1 - VOLUME 1 -2 IN THE UNITED STATES DISTRICT COURT 3 IN AND FOR THE DISTRICT OF DELAWARE 4 - - -5 : CIVIL ACTION RECKITT BENCKISER PHARMACEUTICALS INC., RB : 6 PHARMACEUTICALS LIMITED, : 7 and MONSOL RX, LLC, : : 8 Plaintiffs, : 9 vs. 10 TEVA PHARMACEUTICALS : USA, INC., : 11 : Defendant. : NO. 14-1451 (RGA) 12 13 - - -Wilmington, Delaware 14 Tuesday, November 3, 2015 15 8:30 o'clock, a.m. 16 - - -17 BEFORE: HONORABLE RICHARD G. ANDREWS, U.S.D.C.J. 18 - - -19 20 21 22 Valerie J. Gunning 23 Leonard A. Dibbs Official Court Reporters 24

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2 2 WINSTON & STRAWN, LD 3 WORKE CARLYES SHUBSTORE & RICE, LLP 3 WINSTON & STRAWN, LD 4 -and- 3 RICEARSELE, California) 5 -and- 5 6 -and- 6 7 BY DATEL CARLYES, SQ. 7 8 -and- 6 7 BY DATEL ALDOWLE BO. 7 8 COURSE (For Platinuffs 6 9 (Kew York, New York) 6 10 Coursel (for Platinuffs 6 11 and RB Pharmaceuticals Limited 11 12 13 13 14 RICHARDS, LAYTON & FINCER, P.A. 14 15 -and- 15 16 -and- 16 17 IAM TAN & WATENS LLP 18 18 BY: STRAWN, LLP 19 19 Coursel (for Defendant 10 Coursel (for Defendant 11 IAMER & NOWN ESO. 12 10 13 14 14 PROCEED IN 65 15 -and- 16 -and- 17 IAMER & NOWN ESO. 18 IAMER & NOWN ESO. 19 IAME	1	APPEARANCES:	APPEARANCES (Continued):	4
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6 6 7 TOUTTAK SANDERS LLP 7 AMES N. BOLLTNGER, FSQ. 9 AMES N. BOLLTNGER, FSQ. 9 Curran Apt T RANAM, ESQ. 9 Counsel for Defendant 10 Counsel for Defendant 11 Counsel for Defendant 12 Counsel for Defendant 13 14 14 RICHARDE, LANTON & FINGER, P.A. 15 SY STATUM & FINGER, P.A. 16	5	- a n d -	-and-	
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5-and-4courtroom, beginning at 8:30 a.m.)6LATHAM & WATKINS LLP57BY: BREDA L. DANEK, ESQ. and EMILY MELVIN, ESQ. (Chicago, Illinios)6THE COURT: All right. Good morning, everyone. Please be seated.9-and-8I just wanted to say that I did10-and-9100k at the resumes' of all of the experts and I11LATHAM & WATKINS LLP10did read the amended statement of facts, which I12ISAN Diego, California)11took to be mostly resolving limitations so that1312there was no question that they're not in14Counsel for Defendants 	1 2 3	APPEARANCES (Continued): LATHAM & WATKINS LLP BY: JAMES K. LYNCH, ESQ.	PROCEEDINGS	5
6 5 6 LATHAM & WATKINS LLP 7 BY: BREDA L. DANEK, ESQ. and EMILY MELVIN, ESQ. 8 (Chicago, Illinios) 9 -and- 10 -and- 11 LATHAM & WATKINS LLP BY: B. THOMAS WATSON, ESQ. 10 12 (San Diego, California) 13 10 14 Counsel for Defendants Par Pharmaceutical, Inc. and Intelgenx 15 Technologies Corp. 16 13 17 The COURT: All right. Good morning, each of the experts and I 18 WINSTON & STRAWN, LLP BY: GEORGE C. LOMBARDI, ESQ. 14 18 WINSTON & STRAWN, LLP BY: GEORGE C. LOMBARDI, ESQ. 15 19 MICHAEL K. NUTTER, FSQ. 10 Chicago, Illinois) 20 (Chicago, Illinois) 21 -and- 22 an opening statement. 23 MR. LADOW: Good morning, your 24 Honor. Dan Ladow for the plaintiffs.	1 2 3 4	APPEARANCES (Continued): LATHAM & WATKINS LLP BY: JAMES K. LYNCH, ESQ. (San Francisco, California)	P R O C E E D I N G S (Proceedings commence	5 d in the
bLATHAM & WATKINS LLP6THE COURT: All right. Good morning, everyone. Please be seated.7BY: BRENDA L. DANEK, ESQ. and EMILY MELVIN, ESQ. (Chicago, Illinios)6THE COURT: All right. Good morning, everyone. Please be seated.9-and-9look at the resumes' of all of the experts and I10-and-10did read the amended statement of facts, which I11LATHAM & WATKINS LLP BY: B. THOMAS WATSON, ESQ. (San Diego, California)10did read the amended statement of facts, which I1310did read the amended statement of facts, which I1114Counsel for Defendants Par Pharmaceutical, Inc. and Intelgenx12there was no question that they're not in1613dispute. So with that, I'm ready to go.17Technologies Corp.14Plaintiff, are you ready?18WINSTON & STRAWN, LLP BY: GEORGE C. LOMBARDI, ESQ. (Chicago, Illinois)18ready?20(Chicago, Illinois)20Honor.21-and-21THE COURT: All right. Let's have 22232424MR. LADOW: Good morning, your2424Honor. Dan Ladow for the plaintiffs.	1 2 3 4 5	APPEARANCES (Continued): LATHAM & WATKINS LLP BY: JAMES K.LYNCH, ESQ. (San Francisco, California) -and-	PROCEEDINGS (Proceedings commence courtroom, beginning at 8:30 a.n	5 d in the n.)
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1	Your Honor, opioid addiction is a	1	And as you may recall from the Markman
2	major public health challenge, one that has	2	proceedings, it's placed in the mouth of the
3	grown to epidemic proportions with the increased	3	patient, it's mucoadhesive, it sticks under the
4	use of painkillers, and this has led to a surge	4	tongue and then it dissolves rapidly in the
5	in addiction with a tripling of overdose deaths	5	mouth, and the buprenorphine active ingredient
6	in recent years. And the plaintiff, Reckitt	6	is absorbed through the oral mucosa.
7	Benckiser Pharmaceuticals, which is now known as	7	Now, compared to tablets, Suboxone
8	Indivior, but we'll be using Reckitt Benckiser	8	film dissolves faster, tastes better, does not
9	Pharmaceuticals, or RBP through the proceedings,	9	crumble, and is less readily diverted and abused
10	that's how all the documents are denominated, is	10	than tablets, and because of these advantages,
11	the pioneer in opioid addiction treatment, and	11	it's preferred by both doctors and patients, and
12	it has been a world leader in this treatment	12	it's the leading medication for opioid
13	space for over 20 years.	13	dependence. And it's the very success of the
14	Our co-plaintiff, MonoSol Rx, is	14	film, your Honor, that has brought us here
15	the pioneer in the new area of pharmaceutical	15	today, and it's why the defendants have copied
16	prescription films, and together, the two	16	it.
17	companies are addressing this crisis in	17	Now, prescription, prescription
18	addiction with the medication that's the subject	18	pharmaceutical films are a new dosage form.
19	of this case.	19	The major reason why they're so recent is that
20	In 2002, the FDA approved RBP's	20	making them is very complex and they present
21	opioid dependence treatment product, Suboxone	21	challenges in formulation and manufacturing that
22	tablets, which contain two active ingredients,	22	are very different from tablets. And, in fact,
23	buprenorphine and naloxone.	23	no prescription pharmaceutical films were
24	Buprenorphine is an opioid that	24	approved by FDA prior to just 2009. This is not
	7		9
1	can satisfy cravings and reduce opiate drug	1	like technology that has been around for
2	abuse and it's safer than other opioids, and	2	decades. This is new stuff.
3	naloxone is an opiate antagonist or opioid	3	Now, defendants are going to point
4	blocker that when taken orally does not produce	4	to things like Listerine strips and Chloraseptic
5	an effect, but it's an abuse deterrent, so that	5	strips that became available in the early to
6	if the patient abuses the drug and tries to	6	mid-2000s, but these are not prescription
7	inject it, it can put the patient into	7	pharmaceutical films that need FDA approval and
8	withdrawal.	8	have to meet the uniformity standards that are
9	Now, the tablets were a huge	9	associated with FDA approval.
10	advance in treatment, but they had different	10	And, in fact, sublingual film, the
11	disadvantages, the tablet dosage form, such as	11	commercial product at issue here, was the very
12	dissolution time, taste, subject to crumbling	12	first sublingual film approved by the FDA in
13	and being subject to abuse and diversion, such	13	2010, and this dosage form is so new, that these
14	as by crushing them and trying to inject them or	14	cases before this Court right now are the very
15	snort them or something like that.	15	first ANDA cases that involve a prescription
16	Now, to provide patients with a	16	pharmaceutical film.
17	significantly better dosage form and improved	17	Going to the patents, as your
18	dosage forms, RBP's addiction medication experts	18	Honor knows, there are three Orange Book patents
19	joined forces with MonoSol's film technology	19	at issue in the case. Each of the three patents
20	experts to make Suboxone sublingual film, which	20	relates to a different aspect of pharmaceutical
21		0.4	film innovation that resulted in Suboyone film
	is a new dosage form.	21	
22	is a new dosage form. And you see here on the slide what	21 22	and the infringement and validity issues for
22 23	is a new dosage form. And you see here on the slide what this product look like. On the right-hand side,	21 22 23	and the infringement and validity issues for each patent are really separate and distinct.
22 23 24	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.	21 22 23 24	and the infringement and validity issues for each patent are really separate and distinct. To just briefly introduce the

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	10		12
1	patents, the '514 patent solved the drug content	1	want to balance the properties of adhesion, the
2	uniformity problem in pharmaceutical	2	mucoadhesion in the mouth, dissolution, the good
3	prescription films. And as you can see here in	3	tear resistance, the strength of the film, that
4	this excerpt on the top, if you have a failure	4	what you can do is include about 50 to
5	to achieve this is an excerpt from the	5	75 percent of low molecular weight polyethylene
6	patent a high degree of accuracy with respect	6	oxide, which you are going to hear a lot about,
7	to the amount of active in the cut film, this	7	your Honor, or PEO, optionally combined with a
8	can be harmful to the patient. Of course, for	8	small amount of a higher molecular weight PEO,
9	safety reasons and efficacy reasons, you want	9	with the remainder of the polymer component
10	the patient to get the right dosage.	10	contains a cellulosic polymer like HPMC. So it
11	And when the patent was filed, the	11	provides this polymer profile that you need to
12	inventors noted that about that world regulatory	12	do this.
13	authorities required that the dosage amounts in	13	Now, the '514 patent, the asserted
14	dosage forms not vary by more than about ten	14	claim are the ones that you see here, there's
15	percent of the desired amount of the active, and	15	one independent claim, 62, and then four
16	concluding that that basically mandates	16	dependent claims, infringement of this patent,
17	uniformity in the film. And what the present	17	your Honor, is going to be addressed in
18	invention of the '514 provides, as it says in	18	December. We're just doing validity in this
19	that last excerpt highlighted, is exceptionally	19	trial.
20	uniform film products when attention is paid to	20	Plaintiffs' expert on the validity
21	reducing the aggregation of the compositional	21	of the '514 patent is professor Robert Langer.
22	components.	22	He's an MIT Institute professor. He has over a
23	I'm going to say a very brief, and	23	thousand articles and issued patents and he's
24	really a very brief word about the '832 patent	24	one of the most decorated scientists in our
	11		13
1	11 since it at least relates in part to commercial	1	13 country. He's an expert in the chemical
1 2	11 since it at least relates in part to commercial success, which you'll be hearing about in this	1 2	13 country. He's an expert in the chemical engineering and pharmaceutical drug delivery
1 2 3	11 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	1 2 3	13 country. He's an expert in the chemical engineering and pharmaceutical drug delivery forms.
1 2 3 4	11 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	1 2 3 4	13 country. He's an expert in the chemical engineering and pharmaceutical drug delivery forms. The defendants' two main
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	14		16
1	And then a conveyor belt moves the	1	though it has already been dried is contrary to
2	sheet through a controlled drying process,	2	the specification, it's contrary to common sense
3	drying out the solvent, and this results in a	3	and how one of ordinary skill would understand
4	dry film which is then cut into individual	4	this. What it really is, is a belated claim
5	dosage units as you can see in the bottom	5	construction argument that we think should be
6	illustration.	6	rejected. And as Dr. Langer will testify, a
7	These are the claim terms we've	7	person of ordinary skill in the art would have
8	highlighted that relate to the indefiniteness	8	no trouble understanding the meaning of these
9	issue that defendants have raised with respect	9	claims in this context with reasonable
10	to this patent.	10	certainty.
11	So as you can see on the top, it's	11	Turning to the defendants'
12	a drug delivery composition. It's independent	12	obviousness argument, your Honor, a key
13	claim 62. Cast film comprising a flowable water	13	challenge in film technology was the problem of
14	soluble film forming matrix. And I'm going to	14	achieving what we're going to refer to, and
15	skip down to the last clause, where the flowable	15	you're going to hear a lot about, drug content
16	film-forming matrix is capable of being dried	16	uniformity, or DCU, in a pharmaceutical film.
17	without loss of substantial uniformity, and	17	In particular, prescription pharmaceutical film
18	that the uniformity subsequent to drawing and	18	that has to be approved by the FDA.
19	casting of the matrix is this plus and minus	19	Drug content uniformity must be
20	ten percent of the desired amount that I	20	maintained throughout the manufacturing process
21	mentioned before.	21	in order to meet FDA requirements and ensure
22	Now, Watson, defendants contend	22	proper dosing just as we talked about before so
23	that the claims are indefinite because they say	23	the patient gets the right amount of the drug,
24	a final dried cast film cannot be flowable or	24	not too much, not too little. It has to be safe
	15		17
1	15 have a viscosity or be capable of being dried.	1	17 and efficacious.
1	15 have a viscosity or be capable of being dried. But the final cast film is not required to be	1	17 and efficacious. This was a major challenge
1 2 3	15 have a viscosity or be capable of being dried. But the final cast film is not required to be flowable, as the defendants assert.	1 2 3	17 and efficacious. This was a major challenge because, as Professor Langer will explain, there
1 2 3 4	15 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	1 2 3 4	17 and efficacious. This was a major challenge because, as Professor Langer will explain, there are quite a few forces or gradients that can
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