UNITED STATES COURT OF APPEAL
FOR THE FEDERAL CIRCUIT
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IN RE:
ARMODAFINIL PATENT LITIGATION
CEPHALON, INC., ET AL.,

Petitioner,

Appeal No.:
2013-1360

Vs.

WATSON LABORATORIES, INC., ET AL.,
Respondent.
----------X

June 3, 2014

HELD AT: UNITED STATES COURT OF APPEAL
717 Madison Place, N.W.
Washington, D.C. 20439

BEFORE: HONORABLE TORONTO,
Judge

APPEARANCES: JIM HERTZ, ESQ.
Attorney for the Appellants
MR. LIPSEY, ESQ.
Attorney for the Respondent

TRANSCRIBER: CAMELLIA GRAHAM

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IDENTIFICATION DESCRIPTION I.D. IN EV.

RESPONDENT:
IDENTIFICATION DESCRIPTION I.D. IN EV.

THE COURT: We got a total of four cases today. Two cases are submitted on the brief and we have two cases for oral argument. Our first case is In Re Armodafinil Patent Litigation, Nos. 2013-1360-1361 and 1364 thru 1371, a consolidation of a number of cases.

Mr. Hertz, you may proceed, sir.

MR. JIM HERTZ: Good morning, Your Honors. Jim Hertz. May it please The Court. I'm arguing on behalf of all of the appellants.

First principles prove the invalidity of Cephalon's patent on Form 1, the crystal. And that's because - - advances that occur in the ordinary course without real innovation are legally obvious. And that's what we have here. There's a key piece of prior art, it's the 855 Patent from way back in 1990 and it teaches three key things. First,it teaches that if you take Armodafinil and you recrystallize it in a specific solvent, ethanol, you're going to get white crystals. That's what it teaches. That's Preparation 1. Two, it teaches, you can take Preparation 1 and put it in a pharmaceutical composition to treat sleep disorders. Number three, it teaches that they successfully use that pharmaceutical composition in human clinical trials to

actually treat successfully sleep disorders and the patent says it is a particularly valuable compound in that regard.

THE COURT: Can I ask you this?

MR. HERTZ: Sure.

THE COURT: Suppose that I thought that the district judge focused in part incorrectly on expectations of achieving a particular structure that is Form 1 which rather than focused on whether there was a motivation to take the steps that if, in fact, would lead to letting it be characterized through - -. Where do I go with that conclusion? Is that a basis for a remand for fact finding with the right to motivation question?

MR. HERTZ: I don't think so, Your Honor. I think you can take that and you can rule as a matter of law that the patent is invalid, and here's why: We do think that district court focused on the wrong thing, whether or not the XRPD Patent was predictable. It is beyond dispute. It is no longer contested on this appeal that the 855 Patent created a motivation for one, of skill and the art; two, run the experiment that would be necessary to find the most stable relevant--

THE COURT: [Interposing] There's one fact

I'd like you to address --

MR. HERTZ: Sure.

THE COURT: -- which, at least, potentially looms large. Which you addressed, I think in one-half sentence in your great brief.

MR. HERTZ: Ok.

THE COURT: The fact that for ten years evidently the motivation was insufficient for people who do that. Now you say something - I think the only thing you say about that is that you were forbidden to use it during that time which I don't understand how that squares with 271E - was it 1 or 2? Whatever that American Tegra provision is - it allows research use reasonably related to a potential FDA application among others. So why isn't, at least potentially, the sheer fact that for ten years nobody actually was sufficiently motivated to go and do this a significant fact?

MR. HERTZ: Two points. First, in reality, Cephalon created Form 1 immediately. They did it back in 1990 and then they shelved it and didn't file for a patent application until 2003. So, factually, it happened right away. So there, that shows you the motivation existed. Number two, they had a patent on this compound and they didn't actually have an NBA

approved application. There was no motivation for anybody to work with this compound until the time came when you could start actually filing and within a reasonable way, and that happens- -

THE COURT: [Interposing} That's what I just said in the part I don't understand. I suppose there was some chance somebody would have said this is not patentable because it's obvious. But there is, evidently, some chance that the PTO would say, no, this is patentable. So, why wasn't this in somebody else's interest either to go and do a new drug application? Perhaps it would have been barred by the dominant patent from actually marketing it. But that's real economic value. You can negotiate about it with the dominant patent owners.

MR. HERTZ: I think you're incorrect about that, Your Honor, because there was a patent on Armodafinil that prevented anybody from working with it in any form.

THE COURT: But that's what I asked you about the American Tegra 271E2. Just explain to me.

MR. HERTZ: Sure, sure.

THE COURT: It seems to me, if you're thinking about filing an FDA application, you're allowed to - -

MR. HERTZ: It's the way the regulations work. Okay, first, when somebody gets an NBA application on file, and they actually get approval- and that's Cephalon - they actually get regulatory exclusivity for a period of time so nobody can - patent or no patent - nobody can sell a generic form of it.

THE COURT: Can they experiment with it though?

MR. HERTZ: They can but only when it makes sense, right? You're not going to start working - if you're not going to be allowed to get on the marketplace until say -- I don't have the dates at hand because this wasn't initially addressed. If you're not going to be allowed to get on the marketplace until, say, 2005, no matter what, because of regulatory exclusivity, there's really no incentive to start working back in 1990, 1995, 2000. Whenever the date is that the regulatory exclusivity expired, that's when it started to make sense to start moving forward, and not until then because of regulatory exclusivity and patent protection on the Armodafinil molecule itself.

We know that Form 1 actually is something produced in the ordinary course. And we know that

because back in the prior art in 2003 - -

THE COURT: [Interposing] Let me just state the actual - - before you say that

MR. HERTZ: Sure.

THE COURT: Is there a time period where there's a zone prior to utilization under the patent and yet under the rags you're permitted to experiment with it? Is there some kind of gap there?

MR. HERTZ: You can actually start your experimentation early --

THE COURT: Right.

MR. HERTZ: -- because there's nothing stopping you --

MALE VOICE1: Right.

MR. HERTZ: -- from doing it. But there's no motivation to do so because the patent on the Armodafinil itself and the regulatory exclusivity, keeps you off the marketplace. But, let - -

THE COURT: [Interposing] I do just want to, I guess, point out that the one thing that you say about this - seems to me - on Page 21 of your Reply Brief says you were blocked from working with them. I think we've just come to the point where you now agree that that's just not correct. You might not have had enough of an economic motivation. But, you were not

legally blocked from researching with the Armodafinil itself.

MR. HERTZ: For all practical purposes, Your Honor, when there's a patent on Armodafinil, yes, you could start under the safe harbor to start working. And maybe people did. And we wouldn't know whether they got Form 1 immediately or not because it wouldn't be something that would be published, number one. For all practical purposes, when there's a blocking patent, there's o incentive to start doing the work until that blocking patent moves out the way. We challenged the crystal patent. We didn't challenge the blocking patent on Armodafinil itself. Okay. So we never did that. We only challenged the crystal patent. But look at the prior art too. By 2003 or 2002 --

THE COURT: Is there any precedent from our Court that claims polymorphic forms of known crystals or is this a case of first impression?

MR. HERTZ: This, I believe, is a case of first impression in the following way: There has been no case like this before where the prior art literally says we crystalized an ethanol - and you're going to get white crystals - and then somebody comes along and says I should have a patent on a particular form based

on my measurements of XRPD. That has never happened before. That has never happened before. There's some older cases, long before KSR, which deals with situations where the prior art didn't actually teach that the compound could be produced as the crystal. So this is unique first impression. Certainly the first post-KSR case that could deal with this. Conventional techniques from 2003 - -

THE COURT [Interposing] And you're arguing, finally, that the patent on - - would render patentable all forms of polymorphic forms of structures?

MR. HERTZ: Yeah and really in ways that really can't be defended in a practical matter, Your Honor. Right now today, for instance, there's an entire through-put method to create crystals in large quantities. Just try every variation. Under the District Court's reasoning, it's repeat. It's automated. Under the District Court's reasoning, each crystal that gets spit out of this through-put situation, is a separately patentable invention because you can't predict the XRPD Patent in advance. It's just not logical.

THE COURT: What's the percentage of time that you've come up with Form 1?

MR. HERTZ: Ninety percent.

THE COURT: Is it 90?

MR. HERTZ: Yeah. Look, nobody disputes that conventional techniques will produce Form 1, especially if you use ethanol as taught by the prior art. Our experts did it seven out of seven times. Cephalon used the prior art technique, they admitted, typical bench-top screening, and they got it 90 percent of the time. Thirty out of 34 times. That's KSR. Worthy invention produce itself in the ordinary course without innovation; that's what happened. Ninety percent of the time practically in the prior art, you produce Form 1. And the District Court really did just ask the wrong question. The District Court said, "Was it predictable to come up with the inherent properties of Form 1, this XRT in fact?"

THE COURT When I read the District Court's opinion and started thinking about it and then went back to look at it, it seems to me that some of the things the District Court said in findings were not dependent on the notions that what needs to be motivated and predictable was a particular structure with a particular ethnic faction pattern. But some of them were and it all seemed kind of intermixed. So I was left thinking I'm not quite sure what the finding

of motivation would have been without the unduly particularized focus.

MR. HERTZ: Well, I think the motivation is no longer even contested. Everyone's agreeing now that the 855 Patent created a motivation to find and obtain the most stable readily available crystals. So that's no longer on the table as far as I'm concerned. But to your point, when I read through the opinion, you're right, sometimes the District Court says structurally, structure. You need to predict structure. Sometimes the Court just says, it wasn't predictable to get Form 1. He means the same thing in both instances. Because when he just says Form 1, he has already defined Form 1 is the particular crystal with that particular structure. So it seems to me that the only fair reading of this opinion is the entire foundation was you had to predict an XRTD pattern which Pfizer, Cuban, Sentara [phonetic], Titanium [phonetic], what they all tell you is an obvious stock doesn't suddenly become patentable because you measure an inherent property. That's just not sensible.

THE COURT: What is it about the disclosure of ethanol in the crystallization process, what's its role in leading to Form 1?

MR. HERTZ: Different solvents will sometimes produce different crystals, and ethanol is particularly good at producing Form 1.

THE COURT: Does the prior art disclose that it's going to lead you to Form 1?

MR. HERTZ: What the prior art discloses is that if you use ethanol, you're going to get white crystals 90 percent of the time. Thirty out of 34 times, you're going to get Form 1.

THE COURT: Is it really 90 or is it higher?

MR. HERTZ: Based on the record, Your Honor, it's 90.

THE COURT: Ok.

MR. HERTZ: Or it could be higher if you took -- it's 90. It's in that neighborhood.

THE COURT: At the time that the patent was issued, was it known in New York that the crystallization process with the use of ethanol would lead to 90 percent Form 1?

MR. HERTZ: No. That's part of the routine conventional experimentation that people would do from the patent. And so if in the ordinary course you follow up on the patent and you get Form 1 - -

THE COURT: [Interposing] Well, couldn't you be motivated then to even get to that? I mean you can

achieve many different types of structures through the crystallization.

MR. HERTZ: Because the FDA taught in 1987 they required you to ensure that you had the most stable crystal. It's conventional that you have to use the most stable crystal for a pharmaceutical formulation because if you don't, during manufacturing or storage, it could convert to something else.

THE COURT: Okay, you're into your rebuttal time.

MR. HERTZ: I will reserve the rest of my time for rebuttal.

THE COURT: We'll put you back a few minutes because we took you over your rebuttal.

MR. HERTZ: Thank you, Your Honor.

THE COURT: All right.

THE COURT: Mr. Lipsey [phonetic]?

MR. LIPSEY: Thank you. Good morning and may it please The Court. Aside from the details and findings of the trial courts that are for an inconvenient truth which stand in the way of the grand policy arguments that Appellants want to make - but first--

THE COURT: Well, Mr. Lipsey, let me ask you what looks to me like an inconvenient truth for you

and that is where opposing counsel closed. The FDA guidelines from 1987, it says - it uses the word "should" an appropriate analytical procedure should be used to determine whether polymorphic occurs. How do you reconcile that '87 guideline with your position about unpredictability of polymorphics?

MR.LIPSEY: The same issue arose in the Aberthy [phonetic]-Sandors case. There was an FDA guidance that said what the properties ought to be of an extended release formula and the court there said that identified the goal but it didn't identify the means of achieving it; and that's exactly the same problem here. Those guidelines came out in 1987. -- from doing what the FDA says would be nice. You always found the most stable form. You would never see the debacles like the retonagray [phonetic] situation where they didn't find the most stable form; and you wouldn't see the situations referred in the Gardner and SEMA publication in 2004 where it says almost every company refer in its history to unexpected and undesirable results.

THE COURT: If it's not night follows day, in excess of 90 percent seems, to me, to be pretty predictable.

MR. LIPSEY: And that is where The Court has

been led astray. Any legitimate analysis of obviousness ends where the invention begins. The statute specifically says- -

THE COURT: With white crystals. Which, in fact, at least nine out of ten times, are Form 1.

MR. LIPSEY: Not so. Not so. And the trial court specifically found that and that's the second inconvenient truth. The first one is the claim. It's not just the Form 1. It's the pharmaceutical composition consisting essentially in it. The second is the trial court specifically found that Pages 832 to 41, that the product of 855 Preparation 1 was not Form 1, and the analysis there is quite compelling. The evidence showed that the instantaneous melting point of Form 1 was from 159 to 164 degrees and the instantaneous melting point for Preparation 1 is actually reported there and it was 153 to 154, much closer to Form 2. And that shows that you don't get - - But in fact, the very first time that process was conducted, you got something else. Those findings are not clearly erroneous. In fact, wait, there was no indication on the face of that patent to do anything else.

THE COURT: Did your testing, in fact, show 90 percent?

MR. LIPSEY: The work that the inventors and the patent owner did in developing the invention - none of which is prior art - did show that a large number of conditions can be used to prepare Form 1 as well as two other forms that appear and, I believe, the word was frequently. Although, not nearly as much as Form 1.

That, Your Honor, unfortunately, is using stuff the inventor discovered against him to establish obviousness. And there are, indeed, authorities in this area. One of them is from the International Trade Commission.

THE COURT: Well, it's not exactly. It's using what the inventor disclosed which is a solvent, right? And a resolve, the white crystal, and looking at it and saying what that solvent produces in that white crystal is, in fact, Form 1.

MR. LIPSEY: It is not. That's exactly what the trial court found. What came out of Preparation 1 as described in that patent was not Form 1. Now, if you went to go look to do the research project to see whether it was polymorphicism, which was not predictable at the time; and this showed that the structures could be made, might be, which was not predictable at the time; and if so how they could be

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