

A. I have not.

Q. Thank you.

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

A. Yes.

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

A. That's correct.

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



daltons. Yes?

A. That's correct.

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

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

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

A. The numbers, yes, correct.

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

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

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

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

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

Polyox N80. Yes?
A. That's correct.
Q. And that's a single viscosity average molecular weight. Yes?
A. Yes.
Q. But claim 1 of the '150 requires two average molecular weights for PEO, 1 between 100,000 and 300,000, and 1 between 600,000 and 900,000. Yes?
A. That's correct.
Q. And that's why you and Dr. Yau chose to partition Polyox N80, so you could come up with two average molecular weights; isn't that right?
A. I'm sorry. Could we go back to your previous question? I may not have understood that correctly. Could you ask that again?
Q. I don't know what my last question was.
A. I can't remember if you said molecular weights or molecular weight averages for those.
Q. I believe I asked does claim 1



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



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



better explain your infringement analysis.
On the left, you have one group of people, and perhaps you referred to it as a basketball team? I'm not sure.
A. Tryouts for the basketball team.
Q. And on the right you have, you've broken it up into two groups of people; is that right?
A. Yes.
Q. You've separated. You had one group you've separated into two groups? Yes?
A. That is correct.
Q. So as with the '150 features combining two groups, in order for you to find infringement, you have to separate into two groups, don't you?
A. Yes.
Q. Thank you.
Now I would like to look at the partition analysis --
A. I'm sorry. Can you restate that question? I think I answered too quickly.
Q. You will have an opportunity for your counsel to ask questions again. I'm ready

to move on to another question.
A. All right.
Q. I'd like to look now at the partition analysis that you and Dr. Yau conducted.
Now, I believe you testified earlier that Dr. Yau, he purchased some Polyox N80; right?
A. That's correct.
Q. And he conducted a GPC analysis on it; is that right?
A. Yes.
Q. And that stands for gel permeation chromatography; isn't that correct?
A. Yes.
MR. NUTTER: Mr. Young, if you can put up PTX-143 for me.
BY MR. NUTTER:
Q. And you've certainly seen this, this chart before. Yes?
A. Yes.
Q. This comes from the results section of Dr. Yau's expert report, and these were the results that you relied on in forming



your infringement opinion. Yes?
A. It's part of the results, yes.
Q. Okay. And what we're looking at, I think everyone is in agreement, it's a unimodal distribution curve. That's what Dr. Yau came up with after completing his GPC analysis; isn't that right?
A. That's correct.
Q. And this curve is for the entire sample of Polyox N80. Yes?
A. Yes.
Q. And it's the type of curve you'd expect to get when you examined Polyox N80 like Dr. Yau did; right?
A. I don't know if the shape would be exactly the same, but you'd expect a plot that that was unimodal, yes.
Q. Like most PEOs, it has a broad distribution. I think you testified about that during your direct; is that right?
A. Yes.
Q. And like every PEO ever made, it's a combination of low and high molecular weight molecules, isn't it?



A. I don't know if I would go as far as every, but all the ones that I'm familiar with, yes, a broad distribution of high and low.
Q. All --
A. Except for calibration states. Now, there are specific standards that are made for specific applications, such as calibrating GPC columns, and those are narrower distribution.
Q. Excluding the ones made for standard calibration curve, you're not aware of any PEOs that are not already a combination of low and high molecular weight molecules; is that correct?
A. Yes. I indicated there's -- the actual manufacturing process results in that.
Q. Is that a yes?
A. Yes.
Q. Thank you.
And because it's a collection of molecules with different molecular weights, you're able to come up with an average molecular weight, aren't you?
A. You would have to do an analysis



of some kind, yes.
Q. Sure. And usually, the average molecular weight for a distribution curve like this, usually it's somewhere around the peak, isn't it?
A. Given the shape of this curve, yes, it's going to be close to the peak.
Q. And when the average is around the peak, the molecules to the left of the peak, it's at least smaller than the average size; is that correct?
A. That's correct.
Q. And the molecules to the right of the peak are typically larger than the average; correct?
A. That's correct, yes.
Q. It's what you would expect to see?
A. Yes.
Q. And just like Dow was able to come up with a single viscosity average molecular weight, Dr. Yau was also able to come up with a single viscosity average molecular weight for his characterization of Polyox N80; is that correct?

A. That's correct.
Q. But that single viscosity average molecular weight that he calculated, if you relied solely on is that, Watson would not infringe; isn't that right?
A. I'm not, I'm not clear on the question.
Q. I will rephrase. Dr. Yau calculated the overall viscosity average molecular weight for policy oh Polyox N80 to be somewhere around 105,000 daltons; isn't that right?
A. That's correct.
Q. And you would agree with me that 105,000 daltons is not between 600,000 and 900,000 daltons; is that right?
A. Yes, that's correct.
Q. And so because of that, you sat down with plaintiffs' attorneys and decided that this curve needed to be partitioned at the 600,000 dalton mark, didn't you?
A. No.
Q. That came after discussion with plaintiffs' attorneys; correct?



A. No. I cite that.
Q. So you cited that in your report to plaintiffs' attorneys; is that correct?
A. We had the claim construction, we had the limitations of the patent, we had the plots and the data from the plot, and I looked at that and chose 600,000 because it was the most reasonable place to go.
Q. Well, you came to that conclusion after talking to the attorneys; isn't that right?
A. In what regard? I mean, I was talking with the attorneys throughout the entire process.
Q. You did not reach the decision to partition at the 600,000 dalton mark until after discussing that with plaintiffs' attorneys; isn't that correct?
A. No. They supplied me the data, we looked at it, we talked about it. Of course.
Q. Okay. Thank you.
And you would agree with me that this 600,000 dalton partition, it's at the tail end portion of the uniform distribution curve?



Yes?
A. It's at the high marker rate, yes.
Q. And you and the lawyers, you purposefully selected the 600,000 dalton mark because it's at the lower end of the upper molecular weight limit for claim 1; isn't that right?
A. That's correct.
Q. You chose it because the upper weight range is from 600,000 to 900,000, and so you drew your partition at 600,000. That's why you drew it there. Yes?
A. That's part of the reason, yes.
Q. You looked at claim 1 and said, let's draw the line at 600,000. Yes?
A. The other considerations, such as the 60 percent of low molecular weight that's required.
Q. And to be clear, none of this is discussed in the '150 patent. Yes? You agree with me?
A. That's correct, yes.
Q. There's no discussion about taking a PEO and fractionating it into a lower



molecular weight portion and a higher molecular weight portion. There's no discussion of that anywhere in the patent?
A. I'm not aware of any, no.
Q. Now, according to your partition theory, everything to the left of that line, that's the low molecular weight PEO required for in claim 1; isn't that right?
A. Yes.
Q. And also according to your theory, everything to the right of the line, that would be the high molecular weight portion as required for in claim 1. Yes?
A. That's correct.
Q. And so one of the questions that you need to answer in doing your analysis is, does the average molecular weight of all the molecules on the left-hand side, does that fall between 100,000 and 300,000; is that right? That's one of the questions you were trying to answer?
A. Yes, it was.
Q. And the other question that you were trying to answer was: Does the average

molecular weight of everything on the right-hand side of the line, is that a -- does that fall between 600,000 and 900,000; is that correct?

A. That's correct.

Q. Now, but here's my problem, Doctor. By drawing the line at the 600,000 mark, you sort of rigged the outcome, didn't you?

A. Not at all.

Q. Well, by putting the line at the 600,000 mark, you guaranteed that whatever average molecular weight that you got on the high end, it would always be greater than 600,000, wouldn't it?

A. We picked the best spot to start calculations. That turned out to be the last place we needed to look.

Q. But by drawing the line at 600,000, it guarantees that any average molecular weight that you get for the high end portion, it will always be higher than 600,000, won't it?

A. Sure. That's common sense.

Q. So the question is no longer does



it fall between 600 and 900,000. You've changed the dynamics. You've now made it so, is it greater than or lower than 900,000. That's the question now, isn't it?

A. No, not at all.

Q. It can never be lower than 600,000. You would agree with that?

A. Yes, that's correct.

Q. So you've assured that in every single instance when this is measured, it can never fall -- the high end can never fall below 600,000 daltons; is that correct?

A. Yes.

Q. Now, the patent does not say anything about conducting a GPC analysis on a PEO, does it?

A. It does not specifically say that, no.

Q. It does not say to go ahead and create a uniform distribution curve like Dr. Yau did, does it?

A. No, it does not.

Q. And it does not say anything about partitioning along the uniform distribution



curve and calculating an average molecular weight on either side of that partition. It doesn't discuss that, does it?

A. It does not.

Q. This was otherwise a litigation inspired theory for purposes of completing your infringement analysis; isn't that right?

A. It was the task that I was assigned to to carry out, yes, to analyze the, the molecular weight distribution and to look for the components of that analysis that would meet claim limitations, yes.

Q. All right. Thank you.

Now, this curve could be partitioned anywhere; isn't that right?

A. Yes.

Q. There's an infinite number of possibilities where this curve could be partitioned?

A. No.

Q. Is there a spot on the curve that cannot be partitioned?

A. I'm not sure where -- what you are talking about. I mean, why would you assume



there was an infinite number? You're going to pick your best shot. If the best shot is not correct, the calculated values would tell you which way to move the partition demarcation, and you would recalculate until you got close to where the final values were as close as possible to the -- to meeting the claim limitations.

Q. Thank you.

A. There's not an infinite number of those. There's probably only a handful.

Q. Well, you can move that line anywhere along that curve, isn't that right, and you could conduct the exact same analysis?

A. Well, you could, but no one would.

Q. You would get different results every time, wouldn't you?

A. Yes.

Q. But you only tested your theory at the 600,000 dalton mark; isn't that right?

A. That would be most appropriate place. We started there. It happened to give us the answer that allowed us to come to the conclusion I stated.

Q. Now I'd like to look at the

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

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

A. Yes.

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

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

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

A. Different portions of that sample, yes.

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



A. That's correct.

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

A. That's correct.

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

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

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

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

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

A. It was very precise.

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

A. Yes.



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

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

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

A. Yes.

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

A. A little bit less, yes.

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

A. I disagree.

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

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



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

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

A. Yes.

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

A. Very precisely.

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

A. Yes.

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

A. That's correct.

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

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

A. That's correct.
Q. He did not get a single result, not a single result that falls within the 100,000 to 300,000 range, did he?
A. He did not calculate any viscosity molecular weight for the low molecular weight that fell within that range, that's correct.
Q. Thank you.
Now, just below the 95,000 number, there's a reference to standard deviation. That's 623. Yes?
A. Yes.
Q. And standard deviation, that just takes into consideration potential errors in the equipment. That for a layperson means you can take that 95,895 plus or minus 623. Isn't that generally correct?
A. It's a measure of the precision of measurement, yes.
Q. So even giving the benefit of the doubt that it was measuring low, the closest you could get to 100,000 is approximately 96,518; is that right?
A. If you do that mathematical



calculation, that's correct, yes.
Q. All right. Now I'd like to switch gears and I would like to talk about your opinion that the 1.9 percent of the high fraction does not amount to a stray amount. And that number is calculated to the right. That's where that 1.9 percent comes from?
A. From these calculations, yes.
Q. All right. And actually, before you move on to stray amount, I want to go to the second table, the high end portion. So if we can -- it's over here. I want to reorient you. This is Tab A. This is where Dr. Yau calculated the weight average molecular weight and viscosity average molecular weight for the high end portion; isn't that right?
A. The results of those calculations, yes.
Q. And it is the same nine runs; right? That's why there are nine individual results?
A. Yes.
Q. Okay. And for the weight average molecular weight, he determined that the result



was 917,865. Yes?
A. That's what he calculated, yes.
Q. And you'd agree with me that 917,865 is greater than 900,000?
A. A little bit, yes.
Q. And in your expert report, you rounded 917,865, you rounded that to 920,000, didn't you?
A. That's correct.
Q. And with respect to the viscosity average molecular weight column, the -- the total that he came up with was 900,318; is that right?
A. Yes.
Q. Again, you'd agree with me that 900,318038, that is greater than 900,000. Yes?
A. In terms of calculations, yes.
Q. And one more point that I forgot to make with respect to the first, the lower fraction. The number 95,895, I know you testified during your direct that that should be rounded to 100,000. Yes?
A. It would be considered to be a hundred thousand.



Q. But --
A. I mean, that's how these materials are sold. That's what everybody understands the molecular weights correspond to.
Q. But in your expert report, you rounded it to 96,000, didn't you?
A. As a matter of mathematical rounding, yes.
Q. Okay. And you used that 96,000 number as a basis for your noninfringement opinion; isn't that right?
A. Yes, I did.
Q. Okay. Now I'd like to move to your stray amount opinion. You believe the term stray amount, that means very small or incidental? Yes?
A. Yes. An amount that would not affect the properties of material in the polymer context.
Q. But as you sit here today, you're unable to associate any numbers with the word "stray" based on the Court's claim construction; is that right?
A. Were there any numbers in the

claim construction? Is that what you are asking?

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

A. That's correct.

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

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

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

A. That's correct.

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

A. I didn't have to.

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



any functional significance; is that correct?

A. That's correct.

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

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

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

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

A. Yes, it is.

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

A. That is correct.

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



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

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

Q. I --

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

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

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

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

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

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



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

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

A. Yes, I did.

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

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

A. I did, yes.

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

A. Yes. That's what it says.

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

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

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

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

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

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

A. Yes.

Q. So the process is proprietary?

A. Yes.



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

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

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

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

BY MR. NUTTER:

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

Do you see that?

A. Yes.

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

A. No.

Q. Why not?

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



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

A. They may be part of the synthesis process.

Q. Thank you.

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

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

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

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

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

A. Yes.

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



BY MR. NUTTER:

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

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

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

A. That's correct.

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

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

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

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

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

A. Polyox N80 is not described in this article.
Q. But Dow does not characterize or describe Polyox N80 as a blend, does it?
A. They do not, but they do describe it as a blend in their synthesis process.
Q. We covered that. A blend with the calcium salts and the fumed silica.
A. A blend of batch reaction products.
Q. Okay. Now, I would like to also refer you to the second table in this article. It's on page 2.
Now I note that in your direct testimony, you said persons of ordinary skill in the art, they round all measurements for PEOs to the hundred thousand; isn't that right?
A. When talking about commercial materials, yes. When talking about GPC analysis, no.
Q. And the analysis that Dr. Yau conducted, that was GPC analysis?
A. Right. And he reported his actual data to several community --



Q. Thank you.
A. Just like he did here.
Q. And the weight average molecular weight calculated by these authors, and the number average molecular weight calculated by these authors, that was for the whole sample. It wasn't for a partition of the sample; isn't that right?
A. Yes.
Q. And I believe you talked about a couple of the papers. The Eshuis. Am I saying that correctly?
A. I don't know. We talked about that.
Q. Okay. There was Eshuis, I think that's JTX-76, and the Kulicke paper JTX-40.
Do you remember talking about those?
A. Yes.
Q. If you take into consideration the L'Hote article, the Eshuis article, the Kulicke paper, none of those papers deal with pharmaceutical formulations, do they?
A. They do not.



Q. None of those papers, not a single one of those papers partition a polyethylene oxide and then calculate the average molecular weight on either side of that partition like you've done; isn't that correct?
A. The Eshuis paper does partition and does calculate weights. They don't actually calculate individual weight averages because that's not what they were looking for. They do a partition, just like it was done in this case.
Q. Doctor, not a single one of the papers that you rely on partition a PEO and calculate the average molecular weight on either side of partition as you are asking this Court to do; isn't that correct?
A. It's a two-part question. Did any of those papers partition? Yes. Did they calculate the average molecular weights of those partitions? No.
MR. NUTTER: I have no further questions.
THE COURT: All right. Before you do redirect, Doctor, you mentioned during your



direct testimony something about 105,000 daltons. Do you remember what that was?
THE WITNESS: That was the viscosity average calculated for the entire N80.
THE COURT: All right. So Dow says 200,000; right?
THE WITNESS: Yes.
THE COURT: Are they describing a different kind of molecular weight?
THE WITNESS: Dow uses a, a specification that includes a very broad range of viscosity. So their materials can vary by as much as 16 or 20 percent.
THE COURT: But even if you vary by 16 or 20 percent from 200,000, you don't get 105,000?
THE WITNESS: No. This is something we've talked about at length and I don't have a real answer on.
THE COURT: Okay. The other question I had was: Is there a scientific principle that led you to select 600,000 for the partitioning?
THE WITNESS: Well, you always

make your best first guess, and --
THE COURT: First guess at what?
THE WITNESS: Well, again, you're looking at the claim limitations, you are looking at the way the distribution is supplied, and you know that you have to be to be on the right side of that peak because of the 60 percent or more.
THE COURT: So was basically what you were doing is, you were seeing whether there was any place where you could partition the unimodal distribution to meet the claim limitations? Is that what you were trying to do?
THE WITNESS: We were testing to see if it met the claim limitations, yes.
THE COURT: But in terms of picking the 600,000 as the point to try, that was essentially based on the idea that that looked like a good place to pick with having a reasonable probability based on your expertise of being able to come up with two viscosity average molecular weights that will meet the claim limitations?



THE WITNESS: That's correct.
THE COURT: But in terms of there being a scientific reason for picking 600,000, there isn't?
THE WITNESS: You make your best first guess and then you adjust based on what that calculation -- if we had done values that were off completely from the ranges given, we would have moved the calculation, or -- towards the value that would have given some more likelihood. This is standard scientific procedure. You make your best first guess and you do your calculation, adjust afterwards and see what occurs. We just happened to get lucky on the first guess.
THE COURT: All right. Thank you.
Go ahead, Mr. Bollinger.
MR. BOLLINGER: Thank you your Honor.

REDIRECT EXAMINATION

BY MR. BOLLINGER:

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



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

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

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

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

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

A. That's correct.

Q. Thank you.

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



would choose that?

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

Q. And there --

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

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

A. Yes.

Q. All right. A couple of other things.

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

BY MR. BOLLINGER:

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

amounts of PEOs and large amounts.

Now, when you read claim 1, did you understand it to have a combining step that was sort of like a method?

A. I understood that to mean that the product would have those amounts. The combining results in a combination, so I interpreted it as the analysis needed to be done on the actual combination.

Q. You understand the claim to be a composition claim, a film?

A. Yes.

Q. And so when you did your analysis, were you just trying to find out just to see if the PEO and the fractions defined by the claim were in there?

A. That's the only way you can do the analysis. You have to look at the actual materials used.

Q. Another point came up about Dr. Yau's, the accuracy, precision of his data. Is there a difference between precision and ultimate accurate see of the results?

A. Yes. You can have extremely



precise data but still have errors associated with the actual number that you determine. The example I use in my class in teaching is shooting at a target with a bow and arrow. You can shoot your arrows and have them very close together, which will give you very precise results, but you could not hit the bulls-eye. You could still miss the bulls-eye and still have very precise results.

Errors creep in experimental analysis, and inherently, experimental analysis due to variations in temperature, insolvent purity, in how old the columns are, how old the column equipment is.

The pumps wear out. So there's an inherent error associated with any variation that's made.

MR. BOLLINGER: And just briefly, if we could bring up the Flick article, and I think the page that references the centipoise.

MR. NUTTER: I now renew my objection to the Flick reference.

THE COURT: Yes. I think, I don't think you're going to do this.



MR. BOLLINGER: Well, I was going to because I think he opened the door. He asked him about it.

THE COURT: I don't recall that.

MR. BOLLINGER: He specifically asked about the lot-to-lot variability, and this is the evidence on the lot-to-lot variables.

THE COURT: Well, I don't think that opens the door.

MR. BOLLINGER: Okay. We'll move on.

BY MR. BOLLINGER:

Q. So if you can, in talking about the high molecular weight fraction, did that inform your choice on the 600 partition?

A. Yes. We knew we -- we knew that we needed only a small amount of the high molecular weight fraction. This is consistent with the teachings in the patents. It's consistent with what we know about how high molecular weight material fractions affect properties. So we knew that we didn't need very much of at this time, two percent, three percent, but it had to be within the



specific range for the average molecular weight calculated.

Q. And, in fact, claim construction said a small amount; is that correct?

A. It does say that, yes.

Q. And in the lot-to-lot variation, ignore the Flick article, is it well-known in the industry, there is meaningful lot-to-lot variation in polymer manufacture?

A. It's very common. In fact, that's why Dow uses the specification numbers that they use.

Q. All right.

MR. BOLLINGER: Your Honor, it came up in the cross, the exhibits, the tables with the calculated values, and I would offer those into evidence. It's PTX-538, A through H. And these are just the excerpts of his report, the tables, the tabulated calculations that back up the 1.9 percent and the, the 86 percent.

MR. NUTTER: JTX-143, which is the exhibit that I used, that is already admitted into evidence. I do believe what he's talking about might be snapshots of different portions

of that. I would have to clarify the exhibit.
THE COURT: Why don't you talk about it over lunch.
MR. BOLLINGER: Very good. Thank you, your Honor. And thank you, Dr. Mathias.
THE COURT: All right. And do you have any further questions since I asked him questions? You don't have to.
MR. NUTTER: No, your Honor.
THE COURT: All right. Thank you, Dr. Mathias. You may step down.
(Witness excused.)
THE COURT: All right. I guess Dr. Yau is your next witness?
MR. BOLLINGER: That's correct, your Honor. If it please the Court, we call Dr. Wallace Yau.
THE COURT: All right.
... DR. WALLACE YAU,
having been duly sworn as a witness, was examined and testified as follows...
MR. BOLLINGER: Your Honor, we have the same collection of books.
THE COURT: All right.



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



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



joint exhibit, JTX-032.
BY MR. BOLLINGER:
Q. And, Dr. Yau, have you performed GPC analysis in your career?
A. Yes, I did.
Q. Can you just give me a rough estimate of how many you've done?
A. Must be over many thousands.
Q. All right. Thank you.
And are these mostly in the polymer field?
A. Yes.
Q. Okay.
MR. BOLLINGER: Your Honor, we'd offer Dr. Yau as an expert in analytical techniques as they relate to polymer science, and specifically the determination of properties as synthetic polymers.
THE COURT: All right. You may proceed.
MR. BOLLINGER: Thank you.
BY MR. BOLLINGER:
Q. Were you asked to perform some GPC analysis in this case?

A. Yes.
Q. And what was the sample that you were asked to analyze?
A. It's Polyox N80. It's a commercial polyethylene oxide sample from Dow Chemical.
Q. And can you tell me a little briefly what you know about Polyox? Had you worked with it in the past?
A. Well, chemically, long chain molecules with a very broad molecule distribution with the repeating units of ethylene oxide.
Q. Were you -- do you recall what you specifically asked to do by plaintiff?
A. Yes. To look into the molecule weight and the molecule distribution of that product.
Q. The Polyox PEO N80; is that correct?
A. That's correct.
Q. And what way is the best way to do that?
A. The best way and also the only way



I recommend is using GPC to look at the molecule weight distribution.
Q. In now addressing this question from plaintiff, did you do some research?
A. Yes. Well, to complete the task, I did the research to find and design the best protocol to GPC. Then I contacted your internal laboratory provides such services, that there are so many, I picked the most credible one I can find.
Q. Yes. Were you familiar with the quality of their work?
A. Yes. I know the director of the lab.
Q. All right. And did you retain them to perform the protocol you designed?
A. Yes, I did.
Q. And did you communicate with them regarding the testing as they were performing it?
A. Yes. And I realized the importance of this test, so I made sure everything was done correctly.
Q. All right. And what did the lab



do?
A. The lab communicated with me and we set up the column protocols, how to prepare samples, and derivation curves and actually did the GPC runs and provide me the results, but also the raw data, I can do additional calculations.
Q. All right. Well, let's go to the next slide. Can you explain what this is?
A. Yes. That's the result already shown several times by Dr. Mathias. I think it's a molecular weight distribution curve prior to the log scale as they should be.
Q. All right. So the X axis is a log scale?
A. Yes.
Q. Even though there are integers there?
A. Pardon me?
Q. We'll move on.
I don't want to get into the details about the nine runs, but let me ask you: Were there any problems in the data that came up in signal to noise or any other issue?



A. The way I received the data, I was so impressed with it. There are nine GPC runs altogether and you can barely see any of the noise. If you look for noise, you have to go to the two extremes on both sides. But certainly, there's no signal-to-noise issue here to affect the average calculations in the molecule.
Q. All right. And did you -- the data that was sent to you by the lab, did you do any further analysis on that data?
A. Yes, I did.
Q. What did you do?
A. Well, I was looking -- I was asked to look for publishing and to see the two separate sets of, or subsets of the molecule weight distribution.
Q. And how was that possible with GPC data? Did you have to do anything to it to allow for that type of analysis?
A. To partition into two sets, that's the way to interpret the data. That's what I did.
Q. And have you ever done that before?

A. Yes.
Q. And is it an accepted practice in the field?
A. Oh, yes. In fact, in the polymer manufacturing, I think there's an EPA recordation because of control of organic volatized. So the polymer product will have to be created by EPA so that the molecule weight below 500 molecule weight percentage is not allowed to be produced.
Q. All right. And in this case, were you able to, when you partition it, were you able to determine viscosity averages of molecular weight for the two fractions?
A. Yes.
Q. And can we go to the -- let me ask you this: How did you do those calculations? Were they done on a calculator or computer?
A. Computer.
Q. Can you give me more detail?
A. Yes. Once I received the raw data from the lab, I can set the data arrays in a way to separate it into two pots. One product is lower than 600,000 molecular weight. Other



product is higher than that. In fact, in the spirit of to be helpful and transparent, I had included a template, an Excel spreadsheet in my opening report, so anybody can check it and adduce whatever they want to.
Q. Very good.
MR. BOLLINGER: And can we go to the last slide?
BY MR. BOLLINGER:
Q. I just want to confirm, this has already been discussed, this is the data you generated from your spreadsheet?
A. Yes.
Q. And why so many significant figures? Why all of this data? Obviously, it has come up in Dr. Mathias' testimony. Can you explain why these figures are presented the way they are?
A. The way is a weigh to explain what I said about the signal to noise, because with the 900 than runs, individual variants with all these significant digits, those are required in order to calculate the statistics of those samples and coming up with the standard



deviation. That's helpful to show the high precision of the data.
Q. In characterizing Polyox material such as in the analysis you did here, are you aware of any particular need to have those additional digits' details?
A. Not to say computers are stupid, but those are the calculated variables. They don't interpret how people use them. So these numbers, within three standard deviations or two standard deviations, is not for me to decide. And people interested in the sample, how they perform, the property, that's where you draw the line.
MR. BOLLINGER: Thank you.
Your Honor, we're going to offer the exhibits that Dr. Mathias talked about and now Dr. Yau has talked about into evidence. I think they're the ones -- I'm not sure there's a challenge.
MR. SMEREK: Your Honor, I would object only in as much as I think the testimony has been about Yau Exhibit B, which is already admitted into evidence at JTX-143. We've agreed



to admission. And I think --
THE COURT: Is there any sort of dispute about the numbers? Just looking at the 5.6 I, J, G, Y, I mean, it doesn't seem like this is where the controversy is.
MR. SMEREK: If plaintiffs will just agree that's what they pulled from the exhibit, we'll withdraw any objection.
THE COURT: All right. They'll be admitted for that caveat.
MR. BOLLINGER: Thank you. Thank you, your Honor. All right. We have no further questions.
THE COURT: All right. Thank you, Mr. Bollinger.
All right, Mr. Smerek.
MR. SMEREK: Thank you, your Honor.
CROSS-EXAMINATION
BY MR. SMEREK:
Q. Good afternoon, Dr. Yau.
A. Good afternoon.
Q. Mr. Yau? Dr. Yau?
A. Either way is fine.

Q. I will go with Dr. Yau. Good afternoon. We have not met before. I'm Steven Smerek and I'm going to ask you a fewer questions here. Okay?
A. Definitely. Thank you.
Q. Now, the first thing I just wanted to clear up a couple of questions that you were asked. You said a Polyox N80, you were familiar with that before you were approached by plaintiffs in this case; is that correct?
A. Yes. To certain degree, yes.
Q. And you described it as long chain PEO polymers; is that correct?
A. Yes. They are solvents, and millions of them.
Q. And you said that Dow Polyox N80 is known to have a very broad weight distribution; is that correct?
A. Yes.
Q. And that would have been known prior to 2003. That has been known for a long time; is that right?
A. 2003? Yes. Could you repeat the question?



Q. Sure. You said that Dow Polyox N80 is known to have a very broad distribution of, very broad weight, molecular weight distribution; is that correct?
A. Yes. With specific to PEO, all commercial polymers over any significance will have that property.
Q. And so I just want to focus on Dow Polyox N80. That's the subject of your testimony; is that correct?
A. Okay.
Q. And it's a commercially available PEO grade; is that correct?
A. Correct.
Q. And it has been available since before 2003; is that correct?
A. I don't know.
Q. Well, you looked at the patent, the '150 patent. You at least briefly looked at it; is that correct?
A. Oh, yes, I did.
Q. And that Polyox N80 that we're talking about, that was identified in the patent; is that correct?



A. I don't even remember the date of that '115 patent.
Q. Thank you. But my question right now is that the Polyox N80 is identified in the patent; is that correct?
A. I'm not even sure about that.
Q. Okay.
A. Because I honestly never go through the detail of it.
Q. And you would agree with me that anybody looking at any commercially available PEO product like Polyox N80 would understand that it has the broad distribution weight that you found in your study; is that correct?
A. I think that covered what I already replied. Almost all commercial polymers have the broad distribution.
Q. And that would include Polyox N80; is that correct?
A. Yes, definitely.
Q. And that would have been well-known in the art; is that correct?
A. Yes.
Q. Okay. And you indicated that the



only way that you would recommend to determine molecular weight of a PEO sample was by a GPC or gel permeation chromatography analysis; is that correct?
A. Looking at my --
MR. BOLLINGER: I'm going to object. I don't think that is what he said.
THE COURT: Can you rephrase the question?
Q. I think his exact words, and you can tell me if this isn't what you said, but you were approached to look into the weight of the N80 sample; is that correct?
A. Weight?
Q. The molecular weight, the molecular weight distribution of the Polyox N80 sample that you obtained; is that correct?
A. Correct.
Q. And you said that the only way I would recommend for that pass would be a GPC analysis; is that correct?
A. To look into molecular weight distribution.
Q. And that's not described anywhere

in the patent, GPC analysis; is that correct?
A. I don't know.
Q. And when you determined what approach you would take to evaluate or characterize the molecular weight of the Dow Polyox 180, N80 sample that you received, you didn't look to the patent to figure out how that should be done; is that correct?
A. I mean, there's no relationship. I was asked to do something, so I do it.
Q. And I just want to get for the record, to be clear, you did not consult the patent to figure out the appropriate method to characterize the molecular weight of the Polyox N80 sample; is that correct?
A. Yes. With my experience in GPC, I don't need to consult a patent to do that.
Q. So you just determined on your own based on your 40 or 50 years of experience how you would recommend to characterize the molecular weight of the sample; is that correct?
A. I hope so.
Q. And your determination was you should use gel permeation chromatography even if



that wasn't identified anywhere in the patent; is that correct?
A. I don't know if it's your patent or not.
Q. And you are aware that Dow does not use a GPC analysis to characterize the -- well, strike that question. Let me state it a little differently.
You recognize that Dow reports the molecular weight of Dow Polyox N80 as 200,000 daltons; is that correct?
A. Correct.
Q. And Dow doesn't use a GPC analysis to determine that molecular weight, does it?
A. No. Dow, every division have a GPC analysis, and I think one of the papers put up the -- she reported data on Polyox also.
Q. But when Dow reports how it determines the molecular weight of Polyox N80, it specifically states that it's not using GPC analysis; is that correct?
A. I don't know whether they say it uses GPC or not. I don't know.
Q. They use a rheological method,



don't they?
A. You should have asked that question. That I do know.
Q. Okay. So does Dow, does Dow use a rheological measurement to determine molecular weight?
A. They call that rheological, but basically, it's concentrate solution viscosity. The word "viscosity" is kind of confusing at this point.
Q. And I'm sorry. So they use rheological measurements in order to determine the molecular weight of -- the reported molecular weight of their Polyox N80; is that correct?
A. I am repeating myself. The concentrated solution viscosity.
Q. And that's different, that's different from the GPC analysis that you did; is that correct?
A. That's correct.
Q. Okay. And given your experience with characterizing polymers and GPC analysis, I just want to be clear, you don't have any



experiments in developing pharmaceutical products; is that correct?
A. No, I don't.
Q. All right. I would like to, if we could call up -- actually, let's just flip on -- can we turn on the Elmo? Thank you.
Now, you gave two expert reports in this matter; is that correct? There was your first opening report and then you also did a reply report?
A. Yes, I did.
Q. All right. So this is -- I'm showing you a copy of plaintiffs' reply report of Dr. Wollschlaeger. This is your reply report?
A. Yes.
Q. And you, in your reply report, you talked some about the calibration standard you used in your GPC analysis; is that correct?
A. That's correct.
Q. And without getting too down into the weeds on the science, one of the ways that you calibrate your GPC is you go out and you buy special molecular weight PEO that has been

standardized into different discrete sets of different discrete weights; is that correct?

A. I did purchase a calibration set purposely designed for GPC, and it's nothing close to the commercial Polyox product, which would be very broad.

Q. And two different things. One is sold as a commercial grade of 200,000 dalton, and the other one is sold as a calibration standard, and it has very, very specific discrete sets of molecular weight PEO; is that correct?

A. Yes. Narrow -- narrow viscosity, like weight of a number close to one.

Q. And you do this in order to make sure your GPC, the chromatography is working, is all calibrated to give you the correct results; is that correct?

A. Well, if I have to interpret it more scientifically, in the GPC, you get dilution time of the model coming through the system. The time would have to recalibrate against the molecular weight to come up with the final weight of molecular weight distribution.



That's what these are about.

Q. And there's a figure in your reply report that shows those, the distribution of that set of PEO; is that correct?

A. Yes.

Q. And I've got here now a figure -- this is from your expert reply report. And the axis here, it's very similar to what you plotted for the overall Polyox N80 sample; is that correct? That unimodal single peak sample we've been looking at?

A. Well --

Q. This is also plotted on a logarithmic scale?

A. It says the retention patent there.

Q. Okay. And is this showing us also here many modes, and each one of those modes are going to correlate to a different weight of PEO from your calibration set?

A. I have difficulty to understand your question. If a weight -- we keep on talking about different weight. I'm having difficulty understanding that.



Q. Different molecular weight -- sorry. So if I'm looking at this chart from your reply report, each of those peaks correlate to a different part of the calibration standard representing a different molecular weight; is that correct?

A. Different molecular weight, yes, for calibration. Yes.

Q. Thank you.

And now, Dr. Yau, you mentioned in your report you prepared an Excel spreadsheet, a table, in order to analyze your results; is that correct?

A. Yes.

Q. And we've seen that a little bit, and you've said that anybody can use that in order to determine molecular weight averages based on the partition that you've put into place; is that correct?

A. They can check that.

Q. Okay.

MR. SMEREK: So if I could have up JTX-143, please.

BY MR. SMEREK:



Q. There are a number of tabs at the bottom. And you've created all of those tabs; is that correct?

A. Yes.

Q. And if we can go first to overlay 600K, the one in red. Okay. We'll go there.

And this is the chart that we've seen today; is that correct?

A. It looks like it.

Q. Okay. And then we see little tabs at the bottom, and they start N80A1, N80B1. And there's a separate tab for the results of each one of the runs that you did; is that correct?

A. That's correct.

Q. And actually you only have one sample of Dow Polyox N80 that you analyzed; is that correct?

A. We purchased, yes.

Q. And the way you did your nine runs is you, you separated out three different groups of N80, excuse me, of Polyox N80, and then in those three different groups, you then did three different tests, one -- three for each of the three groups to get a total of nine; is that

correct?
A. Correct.
Q. Okay. See N80A1 that path shows the results of one of the analyses that you did; is that correct?
A. Correct.
Q. And I believe Dr. Mathias had testified that the overlays for those nine runs were so close, that they really can't be distinguished. Would that be your opinion as well?
A. Define distinguished.
Q. I don't know. Let me ask you: Would you distinguish them? Do you think they're so close that we can look at one of them as representative of all nine?
A. No.
Q. Okay. So you would have to look at the different ones? Did you find material differences in the results from each of the nine runs you did?
A. Yes. Mathematically, and the overlay indicates the different runs and the three different vials, more or less I have a



similar, very close molecular weight of, molecular weight distribution.
Q. And so they're materially the same?
A. The data suggests that.
Q. Thank you.
So we're just going to focus on this one sample, N80A1, and if I understand this chart, we have on the right half of this page starting at about Column U, we see the graph that's now specific to this sample; is that correct?
A. Yes. Could you show the top row?
Q. Yes. Absolutely. Does that help you?
A. Yes.
Q. All right. Now, if we could roll back up just so we get the whole graph in, right there.
MR. SMEREK: Your Honor there's a box on the left of the screen starting at column N and in red, at line 8, that eight -- can we move that over a little?
BY MR. SMEREK:



Q. All right. And column N at line 18, there's a number, and that's in red, and it says, 600,000.
And, Dr. Yau, can you tell us what that number is?
A. Yes. That's the molecular weight. I was asked to do the partition of the data for the analysis.
Q. Okay. So the red 600,000 is your input through the attorney that says, slice this, slice this data at 600,000 daltons, and so you put that in. And then am I correct that the other numbers in this table are then automatically calculated based on the experimental results and then your computations of those results?
A. Yes, because the order is -- the formulas are linked.
Q. And so now if we go down, when you partition at 600,000 -- and let me just do this to keep us on track.
MR. SMEREK: Can I get the Elmo back up? Okay.
BY MR. SMEREK:



Q. Now, you were asked to do a partition, and you were asked to do a partition to divide the segment into low molecular weight and high molecular weight; is that correct?
A. I divide the data, not the example.
Q. Okay. So you're looking at dividing the data. And where you were asked to divide it was 600,000 daltons?
A. Yes.
Q. Okay. And when you divide it by 600,000 daltons -- so I'm going to put partition here at 600,000. And that's where you were asked to divide it; is that correct?
A. Yes.
Q. All right. Now, if we could go back to -- zoom out a little bit on this so we can see it. Thank you.
All right. And if we could go back to your spreadsheet, there's an area percentage, and that is in column N, line 22. And what are the numbers that that relate to? I see a 98 percent under low molecular weight and a 1.97 percent high molecular weight.

What do those percentages correlate to?

A. Correlate to the percentage of the area separated by the two subsets.

Q. Okay. So essentially what we have here is you had the partition at 600,000 and that's represented by the dotted line; is that correct?

A. Correct.

Q. And now you're saying that everything to the left is low molecular weight PEO; is that correct?

A. Low molecular weight molecules, yes.

Q. And everything to the right is high molecular weight; is that correct?

A. Yes.

Q. Okay. And then so area percentage tells us the percent on either side of that divide; is that correct?

A. That's what it says.

Q. Great. If we drop down, the next one is MW, and that's in column N, line 23, and that's the weight average molecular weight?



A. Yes.

Q. And so this chart has calculated the weight average molecular weight for the low part of this partition and then differently for the high part in column P; is that correct?

A. That's correct.

Q. All right. So what I'd like to do is focus on the viscosity molecular weight. And can you tell me where is viscosity molecular weight on this chart?

A. Yes. That's in row O-24 and P-24.

Q. And can you tell me what the low viscosity molecular weight is that you, you came up with for a partition sample partitioned at 600,000?

A. No. You have to repeat that question. I don't understand.

Q. Sorry. This was your analysis with a partition at 600,000; is that correct?

A. Correct.

Q. And in column O, it tells us your calculation based on your analysis of the average molecular weight for the low part; is that correct?



A. The low subset, yes.

Q. And based on your calculation, what is the low average viscosity molecular weight with a partition at 600,000 for run N80A1?

A. You want me to read the number?

Q. That would be helpful. Thank you.

A. Okay. 97,223.

Q. 97,223. So if we can go back to the Elmo. Under low molecular weight, a partition at 600,000, your calculations came up with 977,223; is that correct?

A. No.

Q. I'm sorry. 97. I've got an extra seven in there. 97,233; is that correct?

A. I think so.

Q. All right. Let's go back. We can't get those both up; correct? All right.

And then the high molecular weight, what is that then for the average viscosity molecular weight high?

A. Yes. 900,534.

Q. 900,534. So if we can go back to the Elmo, 900,534. Great.



So let's go back to your chart. Now, you were explaining that you had done this so people can run the partition anywhere they would like; is that correct?

A. Yes.

Q. And, in fact, this sample can be partitioned anywhere you would like to partition it; is that correct?

A. Sample cannot be partitioned.

Q. The analysis can be partitioned?

A. Yes. The data is partitioned, but it does not change the data set, it does not change the sample.

Q. And, in fact, that is because just because you've partitioned the data, you've partitioned the results, that actually doesn't change how the Polyox N80 was made or whether -- whether it was ever comprised of two discrete sets. It just says you can take the data and divide it any way you want; is that correct?

A. No, that's not correct. Well, like I said, the partition does not change the sample. The question is, are there materials in the sample that have those --

Q. Okay. So if we look here and I want to go back to cell N18. And now if I wanted to partition this at, say, 300,000 daltons instead of 600,000 daltons, that's a -- that's another partition that you've heard about here today from the patent. It's another molecular weight identified in the patent.

Am I correct that I could just type in 300,000 in this cell and hit calculate?

A. Yes. I started saying that at the beginning. You're repeating.

Q. That is why you calculated this sheet, so you could make this analysis; right?

A. Make this template to be helpful to anybody.

Q. Thank you.

So let's go ahead and do that. So we've done 300 and we hit calculate. Now we see in the graph the partition moved; right? And it moved to the left?

A. It should be.

Q. And now if we, if we decided to partition this sample at 300,000 daltons, what is the average viscosity molecular weight for



the lower portion?

A. It's lower.

Q. And what is it specifically?

A. It's 81,340.

Q. Okay. And then if we look over at the high viscosity molecular weight, what is the average high viscosity molecular weight now?

A. It's 511,309.

Q. Okay. So just by moving the partition, we change the average molecular weight of our high set and our low set; is that correct?

A. We change the two sets.

Q. Okay. And I didn't actually change the sample, as you said.

A. Exactly.

Q. I just changed the analysis?

A. Yes.

Q. Okay.

A. The way you interpret it.

Q. So can we jump back to the Elmo.

So when I do 300,000, I did a low molecular weight viscosity, low average molecular weight viscosity of 81,340, and a high



of 511,309.

Now, let's go back to your exhibit. This is a very helpful. Thank you for preparing it. And I think this is really critical to understand goes exactly how the partition is used to calculate average molecular weights.

A. I was trying to be helpful.

THE COURT: Mr. Smerek, do you have a question?

MR. SMEREK: I do. Thank you, your Honor.

BY MR. SMEREK:

Q. Now, if we change this now to 100,000 and hit enter, now, this will tell us the average molecular weights on either side of a partition at 100,000; is that correct?

A. Yes.

Q. Okay. And so here, the average molecular weight for the low viscosity average is 46,842; is that correct?

A. Correct.

Q. I'm sorry?

A. Yes.



Q. And the high viscosity average molecular weight now is what?

A. 225,306.

Q. Okay. And if we can go back to your chart. And if we now cut it at 900,000, which is the other number identified in the patent, and enter. And now your chart shows us we have a high -- excuse me. It partitioned at 900,000. The low average viscosity molecular weight was 102,673; is that correct?

A. Yes.

Q. And now the high average viscosity molecular weight is 1,260,077; is that correct?

A. Correct.

Q. Okay. So if we can go back to the Elmo for a moment.

So all of these numbers that we are looking at with the partition at 900,000, 600,000, 300,000, 100,000, all of the numbers shown here for low molecular weight and high molecular weight on either side of the partition were derived from the same Polyox N80 sample; is that correct?

A. Correct.

Q. And the only difference here is where the partition line is drawn; is that correct?
A. Yes. Yes.
Q. Okay. And now if I could get JTX-1, I believe it's the '150 patent, up, and if we could look at claim 1.
MR. BOLLINGER: Your Honor, he has not testified about the claim at all. He's not here offering opinions regarding this patent.
THE COURT: So you can ask him a question. You don't need claim 1 to do that.
MR. SMEREK: Thank you, your Honor.
BY MR. SMEREK:
Q. Looking at -- if we go back to the Elmo. Looking at where you were asked to draw the line 600,000, you will agree with me that the low molecular weight 97,223, that is less than 100,000; is that correct?
A. Yes.
Q. And if I move the partition now, if I slide the partition lower and lower and lower from 600,000, my lower molecular weight



average gets lower and lower and lower. It moves away from 100,000; is that correct?
A. Could I make a comment?
Q. I -- I would just like to -- I want to make sure I'm understanding how the partition operates in your analysis.
A. The calculation works.
Q. So if I set my partition at 600,000, if I move my partition lower, lower than 600,000, my had low molecular weight average is going to become lower and lower and lower than 97,000; is that correct?
A. Yes. That's obvious.
Q. Okay. And now if I'm at 600,000 and I move my partition higher than 600,000, as reflected here, it's going to be the high average molecular weight is going to be higher and higher and higher than 900,000; is that correct?
A. Yes.
Q. Okay. So in any way I slice this data, whether I move my partition higher or I move my partition lower, there's no way that I can slice this data that would give me both an



average low molecular weight less -- in the range of 100 to 300,000, and at the same time give me a high average molecular weight between 600 and 900; is that correct? 600 and 900,000; is that correct?
A. Yes. This is a clear observation from the data, yes.
Q. Okay.
MR. SMEREK: Nothing further, your Honor.
THE COURT: All right. Any redirect?
MR. BOLLINGER: Yes. Just briefly.
Can you put that back up on the Elmo?
MR. SMEREK: If you would like to use it, we would move to admit it under 1,006 as a summary of Exhibit JTX-143.
THE COURT: What's your position?
MR. SMEREK: Certainly, I think if they're going to use it for questioning --
MR. BOLLINGER: I won't use it. We don't think it's appropriate to be part of



the record.
THE COURT: All right. Well, it's not admissible.
MR. SMEREK: Thank you.
REDIRECT EXAMINATION
BY MR. BOLLINGER:
Q. Thank you, Dr. Yau. And I just have a brief followup now.
The analysis of selecting different partitions doesn't change the overall data set; is that correct?
A. Not the data set or the sample.
Q. All right. But when you partition at different spaces, you're actually changing the discrete sets. The high and the low, they're changing. The data that now you're looking at has changed; is that right?
A. The whole data doesn't change, but the division of the two subsets changed.
Q. Right. So there's fewer molecules in the low molecular weight slice if you partition at a lower value. There's just less molecules being considered; is that right?
MR. SMEREK: Objection, your

Honor. Leading.
THE COURT: Overruled.
THE WITNESS: Yes. When you moved the way to interpret the data, things change.
BY MR. BOLLINGER:
Q. And in the lead-up during the cross, counsel had repeatedly asked you whether the data from GPC was a molecular weight, and that you had been asked to do molecular weight calculation. I think you were saying it was molecular weight distribution. Is that what GPC calculates?
A. Yes. GPC is a technique, so molecular weight distribution of polymers can be analyzed.
Q. And when you do a rheological or viscosity measurement to determine an average molecular weight, can you tell anything about the distribution of that sample?
A. No.
Q. So that wasn't available as a technique at that time if you needed a distribution like we wanted to show here?
A. I don't know whether that's a --



that's available at that time, because I don't know what that time is.
Q. I'm sorry. I didn't mean to leave it. We'll leave it like that.
Now, you had wanted to say something in response to one of the questions that counsel for defendants asked, and rightfully, he asked you to save it for redirect.
Is there something you wanted to add to your testimony today?
A. One thing is that I should have said that it's that, the Dow uses the so-called rheology measurement. It's actually, I said that it's a concentrate solution viscosity, but that's some empirical way they try to get result of viscosity average molecular weight. But the most fundamental way to get the viscosity average molecular weight is to produce solution viscosity that GPC offers.
MR. BOLLINGER: All right. Thank you, your Honor. I have no further questions.
THE COURT: Thank you.
MR. SMEREK: Your Honor, I just



have one question, please.
THE COURT: Sure.
RECROSS EXAMINATION
BY MR. SMEREK:
Q. And, Dr. Yau, at your deposition, you testified that rheological measurements were not accepted molecular weight technique; is that correct?
A. Yes.
Q. Thank you.
A. In general.
THE COURT: All right. Dr. Yau, thank you. You may step down.
THE WITNESS: Thank you.
(Witness excused.)
THE COURT: All right. Well, I guess we'd better break for lunch, so we'll take an hour. Be back here at five of 2:00. All right?
(Luncheon recess taken.)
- - -
Afternoon Session, 1:57 p.m.
THE COURT: All right. Please be seated. Let's continue.



Am I right, is this where the plaintiff rests on infringement and we move over to the other side?
MR. BOLLINGER: As it relates to the '150 patent, your Honor, evidence is done, but because we have other patents, I guess our case isn't completely over.
THE COURT: Okay. Right. I forgot about that. All right. Well, call your next witness.
MR. LOMBARDI: Your Honor, while we're getting that organized, I guess, I believe the '150 evidence on infringement is done with respect to our clients, and I suspect you wanted to take this at the end of the case, but I will just say that we have a motion that they have not met their burden of proof on infringement.
THE COURT: Okay. Don't let it slow you down from putting on a case.
MR. LOMBARDI: No, we're not. And we're going to bring, we're going to introduce the next witness, which will be a deposition clip.
THE COURT: Okay. Because both of

your other patents against Watson are in December?

MR. BOLLINGER: That's correct. After the '150 on infringement and validity with Watson, then we go to the invalidity, their challenge to the '514 patent.

THE COURT: Okay. All right.

MS. LACKEY: Yes, your Honor. Melinda Lackey for defendants.

THE COURT: Hi, Ms. Lackey. How are you doing?

MS. LACKEY: Good. Thank you. We're about to play a short clip of the deposition of Mr. Gary Myers taken in this case.

Mr. Myers is an employee of MonoSol and a named inventor on the '150, '514 and '832 patents at issue in this case.

THE COURT: Okay.

MS. LACKEY: The clip is under ten minutes. He refers to an exhibit marked Myers 14 in the deposition that was Bates labeled MSL0002715 to 2763, and this is an excerpt from the file history of the '832 patent. And that



has been pre-admitted in this case, your Honor0, as JTX-0006, and we'd just like for it to be recognized that way.

THE COURT: Okay.

MS. LACKEY: Okay.

(Videotaped deposition clip of Gary Myers played as follows.)

"Question: Good morning, Mr. Myers. Are you presently employed?

"Answer: Yes.

"Question: What is your present position?

"Answer: I'm the development -- I work in the R&D group, or I did work in the R&D group. Now I changed jobs recently. I'm more into corporate technology.

"Question: And for what corporation?

"Answer: MonoSol Rx.

"Question: Dr. Myers, I've marked as Exhibit Myers 14 a document with production numbers MSL_2715 running forward to 2763. I would just ask you to flip through this and let me know if you recognize it.



"Answer. (Reviewing.)

"Yes.

"Question: Would you go forward to paragraph 33.

"And my question for you is, does the -- first of all, does the commercial Suboxone film strip product use the combination of high molecular weight, 600,000 to 900,000, with low molecular weight, 100,000 to 300,000, polyethylene oxide that's described in this sentence?

"Answer: Yes, sir.

"Question: And have you ever made a film strip meeting the description here of a high molecular weight, 600,000 to 900,000, polyethylene oxide, and a low molecular weight, 100,000 to 300,000, polyethylene oxide?

"Answer: Have I ever --

"Question: Have you ever made such a --

"Answer: I'm sure I have, yeah.

"Question: How did you determine the molecular weight of each of the two polymers?



"Answer: Those are, as you probably well know, are commercial Polyox numbers.

"Question: And so, for example -- Polyox is a brand name of Dow --

"Answer: Correct.

"Question: -- Dow Chemical, correct?

"Answer: (Moving head up and down.)

"Question: And so if -- so for a high molecular weight polymer of, say, 900,000, you purchased Polyox 900,000?

"Answer: Correct.

"Question: And for the low molecular weight product, you purchased Polyox, say, 200,000?

"Answer: 100,000, 200,000.

"Question: And --

"Answer: 300,000.

"Question: And did you ever separately measure the molecular weight of those --

"Answer: No, sir.

"Question: To your knowledge, did anyone at MonoSol ever separately measure the molecular weight of those polymers?

"The Witness: No, sir."

(End of videotape clip.)

MR. LOMBARDI: That's the end of the deposition clip, your Honor.

THE COURT: All right.

MR. LOMBARDI: And we're now going to be calling Dr. Jason McConville.

THE COURT: All right.

DEFENDANTS' TESTIMONY.

... JASON MCCONVILLE, having been duly sworn as a witness, was examined and testified as follows...

MR. NUTTER: Your Honor, as you expect, we have some binders of material. May we approach?

THE COURT: Yes. Sure.

(Ms. Lackey handed binders to the Court.)

MR. NUTTER: Nut may it please the Court?



DIRECT EXAMINATION.

BY MR. NUTTER:

Q. Good afternoon, Dr. McConville.

A. Hi.

Q. Can you please state your full name for the record?

A. Jason McConville.

Q. Dr. McConville, what do you expect to testify about today?

A. Today I'm going to specifically talk about whether Watson's ANDA product infringes on the '150 patent.

Q. I'd like to first look at what has been marked as JTX-15. Is this your curriculum vitae?

A. Yes, it is.

Q. And is this a true and correct description of your educational and employment background?

A. Yes.

Q. Can you very briefly provide the Court a description of your education and professional history?

A. Yes. Sure. In 2002, I graduated



with a Ph.D. in pharmaceutics from the University of Strathclyde in Scotland. I focused my research there on all drug delivery products.

After that, I moved to the University of Texas at Austin, did a post-doctoral position before joining the faculty there in 2006 as an assistant professor of pharmaceutics. And my research focus was there on inhaled pharmaceuticals as well as all solid dosage forms as well.

Then in 2012, I moved to the University of New Mexico, obtained tenure, and currently an associate professor of pharmaceutics. My research areas here principally are involved now with films for delivery to the oral cavity. I also work on inhaled pharmaceuticals and some oral solid dosage forms.

And I currently have an adjunct position as well at the University of Bonn in Germany.

Q. Do you specialize in any particular drug formulation technology?



A. Yes. Lots of my current research is on pharmaceutical films for the buccal administration, which is the cheek, or the sublingual delivery, under the tongue.

Q. And as part of your pharmaceutical training, do you have experience with the use of polyethylene oxide and sublingual films?

A. Yes. This has been incorporated in several of the research films that I've looked at.

MR. NUTTER: Your Honor, at this time Watson would like to offer Dr. McConville as an expert in the field of sublingual drug delivery and formulation.

THE COURT: All right. You may proceed.

BY MR. NUTTER:

Q. Dr. McConville, first, I'd like to just look at the '150 patent, which has been marked as JTX-1. In a very general sense, what's the subject matter of the '150 patent?

A. Well, simply this patent is related to the preparation of thin film formulation using polyethylene oxide and

specifically targeting the sublingual area of the mouth.

Q. Now, do you have an understanding of what it takes to be a person of ordinary skill in the art as it relates to the '150 patent?

A. Yes, I do.

Q. What's your understanding?

A. Well, I have a slide taken from my expert report on this. And basically I believe a person of ordinary skill in the art should possess a Bachelor's degree in pharmaceutical sciences or a related field with at least two to five years of relevant experience, preferably with film formulation experience in mind.

Alternatively, if they have a higher degree, a Master's degree or Ph.D., then perhaps a little less of this practical experience.

Q. All right. Thank you.

Now, do you know which claims of the '150 patent have been asserted against Watson?

A. Yes. Claims 1 and 4.



Q. Now, you were in the courtroom this morning, and you heard Dr. Mathias testify?

A. Yes.

Q. And you heard him opine that Watson's ANDA products infringe claims 1 and 4 of the '150 patent; is that right?

A. Yes, I heard that.

Q. Do you agree with him?

A. No, I do not.

Q. Why not?

A. Well, I have another slide which takes us through the key areas of my contention here.

So, first of all, I believe Watson's ANDA products do not include discrete sets or two different PEOs, one of a low molecular weight and one of a high molecular weight.

And, in fact, my second point here is that Watson's ANDA products, in fact, practice the prior art as they only have one PEO component.

Then if we move on to Dr. Yau and Mathias' partition theory, it's fundamentally



flawed when you apply it to this '150 patent when you consider the polyethylene oxide are included.

And if we move on thinking about that partition theory, I do not believe that they find numbers within the claim range, so they're outside, and at best, they only find a stray amount of PEO in the high molecular weight range.

Q. Thank you.

Now, before we start reviewing your noninfringement opinion, what legal standard did you use to analyze the issue of infringement?

A. I have another slide with that. And basically, in consideration of Watson's ANDA product, it's my opinion that they do not contain every limitation of the asserted claims 1 and 4 of the '150 patent.

Q. Thank you.

Now I'd like to take a look specifically at claim 1 of the '150 patent. This is JTX-1, claim 1.

Now, I've highlighted numerous



references to the term polyethylene oxide, which I think everyone in the room now knows is also referred to as PEO.

Can you very briefly explain to the Court in your own words what polyethylene oxide is and how it's manufactured?

A. Yes, sure. I have another slide that shows that more clearly.

So basically, we have ethylene oxide monomers, which are reacted together to form the polyethylene oxide polymer. So in the reaction vessel, over time the ethylene oxide joins together to polymerize and form a distribution of molecular weights. At a certain point in time, this process is stopped, and we have distribution of molecular weights around an average.

Q. Now, I see the title of this demonstrative 2.8 is unimodal size distribution of polymers. What do you mean by unimodal size distribution?

A. It's quite straightforward. This really refers to the fact that there's one peak. It's a unimodal distribution of particle sizes.

Q. And how is the average molecular weight determined when there's one peak?

A. Well, basically, with this type of normal distribution, we look at the middle and we find that that is where an average would be.

Q. Now, I see I guess what I would call tails on the bottom portions of the left and right side. What do those tail portions represent?

A. Well, really, these are very small amounts on the left and on the right. The tail ends of this, these are tiny amounts of smaller molecular weight PEO on the left and small stray amounts of PEO at the larger molecular weight on the right. But what you've got to remember, this is a normal distribution with only one average in the middle. We're taking the average of all of that range.

Q. And is it fair to understand that this is a graphical distribution of a single PEO sample?

A. Absolutely, yes.

Q. Now, how would you expect the



distribution to look if it was a sample of two blended PEOs?

A. I've got another slide to show you that. Basically, I would expect a biomedical distribution. I would expect if we mixed two PEOs that had different average molecular weights, is that we would see something like this (indicating) for the bimodal distribution, where the two peaks are combined.

Q. Now, let's go back and look at the language of claim 1 of the '150 patent. Can you explain to the Court all of the requirements of claim 1?

A. Yes. Sure. We can start at the top. And really, if we look here, it must have a water-soluble polymer component, and this water-soluble polymer component consists of the PEOs with the hydrophilic cellulosic polymer. And I've shown this in purple, in green, so you can follow along within the claim language.

The PEO itself consists of two types of PEO. They consist of a low molecular weight PEO, between the ranges 100 to 300,000 daltons, and this has also a high molecular



weight PEO, in the ranges of 600 to 900,000 daltons, as shown in the claim language.

Q. Now, when you say 100 to 300,000, you mean 100,000 to 300,000; is that right?

A. Yes. Sorry.

Q. When you said 600 to 900,000, you meant 600,000 to 900,000?

A. That's correct, yes.

Q. And then what's the final requirement of claim 1?

A. Well, this low average molecular weight PEO component must comprise greater than or equal to 60 percent of the entire film polymer component.

Q. Okay. Thank you for that.

Now I would like to talk about your first opinion, which is that Watson's ANDA products do not include discrete sets of low molecular weight and high molecular weight PEOs.

Turning again to claim 1, JTX-1 of the '150 patent, which limitation in claim 1 includes this requirement?

A. Well, it specifically tells us



that there must be a low molecular weight polyethylene oxide in the range of 100,000 daltons to 300,000 daltons, as I've just described, as well as a high molecular weight PEO from 600,000 to 900,000 daltons, as I've described earlier.

Q. Now, did the Court construe this specific limitation?

A. Yes, they did.

Q. Okay. I'd like to refer you to what has been marked as JTX-244. This is at page 7.

How did the Court construe the low and high molecular weights at issue here?

A. Well, it specifically indicates that there must be at least two PEOs any way, because we have to have one or more PEO with a lower average molecular weight, and one or more PEO with a higher average molecular weight.

Q. Now, earlier you mentioned the term discrete sets, and I don't see that shown here.

Is there elsewhere in the Court's claim construction order where the term discrete

sets was applied?
A. Yes. I believe it's on page 10 of this description.
Q. What --
A. Basically --
Q. What is your understanding of the term discrete sets?
A. Well, my understanding of the term discrete sets is that we have two components here. And each discrete set, if you like, would be this -- one would be a low average molecular weight PEO, and one would be a high average molecular weight PEO. It goes on to indicate that combining small amounts of the high molecular weight PEOs with larger amounts of the low molecular weight PEOs are necessary. It's this combination. When you combine things, you're adding them together.
Q. Now, is there any support in the specification of the '150 patent for your understanding that the term discrete sets requires a combination of PEOs?
A. Yes, there is.
Q. All right. I'd like to return you



to JTX-1 at column 18, lines 11 through 21. Please explain to the Court why you believe this section supports your understanding of the term discrete sets.
A. Well, essentially, this portion of the patent really outlines the entire claim language in claim 1. It shows us that there is a -- to combine high molecular weight PEO, 600,000 to 900,000 daltons, with low molecular weight PEO, 100,000 to 300,000. And these are the PEOs in the polymer component.
It then, in fact, tells us why that is useful. It tells us that certain film properties, such as fast dissolution rates and high tear resistance, may be attained by combining small amounts of high molecular weight PEOs with the low molecular weight PEOs.
It actually goes further to tell us that there must be 60 percent or greater levels of the lower molecular weight PEO in that.
Q. Now, before we continue, would you ever consider a single PEO has been partitioned to be a combination of a low and high average



molecular weight?
A. No, I would not.
Q. Okay. I'd like to go to a different portion of the '150 patent. This is JTX-1 at column 51, lines 30 through 34, as well as table 22.
How does this portion of the '150 patent also support your understanding that discrete sets requires a combination?
A. Well, this table shows us examples of the polymer combinations that I've been talking about, that are present in the patent. And this excerpt is taken from the bottom.
Beneath the table it says that the tear resistance of lower levels of PEO was shown to be improved by combining small amounts of higher molecular weight PEOs. And I showed this in this table highlighted in red just as before, with the lower molecular weight PEOs, and I will show that in blue on the table.
Also included is the hydrophilic cellulosic component, which we show in green from before. And we can see that actually, these compositions DT and DU taken from this



Table 22 of the enabling example is the only two compositions that meet all the polymer requirements of claim 1.
Q. Now, is there any example anywhere in the '150 patent of a single grade PEO that has been partitioned into two parts, each with its own average molecular weight?
A. No, there is not.
Q. Okay. Now, before we look specifically at Watson's ANDA products, I'd like to first refer you to Table 21 of the '150 patent.
Can you briefly explain what's being shown in Table 21?
A. Yes, absolutely. These compositions here and the amounts of them are basically examples of films which could be made using the guidance of the patent. And at the top, we can see that PEO is outlined.
Q. Now, I see a footnote one identified with that PEO. What's that in reference to?
A. Well, that tells us that this PEO is available from the Dow Chemical Company.

Q. And what does this information teach a person of ordinary skill in the art?

A. That the Dow Chemical company's product is dictating the average molecular weight that we should be considering to be applicable in this patent.

Q. And how does Dow report the average molecular weight for its PEO products?

A. They always report it as viscosity average molecular weight, like every other supplier.

Q. Now, what various viscosity average molecular weight PEO products does Dow offer for sale?

A. They offer a wide range of PEO products for sale. And, in fact, their range varies from about a hundred thousand into the millions, but they're very specific about those different grades that are available and they always refer to them with this viscosity average molecular weight.

Q. Now, why would a person of ordinary skill in the art want to use different viscosity at the molecular weight PEOs in a



sublingual drug formulation?

A. Well, the patent describes this as well, and my experience tells me that the different grades of PEO impart different functional properties to a film when you use them.

Q. Now, is there any teaching of average molecular weight in the '150 patent other than this reference to Dow Chemical Company and its viscosity average molecular weight?

A. No, there's nothing else.

Q. Now, let's talk specifically about Watson's ANDA products.

Which company manufactures the PEO that Watson uses in its ANDA products?

A. They specifically use Polyox N80, which is available from the Dow Chemical Company.

Q. Now, what viscosity average molecular weight does Dow report for Polyox N80?

A. 200,000 daltons.

Q. Does Watson use any other PEO in its ANDA products other than Polyox N80?



A. No. They only use a single average molecular weight, viscosity average molecular weight polymer. There's only one. There's not a combination of PEOs in there.

Q. Now, how does the fact that Watson only uses Polyox N80 in its ANDA products support your opinion that Watson does not infringe claim 1?

A. Well, just as I've said, this is a single, considered to be a low average molecular weight PEO, as the patent puts it. This is 200,000 daltons. There isn't any other PEO that's used. This is it. So I mean it really can't infringe because it does not have more than one PEO.

Q. Thank you.

Now I'd like to talk about your second opinion, which is that Watson's ANDA products practice the PEO teachings of the prior art. And to do that, I'd like to refer you to the prosecution history, which has been marked as JTX-4, and specifically pages 1,169 through 1170.

Just to orient you, this is



applicant's response to an obviousness rejection in an office action, and the rejection was based on a combination of references, the Schiraldi prior art reference in view of the Flick prior art reference.

Did you review the Schiraldi prior art reference?

A. Yes, I did.

Q. Can you briefly explain to the Court what is disclosed in that Schiraldi reference?

A. Yes. Sure. If we look down here in the second part of the highlighted paragraph, basically, Schiraldi indicates that a homopolymer of ethylene oxide should have a relatively high molecular weight. In other words, they're indicating this homopolymer of ethylene oxide, which is another way of terming PEO, it's the same thing, there's only one PEO used in the films that Schiraldi suggests. It can have a high, a large range of which PEO is used, but there's only one used. The range given by Schiraldi was 100,000 and preferably above three million.

**Q. Now, what did the patent applicants argument to the PTO to distinguish the claimed invention from what's disclosed in Schiraldi?**

**A. Well, they specifically state that Schiraldi does not disclose any kind of suggestion of a molecular weight combination.**

**Q. Now, how does that support your noninfringement opinion?**

**A. Because Schiraldi is using a single PEO in exactly the same way as Watson's ANDA product.**

**Q. Thank you.**

**Now I'd like to talk about your third opinion, which is that Dr. Yau and Mathias' partition theory is fundamentally flawed.**

**Now, you heard both Dr. Yau and Mathias explain this morning why they believe their partition data shows that Watson's ANDA product infringes; is that correct?**

**A. Yes, I heard that.**

**Q. Do you agree?**

**A. No, I do not.**



**Q. I'd like to refer you now to JTX-143. It's a snippet from the data that Dr. Yau provided in support of Dr. Mathias' infringement opinion.**

**Can you explain what is being shown by this curve?**

**A. Well, fundamentally enough, this is exactly what I expect to see from PEO. This is a unimodal distribution of a polymer, and it's a single peak.**

**Q. Now, how would Dow report the average molecular weight of a unimodal distribution curve like this?**

**A. Well, it's a nice, normal distribution, so we would look in the middle and draw a line and we would get our average.**

**Q. Now, did Dr. Yau and Mathias rely on the reported viscosity average molecular weight that do you provided?**

**A. No, they did not.**

**Q. What did Dr. Yau and Mathias do instead?**

**A. Well, they chose not to draw a line in the middle to get the average. They**



**decided to draw a line at the 600,000 dalton mark on this unimodal distribution.**

**Q. Now, what do Drs. Yau and Mathias consider everything to the right of that red dotted line?**

**A. High molecular weight.**

**Q. And why was that line drawn?**

**A. Well, it's my understanding that plaintiffs' attorneys asked Dr. Yau to put that line there.**

**Q. And you said everything to the right was the high molecular weight; is that right?**

**A. Yes.**

**Q. And what's everything to the left of that red dotted line?**

**A. The low molecular weight.**

**Q. Now, as a pharmaceutical formulation scientist, do you agree with the partition approach of Dr. Yau and Mathias?**

**A. Absolutely not. I've not seen this done before for formulation.**

**Q. And why do you not agree with this approach?**



**A. Well, with basically artificially creating two average molecular weights that aren't there, there's already a single distribution, and we're, in fact, ignoring what the data is telling us.**

**Dow reports the average molecular weight in the middle. That's what I look at is a normal distribution. There's an average there.**

**I mean, we are not chopping up the sample or anything, so we can't obtain in reality two average molecular weights. It's just not possible.**

**Q. Now, can this single PEO sample be partitioned at locations other than the 600,000 dalton mark?**

**A. Well, of course. You could ask me to draw that line anywhere if I was analyzing this unimodal peak.**

**Q. All right. Well, let's do that. So let's draw the line at the 100,000 dalton mark.**

**Now, if you buy into Dr. Yau's partition theory, what would everything to the**

right of this line represent?
A. Again, that would be the high molecular weight.
Q. And everything to the left side?
A. The low molecular weight.
Q. So now according to Dr. Yau and Mathias, the same Polyox N80 sample can have different average molecular weights on the high side and the low side, depending on where you partition the sample?
A. Yes, exactly. We can move this line, put it anywhere we like, and obtain different average values. It's the same sample. You know, this has got an average already. We're just creating two averages out of thin air by doing this, by moving the line wherever we want.
Q. How about multiple times? Under Dr. Yau's theory, can Watson's PEO be partitioned more than once?
A. Yes, of course. You could put several lines and say there were several averages on either side of each of those lines. You could put line after line after line. You



could put an infinite number of lines on there if you wanted.
Q. And, again, a pharmaceutical formulation scientist, does it make sense that the same Polyox N80 sample can have an infinite number of average molecular weights?
A. No, it does not. There's a viscosity average molecular weight reported on the bottle, and that is what I would use as a formulation scientist in making a film.
Q. Now, in your opinion, is Dr. Yau's partition analysis as relates to the '150 patent, is that in any way useful to a person of ordinary skill in the art?
A. Absolutely not. I mean, you've got to remember that this type of GPC analysis, it seems to be quite an exhaustive approach, and I'm -- I'm to make a film formulation. I've got a bottle which has the average molecular weight on it. I'm not going to run a GPC analysis to then try and convince myself that what's on the bottle is wrong, you know. It's, it's, it's just not useful at all to a formulation scientist to approach that. And that's not what



I see in the '150 patent.
Q. Thank you.
Now, in your 20-plus years of experience with oral drug formulations, have you ever used a single PEO sample with two different reported viscosity average molecular weights?
A. Never.
Q. Now, is Dr. Yau's and Mathias' partition theory, is that shown or described anywhere in the '150 patent?
A. No, it is not.
Q. How about in the examples? Are there any examples in the '150 patent where a single sample of PEO is partitioned and then described as having two average molecular weights?
A. I have never seen this in any formulation articles that I've looked at. Whether it be film formulation articles or tableting articles that use PEO, they have never described a single PEO obtained from the Dow Chemical Company or any other supplier as having more than one average molecular weight.
Q. Okay. Thank you.



Now I'd like to talk about your final opinion, which is that even if applicable, the Yau/Mathias data still shows noninfringement. And to do that, I would like to look at the data. Specifically, again, at JTX-143E, and this is under the N80 statistics tab.
Can you very briefly explain to the Court what is being shown in this table?
A. Yes. Basically, all of the data we see in the table is selected from information to the left of that 600,000 dalton mark line.
So basically, if I'm concerned with the claimed range of the low end of the low molecular weight portion, I'm looking at the 100,000 to 300,000 as being the claimed range, and then I would use the data all to the left of the 600,000 line to obtain this information.
Under the sample name here, we do see nine different sample names, but what you've got to remember is that this is only one lot of Polyox N80 that was analyzed. It's just nine repeat runs of the same sample.
Q. Now, I see a column a couple over,

MW.

Do you see that?

A. Yes.

Q. What does MW stand for?

A. That's the weight average molecular weight.

Q. I see a column just to the right of that, MB column. What does MB stand for?

A. That's the viscosity average molecular weight.

Q. What is the difference between weight average molecular weight and viscosity average molecular weight?

A. Well, to put it in very basic terms, the weight average molecular weight considers that every PEO molecule has a different weight, a different chain length. So the atomic weight is slightly different -- I'm sorry. The molecular weight is slightly different.

So we obtain this weight average molecular weight based on their molecular weight, the polymer chain molecular weight. The viscosity average molecular weight in a similar



fashion understands that the polymer chain would have a slightly different inherent viscosity. So the viscosity average molecular weight is calculated by taking that into consideration.

But I will point out that there has been no sort of rheological evaluation of this, no viscosity measurement to determine these. These are back-calculated from the spreadsheet that Dr. Yau presented. So they are subject to the same variance in that data set. They are not measured using a viscosity analysis.

Q. Thank you.

Let's focus specifically on the MW column, the weight average molecular weight.

What does Dr. Yau report as the weight average molecular weight for the lower fraction of Watson's Polyox N80?

A. 107,469 daltons.

Q. And is his number between 100,000 and 300,000?

A. Yes.

Q. Okay. Now let's turn to the next column, the MV column, which is viscosity,



average molecular weight.

What does Dr. Yau report as the viscosity average molecular weight for this lower weight fraction of Watson's Polyox N80?

A. 95,895 daltons.

Q. Now, how does Dr. Yau's determination that the lower viscosity average molecular weight is 95,895 daltons, how does that number support your noninfringement opinion?

A. It's outside of the claim range between 100,000 and 300,000 daltons.

Q. Okay. Now let's look at the MV data. For each of the nine runs, do any of the reported calculations as reported by Dr. Yau, do any of those average molecular weights fall within the claimed range?

A. No. They are all outside of the claimed range.

Q. Okay. Now, Dr. Mathias opines that a person of ordinary skill in the art would know to round the average molecular weight of 95,895 to 100,000.

Do you agree with that?



A. No, I do not.

Q. Why not?

A. Well, the deviation, the standard deviation as depicted by the relative standard deviation, the small percentage at the bottom, actually gives us confidence in this number. So one wouldn't round this. We've already been told it is quite a precise measurement, and there's just no inclination to round this number at all. It's reported as is. All the numbers fall below the claim range. Why would you round it above it?

Q. Okay. Thank you.

Now I would like to look at Dr. Yau's calculation for the higher fraction of the, of Watson's Polyox N80 PEO.

And to orient us, this is, again, on JTX-143 at the N80 statistics tab. It's just a little farther to the right.

Can you very briefly explain again what is being shown in this table?

A. Yes. Now, this is again the same nine runs performed with the same single lot nine times. But this is all the data taken to

the right of the 600,000 dalton line. So that's what we would see in this table, both for the weight average molecular weight and the viscosity average molecular weight calculated from the spreadsheet.

Q. Okay. And, again, focusing on the MW column, what does Dr. Yau report as the weight average molecular weight for this higher fraction of Watson's Polyox N80?

A. 917,865.

Q. And how does that number support your noninfringement opinion?

A. This is outside of the claim range between 600,000 and 900,000 daltons.

Q. And let's look at the individual runs that Dr. Yau did to determine the weight average molecular weight. Are any of those numbers that I've highlighted here, are any of them lower than, or fall within the claimed range of 600,000 to 900,000?

A. No. They are all outside the claim range. They're all above 900,000.

Q. Okay. Now, let's change the focus to the MV column again, which is viscosity



average molecular weight.

What does Dr. Yau report as the viscosity average molecular weight for the, again, the higher fraction of Watson's Polyox N80?

A. 900,318 dalton.

Q. And how does that number support your noninfringement opinion?

A. Again, this is outside of the claimed range.

Q. Now, again, Dr. Mathias testified that a person of ordinary skill in the art would know to round 917,865 and 900,318 to 900,000.

Do you agree with that?

A. No. Again, we have a small relative standard deviation giving us confidence in that number. This number is taken from nine runs. I don't believe you should just start rounding numbers when you got this type of average.

Q. Okay. Now, let's do a quick recap of why you believe, even if applicable, Dr. Yau's data shows that Watson's ANDA products do not infringe. And if you could start with Yau's



viscosity average molecular weight data.

A. Sure. So just -- I show here the range of viscosity average molecular weights on a diagram and the claim range for the low average molecular weight is shown in blue, and the range for the high average molecular weight, viscosity average molecular weight, is shown in red.

Basically, Yau's reported viscosity average molecular weight falls below the claim range for viscosity average. And the reported average of 900,318 falls too high to be in the claim range for the viscosity average molecular weight, which the industry generally relies on, this viscosity molecular weight. Then if we were to use the weight average molecular weight as it has been reported in the data from Dr. Yau and Mathias, we do see that the reported range, size of 107,469 does fall inside the claim range for that one. However, when we look at the upper end, the 917,865 is outside of the claim range as before.

Q. Okay. Thank you.

Now I'd like to talk about your



final opinion, which is that even if applicable, the Yau/Mathias data shows noninfringement because there's only a stray amount of high molecular weight PEO.

And to do that, I'd first like to go back to the Court's claim construction. This is JTX-244 at 10.

What does the highlighted passage on this demonstrative 2.029, what does that represent?

A. Well, basically, this point at the bottom where it says, the Court agrees with the defendants that the product cannot be comprised of only low average molecular weight PEOs, that to me is Watson's ANDA product. It's only a low average molecular weight PEO present.

But then it goes on to say, or only low average molecular weight PEOs with stray higher average molecular weight PEOs. That, at best to me, is what Dr. Yau and Mathias have demonstrated. Perhaps they have found a stray amount in the tail of a low molecular weight PEO product, only one of which they've analyzed.

Q. Now, just focusing on the term stray higher average molecular weight PEOs, what's your understanding of what it takes to be a stray amount?

A. In my experience with films, as films are thin this -- small areas for dissolution, dissolution and tear resistance, very important, as we've seen in the patent. You need an amount that is going to have a functional impact on that film, and anything less than ten percent, I would say, wouldn't be able to affect the functional properties of a given film.

Q. Okay. Now, is there any support in the '150 patent for your opinion that anything less than ten percent would only be a stray amount?

A. Yes, there is.

Q. I'd like to refer you again back to the '150 patent. This is JTX-1 at columns 50, lines 13 through 33, table 22.

Please explain why you believe this table, the highlighted portions, supports your understanding of the term stray amount.



A. Well, if we look at this 900,000 PEO, which is the high average molecular weight PEO present, the lowest that's present in any of the examples that they show is about ten percent.

Q. Now, do you know what number doctor I can't and Mathias reported to be the amount of the high molecular weight portion of, or high molecular weight fraction of Watson's Polyox N80?

A. Yes. They reported it as 1.9 percent. It's shown in the highlighted area here.

Q. Now, just to be clear, would you consider that to be a stray amount?

A. Absolutely. It's way below this ten percent, my experience as well as what the patent shows us is the lowest amount considered, it's way below that. You've got to remember that this is a film, and to impart any functionality in a film, it's not the same as a tablet, for example. You need to have an appreciable amount. This thing is going to dissolve very quickly any way. So in order to



effect that, you do need a good amount. 1.9 percent is just a stray amount in the finished product.

Q. Now, you understand that Dr. Mathias testified that 1.9 percent of the higher average molecular weight, that actually represents trillions of individual molecules.

Did you hear that testimony?

A. Yes.

Q. Does that change your opinion that 1.9 percent of higher average molecular weight PEO is a stray amount?

MR. BOLLINGER: Your Honor, there was no touch testimony.

THE COURT: Well, I'm not sure that there was or wasn't. I thought maybe there was, but if there isn't, then I guess there's no point.

But go ahead, ask the question.

BY MR. NUTTER:

Q. I will just repeat the question. If, in fact, 1.9 percent represented trillions of molecules and that's in the higher molecular weight portion, would that change your opinion



that 1.9 percent is just a stray amount?

A. No, absolutely not. What you have to remember, we see a little insert here. This 1.9 percent, if you calculate trillions of molecules in that little tail end at 1.9 percent, how much do you think is in the bulk of the polymer? I will tell you. It's quadrillion. It's a thousand times more than that little tail end. That tail end would always be a stray amount no matter what kind of fiddle factor you multiply it by.

Q. Okay. Thank you.

Now, finally, I'd like to briefly talk about the L'Hote article that Dr. Mathias discussed during his direct examination, and that's JTX-31.

Now, you reviewed this article; is that correct?

A. Yes, I have.

Q. I'd like to go to Figure 2, which I believe is the figure that Dr. Mathias relied upon.

Can you explain in your own words your understanding as to why Dr. Mathias relied

upon this figure in support of his infringement opinion?

A. Right. It's my understanding that Dr. Mathias indicated that this is not a bimodal distribution of polymers. I mean, there's a couple of things to point out here.

In order to best explain this, I'd first like to go back to Figure 1, if I could, in the same article.

Q. If we can go to Figure 1.

A. Right. Okay. So this looks very similar. I realize that. This is actually the individual PEOs as they were used before they were mixed together to obtain Figure 2.

So I look at this, and they're almost the same. The average molecular weight is almost identical around a million. It's about the same in every single different sample they're talking about.

We're interested mostly in this Polyox 205 and Polyox N-12, these different molecular weight, average molecular weight polymers that Dow has prepared for this analysis.



And if we go back to Figure 2, let's look here. I think importantly -- well, look at the 50/50 blend. That would give us the best shot I think to see some sort of effect on the graph, and that's indicated by this magenta part.

And I follow the magenta line. I'm sorry, but I cannot see that we can make out anything from this plot very easily. We are on a log scale. All of the samples were about a million daltons in size mixed together, what you expect to see from this.

My contention is that it should have been more adequately presented. Perhaps if we had seen this on a linear scale, you would see the same bimodal distribution I was describing earlier when you blend polymers.

The other point about this is that I want to make, and I've said it already. These are all about a million daltons in size. The patent is calling for a low molecular weight and a high molecular weight.

If we mix those together, we would clearly see two peaks. There's no doubt in my



mind that we would see that. But I have a slide prepared to talk you through this issue about the scale.

Q. I would like to refer to Defendants' Demonstrative Exhibit 2.33.

Please explain to the Court how you believe that this explains what you think why the L'Hote article does not support Dr. Mathias' infringement opinion?

A. Okay. Well, I fooled around with that a little bit. I created two hypothetical PEOs with a normal distribution about around the means, but with around a million daltons in size.

One is shown by the dotted blue curve and one is shown by the solid blue curve. And this is the log scale.

So you can imagine this is like Figure 1 when we showed the individual polymorphs run through the system, and we can see somewhat of the different shapes on that.

If you deposit the same thing on the linear scale, this is what I'm saying. I've not changed the data. All I've done is changed



the scales. They are not squished up any more like they are on the log scale.

This is, if you like, stretch things out, so we can see what's going on.

And you can clearly see that the division of these two different hypothetical PEOs I've created.

Now, let's look at how it would appear in the paper, if we had Figure 2, using my hypothetical PEOs.

And, unfortunately, I didn't have access to the full data. This is the L'Hote article. Had I had that, I would have applied the same logic to it.

Well, this is what you would see. You would see a beginning, upward part of server from one of the samples, because it's at the leading edge. And the downward slope from the other sample on the other edge.

However, it would appear as one peak on the log scale, if you get my drift. It squishes things up, so they overlay a lot.

If we did the same analysis on the lineal scale, remember we wouldn't be able to

see what was being mashed in the middle here. We would see that bimodal distribution that I am saying would be present if you blended two PE.

And, in this case, they are very, very similar, my hypothetical PEOs, to the L'Hote article of a million daltons.

Q. Thank you, Doctor.

Finally, I would like to take you to Claim 4 of the '150 patent.

You understand that Claim 4 four has been asserted against Watson, yes?

A. Yes.

Q. Can you just very briefly explain to the Court why you believe that Watson does not infringe Claim 4?

A. Well, since Claim 4 is dependent upon Claim 1, for all of the reasons I've outlined as to why Watson's product does not infringe on Claim 1 of the '150 patent. I also believe the same is true for Claim 4.

MR. NUTTER: I have no more questions.

THE COURT: All right.

Thank you. Cross-examination?



MR. BOLLINGER: Thank you, your Honor.

**CROSS-EXAMINATION**

BY MR. BOLLINGER:

Q. Good afternoon, Dr. McConville. How are you?

A. Hi. Good. Thank you.

Q. In this case, as I understand it, you expressed three separate bases for non-infringement as presented in your slides, and I would like to talk a little bit about that, but I want to know that we're all on the same page here.

You'll agree with me that this claim is directed to a film product, right?

A. Yes.

Q. Okay. So you understand that when a claim is directed to a film, or film, it's a composition claim, so what we're interested in is what's in the accused product.

You'll agree with that, right?

A. Yes.

Q. And, so, the analysis is predicated on whether there's an infringement or



not have of what the content is of the film that Watson is planning on making?

A. Right. I agree.

Q. It doesn't matter how somebody gets to that film. There's no process steps associated with a combination -- I'm sorry -- in a composition claim, correct?

A. There are various elements in the claim which need to be met --

Q. Correct.

A. -- the way I see it, yes.

Q. Right. But I think you suggested that you add things together, and if you don't add things together, you don't infringe as it relates to PEO. I think you said that. I wrote it down here. That you have to add things together to infringe this claim?

A. Claim 1 specifically tells us we have to have a low-molecular weight PEO and a high-molecular weight PEO.

It clearly tells us the different average molecular weight ranges. And, you know, I know, and everybody said so far that these products are available from the Dow Chemical



Company. The Dow Chemical Company always reports a single viscosity average molecular weight, and one skilled in the art we know that's where to look when combining these products to make the film of Claim 1.

Q. Yes. But that was not -- had anything to do with the question I asked.

Could I ask you to answer my -- really, the question I asked was, was there anything in Claim 1 that required to you add things together?

A. The answer is, yes, there is.

Q. Okay. So what element in Claim 1 says you have to add something together?

A. The combination of the low-molecular weight PEO and the high-molecular weight PEO.

And I don't think it's too much of a stretch to realize that they must be combined.

Q. Okay. And Watson has to do the combination? They actually have to physically combine them together to infringe?

A. Well, they don't do that, do they?

Q. Well, if they didn't do it, and

they had to do it, then you would be right, but I'm asking you, do they have to add two things together to infringe, under your view of this claim?

A. Exactly. A low-molecular weight and a high-molecular weight.

Q. Okay. So it's kind of a hybrid. It's not just a composition claim. It's a composition plus method claim, because you have to have this step of adding things together?

A. Not at all. I mean, they listed that. I mean, you know, it's quite apparent to me that you've got two different things that have to be in the same product as the claim.

I'm sorry. I can't see any other way. It doesn't say you have to make mix them together. It shows them separate.

Q. Well, let's move on, because I think maybe we disagree or maybe I'm not making myself clear.

But let me ask you this:

Let's say we have a bottle, right, and Watson comes to you and they say, we want to use this in our film, and we don't know where it



came from, we don't how it was made, and all we know about it is that it's PEO, and we think it's going to work in our film.

Dr. McConville, do we infringe, will we infringe this patent?

I can't tell you how this bottle came together. I don't know if it was mixed from two bottles, three bottles, or four bottles. All I know is, it's in one bottle.

Can you tell me, you don't have to worry, because the one bottle that you are buying, it's not going to infringe?

A. Just to clarify, was it with two different PEOs mixed together?

Q. You don't know. That's the hypothetical. You don't know.

A. Well, I'm not going to be asked to give an opinion on that either way, because I don't know what's in the bottle, right?

Q. You don't know what's in the bottle.

So you would say you can't decide whether it infringes, because you don't know what's in the bottle. You don't know. But the



reason you're saying you don't know if it infringes or not, because up don't know whether it was mixed from two sources, or it was made separately as a single source, is the question?

A. I just don't know what's in the bottle. If you tell me what's in the bottle, if those two different PEOs that have been combined together are put in that bottle, and then, you know, it's suggested that that could satisfy the claim, then that -- that would infringe.

Q. All right.

Let's do this:

Let's say I gave you the bottle, and I asked you, can you tell me whether there are two PEOs in here? And I can't tell you anything else.

Is there a test out there that you might perform on that bottle to determine whether there's two separate PEOs? A high-molecular weight and low-molecular weight fraction?

A. If there was a bimodal distribution you mean?

Q. I'm just asking you the question



the way I phrased it.

A. Well, I guess you might give it to some, you know, polymer expert to say, analyze the sample.

Q. Or give it to Dr. Yang, right?

A. Possibly. It depends on what the average molecular weights at the end it came out to be.

Q. Okay. So then it comes back, and the results show a bimodal distribution, right?

You have your PEOs that you are showing in your illustration that you created. And, so, now, can you tell Watson -- and let's say there are two three peaks. Each of the peaks falls within the low range and one in the high range.

Can you tell whether they infringe or not?

A. You know, then that would -- that sort of information would lead me to try and discover what had happened in the bottle before, because, obviously, it's not just one PEO.

Q. Right. Right. So you would want to know where's this stuff coming from, right?

A. Of course.
Q. And then if it came from two sources you might say, well, we might have a problem?
A. What I will say is that all of the information, for example, on the had L'Hote paper, when there was a blend, they always indicated there was a blend. So I would expect, even if Dow had provided a blended product, they would write it on the bottle to show us what the blends of molecular weights were, as they had in the article.
Q. And, quite frankly, Dow has indicated that they make blends, as you heard from Dr. Mathias this morning, they actually take their product and blend it before they sell it.
Did you see that diagram?
A. You're inferring that those are different molecular weights the PEOs that are blended, and I absolutely disagree with that.
Q. Well, let me ask you this:
You say you're a film formulator. Are you an expert in polymer chemistry, too?



A. Oh, no.
Q. Okay. So you've to Dow's plant, I take it, right?
A. No, I haven't.
Q. Do you have any idea of the actual details of their manufacturing process.
A. It is proprietary.
Q. Well, we actually have some people here that work for Dow for many years who, consulted for them and they testified. So it may be proprietary, but there's certainly a lot of information that people who are experts in polymer chemistry know, but they're in the industry, and I understand you're a film formulator, right?
A. Yes.
Q. That's right. But you are familiar with the PEOs that we're talking about in this case, because you use them quite a bit?
A. I have used them, yes.
Q. Right. But you don't do GPC, do you?
A. No, I do not.
Q. And your lab doesn't have a GPC



device, does it?
A. No. We're always short of the grades we have of the PEOs.
Q. Okay. And you, in fact, you trust the label that the manufacturer puts on for a precise measurement of a PEO, average molecular weight?
A. Absolutely. There have been some in this product for decades.
Q. Did you look at the discrepancy of the reported values in the L'Hote paper from the actual values on the bottles?
A. You mean in terms of the viscosity average molecular weight?
Q. Right. I mean, you presented to the Judge. You said there were six samples. Actually, there were four different grades. And you said they were all about an average of a million. That's what you said.
Because you could tell by looking at Figure 1, they are all a million on average, right? Do you know what Dow reports them at?
A. The reason why --
Q. Please, answer my question.



A. I don't know what Dow reports on those individual grades in the L'Hote paper.
Q. Yes.
A. There's a table in there.
Q. Right. And one was at 600,000, right?
A. Not that I recall, no.
Q. All right.
A. Not one of the ones in the blends, no.
Q. Are you sure?
A. Yes.
Q. Okay. We're going to bring it up and we're going to go through it in a few minutes.
There's one at 900,000, right?
A. Yes.
Q. And then there was one at a million?
A. Right.
Q. Those were the three. And you said they were all about the same.
A. All the ones that are important in the blends about the same, of course.

Q. Important in the blends? Okay.
A. That were reported in Figure 2, the blends.
Q. Let me ask you this:
You said that -- and you'll agree with me that the high-molecular weight fractions in the '150 patent, the ones that are called out in that claim, they play an important role in the final performance of that film.
Would you agree with that?
A. Yes. The patent explicitly states that.
Q. Right. And it's gives examples of ten percent in one instance of the high-molecular weight, a 900,000 from the bottle from Dow, and that's a fairly large amount of high-molecular weight, correct?
A. No.
Q. All right. So it's not in your view, but that's fine.
I guess my question is:
Where in the paper, in that patent, did it actually say that ten percent was the minimum to get the performance they were



asking for?
A. Sorry. In the paper or the patent?
Q. The patent.
A. It gave lots of examples of different compositions and --
Q. Please.
MR. BOLLINGER: I'm sorry, your Honor.
BY MR. BOLLINGER:
Q. Can you answer my question?
THE COURT: I think he actually is.
MR. NUTTER: Thank you, your Honor.
THE WITNESS: Actually, the lowest reported one in that patent was ten percent.
Now, I believe that if they had found that a lower percentage was important for this claim, they would have indicated in their enabling examples that a lower amount of a high-molecular weight PEO should be made in the film. There was no examples of films which had less than ten percent.



It jives with what I'm saying as being a minimum effective amount for functionality in a film.
BY MR. BOLLINGER:
Q. I was just inquiring whether you saw any indication in the patent by the inventors saying that they had to have a certain threshold amount to get the performance. I couldn't find it. I just wanted to know whether you actually saw that language in the patent.
MR. NUTTER: Objection, your Honor. Counsel is testifying about what --
THE COURT: You can answer the question.
THE WITNESS: I believe the example showing ten percent is indicative of the minimum effective concentration of that high-molecular weight polymer. It agrees with what my experience in this field is.
BY MR. BOLLINGER:
Q. And, so, you made a film products for dissolvable films in the accordance with the patent, in the '150 patent?
A. I've made dissolvable films.



Q. Specifically, in the accordance with the claims of the '150 patent?
A. No.
Q. Okay. And you've never tested anything in this case, have you?
A. No, I haven't.
Q. So let me get back to another hypothetical.
Let's say we have a bottle, and it's come from a manufacturer, and we'll say it's from Dow, and it is poly ox, and we -- you do a test on it, and you find -- you send it to Dr. Yau for GPC.
And he comes back and he says, it's an amazing product. It has a unimodal distribution, but it's incredibly poly-dispersed.
Now, you understand what I mean by that, right?
A. Yes.
Q. Okay. So instead of what the is --
THE REPORTER: You turned your head. I couldn't understand you.

MR. BOLLNGER: I'm sorry. Amd now the base extends way out on both sides, right? So now you've got instead of one of these, it's one of the -- I don't know what -- we're talking about channel humps, and things like that, it's a like a igloo dome, okay?

Now, Watson comes to you and says it's a single source. Do we infringe? What do you tell them?

A. There has been no combination of PEOs.

Q. Okay. And let's say that when Dr. Yau does the analysis on that, he shows a line -- and he draws a line at the 600 point, and he shows the averages falling precisely within the two ranges, but now at the high range of instead 2 percent, it's 15 percent. And yet it's still only coming from one bottle, and it's only one manufactured product.

Still no infringement?

A. It's only one PEO.

Q. And let's talk about the Schiraldi patent.

You actually made kind of this



prior art argument. Watson's practicing the prior art, and my question is -- and we can go into whether you really are or not -- but I don't think you're the witness to do that with, but you did cite --

THE COURT: So, Mr. Bollinger, you know, the colloquies are for yourself in your questions. Maybe you can cut things down and ask questions.

MR. BOLLINGER: I apologize. I was really trying to get a question in mind.

THE COURT: You can do it in 15 seconds and no one will complain.

BY MR. BOLLINGER:

Q. So we have Schiraldi, right? And I think you said it shows a single PEO, but on the slide it indicated that it was between 100,000 and eight million.

Is it your understanding that Schiraldi teaches a single PEO with a range of 100,000 to eight million?

A. I said over three million, actually.

Q. So the single PEO that you're



talking about, was well outside of the ranges that are at issue in this case, with Schiraldi, correct?

A. No. The range that Schiraldi indicates falls within the range of a low-molecular weight PEO.

Q. All right.

Maybe I misunderstood your last answer. I thought you said it was between three and five million.

Isn't that what Schiraldi teaches?

A. 100,000. Preferably above three million daltons.

Q. Anyways. But they say, use 100,000 or 300,000.

They don't say, use both, do they?

A. They said the homo polymer of ethylene oxide is a single PEO that's used in the Schiraldi teaching.

Q. And it's your understanding that Schiraldi teaches a single PEO that ranges from 100 to three million?

A. No, no, no, no. That's a misinterpretation.



Q. Well --

A. Actually, because it goes back to there being different grades available. And all Schiraldi is saying is, there are a lot of grades available. Choose anyone of these.

Q. All right.

I'll disagree with that, but since it's not central?

Let's go to L'Hote now. And can we bring that slide up?

And I think, you know, we've established now --

MR. BOLLINGER: This is going to be the third time we're bringing this up, your Honor, and I apologize for that, but I think it's an important point of discussion.

BY MR. BOLLINGER:

Q. In this document you have now created some sort of simulation, right? You've made some diagrams that you think what actually this data would show?

A. I believe that it would be helpful to indicate that a degree of squishing occurs with a log scale in particular.

Q. All right.
And these are experiments that you could have easily undertaken to do to demonstrate what you were talking about, correct?
A. Do you mean repeat this paper?
Q. Repeat the analysis that they did, so you could demonstrate that there is a bimodal distribution?
A. The GPC analysis in there, right?
Q. Right.
A. So I already said I don't do GPC analysis.
Q. Well, there's -- you'll agree with me, it's a longstanding capability that is fairly common and available for people to use, right?
A. Not, no at all. I mean, I work with films, I work with polymorphs. I don't do GPC. I don't know any of my colleagues that work in pharmaceutical film formulations that routinely run GPC.
And do you know why?
Because they have the Dow Chemical



product label and that's what they use in manufacturing films.
Q. Well, let's bring up the table that shows the difference between what the label says, and what you said, and what Dow actually calculated with GPC.
All right.
And, so, if you look at this table, you'll see that the first column shows the various products. And that the poly ox 1105 is a product that they list at nominal 900,000 molecular weight. Viscosity average -- sorry -- viscosity average of molecular weight.
A. I'm looking for the viscosity average of the molecular weight.
Where is that?
Q. Well, I'm sorry. These are weight averages here.
MR. BOLLINGER: If you can go to the page where it shows the calculation in viscosity averages?
(Pause)
BY MR. BOLLINGER:
Q. Okay. If you look at this, you



see that Dow reports that -- and it says there -- these -- the weight average of molecular weights of poly ox 1105 was very similar to the standard deviation of .36S from the GPC column, correct?
A. Sorry. What's the viscosity average of the molecular weight again?
Q. It's the next line.
What I was trying to get across was, they were identifying that their product literature reports this in viscosity average of molecular weight, correct?
A. I'm a little confused as to what you're talking about, because we're trying to -- you know, that -- you're trying to make the point that Dow is reporting a viscosity average molecular weight for these products, the 1105, the 205, and the --
Q. Right.
A. -- and 12.
And I don't know those viscosity average molecular weights. You were trying to get me to look at the graph, and see how they compare to what the deviation might be



associated with that.
And I'm having a -- I don't know what the viscosity average molecular weights are.
Q. Well, let's go back to the graph, and we'll go to Figure 2, which shows the blends, right?
A. Yes.
Q. Now, you'll agree that this draft doesn't show anything about molecular weight, in terms of a calculated average, right?
A. It doesn't show the viscosity average molecular weight, no.
Q. Okay. And what does this actually show? This is the just molecular weight distributions?
A. This is the -- yes, as far as I can tell, the GPC analysis that is performed on the -- well, on these blends, or on the single poly ox 1105.
Q. Right. And in looking at this data, was it your understanding that the Dow researchers were specifically asking whether there was a bimodal distribution when you

blended in these three ratios here form a 600 and a million together?

A. It's my understanding I --

MR. NUTTER: Your Honor, this is the third time he's used the term "600." He has yet to show the number 600 in the paper.

THE COURT: Overruled.

MR. BOLLINGER: It's in there, your Honor. I would just like to quickly go through in this one last topic.

THE COURT: Okay.

BY MR. BOLLINGER:

Q. Specifically, the -- if I can, if you look at it you say, is this showing a bimodal distribution, and you can't tell, because you want to look at in a different scale.

But do you know what Dow researchers concluded? Did you read the paper and understand what they concluded?

A. Dow researchers didn't process this on the linear scale.

I told you that I think the molecular weights of the individual ones are



very close together. I think they would have put their best foot forward having presented this on a linear scale. And I just showed you that if you put molecular weights that are close together on a log scale, you can't separate them out, and that's, to me, is exactly what this figure is showing.

Q. Right. My question was simply:

Did the Dow researchers, who studied and had all the data that you chose not to create, did they actually concludes that this was all uni-modal distribution, blends and non-blends together? Was that their conclusion?

A. That is what they said about their figure, yes.

MR. BOLLINGER: Okay. Thank you.

Your Honor, I have no further questions.

THE COURT: All right.

Thank you. Any redirect?

MR. NUTTER: No, your Honor.

THE COURT: All right. Thank you.

Do you have anything more, Watson?

MR. LOMBARDI: We do, your Honor.



We're calling Dr. Dyar.

THE COURT: Okay.

MR. LYNCH: Good afternoon, your Honor.

James Lynch of Watson for the defendants.

THE COURT: I thought you were Dr. Dyar.

Good afternoon, Mr. Lynch.

MR. LOMBARDI: Your Honor, just for organization, we're moving to the invalidity part of the presentation of this.

THE COURT: Does that mean that you have rested on infringement?

MR. LOMBARDI: Yes.

THE COURT: All right.

And does that mean the plaintiff has nothing further on infringement for the '150 patent, right?

MR. LADOW: No, your Honor, except on validity.

THE COURT: Right, right. Infringement.

MR. LADOW: Yes, your Honor.

THE COURT: Correct. So,



basically, the '150 infringement, we're done?

MR. LOMBARDI: Yes, your Honor.

THE COURT: Okay. That that's all I wanted to establish.

All right. Invalidity.

MR. LYNCH: Your Honor, may I approach with the binders?

THE COURT: Yes, Mr. Lynch.

... STEPHEN CRAIG DYAR, having been duly sworn as a witness, was examined and testified as follows ...

MR. LYNCH: May I proceed?

THE COURT: Yes.

**DIRECT EXAMINATION**

BY MR. LYNCH:

Q. Dr. Dyar, could you please introduce yourself to the Court.

A. Yes. Stephen Craig Dyar. I go by Craig Dyar.

Q. You've been asked to provide expert opinion in this case?

A. Yes, I have.

Q. Please turn to Tab 1 in the binder that's in front of you, please, Exhibit DTX-1316

marked for identification.
Do you have it there?
A. No, sir.
Q. You don't have a binder yet?
MR. LYNCH: Your Honor, May I approach?
THE COURT: Sure.
(Pause)
BY MR. LYNCH:
Q. All right.
Tab 1, do you have it there in front of you?
A. Yes, I do.
Q. Do you recognize this document?
A. Yes, I do.
Q. Is this a current copy of your Curriculum Vitae?
A. Yes, it is.
Q. And does this document accurately reflect your education and professional experience?
A. Yes, it does.
MR. LYNCH: Your Honor, the defendants move DTX-1316 into evidence.



THE COURT: I thought all the resumes were already in evidence?
MR. LYNCH: We would have thought it would have been, your Honor, but there was an objection last night that was not resolved.
THE COURT: Okay. Any objection to this?
MR. LYNCH: It wasn't articulated, other than to say an objection.
THE COURT: Is there an objection?
MR. BRAHMA: No objection.
THE COURT: No.
What's the exhibit?
MR. LYNCH: DTX-1316.
THE COURT: 1366, okay. Thank you.
MR. LYNCH: Thank you.
BY MR. LYNCH:
Q. And, Dr. Dyar, you have a prepared slides to assist your testimony today?
A. Yes, sir, I have.
Q. Can you briefly tell us how your educational background relates to the opinions you've prepared?



A. Yes. I started out with an BS in Biology in 1984, where I was studying chemistry, physics, and other courses. I moved on to a BS in pharmacy in 1987.
I took a little break, seven years as a pharmacist. Then went back and got my Ph.D. in 19 -- from 1994 to l998, three-and-a-half years, and that was in pharmaceutical science, which is basically the study of dosage form development and design, including formulations of suspensions, solutions, tablets, and capsules.
I then proceeded to work in l998 to 2008 for Parke Davis and Pfizer, evaluating and developing drug delivery systems.
I left Parke Davis Pfizer in 2008, and became an Assistant Professor at South University, where I teach graduate courses in pharmaceutics and pharmacokinetics.
Pharmaceutics is, again, the study of how to develop a dosage form. And pharmacokinetics is the study -- mathematical study of what happens to the drug in the body.
At the same time, in 2008, I



started my own pharmaceutical consulting company, where I advised large to small companies on drug delivery research and development, from discovery to its launch. And I currently do the same -- have the same position.
And in 2010, I joined Blachman Consultants, again, helping companies fix problems in the drug delivery arena and continue to do so.
Q. Thank you.
And, Dr. Dyar, in your teaching of students at the School of Pharmacy, do you spend any time in a lab?
A. Yes. Approximately, 50 percent of my time in the lab or directing students in the lab.
Q. And, Dr. Dyar, what experiences do you have in working with films?
A. I did some work, feasibility benchwork early in my Parke Davis days, to evaluate and developing a film, and found it was very easy to do.
Q. Do you have any other experience

working with films, whether it's sprayed or cast?

A. Yes. Tablet coating is one way we create a suspension of a color, to change the color of the tablet and make it identifiable. And we spray that on to the tablet and dry the tablet.

I also worked in the area of hot melt extrusion, which is where we heat up polymers, and drew a screw immediately on to a tray, on to a belt, which are air cooled.

MR. LYNCH: Your Honor, defendants offer Dr. Dyar as an expert in pharmaceutical science, drug development, and dosage form.

THE COURT: All right.

MR. BRAHMA: No objection.

THE COURT: You may proceed.

**DIRECT EXAMINATION**

BY MR. LYNCH:

Q. Doctor, can you please summarize the opinions you've reached in this case?

A. Yes, sir. The asserted claims of the '514 patent are invalid as obvious, in view of Chen, and Bess, connected with the knowledge



of a person of skill in the art. And they are also invalid as indefinite.

Q. And, Dr. Dyar, can you please identify for us which of the asserted claims in the '514 patent you're prepared to testify about today?

A. Yes, sir. Independent Claim 62 and Dependent Claims 64, 65, 69, and 73.

Q. And those are the claims displayed in JTX-2?

A. That's correct.

Q. All right.

And are you familiar, Dr. Dyar, with the Court's claim construction as it relates to these claims?

A. Yes, I am, and I applied that in my opinion.

Q. Before we turn to the substance of your opinions, have you formed an opinion with respect to your testimony regarding the definition of a person of ordinary skill in the art in the context of these '514 claims you are testifying about?

A. Yes, I have.



Q. What is that?

A. It's a person who possesses a Bachelor's Degree in Pharmaceutical Science, Chemistry, or related field, plus two to five years of relevant experience in developing drug formulations. And/or it could be a person having a Master's Degree, or a Ph.D., with less experience.

Q. Dr. Dyar, can I trouble you to speak just a little closer to the microphone?

A. Sure.

Q. Thank you.

Are you aware, sir, that the plaintiffs have proposed a slightly different definition of a person of ordinary skill in the art?

A. Yes, I am. And it doesn't change my opinion.

Q. All right.

Let's begin with your analysis of the Independent Claim 62.

Can you tell us, in plain English --

THE COURT: When you say it



doesn't change your opinion, do you mean that your opinions on invalidity would be the same using the other sides definition?

THE WITNESS: Yes, sir.

MR. LYNCH: Thank you, your Honor.

BY MR. LYNCH:

Q. Turning to your analysis of Independent Claim 62, can you tell us in plain English what this claim means?

A. Well, there are four parts.

There's a uniformity component, there's a cast film component, there's a taste masking component, and a particulate active.

Those are the four key components that are discussed. And when I read this patent the first time, I was trying to identify what they may have in it, because that was the type work that I always have done in the past, in looking at patents, to understand what the invention may be.

And I realize, in my reading of this patent, that I did not find anything unique or different that I didn't already know at the time of this patent.

Q. All right.
And you've identified four categories of claim limitations and you're prepared to testify about each of those?
A. Yes, sir.
Q. You just stated that the claims, in your opinion of the '514 patent are obvious in light of the Chen and Bess, and the knowledge of a person of ordinary skill in the art.
Beginning with Chen, can you briefly explain why Chen is relevant to your opinions in this case?
A. Yes. Chen talks about a cast film that is uniform, has a taste masking agent, and contains a particulate active.
Q. And why is it the Bess reference, though, to your opinions in this case?
A. For the same reasons. It teaches uniformity, it has a taste masking agent, and a particulate active.
Q. In your opinion, Dr. Dyar, would a person of ordinary skill in the art have been motivated to combine the teachings of Chen and Bess?



A. That's what I always do. And when I teach my students to read any relevant patents, and combine those, when it's appropriate.
Q. All right.
Let's turn to the process of making a cast film.
And I know you're looking at Chen, which is JTX-187 at Page 40, Figure 2.
Can you tell us what this depicts and how it relates to making a cast film?
A. Yes. Specifically, Figure 2 -- and I'll just do a real quick overview, and then show you a little animation that makes it become a little clearer.
You have a mixing tank, you have a belt, you have a dryer... you have a mixing tank, you have a belt, you have a dryer, you have a die cutter, and then you have a container that collects the materials.
And here's an animation of this step, just a little slower.
You have a motor, you have a shaft, you have blades that are stirring in this



tank where you put the matrix or the suspension.
Q. Okay. When you refer to the matrix, or the suspension, does that contain every component of what becomes the final product?
A. Yes, it does. And, actually, the yellow is the matrix, and the little blue dots that we made here are the active -- particulate active.
So that is being mixed, stirred, and has sufficient viscosity that it can be meted out by gravity on to the belt. The film goes forward. It goes through the oven. You will see that it's uniform.
And it comes out the other side of the oven. It's dried at this point, it rotates up, and then it's cuts into individual dosage units and then dropped into a container from which it is going on to be packaged.
Q. And can you return to Chen Figure 2 and describe for us a little bit more about the drying process that is depicted in Chen?
A. Yes. Again, this is where the oven was located. This is indicated there as



the drying oven with an aeration controller. And as you can see from the first aeration control, which is where the film is wet, it's a matrix, it's liquid, it can move, and we don't want to force a lot of air directly down, because imagine what you do would if you would force air directly down onto water. It would cause waves, and we don't want that. But we diffuse the air on the first step. As it becomes dryer, the angles steepen, so more air goes directly down so it can dry a little faster.
And in the third aeration controller, the air is pointing directly down. So basically at that point, it's mostly dry.
Q. Dr. Dyar, were there any examples of commercial cast films before the '514 patent?
A. Yes. And this is the '298 patent, which was mentioned earlier. And JTX-183, page 6, this is specifically to the Listerine PocketPaks.
MR. BRAHMA: Objection, your Honor. He has previously offered no opinions

that this patent covers that product.
MR. LYNCH: Your Honor, this is not prior art. It is background. He mentioned it in his opening report in paragraph 57. He's simply provide background about the technology before we get into his discussion of the art.
THE COURT: All right. Well, it's mentions in paragraph 57?
MR. BRAHMA: The two things aren't linked. They're both mentioned in the paragraph. They're just linked in the cover.
THE COURT: I'm going to allow it.
THE WITNESS: So this again is the fast dissolving orally consumable film, Listerine PocketPak. It was made at Warner-Lambert Company in Morris Plains, New Jersey, which is the parent company of Parke-Davis at that time later bought by Pfizer, across the street from where I worked. I worked in Morris Plains.
In 1999, this is when the patent came into existence.
Q. Dr. Dyar, did you have any



experience working with these kind of thin films before the '514 patent?
A. Yes. I did do some consulting work in regard to the Listerine PocketPak, and I also did some thin skill laboratory work around the feasibility of film.
Q. Thank you. Let's turn to the first set of limitations in the '514, claim 62, and that concerns uniformity.
Let me begin by asking: Is content uniformity in your opinion important in drug development?
A. It is an absolute tenet in pharmaceutical development to have content uniformity for the very reasons as mentioned in the opening, that you need to have a product that is uniform to give a safe, efficacious drug, and not have toxic side effects. If it varied by more than ten percent, you could be getting into those toxic ranges.
And actually the '514 patent, as indicated here, JTX-2 on page 38, which is the background of related technology, specifically states, currently, as required by various world



regulatory authorities, dosage forms may not vary by more than ten percent in the amount of the active. When applied to this based on films, this virtually mandates that uniformity in the film be present.
Q. Did this regulatory requirement for uniformity, dose uniformity, exist prior to the time of the '514 patent?
A. Yes. I was aware of it in 1984, when I first started pharmacy school, and it has been around since before then. It is actually the basis for the FDA, the Federal Drug Administration being in existence.
Q. And in your opinion, Dr. Dyar, would a person of ordinary skill in the art be motivated to target a dose uniformity of five percent or less?
A. Absolutely.
Q. And what's your basis for that opinion?
A. My experience is on various projects that I've worked on directly at a number of different companies, that I've gone in to help them fix problems and advised them on



how to develop a product that all of the world and help people to do that, and five percent is the target that we always try to find.
Q. Are there any practical reasons in the manufacture of pharmaceuticals why you would target a uniformity variation that's lower than the required regulatory standard?
A. Yes. The main reason is you do not want product recalls. You don't want it to go back to the manufacturer. We don't want to have to take it back in because it costs money if you do.
If you were to hit 11 percent, say, or 16 percent, you would have a problem. You would have to have the product recalled and all the issues associated with that.
So the further away you are from that mandatory requirement of ten percent to five percent, the safer you are and the more room you have to have potential changes in the percentage.
Q. Dr. Dyar, in your opinion, what does this regulatory requirement tell you about the motivation of a person of ordinary skill in

the art when targeting a uniformity variance limitation?

A. It is a requirement. They would definitely be motivated to do it.

Q. All right. Thank you.

Let's turn now to the specific sub-elements of the uniformity limitations. The first in the '514 patent is a particulate active substantially uniformly stationed in the matrix. First of all, what does that mean?

A. That means that if it does not clump up. It sits there and it's separated out. It's uniformly distributed throughout the matrix that it's in.

Q. Is there a common example of what the matrix is here, what the liquid is here, which particulate actives are added?

A. Well, you can think of, since it's getting close to Christmastime, chocolate chip cookies is the batter that the cookie, chocolate clips are in. So if you have them, if you have the batter too thin, the chocolate chips fall to the bottom and don't get distributed. The right viscosity, you can have them mix it up and you



can meter it out to make the right appropriate chocolate chip cookies with even distribution that we all like. Right?

Q. Does the Chen reference the JTX-187 disclose this limitation?

A. Yes. On page 17, it talks about the active agent being dispersed or dissolved uniformly in the hydrocolloid solution, and then this is the matrix. Even though it says solution, we have it dispersed within that solution, so that makes it a suspension.

Q. Thank you.

And turning to the next limitation in the '514 patent, claim 62, which refers to a viscosity sufficient to aid in substantially maintaining non-self-aggregating uniformity of the active in the matrix. First of all, what does that mean?

A. That means it's thick enough that the active won't settle out and will remain uniform within the matrix.

Q. With respect to viscosity that's referenced there in that part of the claim language, what does the '514 patent say about



viscosity?

A. The '514 of JTX-2 on page 43 talks first about, this is a cup of water, which centipoise is a unit of measure for water, of our viscosity, and water has one centipoise viscosity. Motor oil, on the other hand, has 400 centipoise, and sour cream has 100,000 centipoise.

This is a very broad range. It covers almost any viscosity that you would use in a pharmaceutical film or formulation.

Q. Does the '514 make suggestions about any particular viscosity within the broad range you've just identified that should be used in making the kind of film disclosed in that patent?

A. No, it doesn't teach you how you should narrow it down and what you should really be targeting.

Q. Are there any equations or other disclosures in the '514 patent that relate to viscosity?

A. Yes. There are a number of equations that relate to viscosity in the '514



patent.

Q. Is there anything, including those equations or anything else in the '514 patent about viscosity that was new as of the date of the '514 patent?

A. No, there's not anything new in the '514 patent, as I read it numerous times.

Q. All right. And prior to the '514 patent, would a person of ordinary skill in the art have known that viscosity is a factor in establishing and maintaining uniformity?

A. Yes.

Q. How is that?

A. I'm turning to my next slide. And this, Stokes law, which he developed in 1851. Very complicated looking equation, but I will simplify it in just a minute.

This is from a reference in Carstensen in 1973. Again, this is a textbook reference that I have used over the years. JTX-173 on page 12. And I will make it a little easier.

So it talks about is sedimentation rate. In other words, how fast a solid will

fall in the matrix. It's multiplied times the radius of the sphere. So, in other words, the size of the particle.

The particle density comes into play, how much it weighs. The density of the liquid and also as everything tends to fall upon a gravitational constant that comes to play in the equation.

On the bottom we have the viscosity of the liquid, and that's multiplied times nine. Viscosity of the liquid is how thick it is.

So it has a huge impact because if we increase the viscosity of the liquid, it's a nine fold increase in the viscosity on the bottom, so that the corresponding decrease, significant decrease in the sedimentation rate.

The other factor that we can change is the particle size. Those are the two that we primarily change.

Q. And can you explain how Stokes law relates to your opinion that this claim limitation is obvious?



A. It's one of the primary ways that we use to change a suspension and in order to make it uniform is by adjusting particle size, by adjusting the viscosity of the liquid, and, of course, we can use stirring or shaking.

Q. And, Dr. Dyar, in your opinion, would a person of ordinary skill in the art have reasonably expected that viscosity could be adjusted to achieve and maintain uniformity?

A. Absolutely.

Q. Are is there any other art, prior art on which you rely to support your opinion that this claim limitation is obvious?

A. Yes.

Q. And --

A. And this directly is from Chen, JTX-187, on page 15, where he states, a factor that place a significant role in determining the properties of mucosal surface-coat-forming composition is the viscosity of the hydrocolloid. That basically says that a film depends upon the viscosity of the matrix.

Q. All right. So turning now to the third limitation relating to uniformity, and



that refers to the capability of being dry. Can you explain what this limitation means in plain language?

A. Yes. It means that when you run it through the dryer, it doesn't become uniform. It stays uniform through, as you dry it. So the viscosity is sufficient, that it maintains that uniformity through the drying steps.

Q. And is this claim limitation directed to any particular drying method?

A. No. There's not a specific drying method claim in the '514 patent. It only discusses conventional drying techniques, several of which I've listed here. Microwave drying, room temperature drying, tray drying, bottom airflow, controlling air speed and temperature. Those are all conventional techniques you could use to dry film.

Q. Is there prior art, Dr. Dyar, that you rely upon to support the opinion you just expressed?

A. Yes. I've already discussed the Chen JTX-187 on page 40, Figure 2. We've discussed that earlier. And there's also the



Lachman reference from 1986.

And Lachman is a primary, again, referenced textbook used in the pharmaceutical field, and it's JTX-238 on page 13, where he talks about, to achieve uniform drying, there must be a constant temperature and a uniform airflow over the material being dried.

Q. Dr. Dyar, your opinion, would a person of ordinary skill in the art have been enabled prior to the '514 patent to maintain uniformity throughout drying?

A. Yes, because if you didn't maintain uniformity throughout drying, you wouldn't have a uniform product. And that is going back to the tablet coding example. You wouldn't have a uniform product that was covered.

Q. Thank you.

And turning now to the last uniformity limitation, a cleaving a final product with a dose variance of less than ten percent, can you explain what that limitation is, please?

A. Yes. So this is talking about

subsequent to casting and drying of the matrix is measured by a substantially equal size of individual units to where we have ten percent of the desired amount of at least one active.

And this figure from Chen, again, JTX-187, page 43, is Figure 5. And this shows a dissolution profile. Well, what is a dissolution profile? Well, that's one of these measures that we use to determine content uniformity and release profile in the pharmaceutical field prior to taking it into a human study.

Q. What does the chart depict in particular and what are the bars on the top and bottom of the various dots along the lines?

A. Okay. So the X axis on the bottom is time in minutes and it goes from zero to ten minutes. On the Y axis, you have percent release, which goes from zero. The scale gets to 120, but we're really concerned about the hundred percent, really, so that means a hundred percent of the drug that you expect to be in there is released.

The lines or the dots, the



markers, the circles and the triangles, are all the mean values for the examples that are being tested. And then you additionally have error bars associated with those means.

Q. What is the purpose of running a dissolution study, and what does this study from Chen convey to you?

A. The purpose of the dissolution study is to determine the release profile or how fast it releases or how slow it releases. And you can see that these three are basically over each other and are very rapid and then level out.

I'm going to use the big color pointer. Sorry. All right. Okay.

And level out. Okay? And here, you can see that the error bars are very tight at a hundred percent, a hundred percent release at ten minutes.

Q. In other words, that at ten minutes of the dissolution study, 100 percent of the active content has been released and there's a variation that appears to be within ten percent of the expected amount of active?



A. That's correct.

Q. And how does that support your opinion that Chen enables the development of films with a dose variability of ten percent or less?

A. Because this is, looking at this type of data helps you determine what the, the content uniformity is around that dosage form, and shows that it is very tight, or very good, and you would likely take it into a human clinical study.

Q. Are you aware, Dr. Dyar, that during the prosecution of the '514 patent, the patentees relied on Figure 5 in arguing to the PTO that the Chen films were not uniform?

A. Yes, I am.

Q. And do you agree with that?

A. I do not agree with that.

Q. And why is that?

A. Because this figure to me, after having looked at thousands of these over my 20-plus years of experience and helping companies solve problems shows me that we have a very good release profile, and we have at a



hundred where we can see that it's tight, where we can see the data a little clearer. That we have very tight content uniformity that looks to be at least close to ten percent, if not less than ten percent. It also indicates to me if he's not at ten percent, that a little bit more experimentation, he could easily get there.

Q. And is that kind of experimentation you just referred to a standard part of development?

A. Yes. It's a standard part of development. I'm actually working with a couple companies right now to help them fix problems that are very similar to this.

Q. Do the release profiles here in Chen Figure 5 suggest anything to you about whether the films that are being studied here could be developed into a marketable and approved product?

A. Yes, they do. They tell me at this stage, at this type of development, the profiles that I see indicate that he could develop a film product to be put on the market.

Q. Did you have occasion, Dr. Dyar,

to compare the uniformity data in this Chen reference, JTX-187, to data in the '514 patent?

A. Yes, I did.

Q. And how do they compare?

A. I did not find any dissolution data of this type in the '514 patent.

Q. And, Dr. Dyar, your opinion based on the disclosure in Chen, would a person of ordinary skill in the art reasonably expect to achieve a film that satisfies the ten percent variance limitation?

A. Yes.

Q. Dr. Dyar, are you aware that Dr. Langer, who has testified for the plaintiffs, relied on some references after the '514 patent to opine that the films in Chen were not uniform?

A. Yes.

Q. And have you read the references Dr. Langer cited?

A. Yes, I have.

Q. Do any of those references change your opinion that the prior art enabled a person of ordinary skill in the art to make a uniform



film?

A. They did not.

Q. Why is that?

A. Primarily because none of them discuss Chen at all. None talk about the uniformity was a problem after Chen, and none criticize uniformity within Chen.

Q. Did any of the search references that are depicted here on DDX-3.021 conduct and report any independent scientific analysis?

A. Not in regard to how to develop a product as shown by Chen, and actually there were many copy-and-paste criticisms from the '514 patent and related application.

Q. Did any of the references that you read establish that content uniformity was an unsolved problem that was solved by the '514 patent?

A. Not in my opinion.

Q. The Perumal references that are listed there, did that reference replicate any of the Chen films?

A. It did not replicate the Chen films, no.



Q. And to summarize, Dr. Dyar, would the uniformly limitations in the '514 patent that you just testified about have been obvious to a person of ordinary skill in the art as of the time of the '514 patent?

A. Yes, they would.

Q. Turning now to the next set --

THE COURT: Mr. Lynch, rather than turning now, why don't we take our afternoon break.

MR. LYNCH: Thank you.

THE COURT: So we'll take about 15 minutes and we'll come back.

(Short recess taken.)

- - -

(Proceedings resumed after the short recess.)

THE COURT: All right. Please be seated.

All right. You may continue, Mr. Lynch.

MR. LYNCH: Thank you, your Honor.

BY MR. LYNCH:

Q. Dr. Dyar, before the break, we



were talking about your obviousness opinion regarding independent claim 62 in the '514 patent, and we had just turned to what you had identified as the cast film limitations.

Can you first explain what the first cast film limitation is?

A. The first cast film limitation is -- does it sound good?

Q. Yes, sir. Thank you.

A. Perfect. In regard to a cast film comprising a flowable water-soluble or water swellable film-forming matrix comprising one or more substantially water-soluble or water swellable polymers.

Again, the first reference here is Chen, JTX-187 on page 22. This is the same Chen reference we talked about earlier.

And the films were prepared according to examples 1 through 3. Here, also additional, on page 23, in Table 5, show examples 5, 6, 7 and 8, which correspond to the graph that we showed earlier on the dissolution data. And it comprises a water soluble, water swellable polymer. It's methocel shown here.

Q. And are the examples that you just identified examples of cast films?
A. Yes, they are.
Q. Do those same examples disclose a flowable matrix?
A. They show a flowable matrix, but the final product is not flowable. There's a matrix comprising, but the final cast film is not flowable.
Q. Thank you.
Turning to the next cast film limitation, can you explain what that is?
A. Yes. It's talking about the desired amount of the at least one active, and this is table, this is Chen, 187, JTX-187 on page 23.
Table 5 is talking about nicotine is an active, hydromorphone is an active. Oxybutynin is an active in example 7, and Estradiol in example 8 is an active.
Q. So examples 5 through 8 in Chen that you've just identified teach the limitation that you just identified from '514 about having a cast film with the desired amount of at least



one active?
A. That is correct.
Q. And the bottom part of this slide that we are looking at, which is taken from JTX-187, page 18, it refers to examples 5 through 8 being depicted in Figure 5. Can you explain?
A. Yes. The Figure 5 that we saw earlier showing the dissolution profiles, these are the examples, and the corresponding amounts of drugs in each of those.
Q. Thank you.
Let's turn next to the limitations in claim 62 that you have identified as taste-masking agent.
A. Yes. And from the '514 patent, it talks about a taste-masking agent selected from the group consisting of flavors, sweeteners, flavor enhancers, and combinations thereof to provide taste-masking.
Q. Now, what is your opinion, Dr. Dyar, about whether the Chen reference discloses a use of a taste masking agent?
A. Yes. Chen discloses it on page



11. It talks about encapsulation of the active agent to achieve masking of taste for active agents that are bitter.
And on page 12, it talks about taste modifying agents, which are flavoring agents, sweetening agents and taste-masking agents.
Q. Turning now to your last category of claim limitation in claim 62 regarding a particulate active, can you explain what the '514 claim limitation is?
A. Yes. The '514 claim limitation is a particulate active uniformly stationed in the matrix. And the particulate active in reference to showing Chen of 187 on page 6, and on page 9 and page 11 all talk about an active agent being encapsulated or as an individual particle, and that identifies the particulate active.
Q. So is it your opinion, Dr. Dyar, that the Chen reference discloses using a particulate active in a pharmaceutical cast film?
A. Yes, it does.
Q. Does the Chen reference disclose a



particulate active of a specified size?
A. Chen does talk about particulate actives that are greater than 25 microns, leaving a gritty or unpleasant taste in the mouth when they are placed within the mouth as in a quick-dissolving-type tablet. So he teaches that you need to have a small particle size and not to have a gritty taste in the mouth.
Q. Other than the mouth feel, would a person of ordinary skill in the art have been motivated for any other reason to use smaller particles for the particulate active?
A. Yes. Going back to Stokes law, where we talked about the particle size being small in order to decrease the settling rate or and correspondingly increasing the uniformity of the dosing form.
Q. And are there any other references that disclose more specific particle sizes?
A. Yes. Actually, the Bess reference that I mentioned earlier, 184 on page 8, talks about the particle size of 200 microns or less, and specifically about active agents, complexes

between 55 and 160 are probably between 60 and 150, which are both below 200 microns.

Q. And that's Bess JTX 184?

A. Yes. On page 8.

Q. All right. So can you summarize your opinion that all the limitations of claim 62 were obvious as of the time of the '514 patent?

A. Yes. Based upon this color-coded scheme, we can see that we've already talked about the uniformity and that is shown in Chen. We've talked about cast film being known. We have talked about taste-masking agent being known and particulate active less than 200 microns, which covers the entirety of the independent claim 62 as being obvious to someone skilled in the art.

Q. And, Dr. Dyar, do you have an opinion regarding whether the claims of the '514 patent would have been obvious even if Chen did not actually teach a uniform film?

A. Yes, I do.

Q. And what is that?

A. That he taught how to make a film,



and with a little bit of additional experimentation if it was needed, you could, I could at the time the patent was issued be able to make the film prior to that date.

Q. Let's turn now to the dependent claims that you identified.

Can you summarize your opinion regarding whether these dependent claims were obvious as of the time of the '514 patent?

A. Yes. Let's talk about claim 6 tea four, which is specifically the hundred microns or less. Again, I already mentioned earlier that the Chen teaches small particles. Bess teaches particles less than 100 microns. So that is obvious.

Claim 65 --

Q. Can I pause you before you move on, Dr. Dyar?

A. Yes.

Q. Is there anything about these particle size and the specified microns that are identified that is out of the ordinary for this type of a pharmaceutical?

A. Absolutely not, because you would



want small particles within a film that is very thin, so you wouldn't have a rough surface. So that goes without saying.

Q. Please continue.

A. Claim 65 is talking about less than five percent by weight. Again, I already alluded to the uniformity requirement that a person of skill in the art would be motivated to reach and obtain so that they would not have product that would be outside of that range and have to have product recalls.

Q. And in your opinion, would a person of ordinary skill in the art have been motivated to obtain a variation in dose uniformity of five percent or less?

A. Yes.

Q. And in your opinion, would a person of ordinary skill in the art reasonably expect to succeed in achieving a dose variance of five percent or less?

A. Absolutely.

Q. And have you formed an opinion regarding whether claim 6 tea nine is obvious?

A. Yes. Claim 69 is talking again



about taste-masking agent presented in an amount of .1 to 30 percent. That's a very broad range. It covers basically everything that we've used in taste-masking.

The Chen examples 4 through 8 contain one percent peppermint oil, which is a taste-modifying agent, taste-masking agent.

Q. And have you formed an opinion regarding whether claim 73 is obvious?

A. Yes. Claim 73 is obvious in light of the Chen example 6, which contains hydromorphone, which is an opiate.

Q. Thank you.

Dr. Dyar, let's turn to your second category of opinions regarding the '514 patent as being indefinite.

Can you explain briefly the basis for your opinion that the claims are indefinite?

A. Yes. Well, a better slide, again, color-coded, trying to group things to go here.

The green being the final product, and it is a drug delivery composition of cast film. And looking at the bottom, it's uniformly subsequent to casting and drying of the matrix

is measured by equally sized individual unit ten percent or less. That is the final product.

What's also claimed is that the cast film must have, or must be flowable, which is impossible, practically impossible for it to be a final product that must be solid and not move around on the table that you can take at any point in time afterward within the shelf life of the product and it be the same as when you get it the first day, you get it from the pharmacy.

So it cannot be flowable because that implies that it moves, and the only thing that moves are liquids or air. A solid does not move.

Q. When you refer to a final product, are you referring to the opening line of claim 62, which describes, quote, "a drug delivery composition"?

A. Yes.

Q. Comprising?

A. Yes, that's correct.

Q. All right. Is it physically possible for a drug delivery composition that is



a cast film to also be flowable at the same time?

A. That is practically impossible for it to occur.

Q. And --

A. Not to be stable.

Q. And is it physically possible for a drug delivery composition that is a cast film to also have a viscosity at the same time?

A. It is not because viscosity implies or the only way you can have a viscosity is from a material that flows.

Q. And, Dr. Dyar, with respect to your observation that claim 62 claims a drug delivery composition final product, do you have an understanding about whether the '514 patent covers also intermediate form of that product during the process of it being made?

A. Yes. And this goes to the claims covering the final product, and --

MR. BRAHMA: Objection, your Honor. He has not been qualified as an expert on submitting documents to the FDA for listing patents in the Orange Book.



MR. LYNCH: Your Honor, he replied in his reply report to arguments made by Dr. Langer for plaintiffs that there were intermediate steps in the process that could be flowable, and that's in his reply report.

THE COURT: So I think the objection is not that he didn't put this in the report. I think the objection is it exceeds the scope of his expertise.

And so maybe you want to ask him a question or two, because I'm not a hundred percent sure that -- I don't know whether this is or is not within his expertise.

MR. LYNCH: Right. Thank you.

BY MR. LYNCH:

Q. So, Dr. Dyar, what is your basis for concluding that claim 62 does not cover intermediate steps in the manufacturing process?

MR. BRAHMA: Objection, your Honor. The same objection. I don't think that goes to his expertise.

THE COURT: Well, Doctor, what's your experience with understanding Orange Book listings?



THE WITNESS: Okay. I actually teach this in pharmacy school to pharmacy students what the Orange Book listing means, and my work at Pfizer was involved with helping them list drug products in the Orange Book.

THE COURT: And do you understand where these sorts of questions are being asked here, who provides this information and what it means?

THE WITNESS: Yes. This information is provided by the drug, the company that's developing the product. Specifically in the area of the attorneys, and that area that cover the patents, provide that information as part of the filing.

THE COURT: All right. I'm prepared to let him answer the question unless -- I assume you're Mr. Brahma?

MR. BRAHMA: Yes.

THE COURT: Is there any question you want to ask him before he goes ahead?

MR. BRAHMA: Let him go ahead.

THE COURT: You can repeat your question.

MR. LYNCH: Thank you, your Honor.
BY MR. LYNCH:
Q. So, Dr. Dyar, is there any other support for your conclusion that the claim 62 refers to a final drug product and not to any intermediates?
A. Yes. As Reckitt request for the Orange Book listing shown here as JTX-250 on page 2 talks about the drug product composition formulation, and it says, does the patent claim the approved drug product as defined in 21 CFR 314.3? And they responded yes.
The second question asked: Does the claim, does the patent claim only an enter intermediate? And they indicated no.
MR. LYNCH: Thank you. No further questions at this time.
THE COURT: All right.
Mr. Brahma?
MR. BRAHMA: Thank you, your Honor.

CROSS-EXAMINATION

BY MR. BRAHMA:
Q. Good afternoon, Dr. Dyar.



A. Good afternoon.
Q. Let me first ask you this: You have not published any papers or been involved as an inventor on any patents or as a presenter on pharmaceutical films; right?
A. I have not published or presented on pharmaceutical films, no.
Q. You mentioned earlier you did some work on pharmaceutical films; right?
A. That's correct.
Q. And it's true that that was a single research project that you did at Parke-Davis?
A. On a product to be developed as a pharmaceutical film at the final dosage form, yes, that was a single project at Parke-Davis. However, I've worked on film-related technology in the tablet coating, as I mentioned, and in the hot metal extrusion technology.
Q. All right. But you have never developed a cast, pharmaceutical cast film that actually contained a pharmaceutical active, a drug; is that right?
A. A pharmaceutical cast film as in



the final dosage form that contained an active, no.
Q. And this project that you were working on at Parke-Davis, that was a feasibility study they were doing to determine whether they should proceed with a pharmaceutical cast film dosage form; is that right?
A. No, sir, that's not what the discussions were about. And in particular film, there were discussions about seeing if we could make a pharmaceutical film. And I did some bench scale work as we discussed earlier in regards to that.
Q. And at the end of your work, they decided -- they never made a pharmaceutical product from that cast film work you did; is that right?
A. They never made a pharmaceutical product from the cast film work that I did, that is correct.
Q. And in addition to never making a cast film with an active drug in it, you've never done any experimental testing on any cast



film that contained an active drug ingredient; is that right?
A. I have not tested any films as a pharmaceutical final product that were cast films. I have tested a hot metal extrusion film technology that was used in the tablets, as we discussed.
Q. And this patent is not about hot metal extrusion films; right?
A. It's related technology.
Q. So for your entire 28-year career, you have never made or tested a single cast film with a pharmaceutical active in it; is that right?
A. Not in a cast film sense, but I have again in the hot metal extrusion, which is an alternate technology used to make films.
Q. And even for the purposes of your work on this case, you never tested any of the pharmaceutical film formulations that were discussed in the prior art you cite; is that right?
A. I have not tested the pharmaceutical films that were discussed in the

prior art.

Q. In fact, you've never done any independent analysis of whether any of the films mentioned in the prior art that you cite actually met the drug content uniformity limitations in the claims of the '514 patent; is that right?

A. Could you define independent analysis?

Q. You never tested any of those products to determine what their drug content uniformity was; is that right?

A. I never physically tested the products for content uniformity, no.

Q. And aside from Chen Figure 5, which we'll get to what your interpretation of that is now, you point to no data in any of the prior art that you looked at in which the prior art itself reports drug content uniformity testing data; is that right?

A. I did not point to any -- would you ask the question again? Sorry.

Q. Sure. Putting aside Chen for a moment because we're going to discuss that in



more detail, none of the prior art you looked at other than Chen reported any drug content uniformity data; is that right?

A. They did not report any content uniformity data. However, as I mentioned earlier, if you're developing a pharmaceutical product, you would necessarily be developing a uniform film.

Q. Well, you said it was a critical regulatory requirement to get within that ten percent uniform, drug content uniformity level; right?

A. I said it is are critical to get the content uniformity there for the product prior to you placing it on the market. That's correct.

Q. And if you could, you would get even tighter than that; is that right?

A. I did say if you could get tighter, you would be motivated to get tighter.

Q. And specifically, you said a person of ordinary skill would be motivated to get within five percent; right?

A. I said my targets were always five



percent, and you would want to get as low as you possibly could so that you would not have product recall. That's correct.

Q. And you didn't cite any document showing that a person of ordinary skill in the art would try to get within a five percent uniformity requirement; is that right? That's just your own standard?

A. That is my standard based upon, you know, 28, 30 years worth of experience and working with numerous pharmaceutical companies across the world to help them solve the problems.

Q. And none of them published the document that you cited that shows that a person of ordinary skill in the art would want to get within a five percent uniformity requirement; is that right?

A. I did not cite anything. However --

Q. Okay.

A. -- sometimes things are based upon an absolute need and other times they are based upon what is the best for the company. And so



they're internal metrics that are not always published.

Q. So you were saying earlier that anyone who was trying to develop a pharmaceutical cast film in this time period would have tried to meet the ten percent drug content uniformity level in order to meet regulatory requirements; is that right?

A. I don't think I said anyone. I think I said someone that was going to develop a product to put on the market. If they are doing bench research at a university, it's not common for them to necessarily be worried about content uniformity.

Q. Okay. So tests of films that were made for bench research at a university wouldn't necessarily have met the ten percent content uniformity requirement; is that right?

A. They would not necessarily have met it depending on if they tested it or not.

Q. But the products that were being prepared for commercial production, a company that was trying to make that product would have certainly tested drug content uniformity; is

that right?
A. Not necessarily. It depends on what stage of development they were in.
Q. Well, ultimately, they'd have to submit it to the FDA; is that right?
A. And at that stage you would be correct, they would test it at the appropriate stage when they are going to submit the package to the FDA.
Q. And the way to tell if your film meets that drug content uniformity requirement within ten percent or within five percent of the desired amount of drug, the way to do that is to do a test; is that right?
A. The way to test content uniformity is to do a test.
Q. Right.
A. That's correct.
Q. To do an experiment; right?
A. That's correct.
Q. All right. And none of the prior art you looked at included that test, putting aside Chen for a moment?
A. Did any of the prior art that I



looked at conduct a test for a film specifically, or in general?
Q. Well, you have looked at film prior art; right?
A. Right.
Q. That's what you've been looking at?
A. Yes.
Q. Putting aside Chen, none of the prior art relating to cast films provided any data on content uniformity; right?
A. No, and I wouldn't necessarily expect it to because, again, it's a primary responsibility of when you're developing a drug product, that you develop it with content uniformity. Otherwise, you will not have the requirements, and you would not a safe, efficacious drug.
Q. Okay. So for those other pieces of prior art, instead of looking for experimental data on drug content uniformity, you looked at general statements about homogeneity or uniformity of the matrix; is that right?



A. I saw statements that stated that the matrix was homogeneous or uniformly mixed.
Q. Okay.
A. Which, again, support the fact that they were intending to develop such a product and there would be no reason why they would not be targeting the FDA requirement, so it's understood that that would be the target.
Q. So you applied an assumption that if a prior art reference doesn't report drug content uniformity data, then the films it describes are likely to be uniform in drug content; is that right?
A. I did not apply that assumption necessarily. You are saying that if they did not report it, they were necessarily uniform?
Q. I said the assumption that you applied is that if a prior art reference doesn't report uniformity data, then the films it describes are likely to be uniform in drug content. That's the assumption you applied; is that right?



A. The assumption I applied was they were intending to make a uniform product. Whether they actually met it at that point in the development or not, I don't know if they did or not because there wasn't necessarily data there because, again, it's understood, that is your target.
Q. Okay. So then if I understand correctly, what you're saying now on the stand at trial is that the only reference you can rely on as potentially showing drug content uniformity within the ten percent or five percent limit in the claims of the '514 patent is the Chen reference, because that's the only one with data; is that right?
A. That's not what I'm saying. I'm saying there's not data, but there's the understanding that when you are developing a drug product, that it would have content uniformity. Otherwise, you wouldn't be applying for approval from the FDA to market the product.
Q. And you don't know that any of the prior art films ever led to a request for

approval from the FDA for any particular drug product; right?

A. I did not do an analysis in regard to any products that were, that currently are on the market or that have been on the market in regard to any of the film technology.

Q. Okay. And none of those, none of those films in Chen with those active ingredients, none of those are FDA approved drug product even today; is that right?

A. I don't know the answer to that question.

Q. You didn't even check that; is that right?

A. I do not know the answer to the question.

Q. Let's talk about the Chen reference, and I'm going to start, and that's JTX-0187. And I'm going to start with Figure 5.

A. I just want to make sure I have it here.

Q. You have it on the screen in front of you, Dr. Dyar?

A. Yes.



Q. Okay. And we've previously talked about this at your deposition, too; right, Dr. Dyar?

A. That's correct.

Q. All right. And when we talked about this at your deposition, you told me -- well, let me take a step back. You see that some of those data points there on the curves are above 100 percent; is that right?

A. That's correct.

Q. And you said in your report, the fact that some of the data points -- this is a quote. The fact that some of the data points are above 100 percent signifies a problem with the experiment itself.

Right?

A. I stated that it could signify a problem with the experiments and I stated a number of reasons why that would be the case.

Q. All right. And at that time you said you couldn't rely on the data in Chen to show anything about drug content uniformity; is that right?

A. I don't -- that is not correct. I



think your specific question, as I recall it at that time, was, can I tell precisely, and can I say that this would be an FDA guide and I said no, because I do not have the precise data that is behind this to be able to tell you, yes, it would.

Q. Okay. Well, so, and you remember me asking you this at your deposition; is that right?

A. I do.

Q. So let's look at the questions and the answers. And I'm going to go to page 178, line 16.

MR. LYNCH: Can we get the deposition in front of him.

THE COURT: Do you have a copy of your deposition, Doctor?

THE WITNESS: No, sir, I do not.

THE COURT: All right. Can you give him a copy?

MR. BRAHMA: May I approach, your Honor?

THE COURT: Yes.

(Mr. Brahma handed a deposition



transcript to the witness.)

BY MR. BRAHMA:

Q. Okay. So we're looking at page 178, line 16, to page 179, line 13.

A. Okay. So 178, line 16? Okay.

Q. Okay. And is the first question I asked you was: Looking at this data for the hydromorphone film, does that film meet the ten percent active content uniformity requirement in the '514 patent claims?

And your answer was -- can you read it for me?

A. Yes. Again, I can't tell you without seeing the data because it's all on top of each other, and again you were referring to meeting the FDA requirement.

Q. And that FDA requirement, that ten percent requirement, that's a limitation of the claims, the asserted claims of the '514 patent; is that right?

A. That is correct.

Q. Okay. And your testimony in that deposition was, you couldn't tell from the data in Figure 5 whether that limitation was met by

Chen; is that right?
A. That I could not tell precisely if the ten percent was met because the information, the data was on top of each other. However, looking at it, I would still -- I would say that it appears that they're on the right path and they could, with a little bit more experimentation, be able to develop a pharmaceutical film to be able to place on the market.
Q. Okay. Your statement, your position now on the stand is that Chen, if they had wanted to, could have done a little more experimentation and made a uniform film; is that right?
A. If they did not already have a uniform film, because, again, I don't have the precise data.
Q. But you had the data that's in the figure; right?
A. The data in the figure is very difficult to be able to get the actual numbers from the data to apply the question that you -- that I was being asked about active content



uniformity requirement of ten percent. I could not get that by just deconvoluting the data because it's all on top of each other.
Q. And --
A. I would have loved to have it.
Q. You would have loved to have it. You never asked for it though; right?
A. I -- I don't recall if I asked you for it.
Q. You didn't ask your own attorneys for it?
A. I've been working on this case for a year. I don't know if I -- I think I asked if we could get the data, but I don't recall specifically. I know there was some discussion around that.
Q. Okay. But you were never able to get that underlying data; right?
A. I never saw the underlying data, no.
Q. And so you can't calculate from what's shown on the figures how close or how far the Chen films were from meeting that ten percent or that five percent drug content



uniformity level; is that right?
A. I cannot calculate the actual specific number. However, as I said earlier, based upon examination of thousands of these dissolution profiles, I can tell you that they look reasonable and could be potentially developed into a pharmaceutical film.
Q. Okay. Let's look at the data in the figure itself. You said this was a dissolution test; is that right?
A. Yes. That's my understanding of -- yes.
Q. With four different -- four different films with four different active ingredients; is that right?
A. Four films, yes. Example 5 through 8, if I recall correctly.
Q. Okay. And you do this dissolution test by putting it in a dissolution bath and measuring the amount of drug released from the film over time; is that right?
A. That is correct.
Q. All right. And the 100 percent mark that's on this, this figure on the Y axis



where it says percent release --
A. Yes.
Q. -- that indicates 100 percent of the amount of drug that is desired to be in the film, the dosage; is that right?
A. That is correct.
Q. Okay. And if the curve gets to that 100 percent mark, that means that 100 percent of the desired amount of the drug has been released; is that right?
A. That when it plateaus out and reaches a hundred percent, that is where the release profile has reached that target, yes.
Q. Okay. Well, I wanted to disconnect those two ideas for a second. A point above 100 percent on this figure means that more than 100 percent, more than 100 percent of the desired amount of drug was released from the film; is that right?
A. You're talking specifically about -- do you want to point out a specific point?
Q. Sure. If you take the shaded-in

triangle at minute eight. It's on the nicotine?
A. Okay.
Q. Yes. Go ahead and circle that one.
So that point is above 100 percent release; is that right?
A. That point is above a hundred percent release at that time point.
Q. All right.
A. However, at ten, it appears to be at a hundred percent.
Q. More than 100 percent release of drug from the film means that more than 100 percent of the desired amount of drug was in the film in the first place; is that right?
A. Not necessarily. It could mean that. It could also mean that the potentially analytical error, or a number of other issues that could occur in these type studies.
Q. And you didn't point to anything about the way the Chen inventors did this experiment that suggested that they did the experiment wrong; is that right?
A. Did I look at their



experimentation component and see, analyze it to see if they did anything wrong?
Q. Correct.
A. Is that your question.
Q. Yes. You were talking about their analytical error. You didn't actually point to anything specific?
A. I didn't point to anything specific because I don't think the details were there in order to do that evaluation.
Q. And the dissolution test, that's something you learn in school; right?
A. That's correct.
Q. So pretty basic?
A. It's basic in some sense, but there's -- there can be error associated with it, and it commonly is a range of values because these systems are not absolutely precise.
Q. And you never tried to repeat these experiments; is that right?
A. I did not repeat these experiments, no.
Q. To get your own data about the uniformity of Chen?



A. No. I did not make the films or repeat the experimentation that he did.
Q. Okay. In Chen, you had the exact formulation for these films; is that right?
A. In Chen, I had the formulation for the films, yes.
Q. And Chen says, gives you information about how they were dried; right?
A. He gives information about, as I just talked earlier, about drying.
Q. And yet despite all of that information, you didn't think to make the films yourself, to test their uniformity; is that right?
A. I did not make the films to test their uniformity because I wasn't asked to. And this is not my current area of research.
Q. Okay?
THE COURT: Mr. Brahma, before you go on --
THE WITNESS: Yes.
THE COURT: -- Dr. Dyar, how is this example at minute eight, the thing that's coming out of the triangle looks like a nail



being put into it.
THE WITNESS: Okay.
THE COURT: What is that?
THE WITNESS: That's the error bar. That is the range of values for that particular data point.
THE COURT: So assuming that the scale is relatively accurate here, that would mean at minute eight, the nicotine seems like really one trial release, you know, like 118 percent or something?
THE WITNESS: That would be correct.
MR. BRAHMA: I was just about to go into that, your Honor.
THE COURT: Oh, sorry.
MR. BRAHMA: No problem.
THE COURT: I thought you were moving on to something else.
MR. BRAHMA: We are going to spend a little bit of time on this one.
BY MR. BRAHMA:
Q. So to dots on the curves, those indicate the mean values measured by Chen?

A. That's correct.
Q. For each of those time points for each of those films, they took multiple samples and measured how much drug had been released at is that time point?
A. That's correct.
Q. And the error bars show the standard deviation from the mean; is that right?
A. That's my understanding, yes.
Q. Okay. So in order to get the entire range of drug content measurements from the samples Chen took, you would take the mean plus or minus three standard deviations; is that right?
A. That's correct.
Q. Okay. So those error bars, you would have to triple them in order to see what the entire range of sample measurements was?
A. That would be true.
Q. Okay. And you never did that?
A. However, that's not the standard which is applied here. It's a ten percent variation. That's what we're talking about.
Q. Ten percent variation among all



the samples you take from a film; is that right?
A. Ten percent variation among the samples. What do you mean, all the samples?
Q. Well, the claim language talks about taking multiple samples of individual unit dosage, dosages of the film.
A. Can you point --
Q. And they can't vary by more than ten percent; right?
A. Can you point me back to that exact claim language, because I don't recall it being that.
Q. We can use your slide. DDX-3.004. If you look at that bottom where in limitation, it talks about the uniformity being, quote, measured by substantially equal size, equally sized individual unit doses which do not vary by more than ten percent of said desired amount of said at least one active.
Right?
A. Yes. That's talking about at the end point that I pointed out, where you have at the ten-minute, if you want to go back to the other, the figure Chen. It's not talking about



the variation across every single point is my understanding, although you can see that there is some tight data in the Estradiol, and in my opinion, a little bit of additional experimentation with getting there.
Q. Well, let's talk about Estradiol really quickly, because before you told me that the curve has to become constant to tell how much drug is released from the film; right?
A. I said the curve needs to become constant before you know when it has finished releasing all the drug. That is true.
Q. Okay. And the Estradiol curve, you can't tell whether it has reached the plateau where it becomes constant; is that right?
A. You cannot tell it, and again for the Court, this is the Estradiol (indicating). And you can see at eight, it's a little lower than at ten, but you can see that it's approaching 100 percent and it is somewhat plateauing out.
Q. So at some future time it's going to become constant, but for right now your Honor



every point on that curve for Estradiol is higher than the one before it; is that right?
A. For every point on the curve of Estradiol, the points are higher.
Q. Okay. So that's not study state; right?
A. That's correct. That's not steady state.
Q. Okay. The other three curves, you have an area where it might be steady state; right? A flat part?
A. Relatively flat. Yes.
Q. Okay. Is there -- and there's no reason -- I mean, you said before that you would only look at the time point at ten minutes; right?
A. Well, the time point at ten minutes is giving you an indication that your system is stable at that point because it's plateauing out, and you will have, tend to have less variability at that point in time if you have variability in your system.
Q. Okay. And if your system was steady state at eight minutes, then you could

use those values too; right?
A. If your steady state is eight minutes, you could use this value. Again, we are talking -- we don't have the actual data, so it is difficult to see what the precise numbers would be. But, again, the shape of these curves and the content uniformity that is being shown here are consistent with the product that could be developed and placed on the market.
Q. Okay. So if you saw, if you were able to see what those values were with the triple error bars, then you would be able to tell what the drug content uniformity was of these Chen films; is that right?
A. There's a potential to just show that what state he currently has. It doesn't mean he was absolutely able to get there. But again with minimal experimentation, should be able to get there.
Q. You said this dissolution test, everyone learns it in school in this field; is that right?
A. In pharmacy, people learn how to do dissolution tests, that's correct.



Q. All right. And Chen would have been doing this, according to you your Honor in order to determine the drug content in the films; right?
A. Chen would have been doing it to determine what the content uniformity are. He could have been looking at it in addition to looking at the release profiles I mentioned before.
Q. And if inventor Chen had data that suggested that these films weren't uniform within ten percent, your understanding is, or your assumption is that she would have gone back, tweaked her experiments a little bit, and gotten a better film; right?
A. That if she didn't have, she would have gone back and tweaked her results and gotten better results. Is that what you are saying?
Q. A more uniform fill. That's right.
A. Again, based upon, based upon my experience, patents need to get issued as soon as possible, and we would often put out the



experiments and data that may not be exactly what we wanted at that point in time that was able to be developed and placed on the market, and we would commonly do additional work in order to get it moving forward and additional experimentation.
Q. And you have no evidence that Chen created any subsequent films to this; is that right?
A. I have not looked to see if Chen developed any films or worked on films. I have not evaluated that.
Q. Okay.
A. No.
Q. Let's turn to a different part of Chen. Figure 2. And actually, let's turn to Dyar direct slide 19, so DDX-3. -- I'm sorry, 11.
Okay. And before you were saying that those highlighted red arrows, that's the airflow that hits the surface of the film as it goes through the oven; right?
A. Yes. We're talking about these three aeration controllers. That's the airflow,



that's diffusional airflow. That's more direct, and then direct airflow. That's correct.
Q. Okay. So as the film goes through the oven, your understanding of Chen is that the airflow changes and the viscosity of the film changes; is that right?
A. As we go through, the airflow is different initially because it has a lower viscosity, or the film, you know, film is not dried, and by the time it gets to the end, it's dry so the air can directly aim down on it. Yes.
Q. We can move off of Chen. Let me ask you quickly a couple questions, one about Listerine. You mentioned working at the sister company of Listerine, of the maker of Listerine; right?
A. Yes. I worked at Parke-Davis, which was the pharmaceutical division of Warner-Lambert, and there was a Warner-Lambert consumer healthcare, which is where Listerine was being made.
Q. Okay. You were working at Parke-Davis when the Listerine film strips were

being made and when you were doing your feasibility study on pharmaceuticals; is that right?

A. I was working at Parke-Davis at that time, yes.

Q. All right. And when you were looking around for film formulations to test for your feasibility study, you didn't use the Listerine film; correct?

A. I did not use the Listerine film strip technology, no.

Q. The Listerine films, they're not subject to any regulatory requirement for content uniformity; right?

A. They do not have an active, and so in the normal sense of content uniformity, they're not subject to that. However, the content needs to be uniform. Otherwise, they wouldn't have a product to be able to place on the market for consumers to use.

Q. But there's nothing --

A. And I don't know about the regulatory requirements, again, because I did not work in the consumer healthcare area, which



is a different regulatory environment.

Q. Right. And, in fact, you didn't do any work on Listerine film strips; right?

A. I did not do any physical work on Listerine film strips.

Q. No testing on Listerine film strips?

A. I did not do any physical testing on the Listerine film strips.

Q. And you weren't aware of any internal company requirements for content uniformity for Listerine film strips either; is that right?

A. No, because, again, I was not in the consumer healthcare area, and, again, I wouldn't know the requirements because it's not covered in my area of expertise.

Q. Okay. Let's switch to slide 26 of your presentation.

You said that this statement in Chen would motivate someone to not use particulates or particles with greater than 25-micron diameter in their films; is that right?



A. It says -- well, it says specifically that many quick dissolving products that you place in your mouth, if they have particulates greater than 25 microns would leave a gritty or unpleasant taste in the mouth, which means you would like to have a particulate less than that size.

Q. Less than 25 microns?

A. They could be a little larger, but he is saying -- he's not saying that you have to, but it leaves a less gritty taste in your mouth.

Q. And going to the following slide, the smallest particle size shown in Bess, which is what you say would be combined with Chen under that motivation, is 55 microns, double the size; is that right?

A. Is 55 microns and about a hundred -- yes, 55 is the number that is shown there, yes.

Q. Okay. And I'm going to move quickly to your indefiniteness argument.

You said that, you said that the claims of the '514 patent that you've been



looking at are indefinite because they require a dried cast film to still have a flowable matrix, a matrix that is still flowing; is that right?

A. That's correct.

Q. Okay. You weren't able to find any prior art films that met that requirement; is that right?

A. That met the requirement of --

Q. Of being dried -- of being a dried film that still has a flowing matrix?

A. Of being a dried film that would be afloat go matrix would be practically impossible, because it would be moving. You place it on the table, it's going to move.

Q. Right. And so specifically, none of the prior art that you looked at showed that type of film; is that right?

A. No. The prior art showed a film that would have flow or viscosity, because, again, it's practically impossible.

Q. All right. Last topic. I know you were in the courtroom this morning when Mr. Lombardi told the story about product hopping and he used slide DDX-1.006.

MR. BRAHMA: Can I get that pulled up?

BY MR. BRAHMA:

Q. Do you remember that discussion?

A. About this slide?

Q. Yes. And the discussion about the product hopping. I remembered it was acute term.

A. The product -- sorry?

Q. Product hopping.

A. Product topping?

Q. Hopping, hopping, like a bunny rabbit.

A. I don't actually recall that one.

Q. All right.

A. I must have missed that one.

Q. Well, let me ask you about this slide because it has one piece on there that might be relevant to you. On there, there's a flag for July 10th, 2007, for whether the '514 patent application was filed.

Do you see that?

A. Yes. Yes.

Q. Okay. And within the context of



Mr. Lombardi's story, this is part, the idea is that Reckitt Benckiser and MonoSol got together in 2006 and after that they started filing all these patent applications that supposedly gave them some incentive to hop from a tablet product to a film product.

Do you remember hearing that discussion?

A. I do recall that discussion.

Q. Okay. For your invalidity analysis though, you're not using July 10th, 2007 as the priority date; is that right?

A. I think I would have to look at my report again, because it has been awhile since I wrote the report, and I would be happy to look at that, because I think there were several dates mentioned there.

Q. All right. But your analysis in terms of what you are presenting at trial today uses a priority date of September 27, 2002; is that right?

A. I think that's correct, but, again, I couldn't confirm a hundred percent unless I looked at it. Would you like to...



(Pause.)

BY MR. BRAHMA:

Q. Okay. The September 27, 2002 date, that would be four years before Reckitt Benckiser and MonoSol even entered into an agreement; right?

A. You're asking me that question? I have no idea about that, about an agreement between the parties.

Q. I'm not asking about -- I'm just saying that that flag for the agreement about Reckitt showing 2006, if you were using a date of September of 2002 for your priority date, that would be four years before that even happened; is that right?

A. If I were -- but, again, I don't recall all the dates that I was using, because if I recall correctly, I think it didn't matter if it was 2007, but I cannot recall a hundred percent.

Q. All right. Let's pull up admitted fact 121. Okay. I'm going to put it on the Elmo.

Can you see that, Dr. Dyar?



A. Can you make it a little bigger?

Q. Let's see if we can. It's the one at the top there, number 121.

A. Yes. The asserted claims of the '514 patent are entitled -- can you give plea the paragraph before that?

Q. It relates to a different patent. Would that help you?

A. Okay. I just want to make sure the context I'm seeing everything.

Q. Okay.

A. Are entitled to a priority date of September 27, 2002. However, I think there was some additional analysis within my report about priority date.

Q. Okay. But for purposes of this litigation, the parties have agreed that all of the claims were, all of the claims that we're talking about here from the '514 patent were already supported and described in applications that had been filed as of September 27, 2002.

You understand that; right?

A. I understand that, yes.

Q. So this product hopping theory has

nothing to do with the '514 pat end and your invalidity analysis; right?

A. I'd may have no opinion with regard to the topic, product hopping, product topping idea.

MR. BRAHMA: I think that answers my question. Thank you, Dr. Dyar.

THE COURT: Any redirect?

MR. LYNCH: No, your Honor. No questions, your Honor.

THE COURT: Thank you, your Honor Dr. Dyar. You may step down.

THE WITNESS: Okay.

THE COURT: All right. Okay. Well, so that will be it for today, so we can stop the clock.

How are we doing in terms of your expectations of the schedule? Are we moving along about as you expected?

MR. LYNCH: Your Honor, from defendants' perspective, your Honor, I think we're kind of right where we thought we would be both in terms of the number of hours we got in today and the witnesses we covered. I think we



are in good shape.

THE COURT: Okay. Plaintiff, you're good?

MR. LADOW: I think so, your Honor.

THE COURT: All right. Is there anything else you want to talk about before we go our various ways?

MR. LADOW: No, your Honor.

MR. LYNCH: No, your Honor. Thank you.

THE COURT: All right. Well, I guess we will be in recess then and I will see you tomorrow morning, and so have a good evening.

(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 PHARMACEUTICALS INC., RB PHARMACEUTICALS LIMITED, and MONSOL RX, LLC, | : | CIVIL ACTION |
| 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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PROCEEDINGS

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

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

Are I guess we're ready to continue with the defendants' case.

MS. MELVIN: Yes, your Honor. Good morning, your Honor. May it please the Court, Emily Melvin from Latham & Watkins on behalf of defendants.

Your Honor, our next witness, we'd call Dr. Charles O'Brien. Dr. O'Brien is testifying regarding secondary considerations. The parties have agreed that he can be taken out of order.

THE COURT: Okay.

MS. MELVIN: And, your Honor, may we approach with some binders?

THE COURT: Sure.

(Binders handed to the Court.)

... CHARLES PHILLIP O'BRIEN,
having been duly sworn as a witness, was examined and testified as follows...

MS. MELVIN: And, your Honor, a copy of the slides are in the front pocket of the binders.

THE COURT: Okay.

DIRECT EXAMINATION

BY MS. MELVIN:

Q. Good morning, Dr. O'Brien. Can you please introduce yourself to the Court?

A. Yes. I'm Charles Phillip O'Brien, a professor of psychiatry at the University of Pennsylvania.

Q. And do you have any particular specialty within the field of psychiatry?

A. Well, I have spent most of my career doing research on phenomenon of addiction as well as setting up treatment programs and taking care of patients, and also doing a lot of teaching.

Q. And have you had some slides prepared to aid in your testimony today?

A. Yes, I have.



Q. And, Dr. O'Brien, I'd like you to turn to the tab numbered JTX-17, which is in your binder.

A. Yes.

Q. And what is this document?

A. This is my curriculum vitae.

Q. And does this accurately summarize your education and professional experience?

A. Yes, it does.

Q. And turning to your clinical practice, Doctor, how long have you been treating opioid addiction?

A. Well, I first became involved with this problem in a pretty big way during the Vietnam war. I was a Navy neuropsychiatrist at the U.S. Navy and it turned out that quite a few of, maybe even half of my patients were using heroin and many of them were addicted to it, and even though I hadn't learned much about addiction in my training when I had two residencies, I had to learn fast, and all of us were learning because it was such a common problem. And that was '69 to '71. And so since then, treating addiction has been the major



diagnosis of my practice.

Q. And, Dr. O'Brien, I see on this slide you've mentioned the center for the studies of addiction. What is that?

A. That is a program that I originally set up in 1971 at the Philadelphia Veterans Hospital to not only treat veterans with addictive disorders, but also to study them, because at that time there was very little research data on addiction, and so I saw this as something that was needed to be done, and they were just starting out at the institute at the NIH on addiction. And so I got funding. I got research grants.

So the Centers For Study of Addiction is a large -- it became over time a large research program for studying all kinds of addiction.

Q. And, Dr. O'Brien, what is the Charles O'Brien Center For Addiction Treatment?

A. That is a private practice program which was set up because the University was getting a lot of referrals that were coming for



treatment, but not necessarily to be in a research project. And all of those in the center for studies of addiction were essentially volunteers to be in clinical trials whereas some people just came because they wanted treatment, and the university decided to set up a program for them which was not at the V.A., separate from the V.A., and they decided to name it after me.

MS. MELVIN: Your Honor, defendants offer Dr. O'Brien as an expert in the research and treatment of addiction disorders, including treatment of opioid dependency.

THE COURT: All right. You may proceed.

BY MS. MELVIN:

Q. Dr. O'Brien, have you ever been called upon to give your opinion regarding opioid addiction in this country?

A. Yes, I have.

Q. And can you explain?

A. Well, it started really during the 1970s. This is where the war on drugs really began, and throughout the seventies and eighties

and nineties, I was frequently called to Washington to testify. The time that I remember that was most relevant to the matter here is during the approval process for Suboxone, because my group had done some of the original research on Suboxone, and there was a lot of opposition though because Suboxone is like methadone in many ways. And there were people who opposed this, just another addicting drug. And they also didn't like the fact that the law as was signed by President Clinton in 2000 had more liberal regulations regarding the prescription of Suboxone.

So I testified before the Senate Judiciary Committee at the request of Dr. -- of Senator Charles Grassley and Senator Joseph Biden about, in favor of Suboxone, and ultimately, it was approved, as I requested.

Q. And Dr. O'Brien, when you refer to Suboxone, you're referring to the tablet; is that correct?

A. Yes, I am.

Q. And have you served on any committees relating to opioid addiction



treatment?

A. Well, I have been on a lot of committees at the National Academy of Science and the National Institutes of Health. And we've been asked to consider how the government should respond to the addiction problem, and so I have actually been on committees, just about every drug you can imagine, and also I was the Chair of the Committee of the American Psychiatric Association that defined addiction.

Q. And, Dr. O'Brien, do any of the committees relate to Suboxone?

A. Well, all of those dealing with opioid addiction do relate to Suboxone.

Q. And did any specifically deal with the Suboxone tablet or safety concerns regarding Suboxone tablets?

A. Well, I mentioned that there was opposition to approving Suboxone back in the year 2000, and the way that they managed to compromise and get it approved was that they had to agree -- they, meaning the FDA and DEA, to set up a committee of experts to review the use of Suboxone, how it was actually being used, how



doctors were prescribing it, and what were the good effects and bad effects. And I was asked to be a member of that committee.

Q. And as part of your role in that committee, did you have any discussions regarding the safety of Suboxone tablets?

A. Yes, I did. That was a major subject of discussion on my committee.

Q. And what types of safety concerns were raised?

A. Well, I would say the primary one was that Suboxone being an addicting drug might just be one more drug that kids could use to get addicted to, and that would be a bad thing, and especially because we were more, allowing more liberal prescribing of it. So that was one thing that we were concerned and we tried to monitor that, and there were newspaper articles about how bad Suboxone was, and we studied that and we actually sent people out to those communities to interview some of the doctors there and see if we could figure out what they were doing wrong.

Q. And, Doctor, when you -- again,



when you were referring to Suboxone, you're referring to the tablets, to those specific discussions?

A. Yes.

Q. How, if at all, did the safety concerns that you discussed as part of that committee apply to Suboxone film?

A. Well, it wasn't available yet. However, we know since the last couple of years since the film has been available, that it's abused just like the tablet was.

Q. And, Doctor, do you recall any discussions on the part of that committee regarding the actual dosage forms of Suboxone tablets?

A. No. The discussions were about the doctors who were prescribing it, where the families were keeping the medication because we were also concerned about children getting access to it. But if there ever was a discussion about film versus tablet, I don't remember it. I don't think there was -- we weren't really experts. We weren't pharmacy experts. We were just clinicians, and we were

concerned that the doctors were not being careful enough by giving, say a 30-day supply to someone right after you met them.

Q. And, Doctor, you mentioned children. Were you here for Dr. Wollschlaeger's testimony here today there there's less pediatric exposure for the film than the tablet?

A. Yes.

Q. And in your opinion, does the change in dosage form from a tablet to a film reduce pediatric exposure?

A. No. I don't think that it did. I don't think the evidence says that it did.

Q. And why is that?

A. Well, because it's just as easy to -- for a child, maybe in some cases easier because they get it into their bodies more quickly. So whether it's a film or a tablet, it's liable to be taken in an overdose and poison, as a poison for a child. So I don't think that that is the solution to the child overdose problem.

Q. And, Dr. O'Brien, are you familiar with a study that compared accidental pediatric



exposure from films versus tablets?

A. Yes, I am.

Q. And on this slide I see here you have an exert from JTW-246 at page 5. What is the document that's excerpted here?

A. Well, this is a study, an observational study, that is looking at the outcomes of unintentional exposure to buprenorphine by young children, and so they did couch the exposures and the results of the exposure.

And as you can see from the excerpt there, it was a study of the gross exposures and results, but it didn't differentiate whether the exposure was due to the formulation, meaning film or tablet, or the packaging, which I think is the major factor, or other factors, which is also where it was stored, because it turns out that one of the common root causes was having the adult and family care less about where they put it, so it was easily obtainable by a child. So there were a lot of factors, but the study did not determine that film versus tablet was an



issue.

Q. And, Dr. O'Brien, has the FDA considered the data in this study?

A. Yes, they did, because they were responding to a citizen petition.

Q. And just to stop you right there, on the next slide I see you have an excerpt from page 46 of JTX-163.

What is this document?

A. Well, this is the FDA's response, and they essentially denied the petition, which would have been to only, to stop allowing sales of the Suboxone tablet.

Q. Dr. O'Brien, I believe you said this was the response to the petition. Is this the response to the petition or the petition itself?

A. No. That's the petition.

Q. Okay. Turning to the next slide, we have an excerpt from page 15 of JTX-196. What is this document?

A. I think that is now the response to the, of the FDA, and they essentially state as it shows in the highlighted area there that



withdrawal of the Suboxone tablets is not necessary for reasons of safety. And then a couple lines down they say, the data suggests an encouraging downward trend in accidental pediatric exposure that could be attributed to a variety of factors, as discussed above, which means formulation itself as well as the packaging.

Q. And what were those other factors?

A. Well, the other factors are, first of all, the education of the patient and the patient's family, and the packaging, which I think is probably the pivotal factor in terms of making it hard for a child to able to get access to it when it's left where a child can get it.

Q. And, Dr. O'Brien, in your opinion, does the change from the film dosage form, or, excuse me, from the tablet dosage form to the film dosage form decrease with pediatric exposure?

A. You know, in gross, you know, accounting, it did, but that was only because they didn't just change. They did multiple

things at the same time. And if you are doing research to try to discover the root cause of something, you can't change multiple things. If you change multiple things, then you don't know which of the changes produce the result.

Q. And, Dr. O'Brien, in your opinion, does the film dosage form itself present any benefits over the tablet dosage form with respect to pediatric safety?

A. Well, with respect to pediatric safety, probably, it could have the opposite effect, because it's absorbed a little faster and might mean that a child gets it into their body more quickly.

So, you know, that's, that's a theoretical -- I don't know any evidence to support that, but if you are trying to, you know, measure the effects of film versus tablet, you have to call into play the consideration that there is evidence that the film gets into the bloodstream a little bit faster.

Q. And, Dr. O'Brien, did you hear Dr. Wollschlaeger testify about the abuse potential of the tablet?



A. Yes.

Q. And in your opinion, how does the abuse potential of the tablet compare to the abuse potential of the film?

A. Well, as far as we know, it's approximately the same. You know, it's the packaging that may make the current practice of selling the film better, but it's not the film itself. It's more the packaging.

Q. And, Dr. O'Brien, I believe there was some testimony yesterday about the potential to swallow the tablet. Doctor, in your experience, is that a significant problem with the tablet?

A. Well, it's a problem if you don't tell the patient about it. Patients understand, and especially if you tell them specifically that if they swallow it, it's not going to be absorbed into their bloodstream. You have to hold it under your tongue.

The tongue is a very special place where you have very thin veins, and it can get across very quickly, and that makes it almost like taking it intravenously with a needle. So



when I explain that to patients, they listen to me and they hardly ever swallow it.

Q. And from a clinical standpoint, Dr. O'Brien, do you believe that any other aspect of the film is a significant improvement over the tablet?

A. Well, you know, I think that you could say that there is an advantage by having it absorb quickly, because sometimes you have a long line at the window, but that's not a really major issue. You know, it's only about 60 seconds faster.

Q. And does that affect the safety or efficacy of the drug?

A. No.

Q. And prior to the introduction of the film, Dr. O'Brien, was your clinic able to adequately treat patients with the tablet?

A. Yes, we certainly were and actually still are in other countries.

Q. Dr. O'Brien, in sum, what is your opinion regarding whether there was a need for buprenorphine, the maximum dosage form prior to the introduction of the film?



A. Well, to be honest with you, we didn't really think of it -- I don't remember any discussion of that. You know, if we had had somebody on the committee who said, hey, you know, we could change it from a tablet to a film and make it safer, we might have said, gee, let's try it and see what happens. But I don't recall anyone suggesting that, so we didn't really have an adequate discussion of that possibility.

Q. And, Dr. O'Brien, in your view prior to the introduction of the film, was the Suboxone tablet sufficient for treating opioid addiction?

A. Yes. It was working very well.

MS. MELVIN: No further questions, your Honor.

THE COURT: All right. Any cross-examination.

BY MS. BOURKE:

Q. Good morning, Doctor.

A. Good morning.

Q. My name is Mary Bourke. We have not met before. I'm a big fan of Penn Medicine,

so fortunately I have not had to go to the O'Brien addiction center.

A couple of questions. I understand you're a teacher, a researcher, and a director of the O'Brien Center; is that correct?

A. Yes.

Q. Okay.

A. Actually, the -- I'm a director at -- you know, I might as well, you know, make it very clear.

In the beginning, I was strictly hands-on, and over years, I've become more and more distant. But I'm still the senior clinician, and I make the recommendations to how patients are going to be treated.

For the research center, I am now what's called the founding director because I founded about 45 years ago, and we have someone else in the last couple of years who has taken on the day-to-day management of the center.

Q. Thank you for that, Doctor. I appreciate that.

As I understand it now, you are managing and supervising a staff of prescriber



physicians, like I think in your deposition, you mentioned the Kyle and Emarja (phonetic); is that right?

A. That's right.

Q. Okay. Thank you.

And I understand that when, during your time when you were actually doing the hands-on treatment of patients, you were primarily prescribing the Suboxone tablet; is that correct?

A. That's correct.

Q. And then in 2010, patients started, at the O'Brien Center started getting prescriptions for the Suboxone film; isn't that right?

A. That's correct.

Q. And then as of today, the predominant, predominant opiate use disorder treatment is the Suboxone film; isn't that right?

A. Well, actually, may I tell you, you know, the various things, because --

Q. Well, your counsel can ask you a question. I think you were asked a question in



your deposition.

A. Yes.

Q. And is that -- is it true that today is the dominant treatment for --

A. If you compare the agonist treatment, we also have people being treated with an antagonist, and we also have them being treated with other things like Benovale and Subsol and things like that, so I can't tell you what it is today. But I guess it was during the deposition, I would say that probably we have more people on the film than on the tablet.

Q. All right. Thank you, Doctor.

And I believe that, you know, you put in the report where you were talking about some of the disadvantages of the film versus the tablets; is that correct?

A. Yes.

Q. But you think that they are basically minor differences; isn't that right?

A. Yes, I do.

Q. Okay. Thank you.

And there are advantages to the film over the tablet; is that correct?



A. Yes.

Q. Okay. And you reviewed Dr. Wollschlaeger's report and you generally agreed with that; is that correct?

A. Yes. I mean, it's a subjective difference, and he comes down to the side that the film is better, and I'm not so sure.

Q. But when you read it, and you generally agreed with it?

A. Yes, I do generally agree with his report.

MS. BOURKE: Okay. Thank your Honor doctor. No further questions.

MS. MELVIN: No questions, your Honor.

THE COURT: All right. Doctor, you may step down. Thank you very much.

THE WITNESS: Thank you.

(Witness excused.)

THE COURT: All right. Who is next?

MR. DALKE: Defendants would call Dr. Amiji, your Honor.

THE COURT: All right.

MR. DALKE: We're shifting gears again your Honor. Dr. Amiji is a witness on behalf of the defendants. He's going to testify about the invalidity of the '150 patent.

THE COURT: Okay.

... MANSOOR AMIJI, having been duly sworn as a witness, was examined and testified as follows ...

MR. DALKE: May I approach, your Honor with some binders?

THE COURT: Sure.

(Binders handed to the Court.)

MR. DALKE: May it please the Court, your Honor, I'm David Dalke, Winston & Strawn.

THE COURT: All right. Good morning.

MR. DALKE: Representing defendants.

DIRECT EXAMINATION

BY MR. DALKE:

Q. Good morning, Dr. Amiji.

A. Good morning. Good morning, your Honor.



THE COURT: Good morning.

BY MR. DALKE:

Q. Would you state your name for the record, please?

A. Mansoor Amiji.

Q. What is your current occupation, Doctor?

A. I'm a distinguished professor and chair of the department of pharmaceutical sciences at the School of Pharmacy at Northeastern University in Boston.

Q. Would you tell the Court generally what experience you have in formulating drugs for systemic delivery?

A. I have over 20 years of experience working in pharmaceutical formulations, primarily in polymeric drug delivery.

Q. Did you submit a copy of your CV in connection with the pretrial order that was filed with the Court?

A. Yes, I did.

MR. DALKE: For the record, your Honor, that's JTX-14.

BY MR. DALKE:



Q. What do you intend to testify about today, Doctor?

A. I intend to testify on the state of the art of the '150 patent, and specifically on the invalidity of the claims of the '150 patent.

MR. DALKE: Your Honor, at this point defendants would offer Dr. Amiji as an expert in the field of drug delivery and formulation.

THE COURT: All right. You may proceed.

BY MR. DALKE:

Q. Have you prepared a slide presentation, Dr. Amiji, to assist the Court in understanding your testimony?

A. Yes, I have.

Q. Would you give the Court an overview of your testimony?

A. Yes. I am I will be opining on the fact that the claims of the '150 patent are invalid based on indefiniteness.

Q. And would you a briefly just explain what your opinion is with respect to the



indefiniteness?

A. So the claims require the term molecular weight. A skilled artisan would rely on the manufacturers to provide the molecular weight description. If a skilled artisan is not able to rely on the information provided by the manufacturers, then the claim is indefinite.

Q. Do you have a second opinion?

A. Yes. My second opinion is that that claims of the '150 patent are obvious based on the 2008 priority date.

Q. What issues are important to your obviousness analysis?

A. So the priority date is important because it is a disputed -- the plaintiffs assert the 2003 priority date where as the defendants assert the 2008 priority date.

Q. So let's turn to the '150 patent. Do you recognize this document?

A. Yes.

Q. JTX-1, Doctor?

A. Yes.

Q. Is it the patent that you analyzed?

A. Yes.
Q. When did the '150 patent issue?
A. Well, it issued on September 13th, 2011.
Q. When was if application that led to the '150 patent filed?
A. It was filed on April 22nd, 2008.
Q. And which of the claims are asserted against the defendants?
A. Four claims. Claim 1 and claim 10 are the independent claims, and claim 4 and 13 are the dependent claims.
Q. Just generally, what are the claims directed to?
A. They're directed to a mucosal water-soluble film having a combination of polyethylene oxide and hydrophilic cellulosic in specific proportion.
Q. You mentioned polymer combinations. Why are polymer combinations important?
A. They import specific properties to the film.
Q. Are there specific properties



you're referring to?
A. Yes. Tensile strength, which is a measure of the mechanical integrity and flexibility of the film. It allows the film to be handled by the patient. Mucoadhesion, which is the ability of the film to stick in the mouth. And then water absorption from saliva, dissolution of the film and the release of the film.
Q. Let's move directly to your indefiniteness opinion. What standard did you apply in analyzing indefiniteness, Doctor?
A. So counsel informed me that a claim is considered indefinite if a skilled artisan is not able to understand the boundaries of the claim with reasonable certainty.
Q. For purposes of the subject matter of the '150 patent, what did you consider to be the level of ordinary skill in the art?
A. A person who has a Bachelor's degree in pharmaceutical sciences, chemistry or related field with two to five years of experience in developing drug formulations. Alternatively, it could be a person with either



a Master's or a Ph.D. degree and with less practical experience.
Q. As one of ordinary skill in the art, when you see the term molecular weight in the context of polymers, what does it mean?
A. In the context of polymer, molecular weight always means average molecular weight.
Q. And why is that?
A. Since polymers are synthesized so that you have variability in chain length in a given sample, and each of those chains will have a particular molecular weight, any given sample of a polymer will have average molecular weight.
Q. Do you understand that the Court has construed the term molecular weight?
A. Yes, I do.
Q. And what was the Court's construction?
A. The Court also construed the term molecular weight to mean average molecular weight.
Q. Did you apply the Court's construction in considering your opinions?



A. Yes, I did.
Q. How would one of ordinary skill formulating a drug dosage form know the average molecular weight of commercially available polymer?
A. They look to the manufacturers to provide that information.
Q. And so aside from the way that a manufacturer expresses polymer molecular weight, are there other ways to express average molecular weight?
A. Yes. As we heard from Dr. Yau's testimony yesterday, there are other ways to express molecular weight, such as using the chromatography to determine molecular weight, weight average, molecular weight average or viscosity average molecular weight.
Q. In your experience, do these various ways of expressing polymer molecular weight yield different values?
A. Yes, they do.
Q. Are each of these methods of expressing molecular weight known to those of skill in the art?

A. Yes, they are.
Q. I see on the right-hand side of the slide you've got a graphic. Would you explain to the Court just briefly what that refers to?
A. Yes. That's the column for the gel permeation. Basically, the polymer sample is put on the top and allows for the polymers to separate.
Q. Have you ever conducted the GPC, or the gel permeation chromatography analysis that Dr. Yau testified about yesterday?
A. Yes, I have, in the context of when I synthesized new polymers or looking at the biodegradation properties of polymers, where I need molecular weight information.
Q. Have you ever conducted a GPC analysis when you were formulating a film?
A. No, I did not.
Q. And why not?
A. I rely on the manufacturers to provide me that information.
Q. And does the patent specifically identify the manufacturer or the PEOs that were



used in the disclosed films?
A. Yes. Dow Chemical.
Q. How does Dow express the molecular weight of its PEO products?
A. They use a viscosity measurement or rheological measurement to express molecular weight.
Q. Do you recognize a document is that on the screen, Doctor?
A. Yes. This is the Dow brochure.
Q. And for the record, the Dow brochure is JTX-30.
And at the top on the right-hand column it says, approximate molecular weight.
Can you explain to the Court what that means?
A. Yes. This is the molecular weight that Dow reports for its different Polyox rate water-soluble polymers, and it's based on the viscosity of the polymer in solution.
Q. How does approximate weight relate, if at all, to average molecular weight?
A. So, again, it's because polymers are known to have this variable chain length in



any given sample, this approximate molecular weight would also be an average molecular weight.
Q. So you mentioned before viscosity and the document refers to rheological measurements. Would you explain what rheological measurements are?
A. Yes. Rheological measurement is the measure of viscosity of the polymer in solution. It's the measure of how thick that solution is.
Q. You mentioned that Dr. Yau calculated viscosity average molecular weight. How did Dr. Yau's calculations relate to the average molecular weight that do you reports?
A. They're different. The method that Dr. Yau used was an equation to calculate the intrinsic viscosity average molecular weight using gel permeation chromatography whereas the Dow method measures viscosity of solution and then calculates the approximate molecular weight based on that.
Q. What does the Dow brochure say about the various ways to calculate average



molecular weight?
A. In the footnote of this brochure, it explicitly states that the approximate molecular weight that Yau calculates is not comparable to the gel permeation chromatography.
Q. To be clear, did Dr. Yau use any rheological measurements in any of his calculations?
A. No, he did not.
Q. What does Dow report to be the average molecular weight of Polyox 1080?
A. 200,000 daltons.
Q. And as part of his analysis, did Dr. Yau determine the average molecular weight of the whole Polyox N80 distribution? In other words, before he did any partitioning?
A. Yes, he did.
Q. Did you prepare a summary of Dr. Yau's reported data?
A. Yes, I did. In the next slide I showed the various values that Dr. Yau calculated for the un-partition, or the whole N80 sample when he did gel permeation

chromatography. He had provided the Excel spreadsheet as Exhibit B to his report. I then populated the values in the various cells of this table.

Q. And when you are referring to Exhibit B, that's, for the record, that's JTX-143 that we spoke about yesterday.

What are you describing at table -- I'm sorry. What are you describing at the table shown on this slide?

A. So on the leftmost column are the different molecular weights that Dr. Yau calculated. The weight average, viscosity average, number average. The top row refers to the nine runs that he carried out.

He took one particular sample of Polyox and then he basically had three different categories of those and then ran three different runs for each, so total number of runs that he carried out were nine, and those are designated as N80A1 up through N80AC3.

Q. What do you mean by nine different runs?

A. So he took the Polyox N80 sample



and then had divided it into the three, and then from each of those samples he carried out three runs. So he got a total of nine runs.

Q. So according to Dr. Yau, what's the average molecular weight of the whole Polyox N801 distribution?

A. It varies depending on which type of average molecular weight he has described.

Q. And what conclusions did you draw from Dr. Yau's calculations?

A. So several. One is that he is able to get the viscosity average, the intrinsic average viscosity weight. He calculates the values that he is getting are 105 to 107,000 daltons, which is very different from the value that Dow reports of 200,000 daltons.

And then specifically focusing on the A2 sample, the N80A2 sample, looking at the molecular weight, whether you look at weight average, viscosity average, number average, or Z average, there's a specific difference in the magnitude of these values depending on which type of molecular weight Dr. Yau determined.



For example, if you compare the number average molecular weight to the Z average, there's an eightfold different in the magnitude of the values.

Q. So you focused on this N80A2 example. Is there any reason, any particular reason for that?

A. No. Just one particular example from the table. All the other data that Dr. Yau had provided also has the same variables to values.

Q. What average molecular weight values did Dr. Yau obtain for N80A2?

A. So he in this case, you can see that Dr. Yau calculated viscosity average to be 105,225, the number average to be 40,550 daltons, the weight average to be 132,294 daltons, and the Z average to be 332,372 daltons.

Q. Do any of the values that Dr. Yau reported for the whole distribution correspond to the values that Dow reports for Polyox N801?

A. No. Dow reports the molecular weight of the Polyox N801 to be 200,000 daltons.



Q. What conclusion did you reach after reviewing Dr. Yau's analysis of the whole Polyox N80 sample?

A. So looking back at the claim of the '150 patent, which requires the low molecular weight be in the range of 100,000 to 300,000, and the high molecular weight be in the range of 600,000 to 900,000, the values that Dr. Yau reports, some of them do not fall within the claim limitations even for the low molecular weight range. Some of them do, and then some of them even exceed the low molecular weight PEO range that is required in the claims of the '150 patent. And then none of these values are actually in the high molecular weight range that's required in the claims.

Q. Based on Dr. Yau's analysis, how would one of ordinary skill know if they were using a PEO product that fell within the scope of the claims?

A. They wouldn't be able to know because, again, the values are, some of them are within the low molecular weight range. Some of them do not even fall within that claim range.

And then some exceed that claim range, and none of these values are in the high molecular weight claim range of the '150 patent.

Q. Do the average molecular weight values that Dr. Yau calculated reflect any differences in the properties of Polyox N80 tight?

A. No. This is still Polyox N80 sample. It's just a method that he has used to calculate these different average molecular waits that use different values.

Q. How does the '150 patent describe which method a skilled artisan should use to determine the average molecular weight of a PEO product?

A. There is no disclosure in the '150 patent as to the method by which to measure the molecular weight.

Q. Does the '150 patent instruct a skilled artisan to conduct GPC analysis?

A. No. There is no mention of GPC in the '150 patent.

Q. What is your conclusion about the term molecular weight as it's used in the



asserted claims?

A. So if a skilled artisan cannot rely on the molecular weight information provided by the manufacture, then the different molecular weight measurements provide different values, so an artisan would not know specifically the boundaries of the claim and in this case the claim is indefinite.

Q. Let's move to your obviousness analysis.

THE COURT: Actually, before you do that --

MR. DALKE: Sure.

THE COURT: So I asked Dr. Yau yesterday, I think. 105,000 that he got for the viscosity average as opposed to Dow's 400,000, I asked him what the explanation is of that. I think his answer was he didn't have one. Do you have one?

THE WITNESS: Yes, your Honor. So the method that Dow measured the molecular weight is based on dissolving the polymer at five percent concentration and then measuring the viscosity, how thick that solution is, and



the report on viscosity. And they basically go and say, basically, if you get that viscosity, your polymer is a molecular weight 200,000.

Dr. Yau separated various chains and he applied a mathematical collusion to determine the average viscosity molecular weight. Yes, his values are different than what Dow reports, and they're expected to be different.

THE COURT: And is one of those or both of those methods, do you have an opinion as to whether they're both equally acceptable ways applied differently to determine the viscosity average molecular weight?

THE WITNESS: Well, for pharmaceutical formulation, you rely on the manufacturers, because, you know, it's very much akin to preparing a dish. You test the final product. You rely on the manufacturers to provide you with ingredients of specific quality, and then you test the final product to make sure that it meets the strict test quality control standards. So for a skilled artisan, they rely on what Dow provides as the molecular



weight.

THE COURT: All right. Go ahead.

MR. DALKE: Thank you.

BY MR. DALKE:

Q. Let's move to your obvious opinion, Dr. Amiji.

A. Sure.

Q. Do you understand that there's a dispute over the priority date of the '150 patent?

A. Yes.

Q. And what is the dispute?

A. So the plaintiffs claim that the patent is -- has the priority date of 2003, where the defendants assert the 2008 priority date.

Q. Why does a priority date make a difference in your obviousness analysis?

A. So if the correct priority date of 2008 is applied, then there's a reference, the Yang reference, that renders all the claims obvious.

Q. What standard did you apply in conducting your analysis?

A. So I was informed that a patent is entitled to an earlier priority date if the earlier application satisfies three requirements: The written description requirement, the enablement requirement, and the indefiniteness requirement, and then I specifically focus on the written description requirement. I was informed that that requirement is satisfied if the inventors were in possession of the actual invention, not just the obvious variants.

Q. And how did you conduct your analysis?

A. So I looked at, back at all the different applications that are in the priority chain for the '150 patent and specifically looked at the claim limitations of the '150 patent in order to see if all the claim limitations are present in those prior art exclusions.

Q. You mentioned three important limitations that you focused on. Can you explain to the Court what those were, please?

A. Yes. First, I focus on the term



polymer component, which is identified in the slide as, in the claims as polyethylene oxide and hydrophilic cellulosic polymer, or HCP.

Second, I focus on the polyethylene oxide having low molecular weight, which is a 100,000 to 300,000 and the high molecular weight of 600,000 to 900,000.

And then the third component, which is that about 60 percent or more of the polymer component has to be below molecular weight PEO.

Q. Did the Court construe any limitations in the asserted claims?

A. Yes.

Q. Did you apply the Court's construction in conducting your analysis?

A. Yes, I did.

Q. How did the Court's construction inform your analysis?

A. So the Court construed that the 60 percent limitation that is in the claims of the '150 patent refers to the composition that has the lower molecular weight PEO in the final component in addition to the two PEOs, meaning



the low and the high, as well as hydrophilic cellulosic polymer.

MR. LADOW: Your Honor, I just want to note that the issue of whether hydrophilic cellulosic polymer was necessary or required by the claims was not actually litigated during the Markman. It may come up in other matters, but it wasn't before the Court at the time.

THE COURT: All right. You may proceed.

MR. DALKE: Thank you.

BY MR. DALKE:

Q. How did you conduct your analysis of priority date, Doctor?

A. So I looked at various disclosures, and since the disputed dates are 2003, May 28, 2003, and April 22nd, 2010, I focused on the 902 application as well as the 389 application, and then started to look at the two applications to see where for the first time all the three limitations of claim 1 of the '150 patent are present.

Q. So just for the record, when you



are referring to the 902 application, you're referring to U.S. Application No. 60/473902?

A. Yes.

Q. And that's JTX-249. I believe you may have said April 2nd, 2010 in response to the later, the priority date. Were you referring to 2010 or did you mean 2008?

A. Oh, I'm sorry. It's April 28, 2003 for the 902 application, and April 22, 2008 for the 389 application.

Q. And when you refer to the 389 application, you're referring to the U.S. application 12/107389?

A. Yes.

Q. And that's JTX-4.

And, Doctor, would you explain what you found when you reviewed the 2003 application?

A. Yes. So the 2003 application has a disclosure of the polymer component having polyethylene oxide and hydrophilic cellulosic powder as well as the low molecular weight PEO and the high molecular weight PEO, but it does not have the claim limitation that 60 percent or

more, or about 60 percent or more of the polymer component has low molecular weight PEO.

Q. What did you find when you analyzed the 2008 filing?

A. That's the first time I found all the three claim limitations of the '150 patent being there.

Q. Where in the 389 application did you find the 60 percent range limitation?

A. I found it in both the summary of the invention as well as in the claims.

Q. And you said that the plaintiffs contend the claims of the '150 patent are entitled to 2003 priority date. What evidence did the plaintiffs point to to support their allocation?

A. Well, they go to the various parts of the specification and specifically to Table 22 the specification of the 902 application.

Q. And, again, for the record, the 902 application is JTX-249.

Would you explain to the Court what's shown in this slide?

A. Yes. This table shows on the



leftmost column the various film compositions. The top row shows the polyethylene oxide, the various molecular weight. The last column on the right-hand side shows the hydrophilic cellulosic polymer.

Q. Why is the table colored, Doctor?

A. So I colored the table just to illustrate my point. The blue refers, the low molecular weight claim range is for the polyethylene oxide. The red refers to the high molecular weight claim ranges of the polyethylene oxide, and the green is the hydrophilic cellulosic polymer.

Q. Did the plaintiffs identify any particular film composition from the Table 22 that they alleged supports their claim to an earlier priority date?

A. Yes. They identified a claim composition DW.

Q. Do you agree that DW describes the claimed film?

A. No, I do not.

Q. Why is that?

A. The film composition DW has



80 percent by weight of the 200,000 molecular weight PEO, and 20 percent by weight of the 900,000 molecular weight PEO, but does not have any hydrophilic cellulosic polymer.

Q. And how does film DW comport with the claim language?

A. The claim language requires that the polymer combination has PEO and hydrophilic cellulosic polymer. In this case, the DW does not.

Q. Do plaintiffs rely on anything else from the 2003 application to support their argument for an earlier priority date?

A. Yes. They rely on certain passages of the specification.

Q. And have you reviewed those portions of the specification?

A. Yes, I have.

Q. What did you conclude?

A. That none of those passages in the specification meet the claim limitation that 60 percent, about 60 percent or more of the polymer component, which has both PEO and hydrophilic cellulosic polymer, are present in



the 902 application.

Q. How does the 2008 priority date impact your invalidity analysis?

A. So the -- you said the 2003?

Q. I'm sorry. 2008.

A. 2008. Based on the 2008 priority date, the Yang reference renders all of the claims obvious.

Q. And what standard did you apply in analyzing obviousness?

A. So I was informed that the patent is claimed obvious to a person of skill in the art if that person can use the prior art references and have reasonable expectation of success in combining the teachings to achieve the claimed invention.

Q. When you say the Yang reference, are you referring to JTX-178?

A. Yes.

Q. When did the Yang reference publish?

A. It was published on February 17, 2005.

Q. How did you conduct your

obviousness analysis?
A. So I went back to the claims of the '150 patent and then correspondingly found various sections of the Yang reference that taught the same limitations.
Q. Would you explain to the Court what's shown on this slide?
A. Yes. So on the left side is claim 1 of the asserted claim of the '150 patent, and then on the right-hand side are the various -- the specific limitations that are stipulated by both parties to be present. And I put some checkmarks there.
Q. Did you also analyze claim 10?
A. Yes. Claim 10 has the same limitations as claim 1 except for the 75 percent polyethylene oxide and up to 25 percent hydrophilic cellulosic is changed to a hydrophilic cellulosic polymer, more than one ratio with the polyethylene oxide.
Q. Did you also analyze claims 4 and 13?
A. Yes, I did. And, again, the dependent claims have also been stipulated by



both parties to be present in Yang, and so I put the checkmarks there.
Q. Which claim elements are currently in dispute?
A. There are three. First is the ratios of the polyethylene oxide hydrophilic cellulosic polymer present in claim 1 and claim 10. And in the 60 percent or more of the polymer component being made up of polyethylene oxide.
Q. How does the Yang reference renders obvious the ranges of PEO and HCP found in claim 1 and claim 10?
A. So in Paragraph 116 of the Yang reference, the PEO is in the range of 20 percent to 100 percent, and the HCP is in the range of zero percent to 80 percent. So the claim limitations of the '150 patent are in those ranges of 20 percent to 100 percent PEO, and zero to 80 percent HCP.
Q. And the same thing with claim 10. How does claim 10 in that ratio -- is that found in Paragraph 116 of the Yang reference?
A. Yes. So paragraph 116 explicitly



has the four-to-one ratio disclosed.
Q. And how does the Yang reference render obvious the about 60 percent or more limitation?
A. So the Yang reference in paragraph 120 has the 50 to 75 percent low molecular weight PEO, optionally combined with a small amount of a higher molecular weight PEO, and the remainder of the polymer component being hydrophilic cellulosic polymer. And since 60 percent is in that range of 50 to 75, that renders the claim of the '150 patent obvious.
Q. Have the plaintiffs identified any particular properties associated with films made from the HCP and PEO ratios and the about 60 percent PEO ranges included in the claims?
A. No, they have not.
Q. How can the disclosure at Yang, paragraph 120, render the 60 percent limitation obvious, but at the same time be insufficient to support written description requirement?
A. I understand the standards are different. The 50 to 75 percent disclosure in Yang renders the claim limitation obvious.



However, the 50 percent is lower than the 60 percent that's required here, and 75 percent certainly does not meet the claim limitation of more, 60 percent or more, which would be greater than 75 percent, and therefore this, the Yang reference does not have enough description.
Q. And what is your conclusion regarding the Yang reference?
A. So based on the fact that all of the claim elements are described in Yang, the Yang reference renders the claim of the '150 patent obvious as to the 2008 priority date.
Q. And did the plaintiffs dispute your conclusion that the Yang reference renders the asserted claims obvious?
A. No, they do not. They just assert that the Yang reference is not prior art.
MR. DALKE: Thank: No further questions.
THE COURT: All right. Thank you.
MR. BOLLINGER: Good morning, your Honor.
THE COURT: Good morning.
CROSS-EXAMINATION

BY MR. BOLLINGER:

Q. Good morning, Dr. Amiji. How are you?

A. Good.

Q. My name is Jim Bollinger. We have not met. And I wanted to ask you a few questions, and specifically, I wanted to talk to you a little bit about viscosity average molecular weight. And I think you indicated, and used that term, viscosity average molecular weight several times. We heard a lot of it yesterday.

Can you tell me, did you, have you -- do you recognize that as a term of art in your field?

A. Yes. When you are measuring polymers, so viscosity average molecular weight in the context of this litigation as well as in the art, there are two different interpretations. The viscosity average molecular weight that Dow reports is based on measurement of the solution viscosity. They measure the solution viscosity and measure how thick it is and then relate that to the



molecular weight.

The viscosity average molecular weight, which is the intrinsic viscosity molecular weight calculated using the gel chromatography is a different value and therefore has different numerical values associated with it.

Q. Well, we've seen two different values in this case, so we'll talk a little.

I wanted to ask you though, isn't viscosity average molecular weight one of the most common ways of expressing average molecular weight in industry?

A. It's -- it's used usually when you are characterizing new polymers. When you are synthesizing polymers, you do measure average molecular weight, and you can measure weight average or viscosity average. Those are the most common.

MR. BOLLINGER: Can we put up his report, paragraph 68?

BY MR. BOLLINGER:

Q. I just wanted to confirm it was your testimony before was the most common way.



Do you recognize this from your report?

A. Yes, I do.

Q. And the first two lines where it says that?

A. So the viscosity average, what I'm referring to in this report, is the method that values, that it's basically -- you know, it's a method where you get a range in the viscosity of solution.

Q. Okay. And so people in industry would understand viscosity average molecular weight. There's also what Dow uses to characterize their molecular weight values; is that correct?

A. That's by dissolving the polymer in solution and then correlating that back to the molecular weight.

Q. And you also believe that the intrinsic evidence in the '150 patent teaches somebody of ordinary skill to apply viscosity average molecular weight in the context of that patent; is that correct?

A. No. What I said is that the



intrinsic evidence suggests that a skilled artisan would rely on the manufacturer's information for molecular weight.

MR. BOLLINGER: Can we bring up his declaration, paragraph 14, from the Markman hearing?

BY MR. BOLLINGER:

Q. Do you remember putting this in your declaration?

A. Yes.

Q. I'm sorry. It's your -- I'm sorry. It's paragraph -- claim construction declaration at 14. That's what I have. Page 14. I'm sorry. And I have the quote, for example.

Yes. Do you see there where it says, for example, in the prosecution history of the '150 patent?

A. Yes, I see that.

Q. And then at the end -- so you agree with that. This reference makes clear that the manufacture her calculated the average molecular weight by using the viscosity average. That's what you understand is a viscosity

average molecular weight; is that correct?
A. Yes. It's based on dissolving the polymer in solution and measuring the viscosity.
Q. Exactly. And you testified, you said in this declaration that somebody skilled in the art would rely on that in construing what the term molecular weight was in this patent?
A. That's exactly what I said, that they would rely on the manufacturers. In this case, Union Carbide, which is now Dow Chemical.
Q. Well, let's talk a little bit about that.
MR. BOLLINGER: Can we bring up example, I'm sorry, JTX-30?
BY MR. BOLLINGER:
Q. I think this is the brochure that you had presented a few minutes ago. And we'll go to page 16, which is the page that you indicated through your testimony.
And there's that table. If we can blow up that table that they were reciting. Yes. Thank you.



And you see here, and specifically, these were the ranges of viscosity average molecular weight that do you was reporting?
A. No. If you look at this page next to it, there's actually a second part of this table that shows the actual number of that viscosity of polymer solutions, the ranges that are calculated using this.
Q. Okay. So is this your understanding this is viscosity average or this is not viscosity average?
A. It's approximate molecular weight based on rheological measurement, which is the measurement of viscosity of the polymer solution.
Q. And --
A. It is not the same as the intrinsic viscosity average molecular weight that Dr. Yau calculated by gel permeation chromatography.
Q. I understand that's your testimony, sir. Just looking for -- if you went to the bottom, and I just wanted to correct



something because I think you said that Dow had indicated that it was they are not directly comparable, but that's not directly what it says, I don't think. I think it says that it's approximate -- it is not very clear on that one. But I think it says actually may not be comparable.
Do you recall that from the brochure?
A. Well, it's known to a skilled artisan that the two methods are not comparable.
Q. Okay. But it says here on mine, it says may not be directly comparable, and it's actually talking about something called light scattering and other methods generally.
A. Well, gel permeation chromatography is there as well.
Q. True. True. And light scattering is a way to calculate viscosity average molecular weight?
A. Again, I looked at that brochure and I saw that gel permeation chromatography method is not comparable.
Q. Okay. But light scattering



certainly is not comparable, right, because it calculates weight average molecular weight?
A. You know, it may calculate other methods as well, calculate other methods. But for my analysis, I looked at the viscosity average molecular weight that Dr. Yau calculated using the gel permeation chromatography and these methods are not comparable.
MR. BOLLINGER: Can we go to the page before?
BY MR. BOLLINGER:
Q. And you will see in this page what appears what Dow does here, and I just want to understand, do you understand what Dow does is that they measure a batch and if the viscosity falls within the range of 55 to 90, anywhere in that range, right, and they call it 200,000; is that correct?
A. Yes, that's correct.
Q. Okay. Thank you.
And you know that something that measures 55 is going to have a lower average, viscosity average molecular weight than something that measures 90.

Will you agree with that?
A. Well, as we heard yesterday, these polymers have polydispersity in any given sample, is going to have is going to have polydispersity and so these ranges are appropriate.
Q. Right. So you would look at something at a centipoise of 55 and they'll call it 200,000 and then they'll measure a batch at 50 and they'll call it 100,000; is that correct?
A. That is the weight it has been described here, but, again, these ranges are appropriate because any polymer sample will have variability. And that's what defines the polydispersity of polymers.
Q. So that's a pretty wide range; correct? That's a significant range of different possible average molecular weights. That's why they call it approximate; is that right?
A. Yes. And, you know, that's the value that a skilled artisan would use.
Q. OKAY. You've mentioned that



you've done GPC before; is that correct?
A. Yes.
Q. And, in fact, in your lab and in your work you've had grad students do it and then you review the data; is that correct?
A. Yes.
Q. All right. Thank you.
And in working with PEO, you recognize that the, not only is there the individual molecules that will have a vast array of different lengths, but that the individual batches that are manufactured will vary batch to batch; is that correct?
A. Again, you know, based on the method that the manufacturers then determine molecular weight, they will assign an appropriate term to that. For example, N80 would be 200,000.
Q. Let's turn to the question of prior art, and you've been talking the Yang reference as prior art, and I just want to ask you a few questions. You did look at the file history for the Yang reference; is that correct?



A. Yes.
Q. And you also studied the file history for the '150 patent?
A. Yes.
Q. And is it your understanding that the '150 patent is what we call a divisional of the Yang reference?
A. I have not heard that term before. My understanding is that the Yang reference and then going back to 2001, there's a priority chain to the filing of the '150.
Q. Okay. So they're commonly owned patents and patent applications; is that correct?
A. That's the way -- that's the way I understand priority chain.
Q. Okay. And by looking at that, you were able to tell that not only is Yang the parent of the -- the '150 patent, but during prosecution, didn't the examiner issue what we would call a double patenting rejection? Do you remember seeing that?
A. No, I have not seen that.
Q. And the applicant made clear that



it was a divisional. The examiner accepted that?
A. Again, I don't have that information.
Q. Okay. So do you have any -- do you understand that the patent, the '150 and the Yang reference that you're citing, all four of the same inventors?
A. Yes. I looked at the names of the inventor, but, again, I focus on the claim limitation, and I did not see the third claim limitation in Yang.
Q. All right. Now, and is it -- you know, I think you've pointed out some things that you think are differences in the specifications and teachings, but aren't they nearly identical?
A. Again, I focused on, you know, on the claim limitations of the '150 patent and went through the various parts.
Q. Okay. Thank you, sir. I appreciate your time.
Your Honor, I have no further questions.

THE COURT: All right. Any redirect?

MR. DALKE: No, your Honor. We have nothing.

THE COURT: Dr. Amiji, thank you. You may step down.

THE WITNESS: Thank you, your Honor.

(Witness excused.)

MR. LOMBARDI: Your Honor, that's defendants' last witness on invalidity of the '514 and '150 patents, so we're resting that part of our case. Obviously, as you know, we'll have a rebuttal witness later on today. That's our case-in-chief.

THE COURT: Rebuttal witnesses on secondary considerations?

MR. LOMBARDI: That's correct. That's correct.

THE COURT: That's Ms. Lawton?

MR. LOMBARDI: Lawton, yes.

THE COURT: All right.

MR. LADOW: Your Honor, I anticipate your answer, but plaintiffs would



make a motion for directed verdict on infringement.

THE COURT: Okay. I will take it under advisement with the other ones. Let's go ahead.

MR. BRAHMA: Good morning, your Honor.

THE COURT: Good morning, Mr. Brahma.

MR. BRAHMA: Plaintiffs call Dr. Robert Langer, who will be testifying on the validity of the '514 patent.

And may we hand up exhibits and demonstratives?

(Demonstratives handed to the Court.)

THE COURT: Sure.

... ROBERT LANGER, having been duly sworn as a witness, was examined and testified as follows ...

DIRECT EXAMINATION

BY MR. BRAHMA:

Q. Good morning, Dr. Langer.

A. Good morning.



Q. Could you tell us where you're currently employed?

A. I'm employed at MIT, the Massachusetts Institute of Technology, and also Boston Children's Hospital and Harvard Medical School.

Q. What is your current position at MIT?

A. I'm what is called an institute professor. There are 13 institute professors at MIT. That's MIT's highest honor or highest professorship.

Q. What is your particular area of scientific expertise?

A. Biomedical polymers and drug delivery systems.

Q. And is there a field in which you teach?

A. Well, I teach in those areas. Also in chemical engineering, and also pharmaceutical engineering.

Q. And now I know you have received many awards, and the Court already has your CV, but have you received any particularly notable



awards for your pharmaceutical work?

A. Well, almost all are for that work, but as examples, last Monday I received the Queen Elizabeth prize. That's the largest, it's kind of the engineering Nobel Prize, and I've also received the two highest national awards, the National Medal of Science from President Bush and the National Medal of Technology from President Obama. There are only four people that have those.

Q. Before you started working on this case, have you conducted research directed to pharmaceutical cast films?

A. Yes.

Q. And for how long have you been doing that research?

A. I've probably started it, you know, over 40 years ago. Forty years ago.

Q. And could you give us an example of the type of pharmaceutical film research you were doing?

A. Well, I am involved in a number of companies. I've started companies, but a lot of what I do is kind of more basic research. And

where I got involved in this really goes back to 1974. I was doing post-doctoral work with a man named Judah Falkman and we were trying to isolate what would be called blood vessel inhibitors, antigenesis inhibitors, and we had to develop a bioassay for that, and that was sort of the problem. We needed to be able to release large molecules for several months.

So I was experimenting with different ways of putting molecules into polymer, various polymer systems like polymer films, polymer microspheres, polymer pellets, things like that.

Q. And in the course of your work, have you also worked on drugs that are being prepared for regulatory approval in film form?

A. Well, again, in terms of, I mean, the work that we've done is broad. I mean, most of what we've done is model systems. I mean, I have certainly advised companies, and I've been involved in starting companies that have used all kinds of formulations.

Q. Prior to 2002, were you familiar



with literature about pharmaceutical film products based on your own research and work?

A. Certainly somewhat.

Q. And in what context, what roles made you familiar with this, the literature on this field?

A. Well, a number of things. I'm on a number of what are called editorial boards of scientific journals, including pharmaceutical journals, like the Journal of Pharmaceutical Science.

I've been a reviewer for, you know, different federal grants, like from the National Institutes of Health and various -- National Science Foundation. We do a lot of work in our own lab on various pharmaceutical things.

And then I also have been quite involved with the FDA. I was on the FDA Science Board, their highest advisory board, for eight years. I was chair of it for four years.

MR. BRAHMA: Based on that, plaintiffs proffer Dr. Langer as an expert in chemical and pharmaceutical engineering as well



as in pharmaceutical dosage forms, including pharmaceutical cast films.

THE COURT: All right. You may proceed.

BY MR. BRAHMA:

Q. Dr. Langer, have you reviewed the testimony of defendants' expert, Dr. Craig Dyar?

A. Yes.

MR. BRAHMA: And I'm going to ask to put up slide PDX-1702.

BY MR. BRAHMA:

Q. Doctor, I'm going to ask you to talk about a few points today, starting with some background on cast film technology, then moving to Dr. Dyar's two grounds for contending that the '514 patent claims are invalid. Namely, his obvious argument and his indefiniteness argument, in that order?

A. Okay.

Q. So let's start with the state of the art of pharmaceutical cast films.

For purposes of this litigation, the litigation, the parties have agreed that the priority date for the '514 patent is



September 27, 2002. Did you use that date in your validity analysis?

A. I did, but I don't know that it would matter that much, but I did.

Q. What problems were the inventors of the '514 patent trying to solve in 2002?

A. Well, they were trying to come up with a way of creating pharmaceutical cast films that would have a very high drug content uniformity.

Q. What is drug content uniformity?

A. Well, the way I think about it is, let's say you make a film and then you cut pieces of that film, and you want each piece to have essentially the same, the same amount or, regardless of how you cut it. And in this case, they're trying to keep the variation to less than ten percent.

Q. And in terms of patient treatment, why does drug content uniformity matter?

A. Well, you want to be reproducible in terms of both safety, which is key, and also efficacy, which is key.

Q. Now, before 2002, had other

scientists tried, but failed to make, to achieve drug content uniformity in pharmaceutical films?

A. Definitely.

Q. So what was the, what was the status of the field or what stage of development were pharmaceutical cast films in in 2002?

A. Well, very early, I think, my belief is the first product based on pharmaceutical cast films was in 2009, so many years later.

Q. And when you say it was in 2009, you mean it was approved in 2009?

A. Correct.

Q. Now, we've been talking about cast films. Can you show us what the general process is for making a cast film?

A. Yes. So this is in slide -- I will put -- make sure.

So basically, first you dissolve the polymer into a solvent and then you mix. Then you add the -- step two. Then you're adding the active ingredient and mix the form like a dispersion. Then you cast that



dispersion on some kind of substrate, like it could be glass, it could be metal. Then you dry it into a final film. A lot of things happen here. You know, you're evaporating a lot of things. There's a lot of shrinkage actually.

And then finally you cut into the individual dosage units and you remove it from the substrate. You package it, and that's what you might end up selling.

Q. And in 2002, were there challenges unique to cast films that made them particularly difficult to manufacture in the pharmaceutical context?

A. Yes. Let me put up another slide.

Basically, the big challenge is that you have two phases. There are a lot of systems where you have one phase, but here you have like a solvent phase with something dissolved in it, a polymer, and now you also have this solid phase, which are particles. And the problem is keeping them uniform through all of those five steps. In other words, if at any



point in time you lose that uniformity in any of those five steps, you are not going to get it back. You can't sort of put the genie back in the bottle.

So that's the big problem, is to keep them -- is to keep them uniform through all of those five steps, assuming you even got it to be uniform in the first place. And some of the issues are shown up here, that you have the active, that's the drug. That could actually migrate essentially between dosage units before you cut it.

Also, a lot of things are going on, as I mentioned. When you are drying it, that's one of steps. You're applying heat generally to remove the solvent, so you are not only applying heat, but you are changing the system. You are shrinking it a lot. I mean, a real lot. You're adding different excipients. Those are other substances which could interact with the drug. And as I said, there are issues then in uniformity in all five steps.

Q. As someone who has worked with cast films for decades, what was your own



experience with trying to make uniform pharmaceutical cast films prior to 2002?

A. Well, I guess the way I often think about it, when we started doing some of the work I mentioned earlier on these antigenesis inhibitors and I had a graduate student working on it, he once said to me trying to do this reproducibly was like trying to break glass reproducibly. So it wasn't easy to do. So we actually in the end largely have gone to other kinds of systems to try to create ultimate products, like microspheres, rods, things like that.

Q. Now, did the prior art teach a person of ordinary skill how to achieve drug content uniformity in finished cast films?

A. No, it didn't. If I could have the next slide.

So what you see, if we go to the five steps is the homogeneity. In some examples of prior art, that's discussed, steps like 1 and 2.

The steps 3 and 4, where you're casting it onto a dispersion onto the substrate

and drying it into the film, those are almost uniformly ignored or not achieved in the prior art.

And as far as I could see, I will talk about this more, if you analyze the literature, both patents and, and published literature, I don't think there's a single case where somebody showed, you know, quantitatively that they had achieved uniformity.

Q. And --

A. Before 2002.

Q. And just to kind of line these up with the animation that Dr. Dyar showed yesterday, steps 1 and 2, is that relating to the liquid that's in the tank before it's put onto the substrate?

A. That's correct.

Q. Okay. Now that we've generally talked about the prior art, were there particular references that you found that discussed the issue of drug content uniform tie of prior art films?

A. Well, there are a number, and I will go into them, but let me just go to the



next slide and just highlight two, one before and one after.

MR. LOMBARDI: Your Honor, we had a motion in limine on this series of slides, and you mentioned the order, that we should go ahead and preserve our objection.

And if it's okay with your Honor, I will just read the numbers of the slides and then I won't be popping up throughout, or if you would like me to jump up.

THE COURT: No. Just tell me the slides.

MR. LOMBARDI: It's Exhibit 1706, and then 1712 through 1716. And the grounds again, your Honor, these are post-filing art, and there are a variety of other grounds among hearsay and so forth. But that was covered in the motions in and in your brief.

THE COURT: All right. All right. Go ahead.

BY MR. BRAHMA:

Q. Now, you were saying, Dr. Langer, you had two examples of statements in the prior art about?



A. Well, these are just two and I will show more later. Maybe those are some of the jumping up ones, but I'm not sure.

But the two that I will highlight, one before, Schmidt, which was 1987, wrote that prior art films do not make it possible to obtain the uniform active ingredient distribution.

Perumal -- and I will go over that more -- that's a thesis, and then a scientific article in a review journal. And they did a number of things, but in particular they analyzed the literature, doing a literature search, and they said that an extensive literature search with respect to drug content uniformity in polymeric films shows surprisingly that the majority of papers did not report any assay values. And they have a table on that. That's six years after 2002. And there's more.

Q. All right. So I would like to discuss the extensive literature search that was conducted by Perumal. So if we could look at that table on sum summary.



So this is PTX-215. If we could pull up Table 1.

A. Mm-hmm. Okay.

Q. So they list a few articles in that table. How many of those were published before 2002?

A. Well, what is it? One, two, three, four, five, I believe. Six. It depends on when the sixth one was published.

Q. All right. And for any of those six references, did they find any drug content uniformity assay value?

A. They were not reported.

Q. And if we go to the text slightly below that table. So the line starting from the lack of reported data.

A. So it just says, the lack of reported data on this crucial characterization property of any novel drug delivery system led to the assumption that researchers in this field may also have been experiencing difficulty with this aspect of film characterization.

And then they continue, and this is key. Yet no paper to date, to the best of

our knowledge, in the published pharmaceutical literature has highlighted this difficulty.

It was only a search of patent applications that confirmed the assumption that difficulties with achieving uniform drug distribution in films did indeed exist, as some patent applications that attempted to directly address the problems encountered with non-uniformity in films were identified.

Q. And I wanted to ask you about the assumption there that the Perumal authors were making the assumption that if data wasn't reported, then the authors of that paper were having difficulty getting drug content uniformity.

How does that compare to the assumption that Dr. Dyar is making when he came across prior art references that didn't have data on drug content uniformity?

A. It would disagree with it.

Q. And in your view, based on your experience in the field, which assumption is more appropriate when faced with prior art that does not report drug content uniformity



data?

A. Well, I think this is -- plus this is a peer-reviewed journal, I mean where people looked at it and decided that they thought it was worth publishing.

Q. And so do you agree with the authors of the Perumal article?

A. Yes.

Q. Were the authors of the Perumal article actually trying to make cast films, pharmaceutical cast films?

A. That was the whole intent of what they were doing. They were trying to make cast films and then they also did this literature review.

Q. All right. And then later in that highlighted quote it talks about patent applications that confirm the assumption about the difficulties in achieving uniform drug distribution in films.

What patent applications are they referring to?

A. Well, some of them were in that table. I mean, there's different ones. There



are a range of different ones.

Q. Do they talk about the work that was reflected in MonoSol's '514 patent?

A. Yes, they do.

Q. And what do they say about that?

A. Can we -- I might -- yes. If we could highlight a particular portion.

Q. Yes. In the second column.

MR. BRAHMA: I think you also need to get the first in that former column. At the bottom, if you start at the line that says, in these patent applications.

THE WITNESS: Yes. So if we could just -- yes. Let me -- well, here, let me just do it off of the book.

Okay. So in these patent applications, it was explained that films prepared by the conventional casting technique as used in the literature suffered from the aggregation or conglomeration of particles which rendered them inherently non-uniform in terms of all film components, including polymer and drug.

It then says, it was found that



the formation of agglomerates randomly distributed the film components as well as any active present, thus leading to the poor drug content uniformity. And then they cite this patent, the earlier version.

They continue, the formation of agglomerates was attributable to the relatively long drying times which facilitated intramolecular attractive forces, convection forcers, and airflow, which aided in the formulation of such conglomerates.

They're citing to the Yang patents. Then they start to talk about other attempts that were used and that were abandoned.

BY MR. BRAHMA:

Q. Okay. And we will come back to the Perumal article later to discuss its own work.

But I did want to ask you, in terms of the '514 patents, patent itself, did it discuss whether the prior art films achieved drug content uniformity?

A. Yes, it did, in a number of places in the beginning.

Q. Okay. Do you have a slide summarizing that?

A. Yes. If we could just go to the next slide. And just a couple quick things on this. They point out that Horstmann and Zerbe are deficient because the long length of drying time aids in promoting the aggregation of the active.

They point out that Fuchs' films suffer from the aggregation or conglomeration of particles, in other words, self-aggregation, making them inherently non-uniform. This result can be attributed to long drying times, thereby facilitating intermolecular attractive forces, convection forces, airflow and the like to form such agglomeration. And these are just some examples.

Q. And that last quote I wanted to ask you about, the intermolecular force, the attractive forces and convection forces that are mentioned in that last quote, could you explain what those are and how they could impact content uniformity of an active ingredient in a pharmaceutical film?



A. Well, they, they cause -- there's all kinds of forces. Maybe we could just go to the next slide and I could try to explain what actually happens.

So if you have a system where you have these solids dispersed in this liquid and polymer, a lot of things are going on.

So one of the things that's going on is there's heat generally applied, so you get evaporation. So there's thermal gradients. Obviously, if stuff is moving out, you also have bulk concentration gradients. There's also what are called surface tension gradients. The surface tension is different when you have these air liquid interfaces, and that changes over time.

I think that's also key. All of these things keep changing over time. It's not a steady thing.

You also have what are called Van der Waal's attraction. That's like substances sort of being attracted to each other.

I think one thing that is important in all of this, too, is not only the



effects in what I will call the Z direction, settling, I think you heard some of that yesterday from Dr. Dyar, but else also occur in the XY direction, in this direction.

Also you get what are called Marangoni flows, and I will show a video. Like if something evaporates, and that's what happening here, you don't get a uniform distribution like a coffee ring.

If you pour coffee out, you'll see that it does not, the residue doesn't distribute uniformly. It goes to the edge. I will show that. That is also shown in what are called tears of line.

There's also capillary forces. That's the sixth point on this. Capillary forces is kind of like wicking.

Then there's what's called ballistic Bronian motion, and that's particles, moving back and forth, banging against each other.

Then there's buoyancy. There's Stokes law. That's what Dr. Dyar talked about yesterday. That has to do with particles even



sinking or swimming.

The point is you have all of this going on. It's quite complex because the system is not a static system. It's a system that's losing material all the time, changing temperature, and so it's quite complicated. It's not just one thing happening.

Q. You mentioned that Dr. Dyar talked about Stokes law, and I wanted to ask you, the is the entire phenomenon of drying an active particle migration, can that all be explained by simply Stokes law?

A. I don't see how it can because Stokes law has to do with things settling, and like I say, a lot of these things are moving, you know, in other directions. So it can't explain.

Q. Now, you mentioned that you have a video on the coffee ring?

A. This will just be a quick video just showing the coffee ring evaporation.

(Videotape played.)

THE WITNESS: And you just see the residue going to the edge. In other words, it

does not evaporate, so it goes to the edge. In other words, if it was uniform, it would be distributed throughout, but it's not. It all goes to the edge. This is just an example of one of the phenomenon out of the eight that I mentioned. I won't show videos of the other seven.

Q. So this is what you would see if you saw a drop of coffee grind. Coffee drying. Is that what you are saying?

A. That's exactly right, over time.

Q. And in that example, what is the particle?

A. That's a coffee particle.

Q. All right.

A. I'm not an expert on coffee, but that's a coffee particle.

Q. Now, how do these various --

A. I think the key, again, is just exactly how non-uniform it is.

Q. How do these various forces arise in the context of the casting and drying process?

A. Well, it occurs in those five



steps. And if I just go to the next slide, so there's casting, and there you run into issues on uniformity. But drying can create or exaggerate forces that can cause drug my migration and aggregation.

You can get uncontrolled air currents either above or below the film and that can create non-uniformity. As I mentioned, the whole system shrinking when this happens. You can also get air be bubbles formed and you could get a surface skin when you do this. And you can get rippling and that skin can also rupture.

So a whole bunch of things can happen, and do.

Q. Now, we have been talking about forces and drying conditions that can lead to non-uniformity. Does the '514 patent teach that any one factor or process parameter is critical to preventing that problem?

A. No. If we could just go to the next slide.

Basically, what they are saying in the '514 patent, it says, if the testing shows



non-uniformity between the film samples, then you control the manufacturing conditions, like drying conditions, mixing conditions, compositional components, and film viscosity. And part of the key is summarized here. This is what I've seen in the, this patent that I didn't see in any of the other literature that was cited by Dr. Dyar.

First, the casting dispersion must have viscosity low enough to process but high enough to limit migration and aggregation of the active. And I should add, you have to couple that with all the other properties you might want. Like if you make a film, you still want it to dissolve well. You want it to release well. So that's the first thing.

And the second thing is this idea of locking in. In other words, given that you can get all of this kind of migration at any of these five steps and that once you get it, you can't recover, what they are teaching you in this patent is that it's a combination of matrix viscosity and drying process that quickly locks in the active particle. So it's locked in and



basically preventing it from moving. And then you're drying it in such a way that it keeps it that way and keeps it smooth and so forth.

Q. Now, you mentioned that those are the things that weren't shown in the prior art that you had seen.

Now, Dr. Dyar yesterday talked about the ability of a person of ordinary skill in the art, if they had produced a film that wasn't uniform, to tweak their formulation or their drying process or something else, to get to uniformity.

Can you, can you explain to us, in your opinion, would a person of ordinary skill in the art viewing the prior art have been able to make those tweaks and what tweaks would they have been taught to make?

A. Well, I don't, I didn't see any prior art -- I'm going to go into that in a second -- that went over that. In fact, future art, if anything, as I will go over will show that that didn't happen.

But I would add to that what I just said to you before, that if you started

tweaking and improving one thing, you may -- you run the risk that you will hurt something else. You know, like getting the wrong dissolution rate, getting the wrong mouth feel and so forth.

But maybe the easiest way to do this is, we did a literature search and post the Yang patent. And let me just cite six articles that talk about this not before, but actually after.

Q. Okay.

A. And --

Q. And we'll go to that in one second. I just wanted to go to the claim really quickly so we remember what uniformity requirements we're looking at.

Claim 62. What level of drug content uniformity does that require?

A. It requires that the individual doses don't vary by more than ten percent of said desired amount.

Q. And there's also claim 65 that is being asserted that talks about content uniformity. What variation in drug content does that require?



A. Five percent.

Q. And so now let's get to those post-2002 articles. And you mentioned that you had found some that you wanted to talk about today.

Were these types of references that you ordinarily rely upon in your own work to determine the state of the art in the field?

A. Yes. Most of them are in peer-reviewed journals that I peer-review myself sometimes.

Q. Do --

A. I'm on the editorial board of some of them, too.

Q. Do these articles discuss the contributions of the '514 patent?

A. Many of them do, yes.

Q. And --

A. And they're all post 2002.

Q. And what do those post 2002 articles say about the '514 patent?

A. Well, if anything, they consider it as I will go through a seminal patent. I mean, they're highly complimentary to it. And



as far as I can see, none of the people, at least as far as I could tell that were speaking about it, had any association with MonoSol or anything like that. In fact, one of them I believe testified for the other side, McConville, but I will get to that.

Q. All right. So let's go to those slides. I think the first one is slide 1712.

A. Yes. That's the one I just mentioned.

Q. Okay. And can you tell us about how the Morales and McConville article impacted your analysis of obviousness?

A. Well, it's just one more piece of evidence. As I mentioned, McConville I believe testified yesterday. But it's a peer-reviewed journal in the pharmaceutics area. It's in 2011, so that's nine years later. And they just wrote, when they're discussing this whole field, it's what is called a review article. So that's supposed to be a critical analysis. It's not original research. It's a critical analysis of the field.



But just a couple quick quotes. They said, since the early development of medicated films, content uniformity has been a major challenge. So I mean, that directly contradicts what you heard yesterday, I believe, from Dr. Dyar.

Then they further said that Yang, et al, MonoSol, indicated that self-aggregation was one of the main reasons why films usually show poor uniformity, and in particular the drying process was found to be crucial in preventing aggregation or conglomeration, and so forth.

Q. Now, Dr. Langer, you mentioned that Dr. McConville testified yesterday. I just wanted to make sure it's clear for the record, he was testifying for Watson; is that right?

A. Correct.

Q. Okay.

A. I'm sorry.

Q. But he wasn't addressing the issue of validity of the patent?

A. No, no. I was just -- no.

Q. Okay.

A. He wasn't going over this at all. But I was just saying this is an article that he and one of his colleagues wrote.

Q. Now, Dr. Dyar yesterday criticized this article and other post 2002 articles for, I think his words were, copying and pasting from the '514 patent, and not doing a, quote unquote, "independent analysis."

What is your view on that?

A. Well, I mean, it's partially correct, but I mean the thing is, is what people do, I mean, when they write -- this is a review article. We'll get to some other articles, too. But what people do is they make an analysis of the literature. Sometimes when they see things they like that other people wrote, they copy it, and then they attribute it to them. And that's what's done here.

But the fact is, is when something undergoes peer review, it's usually seen by a number of people, scientific reviewers who are either in industry or faculty members, an editor of the journal, and they review these to see whether what's said is reasonable or not.



My experience has been peer-reviewed articles usually set a higher bar in terms of rigor, scientific rigor like this than, say, a patent in terms of analyzing literature. So I mean, to me, this kind of thing happens, this is pretty standard.

Q. And in peer-reviewed articles like this, when the authors disagree with a statement they find in the literature, is that something they are supposed to note?

A. I'm sorry. Could you repeat the question?

Q. In peer-reviewed articles like this, if the authors found a statement in the literature that they disagreed with, is that something they would be expected to note in the, in their own article?

A. Yes. Like I said, they're doing a critical analysis. They are doing a critical analysis of the whole thing, and so if they did disagree, and they do. Sometimes people say, well, I'm analyzing this, and I don't agree with it, or I'm analyzing this and I do agree with it. So that's quite standard.



Q. All right. Let's go to the next articles on your list there. And you have listed the Perumal thesis and the Perumal article. How did those impact your obviousness analysis?

A. So we talked a little bit about Perumal before. So Perumal did a thesis where there's a Master's advisor in this case, and then they wrote again a peer-reviewed article.

Again, just a couple of quick quotes from those that I think are, that are representative. Films suffered from the aggregation or conglomeration of particles, which rendered them inherently non-uniform in terms of all film components, including polymers and drug.

That is from the thesis. The article, they made a statement, it was found that the formation of agglomerates randomly distributed the film components as well as any active present, thus leading to the poor drug content uniformity. And they're citing the 741 provisional from which the '514 claims priority.



Again, all we see from these is a quite consistent picture that post 2002, these were, these issues were still there and people were still talking about them.

MR. BRAHMA: And just as a quick housekeeping matter, I'm going to move into evidence the Morales/McConville article, PTX-213, as well as the Perumal article, PTX-215, and the thesis, PTX-216.

MR. LOMBARDI: Your Honor, the same objection that we've articulated before.

THE COURT: All right. I'm going to admit them into evidence. It's something you can raise again post-trial briefing.

(PTX-213, 215 and 216 were admitted into evidence.)

BY MR. BRAHMA:

Q. Now, we talked about the literature search that was reported in the Perumal article. Did the Perumal authors also do any experiments of their own?

A. They did. They did that as well. If I could -- yes.

So basically what they found when

they tried to do it was they actually got a standard deviation of 66 percent, and here's just an electron micrograph. So they again were nowhere near when they tried to use a conventional casting technique of what Yang did.

Q. All right. Now, so how does that data impact your analysis of the obviousness of the claims of the '514 patent in light of Dr. Dyar's comment?

A. Again, all of this is is a consistent picture that even post 2002, this was still an incredibly difficult problem. People have not solved it beyond what they had done in Yang.

Q. And the next article on your list is the Nowak 2005 patent publication. How does that affect your obviousness analogy?

A. It will say the same kind of thing. Water-soluble films cast from aqueous solutions containing medications can suffer from the aggregation or conglomeration of particles. Self-aggregation of any active ingredient will make the film inherently un-uniform. But if



possible, portions of the film may be devoid substantially devoid of any medication.

I mean, the theme comes over and over again, and I did not see it come the other way at all.

Q. And then the last two articles on your list are the Kathpalia article, PTX-212, and the Borges 2015 article, PTX-210.

How do these affect your analysis of the obviousness of the '514 patent claim?

A. Yes. So, again, these are in peer-reviewed articles, and now they are 11 and 13 years later, one being this year. The first one again makes the same point that I said we found, that all these people are finding, dose uniformity is difficult to maintain in oral thin films. That's the 2013 article.

The 2015 article actually is very complimentary to MonoSol and Reckitt Benckiser. As far as I know, these people have no association with them. But they say MonoSol is one of the pioneer companies in the oral film industry. The success of Reckitt Benckiser's prescription thin film proves the viability and



value of this pharmaceutical form in the Rx market.

Q. And I just wanted to clarify because there are a number of patents in this case. So when you refer to Yang in your testimony, are you referring to the applications that led to the '514 patent?

A. That is correct. All of these things, if I have not made that clear, all of these things talk to the '514. I have not examined the others.

Q. Now, collectively, do the teachings of these post-2002 references support or contradict Dr. Dyar's view of whether the prior art had already solved the problem of drug content uniformity in the pharmaceutical film?

A. No. They contradict it.

Q. Now, I would like to move to the specific prior art references and background references that Dr. Dyar cites. And Dr. Dyar's testimony focused on two references in the obviousness combination, the Chen reference and the Bess 116 patent. Then he also cited two pieces, two references as pieces of background



knowledge, the Leung '298 patent and the Lachman reference. I would like to go through those in order if I could.

A. Sure.

Q. Have you reviewed Dr. Dyar's testimony about the Chen reference?

A. Yes.

Q. And in your opinion, does the Chen reference, either alone or in combination with the other references Dr. Dyar discussed, render the asserted claims of the '514 patent obvious?

A. No, it does not.

Q. And do you have a slide briefly summarizing why you don't feel the Chen patent renders the '514 claims obvious?

A. Sure. Some of the things that Dr. Dyar said. First, there's certain references to homogeneous, but they at best apply to the dispersion. They don't cover, say, steps 3, 4 and 5 that I was shown, and they don't cover the drug content uniformity of the finished film. That was actually never measured.

He does, Dr. Dyar used Figure 5,

the dissolution data, as a surrogate for drug content uniformity, but, if anything, as I will show, I mean, first that means that you make a lot of assumptions. And, secondly, I will go over them.

But as far as I can see, if anything, Figure 5 would show the opposite, that it does not have drug content uniformity. Also, there's a pharmacokinetic study that Chen is doing, and that to me says nothing about uniformity.

And, finally, I mean, the whole patent is not even about drug content uniformity. It's really about making this kind of mucosal dosage form. That's kind of the invention. It does not really explain how you would maintain uniformity, which, as we've already seen, is a quite complex issue. It does not even touch it during casting and drying.

Q. So let's first go to the statements that are in the Chen reference about homogeneity or uniformity of the dispersion.

Have you looked at those as part



of your obviousness analysis?

A. Yes. Let me just go to four of them.

The first one, and I'm not sure where to best point. But basically, the first statement says, methods are provided for making a dosage unit, that include in one embodiment, dissolving a hydrocolloid in a solvent so as to form a substantially homogeneous preparation.

Later on, they're talking about adding the active agent. But that does not tell you that the active agent was uniformly mixed. Certainly, it does not say anything about it being uniformly cast or uniformly dry.

The second one says somewhat pretty much -- well, the second one says therapeutic agents were added to the homogeneous mixture prior to forming the film, but it does not say anything about any of those issues either from the point of mixing to drying to -- I'm sorry, mixing, casting and drying.

The third one says the hydrocolloid was dissolved under agitated mixing to form a uniform and viscous solution.



Additional ingredients were then added sequentially to the viscous solution. But the ones that they are adding are not drug. They're basically -- it basically says they're adding these until they were uniformly dispersed add and dissolved or dissolved in the hydrocolloid. Again, I'm just going by the words on these.

The fourth one, which I believe was shown yesterday, in an embodiment of the invention, the solvent casting method includes a hydrocolloid that is completely dissolved or dispersed in water under mixing to form a homogeneous formulation. So it's homogeneous there, but that's the hydrocolloid.

Now, it says, in addition to the active agent and the hydrocolloid, any of the ingredients listed above may be added and dispersed or dissolved uniformly in the hydrocolloid solution.

Personally, I think there are two ways you can interpret this because they are not specifying that the active agent is dispersed or dissolved uniformly, but I could see where



that's also a possible interpretation. But nonetheless, even if you take the most positive interpretation, it still says nothing about what happens during casting and what happens during drying.

So nowhere in Chen if you go actually -- and maybe just let me check what I wanted to do.

But if I go to the next slide, because I think this is really key. If you go to the chart where I show the five tables, nowhere in the Chen patent even under the most generous interpretations do they deal with steps 3, 4 and 5. So to me, that's key. They just don't deal with that at all.

Q. All right. So going beyond the mere statements in the Chen reference, let's talk about Figure 5 and the dissolution data that Dr. Dyar talked about.

A. Okay.

Q. Now, did you review Figure 5 of the Chen reference in connection with your opinions on validity?

A. I have, yes.

Q. Okay. And what type of testing is shown in Figure 5?

A. This is what's called a dissolution test. So when you have, like, a dosage form, you know, like you might put it in a simulated solution and see what happens over time, how much drug comes out over time, and then you measure it.

So what they are measuring here is percentage release, and a hundred percent would be like an estimate of if you had a hundred percent uniformity.

Q. All right.

A. So let's say, for example, just for the sake of argument that you put two milligrams in, so 100 percent would be two, 110 percent would be 2.2, 90 percent would be 1.8.

But basically what they are measuring based on that estimate would be how much drug comes out over time, and I believe what they are showing here is standard deviation. It's not a hundred percent clear, but I believe that that is what they are showing



from other statements in the patent.

Q. Okay. So I'm going to break down some of that into smaller bites.

So is dissolution testing common in the pharmaceutical industry?

A. Yes. It's routine. They do it all the time.

Q. Okay. And is dissolution testing like the type shown in Figure 5, is that commonly used to measure drug content uniformity?

A. No, it's not.

Q. And why not?

A. Well, because to do that, you have to make a number of assumptions. And what's usually used to measure drug uniformity -- I mean, the most common way would be to dissolve the entire system and each of the different pieces and see how much drug was left behind.

Q. Okay. So if a person of ordinary skill in the art was to look at Chen's Figure 5 and wanted to go ahead and see what it said about, what it might say about drug content uniformity, what assumptions would they have to



make?

A. Well, I think they have to probably make at least three. First, that what's called steady state is reached, meaning that no more, it's not going to change over time.

Secondly, that all of the drug that was puts in actually did come out.

Ad, third, when you look at this figure -- I mean there's a lot of data points and standard deviations, and you would have to be able to pick out what those data points and standard deviations are. I don't know if that's an assumption, but it would take some analytical work.

Q. And if you make these assumptions, does Figure 5 indicate that the Chen films have the content uniformity required by claim 62 and 65?

A. No.

Q. Okay. And I'm going to break down how you would go about applying those assumptions.

First, how many different drugs



were tested here?

A. Four.

Q. Okay. And there's an X and a Y axis to this. Can you explain what is being shown on the X axis and the Y axis?

A. Yes. I mean, the Y axis is percentage release, and the X axis is time.

Q. When it says, percentage release there, what does 100 percent on the percentage release access mean?

A. Well, that goes to the -- what I was saying before. In other words, if you have -- if you assume that what you got a hundred percent was 2, then a hundred percent would actually be about 2.

But, of course, a lot of times it's not going to be 2. It's going to be higher or lower, depending on how uniform it will be.

Q. So when you say "2," what do you mean be that? Is that the dosage of the film?

A. Well, that -- two would be a theoretical estimate of how much would be in each piece.

Q. That's how much, when you were

making the film, that's how much you wanted to be in there?

A. That's correct.

Q. Okay. Could you show us -- so if we were to draw a line across this chart at the hundred percent mark -- so there are a few of those points that are above the hundred percent mark.

Does that indicate that something was wrong with the way Ms. Chen did this test?

A. Again, I didn't see it. It's certainly possible there could be things that were wrong, but I don't think that, per se, says anything that's wrong. I mean, that's quite common.

Q. And in a dissolution test like this, do you often get data points that are above 100 percent?

A. You'd have to, unless it was absolutely perfect, right?

I mean, you'd have to, unless it was 0 percent error, or a 0 percent drug content uniformity. I mean, you, of course, would get some that were higher and some that were lower.



Q. So what does the point above 100 percent mean on this chart in terms of how much drug is in the film?

A. Well, like I say, if you have -- if what you expected was 2, then it would be greater than 2. Maybe 2.1, for example, 2.2.

Q. Now, the one point that Dr Dyar mentioned earlier, if you -- if you assume that this test was erroneous, or if there was some analytical error, or some procedural error in how this test was run, how would a person of ordinary skill view the other statements in Chen about homogeneity or uniformity?

A. Well, I think -- I mean, that's a good question.

I mean, I think if you felt that one thing was in error, I guess the question would be, how would you know what in the past was an error and what wasn't. You wouldn't know what to trust.

Q. Now, looking at these --

A. I don't think you can cherry-pick and take the things you like, and then all of a sudden cherry-pick the other way, and throw out



the things you don't like. If you don't trust some data, how do you know what -- and there's in really no analysis. I mean, how would you know what to trust?

Q. Now, going back to the graph, and looking at these curves, some of them level off over time.

What does that leveling off indicate?

A. To me that's indicative that it is probably is reaching what I called before a steady state. That is plateauing.

MR. BRAHMA: And if we could pull up the slide focusing on the Estradial curve.

BY MR. BRAHMA:

Q. Does the Estradial curve show it reaching steady state by the 10-minute time point?

A. No. I mean, every data point, as you move along in time, is higher than the last data point.

So the data point of 6 data is higher than a 6, the data point at 10 is higher than 8, so you -- it certainly does not -- you



can't conclude a true steady state.

Q. So, what, if anything, could a person of ordinary skill in the art be able to tell from this Estradial curve about the content uniformity of the Estradial films that Chen made?

A. I don't see how you could. I mean, you would have to make even more assumptions, and those assumptions couldn't be right.

Q. Now, if we remove that Estradial curve, and just look at the other three on the next slide, what portion of this are you saying is steady state?

A. Well, I don't want to overstate this. I mean, to me it's an estimate.

But it looks like, if you eyeball these things like -- and I haven't done statistics on it -- but if you eyeball it, it looks like for four minutes to ten minutes it's fairly steady. I mean, again, what I'm trying to do here is give the best assumptions, sort of to the other side and say, well, if you assume all the things that Dr Dyar said are

true, you could get anything out of this?
So to me, if you do that, I think for 10 minutes seem -- you know, that -- it's looks like it could possibly be a steady state.
Q. Now, did Chen test multiple film samples for each of these three drugs that are listed here?
A. Yes.
Q. Okay. And how do you know that?
A. Well, he's got error -- she's got error bars. So an error bar certainly implies that there are multiple points.
Q. Okay. And the points that are actually on the curves, what do those stand for?
A. I believe they stand for standard deviations.
Q. Are you talking about the vertical bars or the points on the curves?
A. Oh, the points on the curve are the means, and the vertical bars would be the standard deviations.
Q. Okay. So using those means, and standard deviations, how would a person of ordinary skill in the art know what the entire



range of sample measurements was?
A. I'm not sure I understand the question exactly.
Q. Well, so, if you have those means and standard deviations, how does a person of ordinary skill in the art calculate what the entire region of --
A. Oh.
Q. -- samples values are?
A. So what you do is, there's actually what is called a three- segment rule.
And if we can just go to the next slide.
So here are the standard deviations.
One standard deviation is 68 percent. Well, with the two standard deviations is 95 percent. And three standard deviations is close to 100 percent.
So if people use, statistically, three standard deviations to get the whole range.
So, basically, that's called a three-signal rule.



Q. And when you say "people use" this, is this something that is commonly applied by those of ordinary skill in your field of pharmaceutical development?
A. Yes.
Q. Now, can you show us what Figure 5 would look like if the errors bars were triples to account for the three-signal rule?
A. Yes. So these are some estimates, but you triple them, and they look like this, and they go outside that 10 percent range.
Q. So what does this data -- now that you've applied all of the assumptions that are most favorable to defendants, and Dr. Dyar's position, what is the most that a person of ordinary skill in the art could possibly take out of the Figure 5, in terms of whether the Chen films were uniform for drug content?
A. Yes. Well, given those assumptions, it would show you that they don't. They are not within the 10 percent range.
Q. And I take it, then, if they are not within the 10 percent range, would they be within the 5 percent range of claim 65?



A. Pretty hard to do that. They are not in the 5 percent range either, obviously.
Q. All right.
Let's move on to the statement in Chen that Dr Dyar pointed to about viscosity on page 13 of his article.
That's JTX-187, page 13, Lines 1 and 2.
(Pause)
A. Okay.
Q. So the sentence that Dr Dyar pointed to was, "A factor that plays a significant role in determining the properties of mucosal surface coat forming a composition is the viscosity of the hydrocolloid."
And my question to you, Dr. Langer is, does that say anything -- what does that tying viscosity to, is that drug content uniformity or something else?
A. No. When you read the whole patent, it really doesn't -- that's not the point of the patent. It doesn't really address drug uniformity.
What it's addressing is good

mucosal adhesion. You know, if you swallow it, you put it, say, in your mouth, would it adhere well and function well?

So it's about something totally different.

Q. Now, taking Chen as a whole, would a person of ordinary skill in the art understand how to make uniform films by changing the viscosity of, or by controlling the viscosity of those film formulations?

A. I just don't see how. I mean, there's no instruction on them.

Q. The next reference that Dr. Dyar used in his obviousness combination was the Bess '116 patent.

Did Bess teach drug content uniformity in pharmaceutical film?

A. Well, why don't I put up the next slide.

Bess does not. Just some quote.

Bess say, "The films were prepared by adding the oil mixture to the hydrated polymer gel and mixing until uniform." Then there is simply deaeration and casting.



But, basically, again, Steps 3, 4, and 5 in the chart I showed, aren't there. And stating the that coating preparation may be uniform, doesn't mean that the finished film maintains uniformity, certainly not given all the things that we've seen. Another statement is that the film is -- this is in the bottom -- preferably air-dried, or dried under warm air, and cut to a desired dimension, packaged, and stored.

They also talk about the examples being dried under warm air.

But, again, all of these things that we've seen just show that that doesn't -- you just have no idea whether that is giving you drug content uniformity, unless you do a careful selection of these things.

Q. And there was a discussion today I had with Dr. Dyar yesterday about drying, as shown in the in the Chen reference, I believe it was Slide 19 from Dr. Dyar's slides?

That's the one. Thank you very much.

Okay. So Dr. Dyar put up this



slide, and the picture at the top there is from Figure 2. That's the portion that's the drying oven in Chen.

And he said that "The air flow changes from not being directly on the film, to being directly on the film, as you move along the conveyer belt."

Did you review that testimony?

A. Yes.

Q. Okay. In your mind, is that uniform drying?

A. It isn't, but you just can't tell. I mean, there's just no information given on the patent. There is no legend on the figure. You can't tell what they're doing. I mean, you would have to make a lot of assumptions.

Q. When you looked it at Figure 2 of the Chen reference, did you view that as a diagram of the actual drying equipment or a schematic?

A. Well, it's certainly a schematic.

Q. Is there any information given in the Chen reference about the particular equipment used for drying, or the air flows that



are coming out of these vents?

A. I couldn't find any.

Q. Going back to the Bess reference -- and sorry for the diversion -- does the Bess '116 patent say anything about the effect of film matrix viscosity on maintaining drug content uniformity?

A. No.

Q. Does either Bess alone, or in combination with Chen, render the asserted claims of the '514 14 patent obvious?

A. I would not think so for one of ordinary skill, no.

Q. Now, I just want to briefly touch upon the two background references, starting with the Leung '298 patent, which is JTX-183, the Leung patent.

And can you tell me, based on your review of the Leung '298 patent, how did it impact your analysis of obviousness?

A. Well, again, it's the same kind of thing. There is no disclosure of a de-active content uniformity during any stage of the casting process, or in the finished film. There

is no disclosure for particulate active or particle size range.

You know, they actually, if anything, teach the opposite. They point out hydrating the film forming agents in the presence of electrolytes in solution effectively lowers rather than raises the viscosity of the polymer gel being formed.

So that's actually the opposite of what '514 patent. So, if anything, it would teach away.

Q. Now, when Dr. Dyar put up the Leung patent, he had a picture of the Listerine pocket pack strips.

Those Listerine strips, are those subject to the same drug content uniformity requirements that a pharmaceutical would be?

Or, actually, let me take a step back.

Do those even have a drug in them?

A. I was just going to say that myself. They don't have a drug in them. And, obviously, they are not subject to it then.

Q. And then the next background



reference I would like to ask you about is the Lachman reference, JTX-238.

A. I probably should have also mentioned that I was on the Warner Lambert Scientific Advisory Board when a lot of that was done as well. So I have a little bit of knowledge about that.

Q. And, actually, I take it back. The Lachman reference we've already discussed. So I'll skip ahead.

Looking at these four references -- so going pack to Slide 1717 -- looking at those four references, would a person working in the in the 2002 time period have been motivated to combine any of these references to make a pharmaceutical film with a particulate active that met the drug content, that the 10 percent or 5 percent drug content uniformity requirements of Claims 62 and 65?

A. I just don't see how.

Q. And do any of these references teach a person of ordinary skill in the art how they would make a pharmaceutical film with an active ingredient that met those 5 or 10 percent



drug content uniformity requirements?

A. No, they do not.

Q. Now, I'd like to turn to Dr. Dyar's indefiniteness arguments.

Do you understand that Dr. Dyar is arguing that claim 62 is indefinite, because it should be interpreted as meaning that the final cast film has a matrix that is still flowable, has viscosity, even after its been dried?

A. That -- that was my interpretation of his interpretation, yes.

Q. Okay. Do you agree with his argument that the claims of the 514 patent are indefinite?

A. I don't, no.

Q. Let's go to claim 62. I think slide 1730.

I'd like to focus on the highlighted clauses.

So the start of the claim reads "A drug delivery composition compromising a cast film."

What does the term "cast film," as used in the claim here, mean to a person of



ordinary skill in the art who has read '514 patent?

A. Well, I think it means what it says. It means you made a film by casting it and operating off the solvent.

Q. And when you say "casting," is that the five-step process that you were talking about earlier?

A. Yes, that's right.

Q. But this claim also describes the cast film as compromising a matrix that is quote, unquote, "capable of being dried."

Do you see that in that bottom highlighted portion?

A. Yes.

Q. So how would a person understand that limitation about the matrix of the dried film?

A. Well, I mean, it's -- just to make sure, you're talking about the very last statement?

Q. Yes.

A. Well, I think it says what it says. It says, "Water soluble or water soluble

film forming a matrix is capable of being dried."

So that matrix is capable of being dried.

Q. So, now, the matrix that is actually in the final product is already dried, correct?

A. In the final product that's dried, yes.

Q. Okay. So this -- is this term "flowable," does that mean that the final matrix in the film has to actually flow?

A. I certainly don't read it that way, no.

Q. Okay. So when does the matrix that is discussed in this claim have to actually be able to flow?

A. Well, prior to casting.

Q. So that would be when it's in the tank in Dr. Dyar's animations?

A. That's fair, yes.

Q. Okay. And this claim also talks about the matrix having a viscosity.

Does that apply to the matrix



after it's already been dried, or is it, again, talking about the matrix, the qualities of the matrix when it's in the tank?

A. The qualities of the matrix when it's in the tank. The latter of the two things that you said.

Q. Okay. Now, I'd like to ask you about the specification. Are there examples in the specification of the '514 patent, where they talk about this wet casting process?

A. Yes.

Q. Can you show us some of those?

A. Yes. So in the abstract, it says "The composition may be formed by wet casting methods where the film is cast and controllably dried."

It also says, "Wet cast films" -- and it says in the "wet casting process."

And then a third example, it says, "The film products of the present invention may be produced by a wet casting method."

Q. And are there also examples in the specification, or portions of the



specifications, that you could give us as an example that talk about the matrix as capable of being dried?

A. Yes. Why don't I go to the next slide.

So here they are talking about having a drying wet cast films.

And it says, "The wet film may be dried."

And then further it says, "Wet cast film forming methods."

And they point out, again, in the yellow place, "The matrix formed by this combination is formed into a film desirably by roll-coating and then dried."

Q. Now, where in the specification, or at least the example portions of the specification, does it describe -- the matrix, says "flowable and having a viscosity"?

A. Right. If you can go to the next slide.

So here I'll just, again, read these statements.

It just says, basically, "The



flowable water soluble film forming matrix is formable into a dry film."

Here in the second passage, "Flowable water soluble film forming matrix is capable of being dried."

All very consistent with the claims.

And, again, the third one, "Uniformity must be maintained as the flowable mass was formed into a film and dried."

Q. And then what about examples of where the specification talks about the matrix always having a viscosity?

A. If we could go to the next slide.

Okay. Here we are.

So, again, here it just says, "In addition to the viscosity of the film or film forming components or matrix."

It goes on. Here, again, it says, "In a viscol elastic fluid matrix with acceptable viscosity values."

Q. Now, given all of that discussion in the specification, and language in the claims itself, would a person of ordinary skill in the

art, who knew about the casting of film, have understood the scope of the claims of the '514 patent with reasonable certainty?

A. I believe they would, yes.

MR. BRAHMA: Thank you, Dr. Langer.

I have no further questions.

But I would like to, just as a housekeeping matter, enter PTX-205, the Nowak reference. PTX-210, the Borges II reference, and PTX-212, the Kathpalia article.

THE COURT: All right. Okay.

We'll take a break in a second.

Doctor, you can step down if you want.

THE WITNESS: Okay.

(Witness excused.)

THE COURT: I just want to clear up now, in terms of the defendants' objection, I wrote down that you objected to JTX-213, 215 and 216.

Are there any other trial exhibits that you are objecting to?

MR. LOMBARDI: Your Honor, my list



from the charts that we're looking at has 213, 216, as your Honor said. I believe there was a 205, a 212, and a 210.

THE COURT: That were offered by Mr. Brahma.

MR. LOMBARDI: And that was on the chart. And, so, if I neglected to say it, that is part of our objection.

THE COURT: All right.

Mr. Brahma, you were offering those six exhibits for what purpose?

MR. BRAHMA: The relevance would be to show the state of the art, or state of mind of a person of ordinary skill in the art, with respect to their understanding of the difficulty, the continuing difficulty of achieving drug content uniformity in films, as well as what assumptions they would make when reading prior art references that had no data showing uniformity.

THE COURT: So is it case then, you are not offering them to prove any secondary considerations?

MR. BRAHMA: There is some -- also



some statements about secondary considerations such as trays from the -- and we are offering them for that purpose.

THE COURT: Okay. Well, be more precise, because what I'm trying to do is narrow down what is going to be disputed later on.

So you're offering some of these for?

MR. BRAHMA: Well, so, for -- yes. For example, your Honor, the Perumal, the Morales article, and I believe the Borges Article refers to -- specifically to the work done in the '514 patent, as both recognizing the problems that caused drug content uniformity, as well as solving those, and basically creating viable pharmaceutical products.

THE COURT: Okay. You're offering these for praise, and then there's portions that you are offering to essentially show what the state of the art was at some later point in time that you can infer back? Or are you offering -- well, I don't want to make your arguments for you.

So I've the praise, and I've got



something to do with the state of the art, is there anything else?

MR. BRAHMA: I think those are the two things. And if you want me to clarify the argument about the state of the art, the basic argument is, if it wasn't solved in 2015 or 2008, then it sure wasn't solved before 2002.

THE COURT: Okay. I think I understand that argument.

And your objection to those for argumentative purposes is what?

MR. LOMBARDI: Well, with respect to anything going to the obvious -- not to second considerations, but the prima facie obviousness showing is all post-filing.

And, so, therefore, it's hearsay, and there's no state of mind issue here.

THE COURT: So why is it hearsay if it is post-filing, and not hearsay if it is pre-filing?

MR. LOMBARDI: Pre-filing is prior art. And the prior art has a special position in obviousness.

As your Honor knows, post-filing

does not have that special position. And, so, it just becomes an article written by somebody who's not in court. And, so, therefore it's hearsay.

THE COURT: Okay. So that's hearsay.

In terms of the secondary considerations, are you not objecting to the extent it's offered for that basis?

MR. LOMBARDI: And if I understand, it was the Borges' article PTX-210. I think I knew specifically -- let me address that.

I think the Borges one is the one that occurred to me as one that might be secondary consideration. That was something about the success of the product on the market.

That has nothing to do with the analysis that this witness did. He was not a market share witness. And it doesn't say anything about the technology.

THE COURT: Okay. So that's a relevance objection, right?

MR. LOMBARDI: Yes. I'm not



stating a hearsay objection to that particular part of the article.

MR. BRAHMA: And to the extent there's a relevance objection, I'd note that all of those articles were discussed by Dr. Dyar.

So if there are relevant for Dr. Dyar's analysis, I can't see how they won't be relevant for our analysis, just because defendants don't agree with the conclusions, your Honor.

THE COURT: Well, did he discuss them only because he knew that you were going to be discussing them?

MR. BRAHMA: I mean, they were certainly mentioned in our reports first in terms of the expert reports.

THE COURT: Okay.

MR. BRAHMA: But then he talked about what they meant.

THE COURT: All right.

So there's a hearsay objection to the state of the art purpose for which you offered them, and there's -- and your response to the hearsay objection, I'm getting from what



you said beforehand, is essentially experts use these kinds of things.

Is there any other --

MR. BRAHMA: That's right. And just to clarify on the secondary factors, because there are a number them, I mean, this is also -- to put it in the classic terminology, I guess, this also talks about the failure of others to solve the problem, right?

So we were talking -- it was before I just summarized if they hadn't solved it in 2008, they hadn't solved it in 2002. This is really talking about the failure of others.

So, for example, Perumal looks at pre-2002 articles, and notes that the films don't even talk about drug content uniformity. And from that drew the conclusion they must not have had drug content uniformity.

That's failure of other evidence.

In terms of the argument that the prior part somehow isn't hearsay, but post -- post-patent is hearsay, I'm not aware of any case.

THE COURT: That's something that



you can brief later on.

Is there anything some else that you want to say?

MR. LOMBARDI: There was one other point that I did make -- I guess I've got two, your Honor.

On the failure of others, there was no discussion of failure of others in any of these references with the upon exception of Perumal.

That's not what they were offered for. That's not what they did.

And in Borges, PTX-210, was not in the witness's expert report, and he never talked about these kinds of secondary considerations.

THE COURT: Okay. So not in the expert report. That's not, I don't think, an objection that you made in your Motion in Limine.

MR. LOMBARDI: Well, I don't believe that we knew that they were going to present it at trial. I'll check, your Honor, but I don't think we had any notice that they were going to use the document at trial for this

purpose, because it wasn't indicated.
MR. BRAHMA: In his expert report at Paragraphs 142 and 143.
THE COURT: Okay. So that's on the record.
See, and that's part of the reason why it occurred to me that I ought to do something more about this is, because, you know, objections that it's not in the expert report, or objections that are different than what you said in the Motion in Limine, they need to be fleshed out now, at least as to what the parties' positions are, so that if somebody wants to do something about it, they can.
So I think I've heard what the parties' positions are. I'm not suggesting you should, Mr. Brahma, but if there's anything, having heard this statement of what the positions are, that you want to do further with Dr. Langer, I'll give you that option when we come back.
You don't have to, but, you know, I should have fleshed this out a little more at the time.



MR. BRAHMA: Sure. I'll confer with my team and let you know, your Honor.
THE COURT: All right.
So we'll take like a 10-minute break.
(A recess was held at this time.)
- - -
THE COURT: All right. Please be seated. Please continue.
MR. BRAHMA: Your Honor, Plaintiffs do not have any further questions for the witness.
THE COURT: All right. Cross-examination.
MR. LOMBARDI: May I please the Court, Your Honor.
- - -
BY MR. LOMBARDI:
Q. Dr. Langer, my name is George Lombardi. I will be asking you some questions on behalf of the Defendants here.
A. Nice to meet you.
Q. Nice to meet you. Doctor, you have testified in patent cases before; is that



right?
A. Yes.
Q. Generally, you're not a lawyer but you're familiar generally with obviousness and what the analysis is for purposes of the obviousness; is that right?
A. Well, I don't want to overstate my qualifications. I have some sense of it as scientist or somebody who teaches people of ordinary skill. But I do not want to overstate. I'm not a lawyer.
Q. And you understand at least from your work in this case that when you do an obviousness analysis, what you're really looking at is the claims of the patent in question; is that right?
A. Well, again my feeling is you look at the claims in light of the specification as I've understood it and in light of the prior art.
Q. Well, let me just ask you: For purposes of what you're determining what you're determining, whether it's obvious or not, are the claims in question; is that right?



A. Well, I stand by my answer. Again, I'm trying to say it as a scientist or somebody who's looking at it through the eyes of somebody of ordinary skill. So to me it is the claims in light of the specification. I don't want to get into a legal argument with you. I'm just going over how I've understood it to answer your question.
Q. And I'm trying to make you get into a legal argument. I just want to understand what your analysis was in this case. So you understand that claim 62 of the '514 patent was at issue here; is that right?
A. I believe that's was one of them among others.
Q. Correct, among others. But do you consider this a representative claim?
A. It's a claim. I don't know if -- again, it's certainly a claim, yes.
Q. Well, is it okay if we talk about that claim as an example?
A. Anything you want.
Q. Okay. Well, let's talk about it, because in obviousness what we want to figure

out is what was known in the prior art. That's one of the things we want to know based on what's in the claims; is that right?

A. Again, I don't want to get -- claims in light of the specifications.

Q. Well, you did look at the claims, right?

A. I said, yes, of course.

Q. So the claims set forth various elements; is that right?

A. Yes.

Q. Doctor, I don't think we have a dispute about some pretty significant portions of these elements as part of your obvious opinion. Do you agree with that?

A. I'm not sure what you're saying.

Q. Let me restate it. So there's no -- you don't contend that at the relevant time it was novel to come up with a cast film? That's not your contention, right?

A. No, I agree with you.

Q. And you agree that it was not novel to use water soluble or water swellable polymers?



A. Again, if you're just isolating individual elements, I agree.

Q. And you agree there was nothing novel about using an active?

A. Again, if we're isolating individual elements, I agree.

Q. If you skip down to 2(i) you agree that there was nothing novel about using a particulate active?

A. Again, you're only asking that particular phrase and stopping there; is that what you mean? You're taking about the substantially uniformly stationed?

Q. Yes, sir, I am.

A. If you're taking away that, then I agree.

Q. And you agree there was nothing novel about a taste masking agent at the relevant time; is that right?

A. Again, we're just isolating individual elements in and of themselves, I'm agreeing with you.

Q. And then where it says wherein, you agree that it was not novel to use a



particulate active that has a size of 200 microns or less; is that right?

A. Again, with the same caveats that you and I have been talking about, about an isolation, I agree.

Q. There are a lot of references in the claims and I won't pull them up but I think you will know, there are a lot references in the claims to the concept of uniformity. You remember that, right, Doctor?

A. I do remember that, yes.

Q. Now, there was nothing novel at the time of this invention about a scientist being concerned about the uniformity of a pharmaceutical dosage form, was there?

A. We're now excluding a pharmaceutical film dosage form or are you saying any dosage form?

Q. Any dosage form.

A. I'm not sure how to answer it. I guess I would say if somebody came up with a brand new dosage form -- I just want to make sure we're on the same page. If somebody came up with a brand new dosage form, whether it's a



thin film or some other dosage form, there would be concerns. Any time you do something new, there are concerns.

Q. Let me put it this way, in 2001 a person of ordinary skill in the art who was making a pharmaceutical dosage form would be concerned with being able to make it uniform; is that right?

A. To me that's too narrow an interpretation. They would be concerned about making it do what they wanted it to do. Some cases uniform is not actually not what you want, so it depends on the situation.

Q. A scientist who is trying to work on a dosage form to put on the market, Doctor, would want it be uniform; isn't that correct?

A. Not always. If you want, I'll give you examples. That is not a correct statement on your part.

Q. Well, let me ask you this: The FDA had a requirement, but not -- scientists not only were concerned about uniformity, but they were concerned about getting uniformity to this 10 percent variance level, weren't they?

A. In which situation? Some scientists were depending on the dosage form.

Q. If a pharmaceutical formulator as of 2002 were pursuing a commercial product, that formulator would have had as his goal being within 10 percent variation, correct?

A. It may depend where in the world they were doing it, whether it's the FDA or what. There's different situations so you would have to narrow down the situation. That's all I'm trying to say.

Q. You gave a deposition in this case?

A. Absolutely.

Q. And you were under oath when you gave it?

A. Of course.

Q. And of course you answered honestly at the deposition?

A. Of course.

Q. Let's go to page 137 of the deposition.

A. Yes. If I remember Pages 136 and 137, those questions were asked.



Q. Well, let's read it and let's see. Did you give this answer at your deposition.

"Question: If a pharmaceutical formulator as of 2002 were pursuing a commercial product, that formulator would have had as a goal being within 10 percent variation, correct?

Answer: I would think that would be one of the goals, yes."

Did you give that answer to that question under oath at your deposition?

A. Absolutely. But the problem with that is you're taking it in isolation.

Q. And you were asked the question at your deposition and you gave that answer under oath?

A. Of course. But you can't take one page out of the book.

Q. Thank you, Doctor.

A. Okay.

Q. Now, actually at the time, at the relevant time, the folks that wrote the patent also talk about a known level of uniformity?

A. Right. That's at my deposition at 136.



Q. Well, do you recall what the patent says the level of uniformity was that anybody of skill in the art would want to pursue?

A. I do remember that and I can go over that. But the way that was written and actually --

Q. I just asked you if you remember.

A. I remember, yes.

Q. Do you remember that it was 10 percent?

A. We should look at the precise wording, but I do remember that. I remember what they wrote.

Q. Okay. Let's go back to Column 2 of the patent.

A. Do you want to put it up?

Q. I'm sorry. We're just getting it up.

A. No problem.

Q. So Column 2 and let's go down to about Line 40. Let's just go right after where it says FDA. Do you see it says currently?



A. Yes.

Q. Currently, it's as required by various world regulatory authorities dosage forms may not vary more than 10 percent in the amount of active present. When applied to dosage units based on films, this virtually mandates that uniformity in film be present.

Do you agree with the patent's characterization of the state in the art in that regard?

A. Yes and no. Would you like me to explain?

Q. No. That's what the patent says; is that right?

A. Yes. But the FDA says 15 percent. That's also very important to realize.

Q. But you're not --

A. The statement is correct, but the FDA 15 percent. That's all I'm saying.

Q. Thank you, Doctor. Now, we're going back to the claim. And if you need us to blow it up more or you want a particular part blown up, just tell me, Doctor, and we will do it.

A. No problem.
Q. But I'm assuming you can see it okay?
A. I can see it. Plus I have it here in front of me.
Q. Great. It says -- there is discussion of viscosity in this patent claim; is that right?
A. Yes.
Q. And I believe the first mention is up there by the wherein. Do you see the reference to viscosity there?
A. Yes.
Q. And it also references -- well, let's just talk about that. It says, Wherein said matrix has viscosity sufficient to aid in substantially maintaining nonself-aggregating uniformity of the active in the matrix. Do you see that?
A. Yes.
Q. Now, viscosity is essentially talking about the thickness of a substance; is that right?
A. It has to do with -- how are you



defining thickness? What do you mean?
Q. Consistency.
A. Constituency?
Q. As far as to water --
A. Thickness this way, you mean? I think we're on the same page. It has to do with -- a syrup would be more viscose than water, for example.
Q. And it says that the goal of working with this viscosity parameter is to get a nonself- aggregating uniformity of the active in the matrix. Do you see that?
A. Yes.
Q. You understand that nonself-aggregating means that the particles that are being put in the matrix won't clump together, for instance?
A. Yes, I agree with that.
Q. So you agree that this claim doesn't set any specific viscosity levels, does it?
A. Well, it says the viscosity sufficient and then it would tie it back into the 10 percent that we were just talking about



at the end of the claim.
Q. But you know there's a measurement of viscosity, right, a unit of measurement?
A. Sure.
Q. What is that?
A. Well, it could be poise or centipoise. It depends on what system you're using.
Q. And it doesn't specify centerpoise; is that right?
A. I agree with you.
Q. And there's nothing anywhere else in the claim that specifies a viscosity level; is that right?
A. Well, again, the way I look at it is through the eyes of one of ordinary skill in the art. It's a teaching of a viscosity sufficient to do that, that ends up giving you that uniformity of 10 percent, that we discussed, later on and does the other things that are talked about in this claim.
Q. And another thing that's mentioned in the claims is drying, correct?
A. Yes.



Q. And let's just find one that references to drying. Let's go to the wherein second from the bottom about the third line down just to give you a reference, Doctor. There are other references but this is an example.
It talks about the film forming matrix is capable of being dried. Do you see that?
A. Yes.
Q. Now, the claim -- in none of the claims
you looked at specifies parameters for drying, is that correct, it does not specify?
A. Not parameters. But again, you would reed it in light of the specifications.
Q. But in the claim -- and the claim is what we're deciding whether this is obvious or not; is that right?
A. Yes. But again -- again, I'm not a lawyer. I always thought, and you correct me if I'm wrong, that you read the claims in light of the specification.
Q. And my question is, there is no parameter for drying contained in this claim;

is that right?
A. Other than reading -- other than one of ordinary skill in the art would have read the patent and understood what's important about drying and what's not important.
Q. One other element I want to point out.
It's in the next wherein. It says, Wherein the uniformity subsequent to casting and drying of the matrix is measured by substantially poised individual unit doses which do not vary by more than 10 percent of said desired amount of said at least one active. You've read that many times before, Doctor?
A. Yes, I've seen it.
Q. An it talks about a mearsurement -- is it fair to call it kind of a 10 percent variation measurement?
A. I think I know what you're saying and I'm fine with that.
Q. But it doesn't specify a particular way of doing the 10 percent measurement in the claim, does it?
A. But it does in the specification. They give examples.



Q. But it doesn't specify -- well, first, let's take the claim. It doesn't specify in the claim; is that right?
A. Again, we're going beyond my --
Q. Is it in the claim? That's all I'm asking here.
A. Well, if you're just isolating it to that, I think that one of ordinary skill in the art would probably understand what I said about the three-sigma rule, but they give examples in the specifications and that's why I give it --
Q. I'm glad you mentioned the three-sigma rule. Actually, the specification doesn't point out a single method of testing for variability, does it?
A. I think they do. Let me try to see if I can find this for you.
Q. Don't they pick out a number of methods? Doctor, do you remember that?
A. Well, they gave specific examples where if you go through the calculations you get -- you can tell that they're basing it on what I said. I can try to find the examples



for you.
Q. I think I will showing them to you in a little bit. But right now just to understand what you recall about the specification of the patent, is it your testimony that one specific method of testing for variability is what's in -- what the patent calls for? Is that your understanding?
A. I thought they were talking about what I was going over, statistical variation.
Q. Do you think they talk about statistical variation --
A. Maybe I should try to --
Q. Because I have limited time, I will let your lawyer find the place. Is it your understanding -- what did you call it, sigma?
A. Three-sigma rule.
Q. That's discussed in the patent?
A. It's not like that, but they give an example. In fact, Table 5 and Column 44, if you go through that, they're talking about four percent based on the average. So if you go through that, I think you will end up with the



types of things that I'm saying.
And if you go through that analysis on Table 5 you will see that that when you go through the numbers they give you, that if you get four percent, then you're going through that type of analysis.
Q. Well, let's put it up. It doesn't say anything about sigma, does it?
A. It doesn't use those words, no.
Q. And it doesn't say anything about standard deviation, does it, Doctor?
A. It doesn't use those words, no. But it does say four percent based on average.
Q. And we will talk about the testing, Doctor. But do would you agree with me
that the patent specification doesn't say to use this sigma calculation that imposed on Chen?
A. It gives an example. That's all I can say.
Q. And this is an example, this Table 5?
A. That's an example. There may be

--

Q. That doesn't say anything about sigma?

A. It doesn't use those words.

Q. And doesn't say anything about standard deviation?

A. It doesn't use those words, correct.

Q. In fact, there are lots of ways -- are you aware of the various ways that you can test as according to the specification for variability?

A. Well, I'm not sure I understand what you're asking exactly.

Q. Well, let's put the patent aside for just a second. There are lots of ways you can measure for content uniformity; isn't that right?

A. You mean analytical methods or statistical methods?

Q. Any method?

A. Basically, what you do -- they give instructions on this, you take the different examples, I can try to find those for



you too, you dissolve a way -- the material, the polymer, and then you use an analytical technique to determine what the drug level is.

Q. Did you know that the patent uses weight as a means of measuring content variability?

A. They mentioned that, but they've mentioned several methods.

Q. That's what I'm trying to get at. They mention several methods, don't they, Doctor?

A. Well, I think once you realize when you read, it's certainly but not that you would want to use. To be rigorous is a chemical method. That to me is what one of ordinary skill in the art --

Q. They mentioned a number of method, Doctor?

A. They mentioned visual inspection, they mentioned weight.

Q. What the patent says is that one of skill in the art can use whichever method they would like to use?

A. Why don't you take me exactly



where you're looking at.

Q. Why don't we just go here, Column 36.

A. Okay.

Q. It's Line 19 testing for uniformity?

A. Yes.

Q. And it lists a number of ways it can be checked for uniformity. You can take samples of the film that you can remove and test, you can do film thickness, color, assay and active ingredients and overall appearance may be checked?

A. Yes. When I do things myself, I use those things as a starting point. But if I've giving a number, then I'm going to use something like a chemical method and they give them too.

Q. Well, we will talk a little bit more about that in a little bit. Well, let me ask you this in particular -- well, can we put up his slide PDX-1711, please?

You have testified in this case and I believe this morning, Doctor, what you view as the



key inventive part of this patent; isn't that right?

A. I talked about that, yes.

Q. Now --

A. But I think there are several key inventive parts.

Q. But you put this slide up and you talked about this, that this is the important part, the key inventive part of the invention, isn't it?

A. Yes. And also drying and things like that.

Q. Well, let's look at it. So you're quoting from the patent and you say, We'll come to the top one in just a second.

A. Sure.

Q. Let's take the second one first. Casting dispersion must have viscosity low enough to process but high enough to limit migration and aggregation of active. Do you see that?

A. Yes.

Q. Now, that is an inventive step in your mind?

A. Yes.

Q. One that a person of ordinary skill in the art would not be able to come to without the assistance of this patent?
A. I haven't seen it in general and all the things that were cited, certainly not in Chen, and certainly not as we noticed, the six future articles that we looked at?
Q. So it's clear I'm not limiting to you to what's in writing in an article. I'm asking whether that would not have obvious to a person of ordinary skill in the art?
A. It clearly wasn't. Any time somebody invents something, after the fact these things become more simpler.
Q. Well, let's see. What it says is casting dispersion and casting is referring when you put the matrix into the cast, you're actually making the film, you're casting the film, right?
A. Yes.
Q. And casting dispersion must have viscosity low enough to process. Do you see that?
A. Yes.



Q. That means it has to have a viscosity low enough so you can actually get the film -- the matrix to go into the cast, right? It's got to flow enough to go into the cast, right?
A. Yes.
Q. Now, anybody of skill in the art would know that you have to have a low enough viscosity to get the matrix into the film, wouldn't they, Doctor?
A. I think that part is true. By the way, I think it's also important to realize that you're taking these comments in isolation, which I did.
But clearly as I tried to point out in my Direct, you're balancing all these things with other properties you want like release kinetics --
Q. Doctor, I'm just working for the slide you put up, right?
A. I understand. But --
Q. Can I ask you more questions about it?
A. Of course.
Q. And the second half says, But high



enough to limit migration and aggregation of active. Do you see that?
A. Yes.
Q. So Part 2 of this inventive concept is this viscosity, the thickness, has to be high enough to limit the particles from moving around?
A. Yup.
Q. And preventing them from aggregating, right?
A. Yes.
Q. Doctor, wouldn't somebody of skill in the art have understood that the matrix has to be thick enough to prevent particles from flowing?
A. After the fact it sounds straightforward, but it's not. People don't do it.
Q. I'm talking about at the time somebody of skill in the art -- you have this mixture that you are going to put into a cast and you know there are particles in that mixture.
It would take an inventive concept to



know that you just want it to be thick so that the particles won't flow?
A. Like I said to you, when we first started doing it ourselves when I asked my students --
Q. That wasn't my question.
A. Well, it is, because --
Q. You didn't answer my question.
MR. BRAHMA: Your Honor, is Mr. Lombardi going to actually let Dr. Langer answer the question?
THE COURT: Sit down. He's fine.
THE WITNESS: As I said, he thought it was like breaking glass uniformly. I don't think it was very easy to do, and nobody did it.
BY MR. LOMBARDI:
Q. What the patent doesn't do is give direction on the exact viscosity that anybody of skill in the art should use to achieve low enough viscosity on the one end and high enough on the other?
A. Is that a question or --

Q. That's a question.
A. It gives you ranges, but those ranges are broad.
Q. Huge, right?
A. Huge is a relative word.
Q. Well, actually, Doctor, what you think is that while you say that this is inventive, you believe that a person of ordinary skill in the art just given this information would be able to figure out what to do; isn't that right?
A. I think once you understand that and you understand something about the drying conditions and the particle size, then you have a teaching by which you can do a routine experimentation. Once you're taught the trick, so to speak, of locking in and drying correctly, I think one could, yes.
Q. When you say locking in, by locking in, you mean locking the particles in position within the matrix?
A. That's part of what you're doing.
Q. I'm just asking what you mean when you said lock in. And that's what you're



referring to; isn't it?
A. Locking in, in such a way that you're controlling, that they really can't migrate anymore and that you can dry it appropriately.
Q. Doctor, there is actually significant information in the art at all times prior to 2001 -- I shouldn't say all times, but prior to 2001 concerning viscosity and the use of viscosity to affect the flow of particles; isn't that right?
A. There certainly are articles that talk about some of those things, yes.
Q. So it was known in the art back in 2002 and prior that when you have a suspension like this or you have particles within a matrix that viscosity can affect the movement of those particles. That was known, wasn't it?
A. In certain context, but not when you combine the many different things that you had to do to get the film to work.
Q. Actually, the claims just talk about viscosity, is that right, not all of these other --



A. It talks about the entire combination. You can't isolate different elements. You have to put them all together.
Q. Would you agree with me, doctor, that it was well known in the art in 2002 and before how to produce a stable suspension of particles?
A. I'd have to see the situation, what you mean by stable and under what conditions.
Q. By stable I mean particles that don't move much in the matrix.
A. I would have to see the situation.
Q. You talked about the Lachman reference, is that right, this morning?
A. Yes.
Q. Isn't it true that the Lachman reference --
A. Well, actually I'm not sure we did.
Q. You at least put it up on the screen, I think?
A. I did -- no, it was put up on the screen.



Q. If I missed that, then I apologize.
A. To be correct, I think it was put up on the screen and not discussed.
Q. Lachman is a source that's in the prior art; is that right?
A. Yes.
Q. And you would agree with Lachman that when you have a suspension that has particles in it and a matrix, that those particles can fall in the matrix and aggregate depending on various factors; is that right? That was taught by Lachman; isn't that right?
A. Do you want to put Lachman up so we can answer the question?
Q. Can you answer the question as I put it?
A. I want to take a look at Lachman to make sure we're on the same page.
Q. Well, let me ask you generally, it was known prior to 2002 that you can affect particles and whether they're mobile or not within a matrix
by -- you can affect that by playing with the

viscosity?
A. Are you talking about vertically or horizontally or --
Q. Either way.
A. Again, I would have to see exactly what you're referring and what you were trying to do. I think you're oversimplifying it tremendously.
Q. Would you agree that it was known in the art that the parameter most powerful in changing the velocity of the settling of a particle is a diameter or radius and the formulators are best able to control that and the viscosity of the medium.
A. So you're talking about settling vertically now?
Q. Yes.
A. So we're not talking about horizontal movement or any of the other seven or eight parameters that I talked about on my Direct. So you're just talking about settling?
Q. Yes.
A. Can you read the statement again.
Q. Formulators are able to control



the viscosity and thereby have an effect on the settling of the particles.
A. I think that that's probably fair in isolation. Again, I want to see it in context.
Q. In fact, Stokes law you talked about this morning, I think that goes back to 1850s or thereabouts?
A. That was one of the eight different forces.
Q. And Stokes law is actually something that is discussed for several columns in the patent; isn't that right?
A. Correct.
Q. And that's to discuss the positioning and the migration and things like that of the particles within the matrix.
That's why they're talking about in the patent, right?
A. Vertically.
Q. Right.
A. But horizontally, you don't want to ignore that either. That's critical.



Q. But I'm talking about Stokes law right and all the elements of Stokes law were well known at the time, meaning 2002 or before; isn't that right?
A. I guess I'm not sure exactly what you mean by when you're saying all the elements were well understood.
Q. I mean Stokes law, is it fair to call them variables that go into Stokes law?
A. Sure.
Q. That was all well known in 2002 and before; isn't that right?
A. You mean the equation of Stokes law?
Q. Yes.
A. The equation was understood. People are still studying exactly how accurate it is today.
Q. And part of the equation was the viscosity of the suspension; isn't that right?
A. That's one parameter, but there's other things in the law.
Q. There's settling velocity, there's density of particles, there's density of the



liquid, there's the radius of particulate, but those are the main elements of the Stokes law?
A. Those are amongst them, yes.
Q. And Stokes law is used by scientists and was used by scientists before 2002 to help determine the falling of particles, for instance, in a suspension, right?
A. So again, to look at vertical falling in a suspension, people looked at those kinds of things.
Q. Okay. So before I want to move onto a couple of other things here --
A. Sure.
Q. -- you went through a series of articles.
I just want to give you a reference, Doctor. It's PDX1712. And this is just to remind you, Doctor, of the testimony that you gave.
This was a series of what was six articles, these are the articles that were after 2002, and you described what you thought their relevance was this morning; is that right?
A. I think that's fair, yes.
Q. Now, these articles did you choose

these articles?
A. I chose some, yes.
Q. Did you choose all of them?
A. Well, I was involved in choosing all of them, yes.
Q. Did somebody -- did the lawyers give you articles that went on this list?
A. I can't recall all of them. I had one of my associates do a literature search and the lawyers also gave us some. I don't recall which ones were which.
Q. Were there some selectivity in putting articles on this list?
A. Not really. Let me put it this way: I didn't find any articles from the literature that said anything other than what I am showing you here.
Q. Just so we're clear, you're not suggesting that in this post-2002 time frame there's not art showing that people could make a film that had uniform distribution of particles, are you?
A. Well, obviously once Yang did that, others did. But keep in mind, there



wasn't a product that was developed or approved by FDA until 2009. And article after article including one of your own witnesses keep saying this is a heck of a difficult problem.
Q. Let's talk about the article by one of our own witnesses. That's the Morales McConville article?
A. Yes.
Q. Did you read the entire article?
A. I did. I don't have it committed to memory.
Q. How long is the article? Is it a long article or short article?
A. A medium article. If it was somewhere between 10 and 20 pages. I could be wrong. Do you want me to look that up for you?
Q. It's right here. You can pull it up. It's so PTX213. It's about 12 pages.
A. That was my recollection.
Q. What Dr. McConville and his coauthor, what they did -- the portion you're talking was about one paragraph out of that article; is that right?
A. Yes -- well, there may have been



other mentions too, but I think what I highlighted was some of that.
Q. And that one paragraph is at page 191 I believe. And it's the one on the left-hand column. The paragraph says, Since the early development -- and you can see what you're referring to I think was the Yang quotes; is that right?
A. Well, I think the whole paragraph is useful when you read it in terms of addressing units under the points that you were making before.
Q. What you note, Doctor, is that what's noted here is basically cribbing from the '514 patent, isn't it?
A. What do you mean by cribbing?
Q. It's paraphrasing what was in the '514 patent?
A. Again, as a scientist this is a review article. What review articles do is analyze the literature critically. And to use your words, they rephrase certain things from different patents.
They are also talking Schmidt and again pointing out



that this -- the quote that I made, they say it higher up. Content uniformity, in contrast to what you're trying to explain to me content uniformity has been a major challenge for the pharmaceutical scientists.
Q. Schmidt was also from the '514 patent, did you remember that?
A. Of course. I pointed that out.
Q. My question to you was just isn't it true that this is summarizing information from the '514 patent?
A. So the answer is yes. But as I went over in my Direct, this is a review article. What a review article does is exactly what I just said. In other words, it summarizes information from other articles and gives a critical analysis of it and then it's reviewed by people in the field to see if they think that they did a fair job.
Q. What this article doesn't do, it doesn't analyze the claims of the '514 patent?
A. Of course it doesn't. It's a review article.
Q. And I think you said at one point,

maybe I misunderstood you, it doesn't complement the '514 patent; is that right?

A. This particular one?

Q. Yes.

A. This particular article doesn't -- it just states what it states.

Q. Right.

A. It says this is a big problem and that Yang et al. Went on to overcome it.

Q. He quotes that background but what he doesn't -- there's no discussion of the Chen reference?

A. I don't see any reason why there would be.

Q. Is there any discussion of the Chen reference, Doctor?

A. Absolutely not.

Q. Is there any discussion of the Bess reference?

A. No, because --

Q. Is there any comparison of the claims of the '514 patent to the prior art?

A. No.

Q. Thank you. And that's actually



true of all of the six that you put up there on the screen, none of them analyzed Bess or Chen; is that right?

A. To me what these people do is that they are trying to pick the closest things possible. I don't find Bess or Chen very close to the '514 patent myself. I don't think one of ordinary skill in the art would either so that's why I assume that they weren't put up there.

Q. My question was were Bess and Chen considered in any of these references that you put up on the screen?

A. Not to my knowledge. But --

Q. And there was no analysis of whether you -- what you deemed to be the inventive thought, is there any analysis in any of these references about whether that was truly an inventive thought?

A. I would certainly say yes. When you

read --

Q. Let's look at McConville. There's nothing in McConville that says that; isn't



that right?

A. McConville I cited to show there's been a major challenge and they attribute Yang to solving that challenge.

Q. And the Perumal thesis just says the same thing. It's the same kind of information taking from the '514 patent, isn't it?

A. Well, no. The Perumal thesis, if you go to the table, they give a detailed analysis of all kinds of articles that had been discussing content uniformity. And if you go to the table and look at all different kinds of details and they did experiments themselves, so they go far, far beyond what you said.

Q. Let's look at what you put up on the screen. So we have PTX1713. And it just says, Films suffered from aggregation or conglomeration of particles, and it talks about uniformity, and as you say, it's citing specifically just to the '514 patent, right?

A. At that particular place, but I also went over the table that analyzed a lot of literature and I went over their experiments



which couldn't get content uniformity either. You can't cherry pick.

Q. Well, we can talk about cherry pick later. Let's go to PTX1715. And all that Noag(ph) is doing here is stating that water soluble films can have these aggregation or conglomeration of particles. That's what it's saying.

A. It's pointing out the problems again.

Q. And tablets have been around for centuries.

A. Tablets have been around for a long time but we're not talking about tablets.

Q. We're still studying problems with tablets today, aren't we?

A. Sometimes.

Q. People are still writing articles about tablets today, aren't they?

A. Of course, but not about issues like that.

Q. Now, Doctor, let me move along here to another topic. Let's talk about Chen.

You talked about Chen for quite a

while during your testimony. You were on the same page of the Chen patent application?

A. I remember Chen, yes.

Q. I thought you would. And Chen, you talked about some of the things that Chen did in the course of that application, right?

A. I'm not sure I know what you mean.

Q. There's no question that Chen is making a film; is that right?

A. Chen is making a film, yes.

Q. For the delivery of active ingredients; is that right?

A. In some of the examples, yes.

Q. And making it using polymers?

A. Yes.

Q. And taste modifying agents?

A. In some cases, yes.

Q. And at least one of the embodiments that they talk about is actually an opioid?

A. Yes.

Q. And it's a cast film that's being used there?

A. Yes.



Q. Now, the concern in Chen throughout, there is a concern with having a formulation that is actually uniform; isn't that true?

A. Where do you see that?

Q. Well, you disagree I take it?

A. Well, I'm willing to hear what you have to say. I didn't see that so I'm willing to be educated.

Q. Let's start by looking at your chart 1720.

A. Okay.

Q. This is one of the ones you show.

A. Right.

Q. And you agree that Chen is talking about homogeneity in those first two steps, right?

A. I don't even want to go overboard on that. What I said in my Direct is that he's talking about it in Step 1. And in three of the four statements that I showed, I don't think he discussed it in Step 2. And the one statement that I discussed, it's unclear depending how you interpret it whether he's



discussing it in Step 2 or not. That's what I said. We can go back to those four statements if you would like.

Q. But you can see that there were discussions of homogeneity. And were those discussions at least consistent, doctor, with the idea of making a uniform film?

A. First of all, the discussions of homogeneity by and large are only about making the polymer homogeneous, not the drug, not the active.

Q. But my question to you was that's consistent with making a uniform film, isn't it?

A. I'm not -- I don't know that it is. If you want to make a -- you're only talking about dissolving a polymer in a solution.

Q. If you want to make a homogeneous film, you need to have homogeneity in Steps 1 and 2, don't you?

A. You need to have homogeneity once you add the active.

Q. Well, is it consistent when getting homogeneity when you put the active in



to have homogeneity in Steps 1 and 2?

A. I don't know how to answer it. It's not inconsistent.

Q. That's all my question was.

A. It's not inconsistent.

Q. Let's go back to the whole slide. You said there's nothing about homogeneity in Steps 3 and 4.

I want to ask you in Step Five, isn't it clear that what Chen wants is to have individual dosage units that are the same dosage?

A. I don't know. Where do you see that?

Q. Let's look at page 16 of Chen.

A. Okay. Where is that?

Q. It's JTX187.

A. Okay.

Q. And up at the top it says, For example, the cast --

A. Where are you?

Q. At the top where --

A. Oh, I see. For example, the cast film can be die cut?

Q. Yes. So this is talking about

cutting the film after it's been cast, right?
A. Yes.
Q. And it may be cut into a size that contains, for example, a single dosage unit, right?
A. Yes.
Q. So Chen is interested at least in making dosage units that have uniformity, isn't he?
A. Where do you see that? Where does he say uniformity?
Q. Wel, he wants to make a size that contains a single dosage unit, right?
A. Right. But where does that discuss uniformity or what the uniformity should be?
Q. Well, you don't see the word uniformity, right.
A. I don't even see anything that even indicates it.
Q. So you think he just wants cut a size that would end up with multiple different uniformities?
Is that what somebody with skill in the art would do



in this area?
A. Well, first of all, it's a she. And secondly, you can't tell -- what Chen is trying to do in my opinion as I discussed earlier is trying to establish a principal of a system that has --
Q. So you can't tell whether Chen here assumed a person of skill in the art would be interested in developing a film that has uniformity from dosage unit to dosage unit? A person of skill in the art you can't tell whether they would be interested in that during this time period?
A. Two or three points, she might well be but she never talks about that. Just like I was interested when I mentioned early on in my Direct about trying to come up with the dosage form and release an angiogenic inhibitor. I was far more concerned that I could release it for a period of time than I was that it had a certain reproducibility.
Q. And this it says for example, a dosage unit may include a film size with to a particular surface area that contains a dosage



of active agent in the range of 20 to 250 mg. You read that as saying they're only interested in making one single dose, not trying to get uniformity?
A. I don't think you can tell from that. And I don't think you can be mind reader of what she's interested in or not.
Q. I'm talking about what of one skill in the art would --
A. I agree.
Q. The size of the film may be varied according to dosage required. The dosage contained in each square centimeter is selected according to the active ingredient. When a person of ordinary skill in the art is developing a film system at this point in time would be interested in making sure that the dosages that they cut out the film have the same active.
A. It depends on the situation. You have to look at the situation they're trying to do and what their goals were.
Q. Now, I think you mentioned -- if we go back to page 15 for just a second.



A. 15 of Chen?
Q. Same document. And I'm going to put it up on the screen. I think this is something you commented on earlier, the paragraph at the bottom of that page, doctor. You can see again the reference to uniformity. Do you see that?
A. Where are you?
Q. It starts at the top, in an embodiment of the invention, the solvent casting method involved a natural or synthetic hydrocolloid that is completely dissolved or dispersed in water, et cetera. In addition to the active agent and hydrocolloid, any of the ingredients listed above may be added and dispersed or dissolved uniformly in the hydrocolloid solution. Do you see that?
A. Yes, that's one of the things we discussed before. I remember you brought that up on your Cross.
Q. And you can see is it really possible to read as indicating that that the active ingredient is dissolved uniformly. It's uniformly throughout that particular solution,

right?
A. I said either way. But even if you took the case that you want to put forth, then that is Step 2. It doesn't deal with Steps 3, 4 and 5 in my flowchart.
Q. But you need to do this. You need to have that homogeneous mixture if you're going to make a uniform --
A. Homogeneous mixture of the drug.
Q. Correct?
A. That would be critical in my opinion that a homogeneous mixture of the drug at Step 2.
Q. Okay. So --
A. Not at the other steps.
Q. And it goes on to say that the homogeneous mixture, it talks specifically about the viscosity; isn't that right?
A. They mention the viscosity. But of course as you read the whole patent, what you see is the viscosity, the reason they're interested in it has to do with mucoadhesive property. It's not --
Q. But I'm just talking about right



here it's talk the viscosity, right?
A. Oh, absolutely.
Q. And it goes on to say that it makes this dosage and it says, the manufacturing process for forming the dosage unit is illustrated in Figure 2. Doesn't that indicate to you that they're making a dosage unit. Meaning, a unit that has the desired dose on it for administration to a person?
A. I don't understand the question.
Q. Okay.
A. It says what it says.
Q. Well, actually you do know that as part of Chen's work, Chen did actually give some of the film that she made to humans; isn't that right?
A. There was a human pharmacokinetic study, is that's what you're asking. I don't know if she did it herself or what.
Q. But it's reported in the patent that the drug was given to humans; isn't that right?
A. That's correct.
Q. That means that you're making more



than one dosage form?
A. Yes, I agree with that.
Q. And certainly, if you're a person of skill in the art, you would want in your manufacturing process to be making something that has a uniform dosage; isn't that right?
A. I think when you -- my experience when you do a very simple clinical trial, of course you would like things as close as possible. But the goals are much more lenient when you do six patients. And this wasn't even an FDA approved trial. It may have been done in a different country. I don't know but. The leniency when you're trying to do an early test on humans is enormous. It's not anywhere near 15 percent. It certainly doesn't have to be. So you can't conclude there what you're trying to say, I believe.
Q. I want to look quickly at Figure 5, Doctor, if we could and maybe we will take one of your charts. That might be the easiest way to do it.
A. Sure.
Q. I think it would be 1724 or so.



A. Okay.
Q. We will just use this. Do you see it?
A. Yes.
Q. You talked about this, this morning. The base of this is Figure 5 from Chen; is that right?
A. That's correct.
Q. And so what we see here is in Chen you've already taken one of the four actives that Chen was testing off the chart by the time you got here, right?
A. Because it hadn't reached even by any standard what --
Q. Right. I'm just trying to make sure for the record it's clear. We're not looking at the actual chart. You've taken something off?
A. That's fair, yes.
Q. The one that you left behind, what you're getting is results that are plateauing around the 100 percent mark; is that right?
A. Let me just say we're making assumptions that it appears to plateau. I

didn't do statistics on that, but I'm not disagreeing with you.

Q. And doctor, when you do these bars that extend on either side, there should be bars for each one of the doses that you're testing?

A. Correct.

Q. And so theoretically, we should be able to find eight of those as the Judge called it, nails? They look like their nails to be hammered down?

A. I understand your question.

Q. So because some of these dosage forms are overlapping we can't see all of the horizontal lines that make up these bars; is that right?

A. You can't see it on this, no.

Q. And it looks like --

A. That's part of what I said when I say we have to make certain assumptions early on.

Q. Understood. If you look at this, there is one set of those bars that is higher than the others, isn't it?



A. Again, you mean the one at 8 minutes? Is that what --

Q. This is what I mean, if you take the one going across -- there's one that seems to be above the others going all the way through, right?

A. Possibly. I have to go back to my initial notes. I'm not sure it's the same point. In fact, I don't think it is.

Q. But at any rate, if you say, for instance, at the 10 if you took that top bar out, that would be associated with one of the dosages, right?

A. I don't understand the question.

Q. So we talked about how those bars, you're going to have bars with two horizontal lines surrounding each of the dosage forms, right?

A. Okay. I think I understand what you're saying.

Q. And you agree with that, right?

A. You're saying from each point you're going to have a bar with -- and there's going to look like this?



Q. Yes.

A. I think we're on the same page.

Q. And you agree with me that's how normally it would be portrayed?

A. Yes.

Q. Now, there's one if you look over at 10, it might be close to 110 percent. But certainly all the other bars are below the 110 percent; isn't that right?

A. Where are you?

Q. If you can --

A. You're talking about the standard deviation?

Q. Yes, right there.

A. So not the --

Q. There's a top horizontal bar. Do you see that?

A. Yes.

Q. So that's one of the dosage forms, right, and that's kind of close to 110 percent if you eyeball it?

A. If you're talking about standard deviations, not the variation that we're talking about.



Q. Right?

A. If you're talking about standard deviation.

Q. Yes?

A. Standard deviation in that case looks to be about 110 percent.

Q. And the rest of the bars are less than 110 percent in that example?

A. For the standard deviations.

Q. Right?

A. For standard deviations you're saying.

Q. Correct?

A. I just want to make sure we're on the same page.

Q. Yes?

A. Well, actually it looks to me like two of them are above 110 percent.

Q. Let's just start with No. 10.

A. To me for standard deviations, 10 looks to be just below it. Eight minutes looks above it. I would say seven minutes looks above it. I'm having trouble judging six minutes. They're basically touching it to me

at four, five and six minutes.
Q. For each minute you found one bar that was either touching or slightly above or close to that 110 percent mark; isn't that right?
A. On standard deviations.
Q. Right?
A. On standard deviations, I can't tell right now without my notes in front me whether it's one bar or more.
Q. Now, doctor, at least you can say on the -- strike the question. I will move forward.
A. Sure.
Q. Doctor, in a patent there were a few examples were there was testing done on content uniformity; am I right?
A. Which patent are you talking about?
Q. The; 514 the patent-in-suit that we're talking about.
A. Okay. I will go to that.
Q. I will put it up on the screen. So there's an example here in Column 47. Just



to give you a frame of reference, doctor, I will go back to Column 46 so you can see the bottom. That's not going to be a particular issue here, but so you can see where we are. This is talking about Example X to AA. Do you see that?
A. Examples X to AA in Column 46, yes.
Q. I'm just giving you a frame of reference. Then we go over to Column 47 and we talk further about that, correct?
A. Yes, that's are part of examples X to AA.
Q. And they talk about the results in the last paragraph at the bottom of the left-hand side. Do you see that generally?
A. I'm just trying to make sure we are on the same part.
Q. I will give you a specific line reference, doctor, I'm looking at. Let's look at Line 56.
A. Okay.
Q. It says the dried film was .005 inches thick by 5 ml and was cut into a certain



size pieces weighing 70 mg plus or minus 0.7 mg, right?
A. Yes.
Q. And then it says demonstrating a uniformity of a composition of a film. Do you see that?
A. Yes.
Q. So this weighing of the pieces is what demonstrates the uniformity of the composition of the film in this example?
A. In this example, that's what they're using, yes.
Q. So you would agree with me, we talked about this earlier, but weighing the film is a way of determining composition and one that people of skill in the art would be familiar with; is that right?
A. They would. But personally, when I read it I think one of ordinary skill in the art would do everything including chemical composition, but this is certainly an indication of that.
Q. And then is what they did in the patent?



A. This example in this particular instance this is what they did, but I don't view that as exclusive.
Q. And you talked about the Bess, B-e-s-s, reference, right?
A. Yes.
Q. That's at JTX184. I want to go to that.
And Bess, it's another example of making a film with an active ingredient; is that right? I'm talking about in a general sense, Doctor?
A. What do you mean in a general sense.
Q. I'm just trying to give a frame of reference to the Court of what Bess involves. It involves the technology of making films with active ingredients for administration to humans; is that right?
A. Yes.
Q. In Bess -- let's see if we can find an example. Let's go to Column 12 where the examples begin.
A. Okay.
Q. It's on the screen, not in your

slide.
A. Okay.
Q. So this is just the example section and if you want it in front of you, it's JTX184.
A. Yes, I have it.
Q. So you recognize this as Bess actually formulating a film; is that right?
A. Yes.
Q. And he talks about making various preparations mixing them together, right?
A. Yes, I talked about that on my Direct.
Q. And there's one spot where there's mixing. Do you see that in C?
A. Yes.
Q. And then there's a combination in D of some more elements?
A. Yes.
Q. And then in E there's more thorough mixing?
A. What do you mean by more thorough mixing?
Q. Well, it's more mixing, but they



call it thorough mixing; is that right?
A. That's what they say, yes.
Q. And then in F, they talk about putting a dextromethorphan. That's an active ingredient; is that right?
A. Yes.
Q. So then they added that in with mixing. Do you see that?
A. You mean the first sentence of F?
Q. Yes, that's correct. So all that mixing, Doctor, is it at least consistent -- it's not inconsistent with making a uniform film, right?
A. I think it goes to what we said before, you can be up to Step 2 in my flowchart and it's not inconsistent with that. It's not necessarily consistent with it either.
Q. Okay. Let's go to the next paragraph. And now it talks about preparation F. They are actually ready to put it into the mold, right?
A. Let me take a look. Preparation F, yes.
Q. They've got it all mixed together



and they're going to pour on the mold and cast the film et cetera. Do you see that?
A. Yes.
Q. You can see if you go down it was dried under warm air, so that drying element is there again?
A. Yes. But unlike the '514 they pay no attention to really the key issues about drying. That's just a very general statement.
Q. And look at the very end of that paragraph where it says a weight -- it gives the weight, doesn't it?
A. Yes.
Q. Weight plus or minus 3mg; is that right?
A. Yes.
Q. That's within 10 percent?
A. The weight -- now, we're talking about a standard deviation or --
Q. No. I'm talking about -- you just looked at the weight in the patent of the '514?
A. Right.
Q. They said that determined content uniformity, right?



A. Well, let's go over the exact numbers.
Q. Doctor?
A. Yes.
Q. The weight reported here is 70 mg plus or minus 3, isn't it?
A. If that's a standard deviation, then you use that three-sigma rule and you will be up to 70 minus 9.
Q. '514 didn't say anything about using the standard deviation in the example we talked about it, did it?
A. Let me go back to the example.
Q. We will let the record stand on whether it's there or not there.
A. Okay. I'm fine with that.
Q. This says a weight of 70 plus or minus 3mg, right?
A. Right.
Q. That indicates a variation of less than 10 percent?
A. I don't agree with that.
Q. That's exactly the kind of measurement they used in the patent?

A. But that's not standard deviation.
Q. It doesn't say standard deviation there?
A. Well, it doesn't say anything.
Q. Well, let's go back to the patent and Column 47 just to wrap this up, Doctor. A weight of 70 plus or minus 3, do you see that?
A. Yes.
Q. Let's go back to Column 47.
A. Where are you exactly?
Q. I'm getting there. It's the '514 patent.
A. Okay. It's 70 mix plus or minus 0.7.
Q. Let me get it up on the screen. It says pieces weighing 70 mg plus or minus 0.7 mg, no more information, no less information provided in Bess.
A. Well, that's a big difference. One is way less than 10 percent. And that's more than 10 percent if you use the three-sigma rule which I expect people to do. But beyond that, this is just one test that they are giving you as an indication.



Q. That's what the people did in the patent in this example, right?
A. In this one particular case.
Q. No sigma conversation here?
A. You can do that.
Q. Nothing about sigma?
A. It's still less than 10 percent.
Q. Nothing about sigma, sir? Can you answer my question.
A. It's --
Q. I would just like you to answer.
A. In that particular statement, there's no mention of sigma.
Q. Let's go back to Bess.
A. Bess' variation is quite a bit higher. If you do standard deviation, one will be 1 percent and the other will be about 3 or 4 percent.
Q. Thank you, doctor. But that's not in the patent that we just looked at, right?
A. Well, you're looking at isolated places, sir.
Q. And it's not in Bess right there, is it?



A. You're looking at isolated places. You have to look at the patent as a whole.
Q. I'm just asking for an answer to my question?
A. I'm answering it. I'm agreeing with you. But I'm saying you're looking at isolated places and that's not what one of ordinary skill in the art does it.
Q. Thank you, Doctor. I'm running out my self-imposed time limit here.
A. No worries.
Q. Let's wrap this up. We were talking about earlier, Judge --
MR. LOMBARDI: Not Judge. I apologize.
BY MR. LOMBARDI:
Q. Doctor, we were talking about viscosity earlier and you said that a person -- let me just ask you and make sure I'm not mischaracterizing. I want to make a statement. I want to make sure I'm not mischaracterizing what you said.
A. Of course.
Q. A person of skill in the art of



2002 would not have had any idea that increasing viscosity could reduce the aggregation of particles in a matrix?
A. I don't think I said it quite like that. We can read back exactly what I said. But my statement would be that they would certainly not have been led to do that given all the other considerations that they have to do and make when they're developing a novel dosage form that had never been developed before.
Q. Isn't it true, doctor, that at the time the '514 patent filed in 2002 persons of skill in the art were moving viscosity, changing viscosity in order to prevent aggregation from occurring in a film formulation?
A. Where have you seen that?
Q. I'm just asking you.
A. I don't think so.
Q. Well, let's look at the '514 patent.
A. Okay.
Q. Let's go to Column 2.

A. Okay.
Q. Down there at the bottom you mentioned Horstmann and Zerbe. They were all on your slides. Do you remember that?
A. Correct.
Q. And it says, Horstmann and Zerbe incorporated additional ingredients, i.e. gel formers and polyhydric alcohol respectively, why, to increase the viscosity of the film prior to drying in an effort to reduce aggregation of the components?
A. Right. One of them doesn't even have a drug in it so it's a question of what they really trying to say.
Q. This is the '514 patent?
A. I agree.
Q. And you've read Zerbe and Horstmann?
A. Yes.
Q. And you agree with the patent applicants, the inventors' description of Horstmann and Zerbe, don't you?
A. Well, I think that through their eyes because they were concerned with this



issue -- maybe you have read it, but my interpretation when you really read those two patents is they were concerned about at most keeping various components, not necessarily the drug away from each other.
If there are particular quotes that you want to take me to in those patents, I'm happy to look at them, but I don't think you will find them.
Q. My question is, just simply do you agree with the characterization of Horstmann and Zerbe that appears in the patent?
A. I think it's one way to look at it. As I read those patents, it's looking at it through the eyes of somebody who was concerned about these issues. As I said, if you go back and look at Horstmann and Zerbe, I'm happy to look at those with you but I don't think you will find exactly what you're saying.
Q. Let's go to your deposition.
A. Sure.
Q. Let's go to page 151 of your deposition.
A. Okay.
Q. And up toward the top the question



starts and you say yes. My question to you, Doctor, is did you give this answer to this question under oath at your deposition:
"Question: I believe you agree with the statement that the '003 Horstmann patent does teach adding ingredients to increase the viscosity in an effort to reduce aggregation of the components of the film?
Answer: Yes, I'm not disagreeing with that. I'm just trying to give you a complete picture, but I agree with that statement. I think the way the patent characterizes everything is correct."
Is that the answer you gave to that question at your deposition.
A. I think that's what I'm saying now. I'm just trying to give you the complete picture.
Q. And if we go back, doctor, what it shows is that at a minimum in Horstmann and Zerbe there was a recognition that increasing the viscosity of the film to affect and reduce the aggregation of the components was something that a person of ordinary skill in the art



knew; isn't that right?
A. I think that an oversimplification. You have to go to those patents and look at specific statements. And those components don't necessarily have to be the drugs, sir.
Q. I'm just relying on the people who wrote the patent?
A. I agree with you. That's what I'm trying to say, you have to look at the specific statements.
Q. And you know that the people that wrote the patent thought that the method that Horstmann and Zerbe used could have been improved upon, right?
A. Absolutely.
Q. And that's why they filed their patent. It was something they improved upon, they thought, right?
A. Well --
Q. Well, I don't mean to ask you the intention of the patent people. But they said in the specification here that they thought it could be improved, right?

A. I'm not sure I understand what you mean by improved.
Q. Well, I think I already covered the point. But my only point here, sir, is their recognition of the inventive concept that affecting the viscosity of the film prior to drying can be used to reduce aggregation?
A. Of certain components.
Q. Okay.
MR. LOMBARDI: No further questions, Your Honor.
THE COURT: All right. Thank you. Any Redirect?
MR. BRAHMA: Yes, Your Honor.
- - -
BY MR. BRAHMA:
Q. Dr. Langer, I would like to ask you a few different questions about some of the things that Mr. Lombardi asked you about. I will try to be brief but I'm not making any promises.
If we go to the patent JTX2, I will start with the last thing he asked you about so if we can pull that up, Column 2 at the bottom.



A. Yes.
Q. So he asked you about this statement about Horstmann and Zerbe that talks about using gel formers and polyhydric alcohol to increase the viscosity of the film prior to drying in an effort to reduce aggregation of the components?
A. Yes.
Q. Did either Horstmann and Zerbe show a film that actually achieved content uniformity?
A. No. There was no discussion of that there.
Q. And do you know whether Horstmann or Zerbe led to any approved drug product?
A. I don't believe they did.
Q. And going up a little bit in that same column where it talks about the 10 percent uniformity requirement?
A. Yes.
Q. So this is the sentence starting, For this reason dosage forms formed by processes such as Fuchs would not likely meet the stringent standards of governmental and



regulatory agencies such as the U.S. FDA related to the variation of active in dosage forms. Currently, as required by various world regulatory authorities, dosage forms may not vary more than 10 percent in the amount of active present.
I know Mr. Lombardi asked you questions about this but he did not allow you to respond. So I would like to ask you what would a person of ordinary skill in the art have interpreted those sentences to mean?
A. Well, they would interpret the first sentence that for certain dosage forms -- again, these cast films had not been approved yet until another seven years, so they would certainly be concerned about whether Fuchs or the other ones would meet what would be presumed standards. These would be what I call an other category.
The second sentence is a little bit complex, but as I looked into this, the FDA has a variation of 15 percent, not 10 percent. Some other regulatory authorities may have lower ones, but the way I look at that sentence, given what I know the



FDA has, is that certain world regulatory authorities will not allow it to be more than 10 percent, but the FDA would and there's would be 15 percent; and that's true. That's a fact. Anybody can look that up.
And that's what I was trying to say. You're right. I didn't get a chance to complete the answer.
Q. On that note, Dr. Dyar(ph) and Mr. Lombardi suggested that you might be able to tweak viscosity here and there to increase the uniformity. First of all, would a person of ordinary skill in the art know to do that from the prior art?
A. I just don't see how they would know how to do it from the prior art. Like I said, all six references that I cited kept saying well after the 2002 patent, just how difficult and complex this was.
In addition as I was also saying to Mr. Lombardi, it's not just tweaking it, because you can't just change one thing. If you change the viscosity, that may help you on certain things. But you really in any of these cases balancing all different kinds of properties. You're balancing

release kinetics, you're balancing other kinds of things. You can't just change one thing in isolation. If it was just a one-variable thing, that would be one thing, but it's not.

Q. I'd like to ask you a portion of the patent that Mr. Lombardi pointed you to talking about testing for uniformity. It's Column 36 starting at Line 19.

A. Okay.

Q. Right under the heading Testing Films for Uniformity, and the first sentence says, It may be desirable to test the films of the present invention for chemical and physical uniformity during the film manufacturing process. Do you see that?

A. Yes.

Q. Does physical uniformity relate to drug content uniformity?

A. Well, it's possible. It could be -- yes, physical uniformity could be a surrogate for it.

Q. Are there other things that are also encompassed within the term physical uniformity?



A. Yes, I would think so.

Q. The tests that are described below of film thickness, color, overall appearance, do all of those tests relate to drug content uniformity?

A. No, they would not. That would probably be under more of a category of physical uniformity.

Q. Now, in Mr. Lombardi's questioning, he asked several times about the three-sigma rule. The '514 patent, did that invent the three-sigma rule?

A. No.

Q. And you didn't invent the three-sigma rule, right?

A. As far as I know.

Q. So where did the three-sigma rule come from?

A. That's just standard in pharmaceutical practice.

Q. Is that a standard principle of statistics?

A. Yes. That's what I was showing on the one graph.



Q. Does that rule apply whenever someone is using a mean and a standard deviation?

A. Yes.

Q. So if data is reported in mean and standard deviation format, would a person of ordinary skill in the art know to apply the three-sigma rule?

A. Sure.

Q. Now, let's go to the data in Bess that Mr. Lombardi was pointing to you. It's JTX184, and the weight test results that he was pointing you to are in Column 13.

A. Okay.

Q. Starting at Line 1 going through Line 7.

A. Okay.

Q. So it ends there with the weight results of 70 plus minus 3mg, right?

A. Yes.

Q. So in that measurement, is 70 the mean?

A. Yes.



Q. Is 3 the standard deviation?

A. I believe so. It's not specified, but I would think so.

Q. And if you applied the three-sigma rule to that data, what would the range of weight measurements be?

A. 70 plus or minus 9. That's what I was saying to Mr. Lombardi.

Q. Does that range of plus or minus 9, is that greater than 10 percent?

A. Sure. 70 plus or minus 7 would be 10 percent.

Q. I'd like to take you to Figure 5 of the Chen reference. And Chen is JTX187.

A. Okay.

Q. And Mr. Lombardi asked you about the time points at Time 10.

A. Right.

Q. Is that the only data that a person of ordinary skill in the art would look at in determining whether the Chen films had drug content uniformity?

A. I would think they would look at all the data, if they were going to use this

approach at all. Like I said, this approach to me for both sides involves a lot of assumptions. But again, I was trying to pick what I thought were some favorable assumptions in doing an analysis. But somebody of ordinary skill in the art if they were going to do this, they would look at everything.

Q. If one was to apply the assumptions that were most favorable to Dr. Dyar, would they still have to look at the data for all of the time points that are steady state?

A. I would say they probably look at all the time points at steady state and all the time points that are not steady state. If you have a variation and you're really saying that it's reproducible, then I wouldn't think that the points that are even below that plateau you wouldn't ignore them, and some of those have huge standard deviations, so you would consider all the data.

I was trying to take the position that Dr. Dyar was, but somebody would actually take all of the data.



Q. In terms of the claims of the '514 patent, when they apply this 10 percent uniformity requirement, that's saying that none of the samples that you take of the film you make can be outside of that 10 percent range, right?

A. Well they do -- the USP -- I mean, that's true. But they basically have tests where you might do 20 samples and see what happens, something like that. There's specific guidance from the USP on them.

Q. If I can move to Stokes law really quickly. This is slide DVX 3.017 from Dr. Dyer's presentation. I will just use the version that he had put up that explains what the different variables are. You mentioned a lot of these variables were changing and I wanted to ask you about that.

During the drying process, where it says density of liquid, that's the density of the film dispersion, the dispersion that's being cast; is that right?

A. Yes.

Q. Does that density of liquid change



as the film is being dried?

A. Yes. And that's what I was trying to say on my Direct a little bit more too, the density of the liquid changes upon being dried, the viscosity of the liquid changes upon being dried. This is a far more complex thing than just plugging it in because it's a variable over time. Not to mention that it's only one of many things that's happening.

Q. Did any of the prior art references that you saw, either the ones that Dr. Dyar is actually relying on or anything else you saw in your investigation talk about how the density or viscosity of the casting dispersion would change in a matter of time during the drying process?

A. I didn't see anything about that at all.

Q. So is it fair to say then that even the application of Stokes law to the film casting process and drying process was not shown in the prior art?

A. I think it's not shown in the prior art, but I still think it's a huge



oversimplification because it's one of eight things going on.

Q. Last small point, Mr. Lombardi asked you about the discussion of suspensions in Lachman, and that's on PDX 1729.

A. Okay.

Q. And he suggested that in the context of suspensions, those of ordinary skill in the art knew how to use viscosity to keep active from settling.

Do you remember that question?

A. Yes.

Q. What is a suspension? Can you give me an example of a pharmaceutical suspension?

A. A pharmaceutical suspension in contrast to a pharmaceutical film, something like Milk of Magnesia, you shake it up. It's a two-part system and you shake it up before you use it.

Q. So that suspension like Milk of Magnesia, is that dried?

A. No. It's a -- no, you take it as a suspension.

Q. Why does that bottle tell the person taking the Milk of Magnesia to shake it up?

A. Because it settles and isn't uniform. So you shake things up so that you hopefully get a fairly uniform dose right before you take it. It's a very different situation than a film.

Q. And finally, Mr. Lombardi asked you about the post-2002 articles and why they don't refer to Bess or Chen and I'm not sure that your response to that could be completed. So I will you again, why wouldn't the post-2002 articles and references that we talked about earlier, why didn't they refer to either the Bess patent or the Chen reference?

MR. LOMBARDI: I will object, Your Honor. There's no foundation for this witness to testify as to what particular inventors in those patents thought and did.

THE COURT: Why don't you rephrase the question a little differently so he can answer it.



MR. BRAHMA: Okay.

BY MR. BRAHMA:

Q. The Bess or the Chen reference, were either of them directed to the problem of drug content uniformity?

A. No, they weren't. They both had different goals.

Q. Did either the Bess or the Chen reference state that they had achieved films that meant any drug content uniformity requirement?

A. Not at all. They just didn't address it one way or the other.

Q. Would you have expected either the Bess patent or the Chen reference to have turned up in a literature search that was done post-2002?

A. I wouldn't, because when you do literature searches, and we do them all the time, you look for things that are directly relevant to your art. That's why when we did that, we turned up references Perumal and others that really dealt head-on with this issue, not ones that are very peripheral to it at best.



Q. And in the course of the literature searches that were done, for example, in Perumal, would you characterize those references as being more on point with respect to the issue of drug content uniformity than other Bess or Chen?

A. Well, of course. That's what they were directly about. That was their whole point.

Q. The other articles?

A. Well, certainly Perumal. It depends which article we're talking about.

MR. BRAHMA: I have no further questions.

THE COURT: Dr. Langer, you may step down.

MR. LOMBARDI: Your Honor, I have just two that will be very brief.

THE COURT: Are they things that came up during Mr. Brahma's Redirect?

MR. LOMBARDI: Yes, Your Honor.



THE COURT: All right. I will give you a chance.

MR. LOMBARDI: Thank you, Your Honor.

- - -

BY MR. LOMBARDI:

Q. You talked about suspension and Lachman and how that's a special area of art; is that right?

A. I don't think I said it was special. I just said it was different.

Q. Different from the patent; is that what you meant?

A. Well, a suspension is just a different dosage form compared to a thin cast film.

Q. But actually, the patent talks about what they're working with being a suspension all throughout the patent, doesn't it?

A. But they're totally -- it's like apples and oranges. One is a dosage form that you shake before you use it and the other is sort of a means to an to try to create this cast

film.
Q. I will show you two things. Let's go to Column 24 of the '514 patent.
A. Sure, whatever you like.
Q. Let's go to Line 42. And you see there it says a stable suspension is an important characteristic for the manufacture of a premix composition, and it goes on from there, right?
A. Yes.
Q. And that's in the patent. Do you remember that from being in the patent?
A. I can see it there and I remember it.
Q. And Lachman there's no doubt provides exhaustive information about suspensions; is that right?
A. Well, it's a totally different situation, but I'm not sure what you're asking. But he talks about suspension, yes. But that's the final product this is a step in.
Q. And last thing, doctor, you talked about the 10 percent I will call it rule on the FDA and I'm not trying to characterize --



A. Sure.
Q. It's true, isn't it, that if a pharmaceutical formulator as of 2002 were pursuing a commercial product, that formulator would have had as a goal being within 10 percent variation; isn't that true?
A. I think it depends on the situation. We talked about that before. We talked about my testimony before. I'm not sure if you're repeating what we said.
Q. I think you're right and I didn't remember I asked you about --
A. You did. I talked to you about 136 and 137 in my deposition.
Q. Thank you very much, doctor.
MR. LOMBARDI: That's all the questions I have.
THE COURT: All right.
Dr. Langer, you may step down.
THE WITNESS: Thank you.
THE COURT: All right.
MR. LADOW: We're calling Professor Robert Prud'homme, Your Honor.



THE COURT: Okay.
THE WITNESS: My name is Robert Krass(ph) Prud'homme, P-r-u-d-h-o-m-m-e.
- - -
...ROBERT PRUD'HOMME, having been duly sworn, was examined and testified as follows:
- - -
BY MR. LADOW:
Q. Good afternoon, Dr. Prud'homme.
A. Good afternoon.
Q. The court already has your CV as JTX10. Could you give the Court a little bit of background about how your experience relates to what we've been talking about in the case today?
A. I'm a professor at Princeton University. I've been the president of the U.S. Society of Rheology which deals with polymer flow and rheological properties. I've been the Chair of Dow's Technical Advisory Board on Material Science that gives Dow advise on materials they make including polyoxides and



other materials with pharmaceutical applications.
I'm currently on their Technical Advisory Board for Formulations so I'm involved in their guiding, their formulations research which includes pharmaceuticals. We have had research supported by and I've been a consultant for major pharmaceutical companies throughout most of my career.
A. Thank you.
Q. And what area in particular is your expertise?
A. My expertise is in polymers and now especially polymers applied to drug delivery.
MR. LADOW: We would offer Dr. Prud'homme as qualified as an expert in polymer science in the development of pharmaceutical formulations, Your Honor.
THE COURT: All right. You may proceed.
BY MR. LADOW:
Q. Dr. Prud'homme, you've offered

opinions on the '150 patent in this case?
A. Yes, I have.
Q. Are you familiar with that patent?
A. Yes.
Q. I want to go to PDX1803. And if you could explain what your understanding is of the polymer profiles that's provided by the patent?
A. So this is a general overview of the focus of what the patent teaches about polymers and the polymer profile. You see it's talking about the properties when once balancing fast the solution of resistance, and it states to obtain these performance characteristics when one is between 50 to 75 percent and preferably greater than 60 percent of a low intermediate molecular weight PEO and a small amount of a higher molecular weight intermediate PEO.
Q. Thank you. Does the term intermediate molecular weight appear in the patent?
A. This is a term that I come up with, Your Honor. In this case, we will talk a lot about PEOs today and polymers. There are



very high molecular weight polyethylene oxide which were the matter of most of the older art. And there are very low molecular weight polyethylene glycol which are generally called PEGs, so those PEGS have the same molecular structure but are generally 20,000 of weight and lower.
The polyethylene oxides of the most of the prior art is millions of molecular weight higher and this patent focuses on and directs a person to this intermediate molecular weight range between 100,000 and 900,000, and that's really the teaching of this patent. So I call those intermediates. There's going to be a low intermediate between 100,000 and 300,000 and a high intermediate between 600,000 and 900,000.
Q. All right. And you heard Dr. Amiji's testimony today in regard to indefiniteness and obviousness?
A. Yes, I did.
Q. Let's turn to the indefiniteness issue first. Did you agree with his testimony that the '150 patent was indefinite?
A. No.



Q. Let's go to PDX1824. Dr. Prud'homme, do you understand this is the standard for showing indefiniteness in a patent case?
A. Yes, I do.
Q. And the scope of the claim, a person of ordinary skill would understand the scope of the claim with reasonable certainty?
A. Yes.
Q. Is that the standard that you applied in your analysis?
A. Yes, it is.
Q. In regard to the person of ordinary skill, you heard Dr. Amiji about the level of skill of that person. Do you have any material disagreement with that?
A. No material disagreements.
Q. Let's go to PDX1825. Do you recognize this is the Court's claim construction of this case, a portion of it in regards to the '150 patent?
A. Yes, I do.
Q. Did you apply this construction in looking at the indefiniteness issue?



A. Yes, I did.
Q. Now, Dr. Amiji as you heard testified that the person of ordinary skill in the art would not have been able to determine the scope of the asserted claims with reasonable certainty.
And to address that, let me ask you, Dr. Prud'homme, based on the claim and the specification and the file history of the patent, you reviewed those?
A. I have reviewed those.
Q. And based on the claim and specification and the file history of the patent, do you have an opinion as to how a person of ordinary skill in the art would understand the average molecular weight in the claim?
A. Yes, I do.
Q. Can you explain that?
A. Yes. So the viscosity average molecular weight or the average molecular weight, which Your Honor put in the claim construction and I think is appropriate when it's talking about averages, and the average

which Dr. Conville(ph) talked about yesterday, which Dr. Amiji talked about, is a viscosity average. So I believe that's the appropriate average to be describing these low and high intermediate molecular weights.

Q. Thank you. Let's go to PDX1826. What is the significance of this portion of the specification for your analysis?

A. So this is from Table 21 and it's describing the PEOs obtained from Dow Chemical Company.

Q. Let's go to PDX1827.

A. This is a from the file history of a book offered by Flick that was part of the file history and it's talking about the Union Carbide polyox. Union Carbide was purchased by Dow so it's Dow's the polyoxes now. And polyoxes are sold or specified by a grade and it's really characterized in three ways.

There's a name, a grade like N10 and that's also another designation of the approximate molecular weight which is another designation to this and then a viscosity range. So they're characterized by these three things and it defines the viscosity



average molecular weight.

Q. In sum how does this reference in the file history, the Flick reference and the discussion about polyox bear on your understanding of how a person of ordinary skill in the art would understand the claims?

A. I think it directs us to a viscosity is a way to measure molecular weight and, therefore, the viscosity average molecular weight defines the molecular weight which is specified in the patent.

Q. Now, there's different ways of talking about average molecular weight in various context; is that right?

A. Yes.

Q. Did you hear Dr. Amiji talking about that earlier today?

A. Yes, I did.

Q. Let's call up DDX4.011 -- no, let's try DDX4.010. I'm sorry. The one I want is DDX4.013.

Do you recall this slide that Dr. Amiji testified about earlier?

A. Yes, I do.



Q. Now, is the viscosity average molecular weight that's on this slide is that nomenclature of what you're talking about when you say viscosity average molecular weight?

A. Yes, that's a nomenclature I'm talking about.

Q. And there are other labels or measurements for average molecular weight, there are number average, weight average, z average. Do you see that?

A. Yes.

Q. Can you explain to us what the difference is between those and let's take them one by one and I will you about each of them separately.

So with number average molecular weight, would one of ordinary skill in the art reading the claims of the '150 patent have any reason to read those claims as referring to number average molecular weight?

A. No. The number average overweighs the importance of a low molecular weight species and that would not be the average anyone would use.



Q. Let's go to the Z average molecular weight. Is there any reason why a person of ordinary skill in the art would look at the claims in the '150 patent and understand them to be referring to a Z average molecular weight?

A. No. This average overestimates over -- puts an emphasis on the ultra high molecular weight so that wouldn't be used to specify or characterize the polymers that we're talking about.

Q. And this is something that is well-known to a person of ordinary skill?

A. Yes.

Q. And this is the equation that allows you to calculate these numbers and you know it's going to askew one way or the other?

A. That's right. There's no instrument to measure MZ and for these sorts of polymers MN is not measurable for these high molecular polymers. Therefore, those values can only be mathematically calculated. The viscosity average can be experimentally

measured with high precision and that's the appropriate measure.

Q. When you said, for example, the number average, they can't be measured, what you mean is they can't do a physical experiment?

A. There's no experimental apparatus to measure that for these types of molecules.

Q. And then the only way you can do it is through GPC for MN?

A. One must do GPC and then take that distribution and do the mathematical analysis of that distribution which Dr. Malus(ph) has done.

Q. And with respect to weight average molecular weight, is there any reason why a person of ordinary skill in the art would read the claims as necessarily referring to a weight average molecular weight?

A. I don't believe so. The weight average molecular weight is very close to the number average. You can see they vary by something like 10 percent for this type of polymer. But the direct and precise experimental technique would be a viscosity



average molecular weight. Therefore, I think that's the appropriate one to calculate when one is asking questions about the distribution.

Q. In terms of the viscosity average molecular weight, you said you think a person of ordinary skill would apply the claims of the '150 patent.

Can you explain to the Court to what extent that is a well-known measurement and why it might be used in the context of the polymers that we're talking about here?

A. The viscosity average molecular weight has been around since at least 80 years of some of the early work by the early polymer scientists. It is in the Dow brochure that date from the '80s. They describe calculating intrinsic viscosity and how that's related to the weight average -- or sorry. The intrinsic, how that's related to this viscosity average. So that is demonstrated back in the older Dow brochures. So the concept of viscosity average molecular weight has been around for a very long time.



Q. I think we will come back to this slide, but I would like to move for a moment to -- let's try to put back DDX4.011.

So, Dr. Prud'homme, do you recognize this as the Dow brochure that Dr. Amiji was referring to?

A. Yes, this is the more modern Dow brochure.

Q. And it has different grades of polyox, we saw that, and the approximate molecular weight. Can we get maybe the exhibit itself? I think it's JTX30. That's worse so let's go back to the other one.

So there's been a lot of testimony, Dr. Prud'homme, and you've been here listening to it in relationship to polyoxide. What is it really and how is it measured? What does it mean, that it's an approximate molecular weight and that's what I would like to ask you a few questions about.

A. So it had an approximate molecular weight. You can see they break it down by 100,000; 200,000 and 300,000 so for their customers they broke it down to these nice units and chunks and they can buy those of that



approximate molecular weight. That doesn't actually represent the exact molecular weight at any particular lot that they sent out.

So the precise value of what is the weight average molecular weight of a particular sample has to be determined by it says here a rheological measurement. Rheology is the science of flow and solutions. So you take a dilute solution and measure the dilute solution from which one measures the intrinsic viscosity so that's the rheological measurement one would use to precisely get the weight average molecular weight.

Also, there is reference in this brochure to a way in which Dow releases samples or deliver samples to customers and --

Q. She's doing that. Doctor, please go ahead. I'm sorry.

A. So I'm trying to describe three things, there's a name, WSR80. There's an approximate molecular weight. And then for a particular example, there would be a precise molecular weight determined from this intrinsic viscosity measurement. It's also a very crude measure which will be the viscosity of a 5

percent solution.

So that's a way in which a customer when they deliver a sample can quickly see is this in the right ballpark, is representative of this sample I bought. And you will see the viscosity measures for the second pair WSR N80. It goes from 55 to 90, so clearly so it's not just a 200,000 molecular weight which is for every sample sent out. There's a range of molecular weights. And this range of viscosities is their release of criteria for customers to accept it.

The particular precise molecular weight of that particular sample would be determined by the viscosity average molecular weight.

Q. So this is JTX30. Dr. Prud'homme, unpack that a little bit. It's a lot of there.

You heard Dr. Amiji testify that the viscosity ranges that are talked about on the right side of the slide there, of the chart that we have up, the 5 percent solution, et cetera, I believe that Dr. Amiji said that these rheological tests were done and that was correlated somehow with the approximate molecular weight that resulted in the table where you have 100,000; 200,000. Did you hear that testimony?



A. I heard that testimony.

Q. Is that how it works?

A. No, that's incorrect. That 5 percent solution viscosity says that that sample is a WSR N80 for the person who's receiving it. I've been a consultant with Colgate, for example, and they would receive polymer samples and they would run this test and say, okay, does it fall in the 55 to 90 centipoise range of this experiment. And if it did, then they would accept that sample as being this WSR N80 that they purchased from Dow. So this is really a qualification measurement rather than being used to measure a precise molecular weight of that sample.

Q. Where did the approximate molecular weight come from?

A. Historical, at some point it was measured and defined this product line. So it's retained as a way to identify for customers what the approximate molecular weight range for these samples that they want to buy.

Q. Now, Dr. Amiji also talked about that in Dr. Yau's analysis the viscosity



average molecular weight was a lower number around 100,000 as compared to the approximate 200,000 of the N80, and there's been some discussion about how can that be. Can you comment on that?

A. As I said, the approximate molecular weight range is 200,000, is a number that goes back 40 years. So within that designation WSR N80, 200,000 going back 40 years, they sold products which satisfied the release characteristics of their customers of 55 to 90 centipoise. So this material that Dr. Yau did a precise measurement of would satisfy that viscosity range release criteria.

But there's nothing inconsistent with this approximate or nominal molecular weight range specified by Dow, 200,000 and the actual precise viscosity average molecular weight reported by Dr. Yau. Dow will not release any of their viscosity molecular weight average results on individual samples to customers.

Q. Dr. Amiji, I believe, was also asked on Direct Examination how would the person of skill going about knowing if a



particular polymer sample fell within the range of the claims. Do you recall that?

A. Say that again, please.

Q. That Dr. Amiji was asked on Direct Examination, how would a person of skill understand whether a particular polymer sample, the molecular weight of that sample fell within the requirements of the claims of the '150 patent. Do you recall that?

A. Yes, I do.

Q. Let me ask you that same question. How do you think a person of skill would go about understanding how to perform that analysis?

A. As I understood Dr. Amiji's answer would be he would take this approximate molecular weight value off the bottle and say this is what the molecular weight of that sample is. I believe a person of skill in the art at the time of the invention would realize that one needs a precise number if one is going to try to defend the patent or decide whether there's infringement.

So one would use a precise measure of

the molecular weight, the viscosity average molecular weight, to determine the exact characteristics of a sample.

Q. How would a person of skill go about doing that?

A. At the time of the invention, the technique that would be used then and today would be gel permeation chromatography. One needs to look at the entire distribution to know whether there's a component which is in this high intermediate molecular weight and low intermediate molecular weight range. One can't determine whether there's multiple bottles or one bottle. One needs to look at the product and say does this infringe. And one does that by looking at the distribution to see if it satisfies the claim construction which Your Honor defined.

Q. And so if you're going to -- if you have to do GPC, do you have to understand the molecular weight distribution?

A. That's right. If I'm trying to find out whether there are individual steps that fall under the claims of this patent, I



believe one needs to look --

MR. SMEREK: Your Honor, we will object to the extent that we're in the invalidity case. The infringement case has closed.

THE COURT: I was wondering about that.

MR. LADOW: Well, Your Honor, it seems that there is this crossover between their infringement case and their indefiniteness case. And part of that indefiniteness case is you heard on Direct of Dr. Amiji, well, we just don't know what it means, the person of skill wouldn't know what to do, when it comes time to look at infringement, you have all of these molecular weight values and the patent doesn't say what it is. And part of that crosses over between those two and that's why I'm asking Dr. Prud'homme these questions.

THE COURT: Well, I will allow it. but I will not allow it to be part of



the infringement or noninfringement argument. But for this part, go ahead.

MR. SMEREK: Thank you, Your Honor.

MR. LADOW: Understood, Your Honor.

BY MR. LADOW:

Q. Going back to where we were, you need GPC to do molecular weight distribution, I think you said?

A. Yes.

Q. If you wanted to determine whether you had a polymer sample, a person of ordinary skill that met the requirements of the claims and if you understood the claims, what would you do with GPC in order to determine whether your sample met the requirements of the claims?

A. I would do GPC. I would look, therefore, at the distribution of polymers and then the claim construction is are there two different sets of polymers that have this average molecular weight specification.



Therefore, I would analyze it according to that criteria and say are there two different sets which would satisfy this lower intermediate and higher molecular intermediate specification.

Q. You also heard testimony that GPC is not like going to the drugstore, but it's not as readily available to the consumer. But is it well-established and available in the pharmaceutical analytical space?

A. It's a standard analytical procedure, yes.

Q. And if you're trying to analyze whether a sample falls within a claim that you do GPC, what steps would you take after that in order to determine whether a person of the ordinary skill was trying to determine whether his sample falls within the claim? What would they do next?

MR. SMEREK: Your Honor, I believe it's outside the scope of what was offered on the invalidity case and really is an attempt to use infringement.

THE COURT: Well, I will not use

it for that purpose so I will overrule it.

THE WITNESS: Can you state the question again?

BY MR. LADOW:

Q. Yes. So you need a molecular weight, you have a molecular weight distribution, you have to analyze it, you've done GPC, and now, you're going to try to see whether the samples you have meet the requirements of the claims of the '150 patent. What are you going to do next?

A. What I would do looking at the claims of the '150 patent I'm directed towards is there this higher molecular weight component and is it more than a stray amount. Therefore, I would will draw it at that 600,000 molecular weight boundary which is the lower boundary of the weight and say, is there a stray amount or not, if I was concerned about that.

And then I would do the averaging of the components that were in the higher molecular weight distribution and averaging of the components that were in the low molecular weight distribution and I



would see what that average is as Dr. Yau and Dr. Lathis(ph) has done.

Q. And you were asked about partitioning at your deposition; is that right?

A. Yes.

Q. And you --

MR. SMEREK: Your Honor --

THE COURT: Mr. Ladow, I don't understand how this deals with indefiniteness.

MR. LADOW: I will move on, but it's because they have asked as I said Dr. Amiji if a person of -- on indefiniteness, not on infringement, Your Honor. If a person of ordinary skill has a sample, how do they understand what to do with it. And Dr. Amiji said, well, the person of ordinary skill can understand the claims and can't understand how --

THE COURT: Well, that's the question, can they understand the claims. That's what we're talking about what do the claims mean. Once



we figure that out, I think the record will be sufficient as to whether or not they can. But I don't think that's what you're asking about.

MR. LADOW: I will move on. Thank you, Your Honor.

THE COURT: Why don't we take our lunch break and we can come back in an hour and continue with Dr. Prud'homme and whatever else we have.

Is there anything you want to talk about before we take lunch break?

MR. LADOW: No, Your Honor.

(Luncheon recess taken.)

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- AFTERNOON SESSION -

THE COURT: All right. Please be seated. Dr. Prud'homme can come back.

MR. LADOW: Your Honor, should I approach now with these or wait until after his testimony?

THE COURT: I don't know what they are, but, sure, bring it ON up.

MR. LADOW: It just relates to Dr.



Prud'homme.

(Binders handed to the Court.)

MR. LADOW: Shall I begin, your Honor?

THE COURT: Yes.

MR. LADOW: Thank you.

Could we go back to DDX-4.013? I just want to make sure the record is clear on one thing. I may have misheard Dr. Prud'homme.

BY MR. LADOW:

Q. Dr. Prud'homme, viscosity average molecular weight is typically closest to which of the other molecular weight averages that are there?

A. To weight average molecular weight.

Q. And those two typically tend to be fairly close?

A. For this class of polymers, within something like ten percent, yes, they're relatively close.

Q. And viscosity average molecular weight is usually not close in these types if polymers to number average or Z average, the

release that you stated earlier?
A. It is not.
Q. Okay. So to conclude in regard to indefiniteness, Dr. Prud'homme, based on materials that you have looked at and looking at the claims and the specification, the file history, what's your conclusion as to whether a person of ordinary skill in the art in 2003 would have been able to understand the claims of the '150 patent with reasonable certainty?
A. I think they would have understood them with reasonable certainty, yes.
Q. Thank you.
We're going to move on to the priority issue.
MR. LADOW: If we could call up DDX-4.018.
BY MR. LADOW:
Q. Dr. Prud'homme, do you recall that this slide was used during Dr. Amiji's presentation?
A. Yes, it was.
Q. And it related to the priority discussion?



A. Yes.
Q. And that you understand that we're talking about in part, U.S. Application 902, which is JTX-0249?
A. Yes.
Q. And then the question is whether or not the priority of the '150 patent goes back to May 28, 2003, based on the contents of the 902 application; is that right?
A. Yes.
Q. And that Dr. Amiji testified that he located, or he identified three elements that he was looking for in that application, and he said the first two were there that he's got checked off on the slide, but he didn't think the third one was there.
Did you hear that testimony?
A. Yes, I did.
Q. Did you agree with that testimony?
A. No, I don't.
Q. We're going to turn to the 902 application, but before we do that, could you just give us a high level view as to the nature of your disagreement with the conclusion that



the 902 application doesn't set forth this third requirement, which, as I understand it from Dr. Amiji's testimony, is that the low molecular weight PEO is 60 percent or more of the PEO and HCP combination where the PEO has both a lower and a higher, consists of lower and higher sets as described in the claim?
A. I think that as Dr. Amiji and I agree, that the 902 sets forth polymer components as being PEO and hydroxy cellulose that describes a low and high molecular weight PEO component, and I believe the specifications clearly lay out that this low molecular weight PEO component should be 60 percent or greater of the total polymer component. So I think that's clearly laid out.
Q. All right. Why don't we go to that. Let's call up JTX-249 at page 30, and see if we can blow this up.
So, Dr. Prud'homme, do you understand that this is page 30 of the 902 application?
A. Yes, I do.
Q. And you studied the 902



application to see whether or not this, these elements were present?
A. Yes.
Q. And is there anything that you think is significant on this issue in the first paragraph here?
A. Yes. So as being highlighted in the first paragraph, that it describes POE in desirably from about 20 to 100 percent by weight on the polymer component. So it's defining the polymer component and saying PEO is part of that.
And then it says, the hydrophilic cellulose polymer range is from zero percent to 80 percent, and so that's defining a second polymer which may be a part of the polymer component.
Q. All right.
A. And it gives a range zero to 80 percent.
Q. Thank you.
And is there something in the last paragraph you wanted to point us to?
A. Yes. So in the last paragraph, it

says, in some embodiments, it may be desirable to combine a high molecular weight component with a low molecular weight PEO component. Once again, it's identifying that the polymers in the system are, defines this term polymer component.

Q. All right. Can we go to the next page of the 902 application, so that's JTX-209 at 31.

A. Yes.

Q. And we've abstracted out two paragraphs here, and why don't we talk about the first paragraph first.

A. All right. So they are talking about desirable characteristics, and they say, these can be achieved by combining small amounts of high molecular weight PEOs with larger amounts of low molecular weight PEOs. So there it's describing these two PEO components. And desirably, such competitions contain about 60 percent or greater levels of the lower molecular weight PEO in the PEO-blend polymer component. It's talking about the blend polymer component and polymer component has been defined



as PEO plus 8 PMC or HPC, if it is, in fact, there.

So I think it's connecting this term that polymer component means all the polymers in the system. And it's saying that a desirable formulation is one that has 60 percent or greater levels. So I think this speaks directly to claim 1.

Q. All right. Why don't we go to this bottom paragraph and tell us how that bears on this priority issue.

A. The adjacent paragraph says that that film compositions may include about 50 percent to 75 percent low molecular weight PEO optionally combined with a small amount of a higher molecular weight PEO, with the remainder of the polymer component containing a hydrophilic cellulosic polymer. So, again, it is identifying the polymer component comprises or may comprise PEO plus HPMC, or plus cellulosic.

Q. And let me ask you a couple questions about this paragraph. So when it talks about the 50 to 75 percent of the low



molecular weight PEO, do you understand this to be saying that that 50 to 75 percent low molecular weight PEO is in the polymer component?

A. Yes.

Q. And would you understand, do you think a person of ordinary skill would understand the phrase, 50 to 75 percent low molecular weight PEO that we see there as including 60 percent or more PEO?

A. Absolutely.

Q. Let's go on to JTX-249 at page 83. It's page 83 of the 209 application.

And was there something in this passage that you wanted to highlight?

A. So again they're talking about desirable characteristics and polymer components containing about 50 percent or higher levels of PEO, so again they're talking about polymer components.

And specifically, in those films containing combinations of varied molecular weight PEOs, those with about 60 percent or higher of the lower molecular weight PEO and it



gives a molecular weight range for that, dissolved faster. It's defining the 60 percent or higher and is including the polymer components, which has always included both PEO and HPMC if that's in the formulation.

Q. Thank you.

Why don't we go back to the last page we were on, which is page 31 of the application.

You now, Dr. Prud'homme, these passages in the 902 application that you've been covering, are they also found in the same language in the '150 patent itself?

A. Exactly.

Q. And is that shown here on, in what we see is the bottom right from the patent?

A. Yes. The top left is what we've been discussing out of the 902. The bottom right is the corresponding section out of the '150 patent that shows are identical.

So the inventors, I believe, had described the scope of the invention, had that technology, and therefore included it now in the claims of the '150 the.

Q. And this is an illustrative section where it's the same in the '150 patent, and that's true for the other passages that we saw in the 902 application?

A. Yes. Both specifications are essentially identical.

Q. So having gone through this analysis of the 902 application, Dr. Prud'homme, is it your opinion that a person of ordinary skill in the art in 2003 would understand that the inventors of the '150 patent as of that date were in possession of an invention that corresponded to the claims of the '150 patent, including that 60 percent or more of the polymer component would consist of the low molecular weight of PEO where you could also have HPMC as one of the polymer components?

A. Yes, I do.

MR. LADOW: Thank you. Thank you, Dr. Prud'homme. No further questions.

THE COURT: All right. Cross-examination.

MR. LADOW: Oh, I'm sorry your Honor. I do have one other question.



THE COURT: All right.

MR. LADOW: Sorry, counsel.

THE COURT: Direct examination.

MR. LADOW: My apologies.

THE COURT: No problem.

MR. LADOW: Could we go for a moment to PDX- 1822.

BY MR. LADOW:

Q. So is it the case that if your understanding is the 902 application is the priority date of the '150 patent, that the '150 patent has a priority date of 2003?

A. Yes, it is.

Q. And if that's the case, would the Yang reference that you heard Dr. Amiji talk about be prior art for the '150 patent?

A. It would not.

Q. And why is that?

A. Because in the, the 902 disclosure has all of the elements that are common to the '150 patent. It proves the inventors had the scope of the invention, understood the invention at the time of May 28, 2003, and therefore when they filed the '150 patent and added those



claims, they still contained -- they've taken the content of the 902 application.

Q. And the Yang reference was published in 2005; is that correct?

A. Yes.

Q. And --

A. That's after the 2003 date of the 902 patent.

Q. Thank you, sir?

A. Application. Sorry.

MR. LADOW: To revisit having concluded the examination, thank you, Dr. Prud'homme.

THE COURT: All right. Thank you, Mr. Ladow.

Mr. Smerek?

MR. SMEREK: Thank you, your Honor. CROSS-EXAMINATION

BY MR. SMEREK:

Q. Good afternoon, Dr. Prud'homme.

A. Good afternoon.

Q. I want to focus on your opinions on indefiniteness first.

You would agree with me that there



are multiple ways to characterize molecular weight known in the art; is that correct?

A. By characterize, do you mean experimentally, or do you mean to represent the results of experiments?

Q. I mean just in general, there are multiple different methods to characterize molecular weight; is that correct?

A. There are various experiments that allow one to measure and characterize molecular weights. There are various ways of reporting information on distributions to provide information about molecular weights, yes.

Q. And we have not even today talked about all of the various ways to calculate or experimentally determine molecular weight; is that correct?

A. We have not talked about them all. That's correct.

Q. And you've been here for the testimony. You were here yesterday as well; is that correct?

A. I was here yesterday, yes.

Q. And there has been a lot of

testimony about the various ways to calculate experimentally or characterize and determine molecular weights of different polymer samples; is that correct?

A. There hasn't been much discussion of experimental techniques. There was discussion of GPC and to analyze the distribution once one obtains it. And there has been discussion about intrinsic viscosity measurements.

Q. And intrinsic viscosity, that's the rheological measurements that there has been testimony about?

A. That's the rheological measurement or viscosity measurement.

Q. And so you would agree with me there are many other ways to characterize or experimentally determine molecular weight?

A. There are a finite number of ways.

Q. But we have not talked about them all?

A. We have not talked about them all.

Q. The ones we have talked about, we've heard testimony about numbered, number



average molecular weight; is that correct?

A. We have talked about that.

Q. And weight average molecular weight?

A. We have talked about that.

Q. And the average molecular weight?

A. Yes.

Q. And the viscosity average molecular weight?

A. Yes.

Q. And there's also peak average, peak molecular weight. That's another way to characterize molecular weight?

A. I'm not familiar with people describing peak average molecular weight. I've never seen that used.

Q. And, I'm sorry. Peak molecular weight. Not peak average, but just peak molecular weight.

A. I'm not familiar with that being a standard term in the polymer science community to determine, to describe molecular weight distributions or polymer averages.

Q. Are you aware of that at all?



Peak molecular weight?

A. Your expert yesterday, he was questioned, he picked the peak value.

Q. Okay. And all of these different methods that we've talked about and others that we have not, they all result in different, a different answer for the molecular weight of a particular sample; is that correct?

A. Different analyses will give, for a single distribution will give you different averages, correct.

Q. Different average molecular weights?

A. Yes.

Q. And the patent doesn't expressly identify any specific method to determine molecular weight; is that correct?

A. As I've testified, I believe that the patent, because it goes back to the train from Dow materials, Dow specifies materials as viscosity molecular weights and that's the common thing to do. That would be I would say almost universal in my understanding of how to report average molecular weights.



Q. Thank you.

But I just want to be clear. The patent itself doesn't specify any specific molecular weight to use?

A. I said I think it's because it's so universally accepted, it's implicit.

Q. And the patent does not actually say viscosity average molecular weight; is that correct?

A. As I just said, I believe it's implicit.

Q. And I'm just, if you just answer my question: Does the patent specifically reference viscosity average molecular weight?

A. It does not because it's implicit in the, in molecular weight of these sorts of polymers that would be a viscosity average molecular weight.

Q. Thank you.

And I would like to go there because I understand that it's your testimony and your opinion that a person of skill in the art would know, looking at the patent, that the patent would be discussing viscosity

molecular -- viscosity average molecular weight as would be described by the manufacturer; is that correct?

A. As would be commonly understood by a person of ordinary skill in the art, yes.

Q. And let's go ahead. And I think you got that from the references in the patent, you said?

A. Well, also just my general understanding of this field over my career.

Q. And I'm not talking about specifically your testimony about what the patent specification describes for molecular weight. It's your opinion that the patent describes viscosity average molecular weight; is that correct?

A. What I'm saying is, I believe because it uses the Dow material, Dow material is described in terms of the molecular weight, it would guide one in that direction, but I think that one would end up always in that direction anyway.

Q. So just so I'm clear, the answer to my question is that it's your testimony that



the patent specification would teach a person of skill in the art to use viscosity average molecular weight as demonstrated by what was reported by Dow?

A. Not quite.

Q. Okay.

A. I --

MR. SMEREK: Well, can we look at the patent specification? If I could see Table 21, please.

BY MR. SMEREK:

Q. So now we're showing you Tables 21 and 22 from the '150 patent. You've seen these before; is that correct?

A. I have seen these before, correct.

Q. Okay. And focusing on Table 21, there's a footnote at the bottom of the table, and it says, available from the Dow Chemical Company. And that's a footnote referring to the PEO in Table 21; is that correct?

A. Yes, it is.

Q. And that's the basis for your testimony that the specification would teach a person of skill in the art that average



viscosity molecular weight is what one would look to; is that correct?

A. I said that's part of what would direct one to consider how Dow reports their, their viscosity values.

Q. And there's nothing else in the patent specification or the patent claims that talk about molecular, the average molecular weight; is that correct?

A. Not the average. It gives ranges for the average molecular weight.

Q. And there's nothing else in the patent specification except for this footnote here that would tell a person of skill in the art how to compute, calculate, determine average molecular weight as used in the patent; is that correct?

A. No. I believe that it would be implicit in this whole field that if I want to report an average molecular weight, it would be a viscosity average.

Q. And then looking at what was actually reported or used here in Table 22, Table 22 reports different compositions; is that



correct?

A. Yes.

Q. And it uses or identifies different molecular weights for each of those different compositions; is that correct?

A. Yes. Those are the nominal values on the bottles that were used in the experiment, yes.

Q. Okay. So the patent, when it's talking about molecular weight in Table 22, is using the molecular weight as you said, the values provided by the manufacturer on the bottles; is that correct?

A. Correct.

Q. Okay. Now, it's your testimony that you can't rely on the viscosity average molecular weight as reported by the manufacturer; is that correct?

A. I didn't say that. What I said was, these values, these nominal values give you guidance as to the approximate molecular weight of that sample, but one would need to measure that if one is asking questions, do I infringe or not. So this would be general guidance as to

what the ranges one might expect when one is doing this design and experiments.

Q. And I just want to understand. If I'm a person of skill in the art and I see reported in the patent, Table 21, that I can look to Dow and I see reported in Table 22 the, what you would agree is the range of weights reported by Dow, and now you are telling me that I can't use that, I have to use a viscosity average molecular weight that's calculated somewhere else, how is the person of skill in the art to know what the average molecular weight would be in order to fall within the claims of the patent?

A. I think you might have inadvertently used a phrase there where you said Dow reports a range of molecular rates, and that's the whole point, is they don't tell you what range a molecular weight is between the 200,000 or the 300 or the 900,000 sample. They're telling you, this is our placeholder, this is approximately what it will be. If one has to ask the precise question what is that, one needs to measure it.



If one needs to say, are there two sets which have these two different properties on a sample, one would have to take that set apart, do the distribution, and look at it and measure it.

Q. And I'm sorry. I perhaps was not clear in my question. If you look at Table 22, it identifies one, two, three, four different sets, types of molecular weight PEO; is that correct? It identifies 100,000 dalton molecular weight; is that correct?

A. Yes.

Q. And 200,000 PEO molecular weight? 200,000 daltons?

A. Yes.

Q. And 300,000 daltons for a PEO molecular weight?

A. Yes.

Q. And 900,000 daltons?

A. And I think the way you characterize these as types is the appropriate way to characterize it.

Q. They're grades of PEOs.

A. Grades or types.



Q. From Dow?

A. Yes.

Q. And they reflect those identified molecular weights as they're sold by Dow; is that correct?

A. No. The point I just make --

Q. You said no. I just want to understand. Are those the molecular weights for the grades that Dow, that Dow reports?

A. No.

Q. So those -- that's fine.

A. May I answer?

Q. Well, you said no, and that's enough.

A. No. I don't feel that fairly characterizes my opinion when you ask me a question.

Q. Well, let's go ahead and bring up the Dow chart, the Dow brochure, which I believe is, let's see -- thank you.

And we're looking at the Dow brochure. And can I get the bottom as well? You've seen this; is that correct?

A. Yes, I have.



Q. And this is the Dow brochure that we've talked about and they give a molecular weight; is that correct? An approximate molecular weight for the various different grades that a POSA could buy, a person of skill in the art; correct?

A. An approximate molecular weight, and I --

Q. Approximate molecular weight. That's what they say at the top?

A. Yes.

Q. And you can buy them in grades, including 100,000, 200,000, 300,000. We saw those in the patent; is that correct?

A. Yes.

Q. And 900,000. We saw that in the patent?

A. Yes.

Q. So Table 22 in the patent, you would agree, correlates to the grades that you can buy from Dow. A person of skill in the art looking at the patent would know that they could go to Dow and they could buy these grades that are -- that are disclosed in Table 22 from Dow;

is that correct?
A. Correct.
Q. And you're saying that they, they couldn't, the person of skill in the art couldn't rely on those grades as identified in Table 22 in determining whether or not they, they infringe the patent?
A. I didn't say that.
Q. All right. And down here it's correct that Dow reports that these grades are based on rheological measurements; is that correct?
A. Yes.
Q. And that they're going to vary from other methods that we've discussed for describing molecular weight, including gel permeation chromatography, or GPC; is that correct?
A. If you look at the phrase, may not be directly comparable, they're giving themselves some caveat or some room to say that the nominal approximate values are not what one might get from other more precise measurements. And, in fact, for a particular set of, let's



say, type 200,000, if one does the accurate molecular weight measurement, one will get a value which is not exactly 200,000.
Q. And that accurate weight measurement is a GPC analysis, in your view?
A. If one is asking the question about the entire distribution, one can do an intrinsic viscosity experiment, which is done by a rheological measurement, diluting solutions, floating them through a capillary, measuring time to get one number.
Q. You were here during the whole part of the trial yesterday and today; is that correct?
A. I have been here, yes.
Q. You didn't hear any testimony from any of the experts about anybody doing any kind of rheological measurements on any samples; is that correct?
A. I --
Q. Just, if you -- if you heard it or didn't hear it, I didn't hear anything and I just want to know if I missed something.
A. Okay. Based on rheological



measurements, what Dr Yau did was a GPC separation and then analyzed each fragment.
Q. Thank you.
A. Based on rheological measurements, which correlates the intrinsic viscosity to the molecular weight.
Q. You didn't hear anybody actually did rheological measurements on a sample of Dow N80; is that correct?
A. I did not see intrinsic viscosity measurements that anyone has done, that is a single experimental intrinsic viscosity measurement done --
Q. Thank you.
A. -- on any sample.
Q. I now want to move over into the priority date argument. And I guess just the first question: You offered no opinion in your -- you addressed Yang in your expert report by contending that that reference was not prior art; is that correct?
A. That's -- yes.
Q. And you offered no opinion in your expert report that if Yang was determined to be



prior art, because the priority date shifted, you offered no evidence in your expert report that it, that it wouldn't render the claims, the asserted claims of the patent obvious; is that correct?
A. I offered no opinion because it was no prior art.
Q. Thank you.
If we could go ahead and look at JTX-249. And if we could jump to, I think the page you were looking at was 31 that you said had the description of the 60 percent limitation.
And if we could look -- do you remember, it was the top, top paragraph and top two paragraphs and the bottom paragraph, I think.
Now, let me just stay here for a moment. And I think you mentioned 60 percent, and you said that in your view, we see 60 percent, and you mentioned, you said 60 percent was between 50 percent and 75 percent; is that correct?
A. It is.

Q. And that was the basis of your opinion, or at least part of your opinion as to why Yang was not prior art, because 60 percent clearly fell inside of 50 to 75 percent?

A. We looked at several of these sections of the specification. I believe that they clearly lay out that the low molecular weight PEO is to be 60 percent or greater of the total polymer component, yes.

Q. Well, this does not say 60 percent or greater, does it? 50 to 75? Well, let me --

A. I'm looking above. 60 percent or greater levels of the PEO blend. That's the total polymer component. I believe that clearly says it, yes.

Q. Thank you.

So let's look up at the first paragraph. That's where you were looking?

A. Yes.

Q. It says 60 percent or greater levels, okay, of the lower molecular weight PEO, so we have that. And then we say, in the PEO blend polymer component. So there it's looking at 60 percent of the low molecular weight PEO in



the blend of low and high molecular weight PEO; is that correct?

A. I interpret polymer component as I showed in several places to mean whatever polymers are there.

Q. Okay. But in this particular sentence, it's only disclosing the PEO blend; is that correct?

A. They -- this experiment is on the PEO.

Q. Okay.

A. Part of the polymer.

Q. And so if I could look at the next paragraph, it says, to balance the properties of adhesion, and goes on. And then it says, film compositions may include 50 to 75 percent low molecular weight.

Now, let's just stop there. The asserted claims are 60 percent or greater of the overall polymer component is low molecular weight; is that correct?

A. Yes.

Q. And you would agree that 60 percent or greater, that's the claim term --



you would agree that 50 percent to 75 percent does not fully describe the range of 60 percent or greater; is that right?

A. No. I believe it does. And --

Q. Well, so let me explore that.

So if I had 80 percent low molecular weight PEO, would, in your opinion, your expert opinion, would 80 percent low molecular weight fall within the claim of 60 percent or greater that we see in the patent?

A. I believe that second paragraph --

Q. I'm sorry. Right now I'm talking about the patent. Would the limitation of 60 percent or greater, would 80 percent low molecular PEO fall within the limitation of 60 percent or greater?

A. If it satisfied all three of those elements of the, of the patent claims.

Q. Thank you.

A. Both PEO, possibly HPMC, high and low molecular weight set and 60 percent or greater, it would fall within the claims I believe.



Q. So if we had 80 percent low PEO and we also had in your view the high molecular weight PEO component and the HPC component, that would satisfy 1 and 2, the other two parts of this claim, you would agree that 80 percent would be covered; is that correct?

A. If all three of those elements are in place, yes, I believe it would.

Q. Thank you.

And so now --

THE COURT: Mr. Smerek --

MR. SMEREK: Sorry.

THE COURT: Just try not to start talking while he's actually -- you know, I know what you are trying to do and I understand it, but let him finish the sentence first.

MR. SMEREK: Thank you, your Honor.

BY MR. SMEREK:

Q. And if --

THE WITNESS: Thank you.

BY MR. SMEREK:

Q. And if we now look at the second paragraph, 50 percent to 75 percent low

molecular weight.
And would you agree with me that a low molecular weight PEO of 80 percent would not be described by the range of 50 percent to 75 percent low molecular weight PEO?
A. As we write patents in my group, what you do is you first set out to do research, and you come up with a design of experiments like they have in Table 22. Then one does those experiments. Then one starts writing the patent to decide, here's what we've learned, here's what we're going to teach.
And then one says, now within what we've learned and what we are going to teach, what do we want to claim, and what are the claims of the patent.
So here they're describing what they have learned, and I think that 60 percent or greater. And then this next one is for adhesion prevention, fast dissolution rate, tear resistance, 50 to 75 percent works well, and optionally a higher molecular weight polymer. So they're laying out what they've learned. And then they took all of their learnings, which is



in all of the specifications, and said, here's what we're going to put in our claims that we can defend.
And I think they have clearly shown that the 60 percent or greater levels was something they decided, this is what we wanted, this is what we can prove infringement, and therefore this is our claim.
So the claim is more specific and narrower than all the teaching specification. But I believe this teaching and specification covers what is eventually claimed.
Q. And I had a very simple question, and it was just: Can we agree that low molecular weight of 80 percent would not fall within the range described by 50 percent to 75 percent low molecular weight?
A. It would be above 50 to 75 percent.
Q. And -- thank you.
MR. SMEREK: Nothing further, your Honor.
THE COURT: All right. Any redirect here?



MR. LADOW: Nothing further, your Honor.
THE COURT: All right. Professor Prud'homme, you may step down. Thank you.
THE WITNESS: Thank you very much.
(Witness excused.)
MR. LADOW: Your Honor, we had originally planned for two other witnesses, but in the interests of time, plaintiffs are not going to put on their commercial success witness, and if I understand correctly, defendants are not putting on theirs since there's nothing to rebut.
THE COURT: So does that mean that you're not calling Professor Bell, or Dr. Bell, and they're not calling Ms. Lawton?
MR. LOMBARDI: Your Honor, we were presented with this literally five minutes before we came in. I wondered if your Honor can give us a minute to --
THE COURT: I can certainly give you a minute. In other words, Mr. Ladow, you're not calling Dr. Bell?
MR. LADOW: That was the



intention, your Honor.
THE COURT: Well, okay. I mean, now we're turning that intention into a reality. Right?
MR. LADOW: Yes, your Honor.
THE COURT: Okay. All right. So they're not calling him.
And maybe or maybe not, but I will certainly give the defendants a chance to think about it, though it's hard to figure out -- well, in any event, I will give them a chance to think about it.
Do you have any more people you want to call today or is that it for you?
MR. LADOW: That would be it for today, your Honor, and the rest would be in December.
THE COURT: Okay. Well, do you want to take a little recess and I will let you all talk about it?
MR. LOMBARDI: That would be fine.
THE COURT: Take as much time as you need. Since we're not going to be doing much more today under any circumstance, why

don't we just take a 15-minute break.
MR. LOMBARDI: Thank you, your Honor.
(Short recess taken.)
- - -
(Proceedings resumed after the recess.)
THE COURT: All right. Please be seated. So what's the status now?
MR. LOMBARDI: Well, your Honor, the bottom line is, we believe we should go ahead and present a streamlined version of this witness. I can explain to you why.
There is a difference in understanding between the parties on what the commercial success evidence has been so far and what witnesses --
THE COURT: I would have said right now there's no commercial success.
MR. LOMBARDI: I'm sorry. I should have said secondary considerations, your Honor. That was a misstatement on my part.
THE COURT: Okay.



MR. LOMBARDI: But with secondary considerations, there have been witnesses who, as you know, have testified to things that we believe they shouldn't have testified to. We don't know what the status of that is going to be.
We have offered to do things like to defer this witness until December and reserve our right depending on things that happen in our review of the record, but we weren't able to reach agreement on that.
So I think what we need to do, because she does respond, she does provide evidence that we can argue from on things like long-felt need and --
THE COURT: Is it an economist?
MR. LOMBARDI: She's going to talk about the market and what was in the market before the film and what happened when it went to the film.
And so that gives us -- I agree, your Honor, it's obviously not an economist on the other side that she'll be rebutting at this point, but there's still --



THE COURT: Okay.
MR. LOMBARDI: -- evidence out that there bears some relevance.
THE COURT: Mr. Ladow, what do you have to say? I mean, you don't actually have to say anything.
Well, so they want to put on a witness. Do you oppose that?
MR. LADOW: Absolutely, your Honor.
THE COURT: Okay. That's what I wanted you to say. So why?
MR. LADOW: We have the two doctors, as you know. They were the opposing experts in terms of the field that they were covering.
THE COURT: Yes.
MR. LADOW: The commercial success witness that they're talking about, Ms. Lawton, she's entirely a rebuttal witness to our commercial success witness, Dr. Bell. That's all she did. Her report said, I am rebutting Dr. Bell's commercial success testimony. It's market, economic kinds of information, and it



just has nothing to do with the doctor testimony.
And so there is no commercial -- we're not putting on Dr. Bell. There's no commercial success case to rebut. There can be other secondary considerations in the case in addition to commercial success, but there is no commercial success case here to rebut, and therefore that witness shouldn't go on.
THE COURT: Mr. Lombardi, you're saying you want to call this person, this witness, this expert, not to address commercial success, but to address, you said, long-felt need?
MR. LOMBARDI: Long-felt need and just the general pattern, the general progress of this product in the market.
They have tried -- so for instance, today, we had arguments about, and your Honor deferred ruling about Dr. Langer using -- he put in some documents today from which they want to argue secondary considerations of obviousness, and we offered actually just to drop all secondary

considerations and then we wouldn't be having this discussion.

But our concern is that if we don't put this witness on, that we may be in a position where we don't have evidence we need to rebut any arguments about long-felt need, and so forth.

And so --

THE COURT: Okay. So here's what I propose to do unless, Mr. Ladow, there's something else you want to say right now.

MR. LADOW: I suppose it depends on what your Honor says.

THE COURT: Your right to say something evaporates once I say something. There's nothing you want to say?

MR. LADOW: No, your Honor.

THE COURT: Okay. Well, I am dubious that this witness has any relevant information, but I really can't tell that without hearing what the witness has to say.

So I assume she's here, they're ready to go, you're ready to cross-examine her. So I'm thinking let's have her called, have her



testify. You can cross-examine her, and if it turns out that she has no relevant information, you know, I wasn't planning on doing anything else this afternoon anyhow.

MS. BOURKE: Can I add to Mr. Ladow's comment?

THE COURT: Okay.

MS. BOURKE: Ms. Lawton put in a rebuttal report to Dr. Bell. But for Dr. Bell's report, Ms. Lawton wouldn't have put in a report.

I can read to your Honor the assignment that she had.

THE COURT: Well, why don't you pass it up. Well, no. Put it on the record. Sorry. Go ahead, Ms. Bourke.

MS. BOURKE: Sure. She said, I have been retained to analyze and provide my opinions regarding plaintiff Reckitt's claims that the alleged commercial success of Reckitt's Suboxone sublingual film is attributable to the '832 and the '514 patent as set forth in the expert report of Gregory K. Bell, PAC, dated April 10, 2015. Her report goes in in May.



She says, My analysis in response to Dr. Bell's report is divided into two main compounds. Then she goes on.

She's a rebuttal witness to Dr. Bell, and but for Dr. Bell, she wouldn't be here today. And if we have withdrawn Dr. Bell, then Ms. Lawton doesn't have a basis to testify.

THE COURT: All right. I understand what you're saying.

Mr. Lombardi?

MR. LOMBARDI: Yes.

THE COURT: What do you have to say to that?

MR. LOMBARDI: Well, the fact that she got into the case in the first place as a rebuttal to one of their witnesses doesn't dictate whether what she says has some relevance.

So we heard Dr. --

THE COURT: Well, but I mean, she's a rebuttal witness on commercial success, and if it seems to be agreed that commercial success is not in the case anymore; right?

MR. LOMBARDI: They are dropping



commercial success, but, for instance, we heard from Dr. Wollschlaeger, I believe I have that right, who talked at length about the switch from tablets to the film. He talked about that from a medical perspective. She can shed light on that from an economic perspective. And the fact that they've withdrawn somebody who can talk about the economic part doesn't mean that she's not relevant to the economic part.

So, Judge, we're in a position right now where we have to decide for the whole case, because we're coming back in December, whether to put this witness on.

We asked for --

THE COURT: I mean, I understand, more or less, that this is a good time to decide, and that nothing -- my impression is nothing that's going to happen after this is going to change whether she has relevant testimony or not.

MR. LOMBARDI: We tried to get that agreement. We asked if there would be an agreement there would be no further secondary testimony, no surprises, nothing like that, and

we couldn't get an agreement to that.
So here we are in a position where we can't nail down -- we actually don't now what the record says right now. We have a recollection, but we have not had a chance to look at it. So we can't nail down exactly what has happened now. We don't know what will happen in the future, and if what happened the last two days is any indication, there could be surprises in the future. And we're being told that you should have to give up this witness just because we have given up a witness that we -- that we don't want to call.
So I guess I would suggest this, your Honor. I think, I understand that there may be a dispute about whether it's ultimately relevant, and I think I'm not trying to foreclose that at all. I mean, I understand that if you were to take this testimony, there would be argument about that.
But I think we ought to go forward with it, or -- and I think that's the most efficient way of doing it. But if we are not going to do that, to foreclose us completely I



think would be prejudicial to us, because we don't know what's going to happen in December.
And so, at a minimum, we should be able to reserve the right to bring her back in December. And we tried to get that agreement, too, and we couldn't get that agreement.
So I think the efficient use of time probably, assuming your Honor has the time for it this afternoon, is just to get it done and get it out there, and then we can argue about its significance later. But the one thing I think that would be prejudicial is just to say that we can't do it at all at this point.
THE COURT: Well, and there's no reason why I have to say that at this point, because we have December.
All right. Well, so here's what I think. I recognize the strength, or at least what seems to me the strength in what Ms. Bourke said, and maybe that means -- and maybe that means I shouldn't be allowing this testimony at all. But since we're here, we have the time, and we have time between now and December when you can argue about whether whatever it is I'm



about to hear means anything, why don't we go ahead and you put on the witness for whatever it is that you think she has to offer and, you know, we'll add to the list of things we have to resolve later. We're here, and it just seems like an efficient use of time.
MS. BOURKE: Your Honor, can I just take one more stab at this, if I may?
THE COURT: Okay.
MS. BOURKE: May I hand up the table of contents to her expert report because she can't testify outside the bounds of the opinion that she has provided in her expert report.
THE COURT: I do understand that generally, yes.
MS. BOURKE: So maybe if you took a look at what her stated opinions are.
THE COURT: Okay. Okay.
(Ms. Bourke handed documents to the Court.)
(Pause.)
MS. BOURKE: Perhaps I gave you the pages out of order. I apologize.



THE COURT: That's all right. I've figured it out.
(Pause.)
THE COURT: I take it plaintiff -- what secondary considerations is the plaintiff arguing in this case?
MR. LADOW: So, your Honor, for example, I believe in the expert report of one of the experts who is going to testify in December in connection with another patent that we have not done here today, there's some -- a reference to copying, so that would be a kind of secondary consideration.
THE COURT: Well, so I've heard, or I thought I've heard here one time or another copying, praise, long-felt need?
MR. LADOW: Yes. So what we --
THE COURT: What I'm trying to do is get what the maximum universe of secondary considerations that you either have, that you have, or will in the future put on.
MR. LADOW: Well, one of them is not going to be commercial success.
THE COURT: No. I understand

that, too.
MR. LADOW: And so in regard to what we're going to put on in the whole, yes, it's possible there could be some on copying. There could be some on long-felt need, but I'm just kind of going through categories.
THE COURT: Well, that's what I'm trying to --
MR. LADOW: And --
THE COURT: So --
MR. LADOW: May I, your Honor?
THE COURT: Yes. Go ahead.
MR. LADOW: Yes. For example, one of the things that counsel referenced was that Dr. Langer today, that Dr. Langer today talked about those post 2002 articles, post 2003 articles. And those articles were discussed by his opposing expert, Dr. Dyar, in his testimony. And Dr. Langer said it looked like that was a recognition that this problem had been solved.
And so we can't -- and, you know, there's also unexpected results could be a secondary consideration.



So what we said to defendants is, we can't give up the right to argue any secondary consideration, but what we're clearly doing is we're not presenting commercial success, and therefore the reciprocal evidence doesn't come in.
We have the two doctors. They opposed each other. It does not make any sense for Ms. Lawton to oppose Dr. Wollschlaeger. He's a medical doctor. She's a damages expert.
The other category, your Honor, is typically praise, long-felt need, failure of others, copying and unexpected results are the typical -- and commercial success are the typical categories.
THE COURT: All right.
MR. LADOW: And what Ms. Lawton is really talking about is her view of the internal company history and about the marketing and price and trying to argue that that was a drive, as I said in my opening.
THE COURT: Right.
MR. LADOW: And the person who, that raised those issues was Dr. Bell's report,



that she responded to. So it's not sort of just an incidental fact that she got into the case that way. That's her only reason for existence in the case.
THE COURT: Well, so I'm either going to do one of two things. I'm either going to hear Ms. Lawton right now, or I'm certainly going to say that the defendants can call her, if appropriate, in December.
Which one of those do you want to do?
MR. LADOW: December, your Honor.
MS. BOURKE: Yes. I think it might be better to have the latter, because there are a bunch of highly confidential, outside attorneys' eyes only slides that she has presented, and therefore it's going to raise all sorts of issues about how we're going to publish or not publish, and what we're going to do with those, which we have not resolved with the defendants yet. So if you reserve, we may be able to negotiate that without taking up the Court's time right now.
THE COURT: And, Mr. Lombardi, is



it much of a problem for you to reserve her?
MR. LOMBARDI: Well, there is always the expense, Judge, because --
THE COURT: Yes. It seems like there's a lot of expense going on here.
MR. LOMBARDI: There is. There's no doubt about that. But it's another component of it. She would have to come back and get ready and appear, and she is here and ready to go. And we have actually been able to hone it down, we think, so that it will not be a lengthy amount of testimony. So from our point of view, efficiency would say to do it today.

THE COURT: What did we save for this day, December 18th? We saved infringement of two patents and invalidity of one patent; right?
MR. LADOW: Yes, your Honor. It's infringement and invalidity of the '832 patent and infringement only of the '514, since we heard validity on the '514 during the last couple days.
THE COURT: Okay.

MR. BROWN: In addition, there's infringement of the '150 on Par.

THE COURT: I'm doing that on a different day.

MR. BROWN: I'm sorry.

THE COURT: So I'm not too worried about that. But thank you, Mr. Brown.

So if it turns out, Mr. Ladow, that everything Ms. Lawton has to say is irrelevant, is there some prejudice here to you?

MR. LADOW: Yes. I think so, your Honor. There's -- having made a decision to not put forward commercial success, and since, respectfully, I don't think that they really should be able to do that, I think that it colors the situation to hear it in a one-sided way. And in addition to that, we have these confidential -- she's really, you know, sort of just reading a lot of documents, not offering an expert economic opinion, and she's sort of doing a narrative history of 30 years at the company, and marketing practices. And I think it is potentially prejudicial, and there's also



the confidentiality issue that we mentioned before.

And there's no prejudice to them, putting aside a modicum of cost in the overall scheme of things, waiting until December to see if it's actually relevant, relevant to anything that happens in the case.

And I just wanted to add to that that when counsel was talking about, well, we don't know what's going to happen in December, well, we do know what is going to happen in December. We're going to put on the infringement and invalidity cases we just talked about. We're not going to put on any more doctors. We're not going to put on any more economists. So the things that she would be addressing, you know, we're not putting on in December. That could be resolved then and she could be available then, as you said. So we would respectfully suggest that that is the best course.

THE COURT: All right. I think actually, the -- I'm thinking that the better course here actually, Mr. Lombardi, is not to do



any more today.

I am just thinking about what I've heard so far and what I might hear from doctors or professors who are not economists in the future. I am really finding it hard to believe that a person, an economist, who has written a commercial success report, I'm thinking it's real unlikely that she has much to add on any of these secondary considerations.

I'm not saying that she doesn't, so I will give you a chance in December, and it may be the case -- so that's what I'm going to do. I'm not going to hear her testimony today. And what I've just said is without prejudice to your presenting her in December.

So what I would like to do is hand back the three pages that I got from Ms. Bourke. And does that mean that in terms of testimony, we are through for today?

MR. LOMBARDI: I believe so, your Honor.

THE COURT: All right. One of my staff mentioned that at some point, somebody was talking about a deposition of Myers. Does



anyone know what we're talking about here?

MR. SMEREK: Myers was played yesterday. There was another deposition that I believe plaintiffs were going to play today, but that has been withdrawn, their withdrawal of the commercial success.

THE COURT: Oh, all right. So let's just talk about December for a minute.

My thought had been that we were going to do infringement for Par starting on December 17th, the day that had been scheduled, and we would just do that until whenever it ends. Having seen how long we spent on infringement in this case, I'm wondering, do you have a sense whether, how much time we're going to need for this? I'm wondering whether we actually need -- how much of the day do you think we're likely to need for this?

MR. LADOW: Your Honor, if I could give you a little information that may help with that. I think it's -- I think counsel would agree that the infringement case against Par on the '150 patent, so not the other two patents, but on the '150 patent, much of that case is

much the same as what you heard today because of the particular polymers.

THE COURT: You mean we're going to have a graph with a line drawn through it?

MR. LADOW: The very one.

THE COURT: Okay.

MR. LADOW: And so while they have their own formulation that comes into play at a certain part in that analysis when you look at the percent, the other part of it, you know, is --

THE COURT: Okay. I get that.

MR. LADOW: Yes. And -- well, so what I'm saying is, is that depending on how the Court wants to deal with that, we don't necessarily have to put on all of that same testimony again. It wouldn't mean that the people wouldn't be available to be examined by counsel.

THE COURT: Well, that's something you can work out with Mr. Brown. I mean, you can talk to each other and decide what you want to do about that. You know, Par deserves their day in court, so whatever they want to do is



fine by me.

Well, I guess what I'm wondering is, do you think, since we've -- do you think you can do the rest of this trial in the seven hours that you're allotted December 18th?

MR. LADOW: I think, your Honor, if we could potentially use some of the 17th and then not have the potential of trying to keep anybody later, particularly on that Friday.

THE COURT: Yes, yes, yes. It's not the best time.

MR. LADOW: So I think that from our point of view, if we could bridge between the days and just continue after Par, if that is how the Court wants to do it.

THE COURT: Well, no. I'm perfectly happy to do that. Basically, do Par for however long Par takes on the 17th. Assuming that it does not take until 5:00 o'clock, then just start wherever it is we would start and carry on over into the 18th.

MR. LADOW: That's what we



would -- putting aside whatever discussions we may have about working anything else out, we would propose that, yes.

MR. BROWN: Your Honor, in discussions with Watson, what I think we would propose is that the infringement cases, rather than breaking, having like a special time for Par and then go into basically the same case against Watson, I think you are going to find similar repetition you would see versus the '150 patent. We think it would be much more efficient and easier for the Court to have the infringement cases go forward.

THE COURT: In other words, what you are saying is, what when I originally separated them, merge them back together?

MR. BROWN: Exactly.

MR. NUTTER: It has become that, your Honor.

THE COURT: I'm perfectly fine with that.

MR. LADOW: I think that that would probably make sense, too, your Honor.

THE COURT: All right. Well, I



don't know how -- I am perfectly happy to do that.

Maybe you can just talk amongst yourselves, make sure you've got the details and schedules, and I don't know what else.

MR. LADOW: I think since the Court seems to have some flexibility on it, if counsel can get together and come to an agreement and make a proposal that we could present for your consideration.

THE COURT: Yes. You don't really have to present it for my consideration unless you've got something really odd and go -- you know. I mean, I'm just going to show up on the 17th, and whatever it is you're ready to do, I'm ready. You know, it's like -- well, whatever you want to do is fine.

MR. LADOW: Understood.

THE COURT: And as long as you're agreed amongst yourselves as to what it is. If you have a dispute as to what it is you're doing, then I'd like to know about it in advance. Okay?

MR. LADOW: Thank you, your Honor.

THE COURT: All right?
MR. NUTTER: Yes, your Honor.
MR. BROWN: Yes, your Honor.
THE COURT: All right. So what I'm wondering though is one of the things, what I've heard in the last few days is kind of fresh in my mind right now. It's not going to be fresh in my mind in December.
And I was wondering, it would be helpful to me, assuming that it's not a bad idea for some reason or other, to maybe get in fairly short order what I was thinking was some sort of proposed findings of fact for the infringement of the, I guess the '150, and the invalidity of the '150 and the 541, or whatever the other one is that we've been doing.
And where I sort of imagined, you know, I was thinking -- actually, what I was thinking, and it's just a suggestion is, essentially, five double-spaced pages on each of those three issues, infringement, invalidity of the one patent, invalidity of the other patent, just proposed findings of fact, no legal conclusions, no legal arguments.



You know, I kind of -- this is kind of like Mr. Lombardi was saying. He doesn't know exactly -- he would like to review the record and see what it was that was proved on secondary considerations so far.
I would kind of like you all to get the record, which I assume is probably available real soon, am I right? Okay.
THE COURT REPORTER: Yes.
THE COURT: And tell me what, you know, what it is you think that you proved, and then I wasn't really going to do much with this other than internally digest it while it's still fresh in my mind.
Do you understand what I'm suggesting?
MR. LADOW: I believe so. I take it it would just be regular proposed findings OF fact with record cites, et cetera?
THE COURT: Right. Is that something that you're agreeable to doing?
MR. NUTTER: I believe so, your Honor, speaking on behalf of both defendants.
THE COURT: All right. Is it



something that could be done -- you know, we are talking about less than two days of trial. And obviously, you know, part of the reason for saying five pages per sort of issue is whatever level of detail that allows you, that's about as much detail as I can absorb. I mean, I'm sure you could write 15 pages on each of these issues, but that's not actually -- that's not going to be helpful.
So how long do you think would be a reasonable -- I was thinking maybe this is something you could do by sometime next week?
MR. LADOW: Perhaps the end of next week?
THE COURT: Yes.
MR. LADOW: Or two weeks, your Honor, maybe?
THE COURT: I'm sorry?
MR. LADOW: Perhaps two weeks?
MR. NUTTER: Two weeks, I think.
THE COURT: Two weeks? Okay. All right.
And this is not to say that there might not be some kind of legal briefing on



these things after we do the other trial, but I am cognizant that at least, to some degree, you're going to be preparing for this next trial in the meantime.
And I forget. Do I have a pretrial conference on the Par part of this?
MR. LADOW: Yes, your Honor. I believe it's on that Monday.
MR. FINEMAN: Yes, your Honor.
MS. BOURKE: You do, your Honor. It is on the Monday of that week. The 14th, I think it is.
THE COURT: Okay.
MR. NUTTER: Would you like Watson to attend if it's going to be intertwined, your Honor?
THE COURT: I think you'd attend whether I wanted you to or not, so, yes, you might as well attend.
And, in fact, I will leave it to you all to figure out whether the full pretrial -- I mean, because I guess you probably have not started the exchanges yet.
What is appropriate given that

I've already heard -- you know, I leave it to you to figure out exactly what you want to do in terms of a pretrial conference. It does not have to be the full thing if that does not really make sense.

But is that something, Mr. Brown and Mr. Ladow, you can just figure out what makes sense to do?

MR. BROWN: I think we can, I think we can work out the minimally effective amount of pretrial --

THE COURT: I like that phrase, minimally effective. That's good.

MR. LADOW: We're going to try to work out the maximally effective.

THE COURT: I guess there's something to be said for that, too.

Okay. All right. And then I guess the other thing is, do you want to, in light of the reservation here, do you want to submit some more paper on these six exhibits that the defendant objected to?

MR. LOMBARDI: Sure, your Honor. We're happy to do that. And we probably can do



it quicker than the two weeks, but is it better to have everything come in --

THE COURT: It's probably to have everything, you know, yes. It's probably better to have it come in at the same time.

MR. LOMBARDI: Okay.

THE COURT: But the only thing is, since that's kind of a legal thing, whereas I imagine on the findings of fact, you would just submit them simultaneously, legal thing, it's usually better to have one side go first so the other side can respond to the particular arguments. And I'm trying to think who it makes sense to have go first.

MR. LADOW: Well, I certainly think, your Honor, that it would be the defendants that should go first because they've made a motion in limine already. It was rejected. You've heard the testimony. If they continue to present an objection to it, we would need to know what the grounds are.

THE COURT: What do you say there?

MR. LOMBARDI: No problem.

MR. BROWN: That's fine.



MR. LOMBARDI: No problem.

THE COURT: Okay. When would you like to submit it?

MR. LOMBARDI: I would think a week we could do it.

THE COURT: All right. And I don't think -- I'm not necessarily -- would you rather submit a brief or a letter?

MR. LOMBARDI: And that makes no difference to me, your Honor. Whatever would be easier for you.

THE COURT: Do you have a --

MR. LADOW: A letter is fine, your Honor.

THE COURT: How many pages of single-spaced letter do you think you need?

MR. LOMBARDI: I wouldn't think it would be more than five for sure, Judge, but it would probably be less than that. I'm just trying --

THE COURT: Okay. So I will give you six pages.

MR. LOMBARDI: Okay.

THE COURT: If you write less,



that will be nice, but six would be fine. And I will give you the chance to write up to six in response.

And so you said a week. Today is Wednesday. So next week?

MR. LOMBARDI: Yes.

THE COURT: And then -- okay. Well, you'll be working. We're on holiday.

But, yes. Why don't you just file something next Wednesday. And, Mr. Ladow, you can file something the following Wednesday.

MR. LADOW: Yes, your Honor.

THE COURT: All right. And so I guess in the two weeks for the proposed findings of fact, that would then coincide with when you're filing that other. Everything would then be due a week -- I forget. I already lost track. When did we say that your findings of fact was going to be? That was two weeks, too. Right?

MR. LADOW: Yes.

THE COURT: The 18th. Is that all right? I'm not putting too much of a strain on you since you'll be writing both of these things

at once?
MR. LADOW: I think that's fine, your Honor.
THE COURT: Okay. All right. Is there anything else you want to discuss while we're here today?
MR. NUTTER: Just a clarification regarding the findings of fact requested by the Court. And I understand it is five pages per issue, three issues begin infringement of the '150 patent, alleged infringement by Watson, the invalidity of the '150 patent, and the invalidity of the 154 patent.
THE COURT: Right.
MR. NUTTER: Now, as you know, in addition, they've identified six secondary considerations.
THE COURT: Well --
MR. NUTTER: Can we have five pages on just -- can you make secondary considerations a fourth topic, or should we weave those into the --
THE COURT: Why don't you weave them into the nonobviousness part of your, or



obviousness, whatever your position is. I've already said that secondary considerations that have been done so far is pretty light.
MR. NUTTER: Thank you.
MR. LADOW: Your Honor, if I may on that, I think it -- well, there may be some that, you know, are in December, as we talked about.
THE COURT: Well, no, that's true. So if you think you've done something, put them in yours. If you think they have not done something -- I mean, obviously, all you can comment on is the things they've actually talked about, but if you want to say, you know -- I mean, there's a limit because there may be more of these later on.
MR. NUTTER: Correct.
MR. BROWN: Your Honor, I think that's exactly the issue, which is this trial, but for perhaps copying, the copying issue. But this trial, our understanding, was to be the presentation of all secondary considerations for all patents.
And so we think it would be very



helpful, we want to remove the mystery out of this record that they think is a secondary consideration supporting the '832 patent that's going to be litigated in December so we know what we have to do. You know, whether we have to bring Lawton back.
THE COURT: I thought you were going to read the record and figure that out for yourself.
MR. LOMBARDI: Just frankly, your Honor, part of the issue is, when you asked counsel what secondary considerations were being provided, we've been trying to figure that out as well, and the problem we have is in a normal case we'd be done with the '832 patent before we had to make a call on what we're going to, what we're going to be doing in rebuttal.
And so our understanding was they were supposed to be done the secondary considerations from now, and so --
THE COURT: Well, of course, now continues on to December 18th. Right?
MR. LOMBARDI: No. We thought secondary considerations for everything was --



MR. LADOW: Your Honor -- I didn't mean to interrupt you. Go ahead.
MR. LOMBARDI: That was our understanding, that this two days was the time for secondary considerations overall was how we --
THE COURT: This is an understanding that the parties have sort of reached bilaterally?
MR. LADOW: Absolutely not, your Honor. I mean --
THE COURT: Hold on a second.
I mean, this wasn't something that I was involved in. Right, Mr. Lombardi? This was basically Mr. Brown, the --
MR. BROWN: Our understanding was that all that was being moved was because of Dr. Davies situation. He was being moved, and our witness on the '832 invalidity that had a response to Dr. Davies was also being moved. Neither one of those individuals, to my knowledge -- and correct me if I'm wrong -- but I don't believe those individuals are addressing secondary considerations other than perhaps a

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mention of copying in there somehow. Other than that, I don't think there's any secondary considerations.

THE COURT: Okay. So actually, I guess I thought that was my understanding, too, is, we were accommodating Dr. Davies.

We -- part of what you worked out was then Dr. McConville, who I guess opposes Dr. Davies on something, whatever Dr. Davies is about. But they were being moved back. Is that a wrong understanding?

MR. LADOW: No. That's absolutely correct, your Honor. The only thing that I'm saying is, is that let's say that there is something in Dr. Davies' expert report about copying, or maybe there's something about unexpected results. But I didn't want to be in a position today to commit that encyclopedically and comprehensively, there were no secondary considerations in what could happen in December. I didn't think it was fair to us.

THE COURT: All right. Doesn't that mostly resolve your problem, is the only witness they're going to be presenting is Dr.

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Davies, and presumably, he has written multiple reports and? I have to say, I've seen him a few times. Usually, he does testing. Is he doing something different in this case?

MR. BROWN: Yes, your Honor. He's not doing testing in this case.

THE COURT: All right. Okay. All right. Well, in any event, he has written some reports.

So by asking, by asking you to submit this, I'm not trying to foreclose anybody from doing whatever might arise on the third day of trial, and I'm not going to decide anything based on these. That's really like fixed in my mind what it is you think you have proved so far.

So things that have not happened yet, you don't had a to address. And what's more is, if you don't say something now, I'm not going to consider it as a waiver of saying it later on. So to the extent that defendants don't want to use their five pages addressing secondary considerations, you don't have to do that. Okay?

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And maybe -- well, does it make sense actually, because the secondary considerations, they actually could be short of discretely just severed.

Do you want to just spend the five pages addressing obviousness and indefiniteness where the obviousness doesn't include secondary considerations even though I understand the Federal Circuit says I must consider them, but just the straight obviousness analysis, or I guess on the one, the priority date analysis, really.

MR. LADOW: Well, it's really whatever you want, your Honor, but we could just -- we could just defer that until December because we're going to have to do post-trial briefing anyway.

THE COURT: You're talking about deferring the secondary considerations? Maybe that makes sense since they're somewhat out of flux there.

MR. LADOW: And obviously in the trial that we've had the last couple days, the secondary consideration-type witnesses or even

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the portion of the witnesses who have talked about anything that might be construed as secondary considerations has been a very small fraction of the overall --

THE COURT: Yes, I would say that's true.

MR. NUTTER: Conceptually, I think that's fine, at least for both defendants. I mean, the concern we have on our end is it has been difficult to pinpoint the secondary consideration that we actually intend to rely on. We were hoping your offered submissions would help us in that regard, but we understand that the Court does not want unnecessary paper, so we're --

THE COURT: Okay. Why don't we do that. Leave the secondary considerations out.

You know, I do understand that there was some dispute between Dr. Wollschlaeger and Dr. O'Brien. It was probably teed up a bit, but they were actually talking in fairly understandable fashion. It might stay in my head longer, so I'm perfectly happy to just put that off until later.

But I would like to -- so I'd like the three submissions, and basically, the two that are about invalidity won't include secondary considerations. Okay?

Anything else?

MR. LOMBARDI: Not for us, your Honor.

MR. LADOW: Not for plaintiffs, your Honor. Thank you.

THE COURT: Okay. Well, thank you all.

You know, it's always good -- you know, it's probably never a good idea to say anything nice until the trial is over because, you know, it would be like Villanova naming their sports thing the John DuPont Pavilion. Something could happen.

But I do want to compliment you all, because you have seemed to be very professional in working together to get this difficult case tried efficiently, and I appreciate that. All right? We'll be in recess.

(Court recessed at 4:08 p.m.)

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