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 MONOSOL RX, LLC, Plaintiffs, vs. DR. REDDY'S LABORATORIES S.A. and DR. REDDY'S LABORATORIES, INC., Defendants.	:	CIVIL ACTION NO. 14-1451 (RGA)

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Wilmington, Delaware
Monday, November 7, 2016
8:32 o'clock, a.m.

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

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P R O C E E D I N G S

(Proceedings commenced in the courtroom, beginning at 8:32 a.m.)

THE COURT: All right. Good morning, everyone. Please be seated. Let's begin. Actually, I don't need to have introductions. Let's start.

MR. LADOW: Your Honor, may we hand up some slides?

THE COURT: Yes. And, by the way, I did sign the two stipulations a few minutes ago that you submitted over the weekend or Friday, so they are all signed.

MR. LADOW: Thank you.

(Ms. Severance handed slides to the Court.)

MR. LADOW: Good morning, your Honor. You know I'm Dan Ladow from Troutman Sanders for the plaintiffs, and we're here today just addressing the '150 patent. The two other patents are being addressed as you know in the later trial days, and as the Court will recall,

Dr. Reddy's Laboratories acquired two ANDAs from Teva and they've substituted in. We'll be referring here to Teva's ANDA and the accused products as Dr. Reddy's or DRL's accused products in ANDA.

The asserted claims that we're dealing with are independent Claim 1 of the '150 patent and dependent Claims 4, 5, 8 and 9. And we're going to be presenting two experts to provide testimony. The first will be Dr. Lon Mathias on infringement. You are familiar with him. You have his CV, which is PTX-42, he's an emeritus professor at the University of Southern Mississippi and an expert in polymer science.

Our expert on validity is Robert Prud'homme, who is a professor at Princeton for a number of decades with vast experience in the field and is also an expert in polymer science and pharmaceutical formulations, and his CV is PTX-43.

Turning to the patent, as the Court notes from the prior cases, the '150 patent and its claims are generally directed to

a rapidly dissolving film containing an analgesic opiate, and the films of the patent have a particular polymer profile that's meant to balance a number of different film properties, such as fast dissolution, mucoadhesiveness, tear resistance and flexibility.

And going right to the claim of the patent, the Court is familiar with the claim. I just want to highlight in the left-hand column we've done sort of a shorthand for some of the limitations and it can be regarded as having these five categories of limitation.

And there's no dispute in the case that as far as limitations 1 and 2, the mucosally adhesive film and the analgesic opiate active, that the Dr. Reddy's proposed product meets those limitations.

Limitations 3, 4 and 5 define the polymer profile of the product that the claim provides. And the evidence will show that DRL's proposed product meets the limitations as to 4 and 5 as to the PEO molecular weight limitations

and we expect that particular showing to be uncontested.

So the dispute on infringement ultimately will focus on limitation 3, and that limitation requires that there be greater than 75 percent polyethylene oxide and up to 25 percent hydrophilic cellulosic polymer within this water soluble polymer component.

And in its formulation, DRL uses a polymer called polyvinyl pyrrolidone or PVP. It's also sold under trade names like Povidone or Kollidon, and they use this as a substitute for the hydrophilic cellulosic polymer in their product. And we contend, plaintiffs contend that DRL's use of this PVP satisfies this limitation number three under the doctrine of equivalents. They contest that DOE applies and they also assert that they don't infringe based on an argument having to do with dedication to the public and they have a prosecution history estoppel argument.

So the infringement case really revolves around the doctrine of equivalents, and as the Court is aware, the legal standard for

that is applied here, would be whether the PVP's and the PEOs in Dr. Reddy's product are insubstantially different from the claimed polymer component in the claims or, to put it in the other way of the test in the case law, that they perform substantially the same function in substantially the same way to provide substantially the same result.

And the evidence will show that the answer to these questions is yes, that the use of PVP by Dr. Reddy's is insubstantially different from the use of a hydrophilic cellulosic polymer.

Just briefly, this is from Dr. Reddy's ANDA, and it shows the three grades of PEO that is used in their products. So the claims require that you have PEO that's between a hundred and 300,000, as you'll recall, so the first two categories, the first two grades of PEO that are listed there fall within that requirement, and then the claim also requires some of the same molecular rate PEO, between 600,000 and 900,000, and they are using the 900,000 grade. In fact, these are the

same grades of PEO that are used in Suboxone film.

Now, this is another excerpt from DRL's ANDA, and it compares the ingredients in the proposed generic product, which is the middle column, to -- and this, by the way, is JTX-11 at 38. This compares the proposed generic product in the middle column to the ingredients in the reference listed drug, and, of course, the reference listed drug is the Suboxone film that they are proposing to make a generic version of.

And then in the right column, you can see that the function is -- a function is described in the ANDA to each of the ingredients. And it's pretty evident from looking at this that Dr. Reddy's simply copied the polymer profile in the reference listed drug save for their substitution of this povidone, or Plasdone is another trade name. They use two grades of PVP, so they substituted PVP for some hydroxypropyl methylcellulose, or HPMC in the brand product. And the evidence will show that these two are functionally equivalent.

And if we just confine ourselves to what we're seeing on the screen here in this part of the ANDA, you can see that they're both described as having the function of being a binder.

And, in fact, as their ANDA indicates, Dr. Reddy's understood the proposed product using this PVP, as you might expect, to be substantially equivalent to the brand product that they were trying to make a generic version of.

In other words, they expected that their proposed generic version of Suboxone film, which merely substitutes the PVP for the HPMC, would perform in substantially the same way as the brand product and therefore would be equivalent.

Now, if we look at -- you'll hear testimony from Dr. Mathias about more details about the polymer profile and every aspect of the polymer profile is identical. In Dr. Reddy's product, as we can see here, they have the low PEO with the grades that they are using. They have the high, higher molecular weight PEO.

60 percent of the low. They have more than 60 percent of the low as part of the polymer component satisfying that 60 percent or more limitation, and they have greater than 75 percent PEO in the polymer component, which is another aspect of the polymer profile. And then they have the PVP, as I said, instead of the hydrophilic cellulosic polymer.

But Dr. Mathias will be presenting evidence on all of these. And basically what they would have you believe is that substituting one binder, the PVP for the HPMC, would allow them to escape infringement, but this is exactly why we have the doctrine of equivalents, so that an infringer who is using, who makes a substantial -- insubstantially -- who makes an insubstantial change from what is covered by the patent does not escape infringement. And at the end of this case, we expect that there will be a check in that last box on that basis.

And if we had just confined ourselves to the ANDA, as I said, we would see that both the PVP and the HPMC were listed as having the same function as being a binder. But

Dr. Mathias' analysis will show that actually, these polymers provide, have a number of different functions in the film, and influence a number of different film properties. And, in fact, their functions are substantially equivalent.

Now, I'm sure you're going to hear from our colleagues on the other side that the chemical structure of PVP and HPMC is different, but what matters is not whether the chemical structure is the same, but whether they have the same functional equivalents in the product, which is what Dr. Mathias' evidence will show. And so that will show that because they have that equivalence, that it meets the cellulosic limitation under the doctrine of equivalents.

I mentioned that DRL also has a defense based on dedication to the public and the legal standard there is whether the unclaimed subject matter is identified in the patent as an alternative to a claim limitation.

So as you know, the claimed polymer profile uses at least two grades of PEO,

so you have the lower molecular weight and the higher molecular weight, the hundred thousand to 300,000, the 600,000 to 900,000. And DRL points to some examples in the patent, which we've illustrated here, where, for example, in the top left of Figure 38, there's a couple examples of PEO and PVP, and there's in this E series of examples in the patent, there are some instances where PVP is being used with PEO, and the section of the slide on the right is also from this E series.

And every time PVP is used in the patent with PEO, there's only one grade of PEO that's used. It's never the situation in the patent where you're using two different grades of PEO with PVP while there is a discussion in the patent that mirrors the claims where using two grades of PEO with HPMC, and that's particularly in columns 17 to 18 of the patent.

So the '150 patent simply doesn't disclose PVP as an alternative to hydrophilic cellulosic polymer in the claimed polymer profile of the patent, meaning using two or more

grades of PEO where there's a higher molecular weight grade, high molecular weight of 600,000 to 900,000, and a lower grade and for that reason, the dedication to the public analysis can't apply because PVP is never disclosed as an alternative to that formulation anywhere in the patent.

Dr. Reddy's also has a prosecution history estoppel argument which, of course, requires a clear and unmistakable surrender of the subject matter at issue, but what the evidence will show is that the applicants never distinguish any prior art on the ground that it contain PVP or did not contain cellulosic polymer.

And if I can turn briefly to validity, just, I guess a couple nights ago, Dr. Reddy's withdrew its other obviousness defenses.

So as I understand it, the only invalidity defense is obviousness that you'll be hearing today that really falls into two categories. There's an attack on obviousness. That's based on asserting certain pieces of

prior art where the priority date of the patent is assumed to be May 2003. Then, in an approach that will sound familiar, because it's the same thing you heard in the Watson Par trial, Doctor Reddy's is also alleging that there's a Yang reference which is actually the parent, parent application to the '150 Patent that was published after this May 2003 date and that lacks priority and so that the actual priority date of the patent should be 2008. And that's something that you already rejected last year.

So, just in terms of the state of the art, as of May 2003, prescription pharmaceutical films were a new field of pharmaceutical development and manufacturing and there was a number of different variables to consider at the time. There was no established film in place and it wasn't until years later that we have the first prescription pharmaceutical films approved and the brand product here, Suboxone film was the first sublingual prescription film, that wasn't until 2010, to give some idea of the movement of the field. A challenge in making a pharmaceutical

film at that time back in 2003 was trying to find the right blend of polymers to provide the optimal film properties that one would want. And there's a number of different polymers that could be used and that were used in the prior art. Many different ones. And one of the ones that there are some examples of in the prior art and you'll be hearing about them today, involve PEO. PEO itself is sold in a wide range of molecular weights from very low all the way up to 8 million. And so the particular polymer profile that's in the patent is just what's shown in these narrow bands here. It's, as we said, the hundred, the 300,000 molecular weight that's going to be at least 60 percent of the polymer component and then some of the higher molecular weight of the 600,000 to 900,000. And prior to the '150 Patent nobody taught this polymer profile in the prior art. There was simply no teaching of it. You'll hear from Doctor Prud'homme about that. There was simply no teaching about how to balance film properties using a profile like that.

And the prior art I believe that

you'll be hearing about today is basically three references; Chen, which doesn't teach using PEO's of difference molecular weights at all. There's a reference called Verma, which is actually a film coating on a capsule where the film coating itself doesn't contain an active ingredient and it also doesn't teach the at least 60 percent of the low PEO. And then there's an older reference called Schiraldi that was in front of the examiner when the patent was prosecuted, patent was issued over it. And that patent, Schiraldi, focuses on very high molecular weight films in the range of three to five million molecular weight. And Doctor Prud'homme will testify a person of ordinary skill in the art simply would have had no teaching, no motivation from these pieces of prior art or from the general knowledge in the area to combine, to combine them to try to come up with the polymer profile of the claims. And the Defendant's arguments in this regard, essentially rely on starting out with the '150 Patent, seeing what the polymer profile that it has, and then looking back into the prior art

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