IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

- - -

PFIZER INC. and UCB PHARMA GMBH,) Civil Action
)
Plaintiffs,)
)
v.)
)
ALKEM LABORATORIES LTD., et al.,)
) NO. 13-1110(GMS)
Defendants.) CONSOLIDATED

- - -

Wilmington, Delaware
Monday, July 13, 2015
9:00 a.m.
Day 1 of Trial

- - -

BEFORE: HONORABLE GREGORY M. SLEET, U.S.D.C.J.

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-and-
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09:00:31 THE COURT: Good morning. Please, take your
09:00:34 seats. We are going to have to be here -- I am not sure
09:00:47 exactly how long, actually. I know some work is being done
09:00:50 on the audiovisual system in my courtroom, which is has
09:00:55 really plaguing us of late. Fortunately, Judge Robinson is
09:01:00 on vacation. I am going to have to get used to this very
09:01:03 different configuration that her predecessor and mine, Rod
09:01:09 McKelvie, decided to build. He is gone now, so I can't say
09:01:12 too much about him.
09:01:14 Let's start out with introductions. Mr.
09:01:16 Blumenfeld.
09:01:17 MR. BLUMENFELD: Good morning, Your Honor.
09:01:21 Jack Blumenfeld from Morris Nichols for the
09:01:23 plaintiffs' Pfizer and UCB. Can you hear?
09:01:27 THE COURT: This is strange. Can the folks in
09:01:33 the well of the court hear?
09:01:36 MR. BLUMENFELD: I will speak up and get a
09:01:39 little closer to the mike. I guess we will all try to do
09:01:41 that.
09:01:42 At counsel table from White & Case are Jeff
09:01:46 Oelke, Jim Trainor, and behind them are Robert Counihan and
09:01:52 Lauren Moran.
09:01:53 (Counsel respond "Good morning.")
09:01:54 MR. BLUMENFELD: Also from White & Case.
09:01:56 In the first row, Stephane Drouin, Jurgen Hassa

09:02:02 from UCB. And in the second row Chase Romick, who is here
09:02:07 from Pfizer.
09:02:07 THE COURT: Good morning.
09:02:09 Ms. Farnan.
09:02:10 MS. FARNAN: I will start, Your Honor. Good
09:02:11 morning. Kelly Farnan from Richards Layton Finger. I am
09:02:13 representing Accord and Amneal and Alkem. I also have with
09:02:18 me my colleague from my office Christine Hayes.
09:02:20 THE COURT: Good morning.
09:02:21 MS. FARNAN: Then on behalf of Accord and Amneal
09:02:23 I am working with Sughrue Mion, we have Mike Dzwonczyk,
09:02:27 Renita Rathinham, and Alton Hare is in the back.
09:02:33 Also here on behalf of Amneal from the company
09:02:36 in the back as well, Ken Cappel, Brian Sommese, and Lars
09:02:36 Tavolla.
09:02:44 THE COURT: Good morning.
09:02:45 MS. FARNAN: I also represent Alkem, Your Honor.
09:02:47 And I am working with Wiley Rein. At counsel table is
09:02:51 Rachel Hunnicutt and Neal Seth.
09:02:53 THE COURT: Good morning, counsel.
09:02:55 MS. FARNAN: Thank you, Your Honor.
09:02:56 THE COURT: Mr. Poff?
09:02:58 MR. POFF: Good morning, Your Honor. Adam Poff
09:03:00 from Young Conaway on behalf of Sandoz. Working with me is

09:03:06 And from my office, Pilar Kraman.
09:03:08 THE COURT: Good morning.
09:03:10 All right. Counsel.
09:03:14 MR. ATHEY: Good morning, Your Honor. Clayton
09:03:18 Athey from Prickett, Jones & Elliott from the Amerigen
09:03:21 defendants. With me today are William Hale and Gabriela
09:03:27 Materassi. Also from Amerigen, Jonathan Nichol.
09:03:31 THE COURT: Good morning.
09:03:33 I think that's it. Right?
09:03:36 Counsel, are there any housekeeping matters we
09:03:40 need to talk about before we begin?
09:03:43 MR. OELKE: I don't believe so, Your Honor.
09:03:47 MR. DZWONCZYK: Not from defendants, Your Honor.
09:03:49 THE COURT: Let's start with the opening
09:03:51 statements then.
09:03:56 MR. OELKE: Your Honor, I have some slides.
09:03:59 THE COURT: Mr. Buckson will take those from
09:03:59 you.
09:04:01 I am going to ask you to see what you can do
09:04:04 about keeping as close to the mike as you can without being
09:04:07 uncomfortable so that everyone can hear.
09:04:24 MR. OELKE: Good morning, Your Honor.
09:04:28 Your Honor, the invention in this case arose
09:04:34 amid an active field of pharmaceutical research. And that
09:04:37 was an active field to look for a better treatment for

09:04:42 urinary incontinence, a condition that is also going to be
09:04:47 referred to in this case as overactive bladder or OAB.
09:04:51 In the late 1990s, a number of different
09:04:54 research organizations were looking into developing a better
09:04:58 drug to treat this condition. But the invention here
09:05:01 occurred because a group at a small German pharmaceutical
09:05:05 company, Schwarz Pharma, took a different path. They
09:05:11 started in 1997. And they tried to develop an OAB drug
09:05:16 taking a different path than all these other research
09:05:20 groups.
09:05:20 To orient the plaintiffs in this case, Your
09:05:22 Honor, in 2006, Pfizer entered into an agreement with
09:05:27 Schwarz concerning the compound that came out of this
09:05:30 research. That is fesoterodine. So they are one of the
09:05:33 plaintiffs. And then UCB later acquired Schwarz in 2007.
09:05:38 So they are the other plaintiff.
09:05:41 Now, the work of the Schwarz scientists resulted
09:05:44 in five patents that are at issue here. We have them up on
09:05:49 the screen. There is 12 asserted claims from these patents.
09:05:52 Four of the patents are related. We refer to
09:05:55 them as the compound patents. They have a priority date of
09:05:58 May 12th, 1998. They all concern compounds and methods of
09:06:05 treatment administering those compounds. And the asserted
09:06:08 claims all concern fesoterodine, the drug at issue.

09:06:15 or the '650 patent. It has a priority date of November 16,
09:06:19 1999. And that patent concerns specific salt forms of
09:06:25 compounds, and the asserted claims concern specific salt
09:06:28 forms of fesoterodine, which we will talk about, and a
09:06:31 method of using, of administering those salt forms.
09:06:35 Now, some of these claims do encompass more than
09:06:41 just fesoterodine. The issue here will be about this
09:06:46 compound, fesoterodine, which is on the screen, Your Honor.
09:06:51 Fesoterodine, that is the structure of the
09:06:54 compound with the salt, the fumarate salt. We have
09:06:57 highlighted a few things here just to give a short preview
09:07:02 of the portions of the compound we are going to be talking
09:07:05 about in the case.
09:07:08 You see the ester group there circled in blue,
09:07:10 or at least it's blue on my slide. I am not sure if it's
09:07:14 blue for you, Your Honor. That ester group is one location
09:07:18 on the ring for potential substitution. The alcohol group
09:07:23 is another location on the ring for another possibility for
09:07:28 substitution, which we will be talking about more during the
09:07:30 trial. Finally, in yellow is the fumarate, the salt portion
09:07:34 of the compound.
09:07:37 This compound arose out of that research that
09:07:40 the Schwarz scientists conducted. And the result of that
09:07:43 compound was it benefited the most difficult-to-treat
09:07:48 patients, many of which were failures on the prior art drugs

09:07:54 that we will be talking about.
09:07:58 If we could go to the next slide.
09:08:01 Now, overactive bladder, Your Honor, it
09:08:06 affected, at the time frame, as I said, 1998-1999, it
09:08:10 affected over 45 million people in North America alone at
09:08:14 that time. Over 500 million worldwide. And it was an
09:08:17 underserved population. A lot of people were not getting
09:08:20 treatment for it.
09:08:22 There were severe consequences for some of these
09:08:24 people. I mean, consequences of anxiety, depression, shame.
09:08:29 I mean, these were real issues for some of these patients.
09:08:32 So some of the coping mechanisms, the
09:08:35 traditional coping mechanisms, a lot of people wore diapers.
09:08:38 Other people did toilet mapping, which basically meant
09:08:41 before they left their house they mapped out every place
09:08:44 they were going to stop along the way to their destination.
09:08:48 Some just never left their house. It got to that point for
09:08:51 some of these patients.
09:08:53 In this time frame, there were some drug
09:08:56 options. These drug options were all what were called
09:09:01 antimuscarinics. These antimuscarinics all work on
09:09:05 muscarinic receptors that reside in the bladder. So here
09:09:08 are three of the drugs that existed at that time in 1998.
09:09:13 The problem with a muscarinic receptor is it's

09:09:20 in the brain. It's also in the salivary glands.
09:09:24 So these drugs all had deficiencies with each of
09:09:29 them.
09:09:29 Oxybutynin, for instance, had a severe dry mouth
09:09:34 problem. Most people that took oxybutynin, up to 70 percent
09:09:38 of people that took it had a dry mouth issue. In some it
09:09:42 was so severe they couldn't take the drug. They had to go
09:09:45 off of it.
09:09:46 Propantheline was another antimuscarinic. It
09:09:51 had a wide variety of absorption. Some patients needed a
09:09:54 huge amount. Some patients didn't need as much. And
09:09:56 doctors really didn't know how to dose it.
09:10:00 Tolterodine was the new drug on the market. In
09:10:03 March of 1998, tolterodine was introduced. And the trade
09:10:07 name for that was Detrol. That drug came on the market in
09:10:11 1998. And it solved some of these issues. But it had a
09:10:15 problem with it as well. That was a dose ceiling. You
09:10:19 could only give four milligrams a day of tolterodine. The
09:10:21 reason for that was because of a condition called urinary
09:10:26 retention. Basically, in some patients, if you went above
09:10:29 four milligrams a day, it froze their bladder. So then they
09:10:33 couldn't urinate at all. And that is called a backup. That
09:10:37 wasn't just an uncomfortable side effect, that could be a
09:10:40 serious side effect. It could actually lead to kidney
09:10:42 failure.

09:10:43 So doctors just would not go above that ceiling
09:10:45 of four milligrams a day with tolterodine.
09:10:48 These were the options that existed.
09:10:50 So there were a large number of research groups
09:10:53 that were looking at OAB drugs at this time knowing there
09:10:57 might be a better solution.
09:10:59 Here are some of the targets that they were
09:11:01 looking at. Of course, a number of them were looking at the
09:11:04 muscarinic receptors and trying to find out whether they
09:11:07 could make a selective antimuscarinic compound, one that
09:11:13 would work on the bladder and not work on the other areas of
09:11:15 the body to the same extent.
09:11:18 Others were looking at other pathways in the
09:11:21 bladder. There are other receptors that act on the bladder.
09:11:24 So they were looking at calcium channels, potassium
09:11:28 channels, adrenergic receptors. All of these were
09:11:32 possibilities.
09:11:34 Here you can see, all of these companies on the
09:11:37 left were looking at ways to make a novel, active compound
09:11:45 that would work on OAB.
09:11:48 Looking at all of these different possibilities,
09:11:50 some were looking at muscarinic receptors. Some were
09:11:53 looking at other pathways.
09:11:55 What the scientists at Schwarz did was

09:12:01 to work on the same compounds as these other companies.
09:12:05 They worked on tolterodine. They started with tolterodine.
09:12:08 One of the inventors of fesoterodine that came to work with
09:12:13 Schwarz had been an inventor on tolterodine. And they
09:12:17 started with tolterodine, and then they decided, well, let's
09:12:21 focus on the metabolite of tolterodine. Then, not only
09:12:24 that, they decided, let's make a prodrug.
09:12:27 A prodrug, no one had made a prodrug in this
09:12:30 area. No one had made a prodrug with antimuscarinic. And
09:12:35 no one had made a drug with an OAB drug at that point. So
09:12:38 they were working on a blank slate in this area. No one had
09:12:41 made an antimuscarinic prodrug.
09:12:43 Just to give you a concept quickly, Your Honor,
09:12:45 of what a prodrug is, this is kind of our crude
09:12:50 representation of how it works. The idea is that if you
09:12:52 have an existing drug and it has a problem associated with
09:12:55 it, for instance, you can't get it through a membrane. If
09:13:00 you have an oral dosage form, it can't get through the gut
09:13:03 wall. So it just passes through the body. You see here, it
09:13:07 just can't make it through the gut wall.
09:13:10 So the possibility with a prodrug is, ideally,
09:13:12 if it would work, is that it would deliver that drug across
09:13:17 the gut wall, and then when it gets to the intended site of
09:13:22 action, an enzyme cleaves off the prodrug group, leaving the
09:13:27 intended drug at the appropriate site.

09:13:30 But there is a reason no one was looking at
09:13:33 prodrugs at that time, because prodrugs are a very difficult
09:13:38 set of compounds to try to develop because you are
09:13:41 essentially trying to thread a series of needles to get a
09:13:45 prodrug to work. We see here, you have to balance stability
09:13:51 and volatility at the same time. You want it to be stable
09:13:55 like any drug when it's being stored and manufactured, and
09:13:59 you want it to be stable when it's going through the GI
09:14:03 tract. But once it gets to the intended location, you want
09:14:06 it to be volatile. You want it to convert to the drug.
09:14:11 It has to have an appropriate balance of
09:14:13 absorption and solubility. Those two things are the
09:14:17 intention, but it has to meet both of those. It has to be
09:14:21 water-soluble if it is an oral dosage form but yet it has to
09:14:24 be able to penetrate the stomach wall.
09:14:26 Finally, it has to be nontoxic, like any drug,
09:14:29 and yet not nontoxic to just the one drug, it has to be
09:14:33 nontoxic as to the prodrug and to the portion that cleaves
09:14:36 off.
09:14:37 So there is multiple components that you have to
09:14:39 worry about with toxicity.
09:14:33 Now, this is understood, there are treatises
09:14:36 and there has been court decisions that talk about how
09:14:40 prodrugs are disfavored and how they are an option of last

09:14:46 the grain when they decided let's try to make a prodrug in
09:14:49 this field. No one had ever done it before.
09:14:51 Now, the issue of obviousness, where we're going
09:14:56 to start, there are four issues, Your Honor, that remain in
09:15:01 the case: obviousness, anticipation, indefiniteness I
09:15:07 believe, and then one small issue of infringement as to
09:15:10 Sandoz on two of the 12 claims. But obviousness is the
09:15:13 issue that touches on all of the claims. I'm going to spend
09:15:18 my time speaking about that issue first.
09:15:21 The issue of obviousness is addressed from the
09:15:26 person from the standpoint of a person of ordinary skill
09:15:29 and what that person of ordinary skill would have been
09:15:33 confronted with at this point in 1998, a series of
09:15:39 questions. And these series of questions all have to be
09:15:42 answered in a particular way in the defendants' favor for
09:15:44 them to carry their prima facie burden.
09:15:48 Now, the first question is what is the classic
09:15:53 compound you are going to look at. As we saw, there are
09:15:55 more than just antimuscarinics that were possibilities. The
09:15:56 defendants say you just focus on antimuscarinics.
09:16:00 But even if a person of ordinary skill decides,
09:16:02 okay, well, I'll focus on antimuscarinics, you go to the
09:16:06 next step. You go to the second step. And there you have a
09:16:14 number of possibilities. These are all compounds that were
09:16:16 either, that were either antimuscarinics or in development

09:16:21 or some companies were looking at it and Dr. Maag, who was a
09:16:27 prodrug specialist and a medicinal chemist who worked at
09:16:32 Roche at this time will testify about these possibilities.
09:16:33 He was working in the field at the time.
09:16:35 The defendants will say you focused on
09:16:38 tolterodine because it was the hot new drug that had just
09:16:42 come out. But these were all possibilities here.
09:16:45 And once defendants say, well, lets focus on
09:16:49 tolterodine, then they actually want you to switch. They
09:16:53 want to say, well, follow what the inventors did and look
09:16:56 over at the metabolite. But there is reasons why you
09:17:00 wouldn't look at that metabolite, and the metabolite is
09:17:03 5-HMT, just so when you see that name, that is referring to
09:17:07 the metabolite. That's the compound we have up there.
09:17:10 Now, 5-HMT would not have been an attractive
09:17:16 lead compound for a number of reasons. One, it has never
09:17:19 been studied as a drug. It had only been studied as a
09:17:23 metabolite. It was a metabolite of tolterodine, but no one
09:17:27 had ever dosed it as a drug. So there was no experience
09:17:30 with the compound as a drug, only as a metabolite.
09:17:34 There was no expected differentiation from
09:17:36 tolterodine because the two compounds both work on the
09:17:40 bladder which we'll discuss.
09:17:41 It had never been orally administered.

09:17:49 on 5-HMT, but the defendants will give two reasons why you
09:17:52 would switch. You would look at tolterodine first and once
09:17:55 you are looking at tolterodine, then you would look over to
09:17:58 the metabolite.
09:17:58 They'll say, well, variability of metabolism was
09:18:01 an issue with tolterodine.
09:18:03 There were two groups of patients, Your Honor.
09:18:08 One would be extensive metabolizers and the other would be
09:18:12 poor metabolizers. The reason for this is the enzyme in the
09:18:16 body that works on tolterodine to convert it into the
09:18:20 metabolite, what is called CYP2D6, you will hear that, that
09:18:26 enzyme some people just don't have it or they don't have
09:18:28 much of it in their body. So those patients don't convert
09:18:31 to the metabolite or very little. They're called poor
09:18:35 metabolizers.
09:18:36 But what the prior art shows is it doesn't
09:18:38 matter, because both tolterodine and its metabolite are
09:18:42 active at the bladder. And so the label for Detrol actually
09:18:47 states the net activity of Detrol tablets is expected to be
09:18:51 similar in extensive and poor metabolizers.
09:18:54 So there really was not an issue here. When a
09:18:57 patient came into the doctor's of office, the doctor didn't
09:19:00 try to figure out is the patient a extensive metabolizer or
09:19:04 a poor metabolizer because the label said it doesn't make a
09:19:07 difference. Both get the same effect.

09:19:09 The second reason they're going to give is
09:19:11 they're going to say, well, it's known that 5-HMT, the
09:19:14 metabolite, is more potent than tolterodine, but the
09:19:19 information they cite to for that is early clinic,
09:19:23 pre-clinical work in cats.
09:19:25 That did not prove to be the case in humans. In
09:19:28 humans, they're equipotent. They have the same potency.
09:19:34 You shouldn't focus on the cat data once you have the data
09:19:35 in humans.
09:19:36 So that basis for focusing on 5-HMT also did not
09:19:39 hold up.
09:19:40 But, Your Honor, even if you decide to focus on
09:19:46 5-HMT, you have a number of options once you start with that
09:19:49 as a lead compound. And that is what we have labeled as No.
09:19:52 3 on this slide.
09:19:53 You can make a structural analog of the
09:19:56 compound. You can make a structural analog of tolterodine
09:20:00 or you could make a formulation. If there really is an
09:20:03 issue with 5-HMT, then you can make a formulation.
09:20:07 The defendants are going to say the reason you
09:20:10 have to alter 5-HMT into a prodrug is because there is an
09:20:14 absorption problem of 5-HMT, but this goes back to what I
09:20:18 talked about before. No one has ever actually tried dosing
09:20:22 5-HMT as a drug, so we don't even know if there is an

If you did have an absorption problem, you could address it through a formulation or you could address it through making a structural analog. The prodrug would be your last approach. The defendants say that is what you would go to first.

Now, if you do go to a prodrug, Your Honor, even then you have the number of options for the types of prodrugs.

And we have labeled this as No. 4. You have ethers, you have esters, you have phosphates, carbamates, carbonates. These are all possibilities.

Defendants are going to say, well, you only focus on esters. Just try ester prodrugs. They say those are the old prodrugs that have been around since the '60s or '70s so start there.

But by 1998, the time of the invention, many of these other types are being used. And one of the reasons is because ester prodrugs have an issue with them. They convert in the stomach in many cases because the enzyme that converts ester prodrugs is in the stomach. So you have an early conversion problem with ester prodrugs in some cases and it would have been a concern for 5-HMT if you decided to make a prodrug of 5-HMT.

But even then, Your Honor, if you decide to make an ester prodrug, you still have to decide where am I going

to put that ester?

If you look at the structure again that we put up earlier, now this structure we're going to put up is actually 5-HMT, but again it has the two rings and it has the two locations on the ring: the phenolic location which we highlighted in blue, and the benzylic position or the 5 position which we highlighted in green. Those are both possibilities of where you could put an ester and, in fact, most of the prior art taught you put an ester in both locations so you would have to consider both locations alone and both locations together.

And then you have to consider, well, if I make one ester at one location and a different ester at another location, these are all possibilities.

The calculation that Dr. Roush, our medicinal chemist expert has made is that it would be over 7,000 possibilities, and that is with a very conservative estimate because it is only going to up six carbons. There are prodrug references showing carbons of more than six which would means the possibilities are even greater. So these are allocations that are -- both these locations are possibilities for where you would locate an ester.

Then you have yet another question. Well, let me back up to the defendants' prior art that they will cite,

If you go to the next slide.

They will point to two references, Your Honor, prodrug secondary references; and one is called the Drustrup reference. This reference concerns morphine. It has nothing to do with antimuscarinic or OAB. The structure as you can see is very different. It's a very rigid structure morphine, and, of course, it is not meant for OAB. It's an analgesic.

And this reference actually discusses how it's a very slow conversion, which is the last thing you would want if you are making a prodrug of 5-HMT.

The only way you would get to Drustrup is if you needed just for focusing on one of the two locations.

A person of ordinary skill looking at the problem that was confronting people in the OAB field is not going to look at a morphine reference, Your Honor.

If you go to the next slide.

Even if you decide where you are going to put that prodrug group, then you have to decide what group am I going to put at that location, or at both locations.

And what defendants will say is you would naturally go to the isobutyryl group which is in fesoterodine. That is what we show here as the final compound. But, of course, this is just one of many possibilities, as Dr. Roush will testify.

The defendants will going to point to the Daas reference to say you would focus on the isobutyryl group but, Daas has nothing to do with antimuscarinics, it has nothing to do OAB. It has to do with Parkinson's decease. It is a drug that is used to treat Parkinson's. Again, the structure is very different. It has one OH group.

So this compound again, the only reason you would look at it, is if you needed a justification to get to what the inventors did.

In the end, Your Honor, if you look at the -- if you go to the next slide, if you look along the path here, this is the path where an inventor would have to consider all of these possibilities and the person of ordinary skill would have to consider all of these possibilities from the beginning.

The only way to make your way along this path is to start at the fend end with the claimed compound and get all the way back to the beginning. But the inventors didn't have the benefit of this roadmap, of this blueprint, and neither would a person of ordinary skill.

Now, if you would go to the next slide.

As to the '650 patent, it concerns salt forms, and there are a few additional reasons why that patent, why those claims would not be obvious. They argue that the

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Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

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Sync your system to PACER to automate legal marketing.