REDACTED PUBLIC VERSION

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

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TAKEDA PHARMACEUTICALS U.S.A., INC., Plaintiff, vs. PAR PHARMACEUTICALS, INC., and PAR PHARMACEUTICAL COMPANIES, INC., Defendants.	:	CIVIL ACTION NO. 13-1524 (SLR)
TAKEDA PHARMACEUTICALS U.S.A., INC., Plaintiff vs. AMNEAL PHARMACEUTICALS, LLC, Defendant.	:	CIVIL ACTION NO. 13-1729 (SLR)
TAKEDA PHARMACEUTICALS U.S.A., INC., Plaintiff vs. WATSON LABORATORIES, INC., Defendant.	:	CIVIL ACTION NO. 14-268 (SLR)

Wilmington, Delaware
Tuesday, June 16, 2015
4:26 o'clock, p.m.

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BEFORE: HONORABLE SUE L. ROBINSON, U.S.D.C.J.

APPEARANCES:

WOMBLE CARLYLE SANDRIDGE & RICE LLP
BY: DANIEL ATTAWAY, ESQ.,

-and-

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-and-

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APPEARANCES (Continued):

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Counsel for Defendant
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PROCEEDINGS

(Proceedings commenced in the courtroom, beginning at 4:26 p.m.)

THE COURT: Good afternoon, everyone.

(Counsel respond, "Good afternoon, your Honor.")

THE COURT: Why don't we do some reintroductions.

MR. ATTAWAY: Good afternoon, your Honor.

THE COURT: Good afternoon.

MR. ATTAWAY: Daniel Attaway with Womble Carlyle Sandridge & Rice for the plaintiff, Takeda Pharmaceuticals USA Inc., and with me are Ted Dane and Elizabeth (check) law ton, both of Munger Tolles & Olson, and also with me is Tryn Stimart, also with Womble Carlyle.

THE COURT: All right. Welcome. Thank you. Mr. Fineman?

MR. FINEMAN: Good afternoon, your Honor.

THE COURT: Good afternoon.

MR. FINEMAN: Steve Fineman from Richards, Layton & Finger on behalf of Par.

Also at counsel table with me is Janine Carlan from Arent Fox, also on behalf of Par.

MS. CARLAN: Good afternoon.

THE COURT: Good afternoon.

Ms. Matterer?

MS. MATTERER: Good afternoon. Mary Matterer on behalf of defendant Amneal, and I have with me Kevin Noonan from the law firm of McDonnell Boehnen.

THE COURT: All right. Thank you.

MS. SHARP: Good afternoon, your Honor. Melanie Sharp from Young Conaway Stargatt & Taylor on behalf of the Watson defendants.

With me at counsel table, from Carlson Caspers, is Matt Goggin.

THE COURT: All right. Thank you very much.

All right. I hope you all didn't come here in vein because the purpose of this meeting is to see whether there's anything that claim construction accomplished in terms of moving the case forward or narrowing the issues at least for purposes of expert discovery.

So I will start with plaintiff's counsel to see what, if anything, we should be discussing today.

MR. DANE: Thank you, your Honor. Your Honor, we had, presently we have in the case 17 patents with a total of 80 asserted claims. We have looked at them, both in light of the Court's claim construction and independently to see if we need all that many patents and claims, and we think that we can eliminate six of those patents, and along

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with them that would reduce 25 of the claims, which would leave us with a total of 11 patents and 45 claims in the case.

And if the Court would like, I could very briefly explain why we have that number of claims and why we think that they're appropriately included.

The patents that would remain if we reduce it down to 11 would fall into three basic categories. One set of patents are patents that are specifically about the F and F indication, which is included in the labeled that the generic defendants are submitting to the FDA, and those involve coadministration of colchicine for F and F together with one of three different types of drugs that are known to cause DDI interactions.

So there are three patents that cover that subject matter, one for each of the drugs, and a total of 20 claims, which all have slightly different limitations, but it's basically the same idea. It's just the same idea as applied to different drugs with clarithromycin being one, Ritonavir being another, and Citacamazole being third, can so that's one category.

The second two categories are for gout, which is the subject of our contributory infringement claim. Gout is not, as the Court is aware, in the current label that's being proposed by the generic companies.

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There are two types of gout patents. One group of those also are DDI patents, so they also include reduced dosing regimens, but this time when colchicine is administered for purposes of treating gout either prophylactically or for an acute gout flare together with the three drugs that I mentioned, Ticonazole, Ritonavir and Clarithromycin, and also Veratin (phonetic).

Those patents, there are six patents that cover those methods of administration, and I believe the total number of claims among those patents is 18, so once again, although it's not -- there are a couple more patents than just a one-to-one correspondence of one patent for each drug. It's roughly the same. The reason there are a couple more patents is that some of the patents are specific to whether the gout treatment is for key flares. Some of them are specific to whether it's for prophylaxis, but that's again the basic idea with those patents.

And then the last group are the gout patents that are directed to the low dose acute flare treatment. There are four patents that relate to that, a total of only eight claims. And those patents, the difference among them, they're all very, very similar in terms of what they claim. They claim the acute dosing regimen of 1.2 milligrams followed an hour later by .6. One of the patents ended that.

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Another of the patents which the Court looked at in the claim construction hearing, then talked about the resumption of prophylactic treatment some period of time after that, they put those in two separate patents instead of the same one, which is why we have two different patents. Those are the differences in those claims.

And then the other claims for those patents involve limitations that have to do with the low incidence of side effects for that acute -- acute gout flare regimen compared to a placebo, which was one of the surprising results of the testing that was done by mutual. And the other one has to do with some of the specific, the pharmacokinetics, what the blood concentrations are of colchicine when that acute dosing regimen is administered.

So we have still a fairly large number of claims, but it's because there are all these different subject matters that we're attempting to cover. But in terms of the issues that are involved, we really have the low dose acute gout flare regimen, which is one set of infringement and validity issues.

And then we've got the DDI patents, that there are a number of them because some of them pertain to gout, some of them pertain to gout acute flare treatment, some of them pertain to FMF. But, again, the idea is the same for

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all of those, which is if you are co-administering one of these other drugs with colchicine, it just prescribes the amount by which you reduce the does. So how we got to the total number.

THE COURT: All right.

MS. CARLAN: Your Honor, Janine Carlan.

And I'm going to address the proposal by Takeda on behalf of Par and Watson. And first, your Honor, to let you know, we have met and conferred on this, so the parties have spoken and exchanged e-mails about proposals, and Takeda has sent us this proposal that they suggested to you today. And defendants have offered two counterproposals and Takeda has not accepted those. But I'd like to present them to you and also let your Honor know some of the concerns the defendants have with Takeda's proposal.

First, Takeda's proposal is really only taking out some redundancies. It's not narrowing the case. It's not narrowing the scope of the case, and it's not reducing the -- it's only reducing patents, some of the patents and the claims, but not necessarily reducing topics, experts.

And I do have something that might be helpful, a visual aid to show you why that's the case, if your Honor would indulge.

THE COURT: All right.

MR. FINEMAN: Your Honor, may I approach?

THE COURT: Sure.
(Mr. Fineman hand head slides to the Court.)
THE COURT: Thank you.
MS. CARLAN: Now, counsel for Takeda has discussed a little bit about the background, and on the first visual aid here, you'll see all of the patents listed. And as Mr. Dane described, there are several different categories, including those that go to FMF, those that go to acute gout flares, prophylaxis of gout, and also some in combination with other drugs, coadministration with interacting drugs in addition to colchicine. So that's what's shown as the scope of the case as we sit here today.
The proposal from Takeda is visually represented on the second page, which shows why defendants were not exactly enthusiastic about the proposal in that it does not really take anything out of the case.
So, for example, the first black line in one of the patents that has been removed, or is proposed from Takeda to be removed, the '509 patent, for the treatment of FMF with coadministration with Ritonavir. But just looking down on the next line, the '297 patent addresses FMF with coadministration of Ritonavir. So that issue is still in the case.
Similarly, for the 731 patent, which is blacked

out here, it's for treatment of FMF with coadministration of clarithromycin.
The next line down is a patent that would still be in the case, '298, it's for the treatment of FMF when there's coadministration of clarithromycin, and so on. For each of these black lines, which represents the patents that Takeda proposes to withdraw, it's covered by another patent that remains.
So while the proposal from Takeda may help reduce some paper from the expert reports, it may reduce some, I guess, claim charts, we don't see that this will take away any experts or any days of trial or any significant time for -- that we would hope that we could narrow the case.
So even though the number is 17 to 11, 17 -- 11 patents is still quite a bit. 45 claims will need to be invalidated and they'll need to prove infringement for all of these different types of claims and patents, and in that respect, the proposal from Takeda does not narrow the case in a way that is significant. It's really more cosmetic.
So Par and Watson had proposed two other options. The first one was to withdraw all of the gout patents, and, of course, that is something that Par and other defendants have been concerned about for some time in that the labels will be FMF only and not gout.

So we did propose that option and, of course, removing the gout patents results in what's represented on --
THE COURT: Hadn't I already decided that though? I mean, wasn't that --
MS. CARLAN: I think in that case, your Honor, you've allowed the claims to come in initially in the case and did not decide to see a summary judgment motion on it at that time. If your Honor is willing to address it again, we would like to be able to, and we would like to propose this as an option for narrowing the case.
It does, as seen on visual aid 4, significantly reduce the number of patents, the claims, prior art references and the experts. The defendants' experts would be reduced. No more need for rheumatologists. The issue of commercial success would no longer be in the case since that would be only for gout. And, of course, there would be no issues of 271(c), which will take a lot of time that's fact intensive. That would take a lot of trial time, of course.
So based upon your comment, if this is something that is off the table at this time, we have another option, which is we call option B, which is withdrawal of the acute gout patents. And these are -- they cover a couple of different categories. The acute gout patents would take

away treatment of acute gout with just colchicine or treatment of acute gout when there's an interacting drug. What would remain would be the FMF patent and any of the coadministration patents that deal with prophylaxis of gout.
So with this option, the as can be seen on visual aid 6, the asserted patents are still reduced down to nine, so it's still significant, not quite half. Asserted claims are down a bit. Prior art, of course, and experts.
Experts could be reduced even further if secondary considerations do not include commercial success. That would be whether or not that would continue on according to what Takeda keeps in the case. And this particular option is one that should be considered as viable for not just because it reduces all of these topics in the case and it would also reduce a lot of time at trial, but at this point in time we've seen no proof of infringement for these claims. In fact, we have admissions from Takeda that there's substantial noninfringing uses, and the contentions that we've received are deficient.
So having these removed from the case would have patents that remain, including FMF and prophylaxis of gout in DDI.
So these are the proposals from Par and Watson,

and I believe that Amneal may have a further addition.

THE COURT: All right. Thank you very much.

MS. CARLAN: Thank you, your Honor.

MR. NOONAN: Good afternoon your Honor. Kevin Noonan for Amneal.

Looking at the calculation that plaintiff just gave us, our position has been that we think that the DDI patents, the coadministration patents, should not be part of the case and we've asked plaintiff to take them out.

The only difference between this, and you remember our summary judgment motion, or request for summary judgment motion that we gave you a couple of months ago, is that recently, as recently as yesterday, plaintiff admitted or agreed with us that, in fact, this is a purely legal question, and so it may be something that would be amenable for us not dealing with at trial, and in that case, from their calculations, we'd be down to four patents and eight claims. So if you want to reduce the scope, that's one way to draw lines to say the DDI patents should be in the case. And that's our proposal.

THE COURT: All right. And can you just identify where that would leave us?

MR. NOONAN: Well, it's not in that.

THE COURT: I know. I know. Can you tell me? It would --

MR. NOONAN: I have a list of all the DDI patents, your Honor.

THE COURT: That would be good.

MR. NOONAN: A long list.

THE COURT: Yes. Well, okay. All right. Thank you very much.

MR. NOONAN: Thank you, your Honor.

And just pretend for you a moment that you can't have everything, that you would have to give up something.

MR. DANE: Okay. I will, your Honor.

Well, first, with regard to the proposals from Par, their proposals are essentially -- removing all gout patents is another run out of let's take it out of the case entirely. Two runs at that. This is a third attempt. But that isn't what case narrowing is about. This isn't we looked at the claims, we looked at the claims that were duplicative, we looked at the claims that covered very similar subject matter, and we reduced ourselves down to the claims we thought covered the different types of inventions, and in our view, we don't think it would be fair to Takeda to say, well, you have this set of claims that go toward this type of a method, say the DDI method with FMF, but we are not going to let you litigate whether there is infringement of your gout patents.

THE COURT: Well, the question is this. It is whether we get a good decision when you are making the decision-maker, whether the jury or a Judge make so many decisions, so many patents and so claims. If you're not getting a good decision, then you're wasting everyone's time.

So the question isn't so much whether you can ever try them. The question is whether this should be staged, and, if so, is there a way to make the process more meaningful without undue burdens or prejudice to any party? So that's where I am. I do a lot of staging because plaintiffs tend to bring multiple patents, multiple defendants, and, quite frankly, a jury can't handle it, and, quite frankly, with me and my limited resources, I'm not sure I can handle it.

So that's what I'm asking you to consider, is where are your priorities?

MR. DANE: Well, I think, your Honor, our priorities would be in terms of these large categories that I described, we certainly would want the ability to continue to litigate the acute gout flare claims. We would want to continue to have the ability to litigate some of the claims that involve DDI administration for gout together with --

THE COURT: So you want everything. You are

going to get to a point of how we prioritize though.

MR. DANE: In terms of subject matters?

THE COURT: Well, I don't know. I don't know whether it's a question of the subject matter, if it's a question of taking one of the patents having to do with acute gout flares, one of the patents with FMF, one of the patents about prophylaxis of gout and trying those first. I don't know.

But as I said, even at this stage, going through expert discovery, when you've got so much material, the expert reports tend to be less than helpful, and, quite frankly, I have found that when you try to cover too much material and your experts are limited to what's in their report, if your experts miss anything, all of a sudden, they can't testify about it.

I just want to make this a meaningful process because I don't want to waste my time. The Federal Circuit doesn't want their time wasted, and even your client shouldn't be trying to slip something by.

So if you need a minute to think, I'm just asking you to come up with a plan to prioritize what should go forward first. I'm not saying -- and this might be different because of the dates and, you know, whatever else is going on. I can't keep track of what this particular case, what we're facing in terms of a 30-month stay or

anything else, which makes it different than my other patent cases. But if you were going to stage, not necessarily make Takeda drop so that the experts have a viable opportunity to actually review the materials and I have a decent chance to understand what's going on at trial and write a decent opinion. That's what I'm asking you.

MR. DANE: Okay. Your Honor, I did want to correct myself. I misspoke earlier. I said there were originally 80 claims and there are only 70, and Ms. Carlan corrected stated that there were 70. So I just got that number wrong.

You know, one thing we could certainly do if your Honor wishes to is, you know, we took this cut of the claims that we thought was a meaningful movement.

Defendants, I will note, have cited 226 prior art references in their invalidity contentions and they have not offered to drop a single one of them.

THE COURT: Well, they will have to, but we have to start with your side first so they can prioritize their prior art references. It's, you know, a moving target, give-and-take. So trust me, they will not be going into trial with, or even expert discovery with 246.

MR. DANE: So I don't know that, you know, as I stand here today, I could tell the Court what additional cuts we could make. We could certainly look at this

universe that we have now of the 45 claims. We could try to reduce that further.

THE COURT: Well, I mean in other cases and other Courts and other Judges just come up with a number. At this stage of the game, no more than ten patents, no more than 20 claims, whatever it is. I can come up with a random number, and that's not to say that you will never be able to try those other cases, although as I say in an ANDA context, it gets more complicated because there are more deadlines. But I'm happy to give you an opportunity. I don't think 11 patents and 45 claims is quite where we need to be going into expert discovery.

MR. DANE: Could I ask, your Honor, if you would give us the opportunity, and we can go back and look at this very closely and attempt to get that number down further, both in terms of the patents and the asserted claims?

THE COURT: Well, yes, I will give you that opportunity, but I think we need to talk about what the most -- you need to tell me where we stand in terms of 30-month stay and how easy it will be to stage, and then I need to talk to the defendants about the commensurate reduction in prior art references once we come up with a magic number for the number of patents and claims to go forward at this point.

MR. DANE: Sure. Well, this is a bit of an

unusual case because we have something that actually is a greater block right now than the 30-month stay, which is the orphan drug exclusivity, because the generics are seeking approval only for FMF. There.

Is orphan drug exclusivity until July of 2016, which means they cannot come onto the market until July of 2016. The 30-month stay would expire before that, of course.

THE COURT: Right. So how does -- I mean, I know this is a really complicated ANDA because we have defendants who are not going to label their drug for gout even though -- well, you have my reasoning or that in the first instance.

So what happens with those patents? I mean, even though the 30-month stay does not technically attach, is there any limit on the gout drugs when the defendants have chosen not to label their drugs for gout?

MR. DANE: Well, I think, your Honor, with the current scheduled trial date, we have November 30th of this year.

THE COURT: Right.

MR. DANE: And your Honor set that date to give your Honor plenty of time in advance of the expiration of the 30-month stay, so if there were a judgment in Takeda's favor by operation of Hatch-Waxman and the way the statute

works, there would be a prohibition against the defendants coming to market until the expiration of the patents, which is a long way off. 2028 is the general raining of that.

If Takeda lost, then there would obviously be no injunction, and the only bar as I understand it at that point would be the orphan drug exclusivity until summer of next year.

THE COURT: And, defendants, if you win at my level, just remember what happened at whoever that defendant was who launched and the Federal Circuit very graciously reversed my opinion, so keep that in mind.

All right. So you're down to 11. The defendant ideally, once you hit five, have offered nine. I don't know Amneal, how many patents you came out.

MR. NOONAN: Four, your Honor.

THE COURT: Well, that's probably a little low. So we're someplace I think in the, at this stage of the game, closer to the nine, nine patents, if not eight.

So let me talk to defendants about how many prior art references in total. If we are at eight patents, and I don't know how many claims that would be, but anyway, let's say eight patents, let's talk about numbers. If you can't work this out, then we're just going to throw numbers out.

MR. GOGGIN: Your Honor, Matt Goggin for Watson.

THE COURT: Sure.
MR. GOGGIN: I've got an alternative proposal that I think is a bridge.
THE COURT: Sure.
MR. GOGGIN: And I'm speaking on my own behalf. None of the other defendants have agreed, but not because we disagree. It's because it's something that came to me this afternoon. It's something that might work.
THE COURT: Okay.
MR. GOGGIN: I think Mr. Dane was generally accurate in describing the categories of claims, that there was gout prophylaxis treatment, acute gout treatment, and FMF, and I break it into four categories instead of three. I say that it's acute gout, prophylaxis, FMF and drug-drug interaction.
And, you know, on the defendants' side, we've tended to focus on gout because of the history that we've had concerning the label and the restrictions and the carveout, but that's water under the bridge as far as the Court is concerned, and I understand that.
But on the other side, you know, I think that Takeda's proposal -- you know, I'm in agreement with the defendants' position that they've tended to carve things out that really don't render things more simple. It is just redundancy.

And expanding on the theme that your Honor introduced, I mean, what I would propose is whether it's one patent or two patents in each one of these four categories, it would simplify things considerably, the presentation of the evidence. And I don't think that Takeda would be prejudiced in any significant way, and this is why.
Although there are 17 patents here, they all arose from a very small number of original patent applications, and many of these patents were only allowed because after they had been rejected for double patenting, in other words, the Examiner looked at the application and said, hey, Takeda, or URL, this is exactly what we allowed earlier. We're not going to give you this. They filed something called a terminal disclaimer that says that, well, okay. These things are all going to expire on the same day.
So they are not going to be prejudiced. They essentially acquiesced in the Patent Office's view that in each of these four categories, or at least in a few of them, that there's really one invention here. The Patent Office didn't really -- they gave them separate patent numbers, but it was subject to this terminal disclaimer.
And I think in this situation, going from 17 to 4 patents, one in each one of these categories, it's fair to Takeda, it's fair to the Court, it's fair to the experts, and it allows us to have a complete record, you know, on the

significant issues.
This whole issue of acute gout treatment, I mean, there's one issue here, and that is whether a low dose of 1.2 milligrams followed by .6 milligrams an hour later is or isn't obvious. That's the only issue. We shouldn't have to litigate how many patents we have here, 12 patents that raise that issue. I mean, it's going to confuse everybody. It's a simple issue. The prior art is concise. The experts, I think they'll come in, and I think that in a couple days we can wipe that entire thing out, but it's not going to happen if we've got 45 claims with all of these different constellations. It's acute gout plus DDI or FMF plus DDI. Let's have one patent in each of these areas. I think we'll all have a clear head about what's at issue, it will assist the Court, and we'll be done in a reasonable time.
And, you know, this isn't meant to stop us in the future, but if they win on one of those, it's over. It's not staging anything.
But I think that that is the most efficient way to go forward. Thank you, your Honor.
THE COURT: All right. Thank you very much.
MR. DANE: May I proceed?
THE COURT: Certainly. I'm not expecting -- yes.

MR. DANE: You're not expecting any agreement?
THE COURT: Well, I assume, or I didn't expect you to certainly agree without thinking it over.
MR. DANE: Yes. Yes. You know, I heard what the Court suggested, which is us getting down to nine or eight, and we are certainly happy to attempt to do that.
With respect to Mr. Goggin's suggestion, just an example why this becomes problematic. The simpler claims are in the acute gout flare patents in terms of how they're written. One of them prescribes or claims the dosing regimen, which is the 1.2 milligrams, wait an hour, .6, stop. Another claim talks about resuming prophylactic treatment within a certain period of time after that. There's another claim that goes on to say, and when you do this, the incidence of side effects is not materially different than it is for a placebo. And that was one of the surprising results of the study. You know, if we think about, well, why do you need both of them? They're kind of the same thing.
Well, the original claim for the dosing regimen, that's something that no one is going to be able to argue is not what the guidelines of the ACR say to do, what --
THE COURT: You're getting into the weeds here and I'm not sure I'm going with you there.
MR. DANE: Okay.

THE COURT: Let me just have you think about, because I think it is an interesting idea, whether it's four patents, but to identify the primary issues that you're arguing about, find out which patents present those primary issues, go forward with trial on the primary issues, and if there are truly ancillary issues that, you know, I don't want the tail wagging the dog, the ancillary issues pretty much get resolved once the primary issues are out there and on the table.

So I understand there could be lots of issues to litigate, but in terms of what you are really fighting about, is that not a little more streamlined, and are there not patents that highlight those issues?

MR. DANE: Well, I think, your Honor, at a high level, we would be doing that and getting down to the nine or eight that you suggested, as we will be trying to keep in patents that cover our high level issues and making sure we've got them all covered in the best way.

THE COURT: All right. Well, so the median ground is do eight, and theoretically, that will give you two patents per category. You don't have to take two patents per category, but --

MR. DANE: I'm sorry. I'm sorry, your Honor. You had previously talked about eight patents.

THE COURT: Eight patents.

MR. DANE: Eight patents, not eight claims.

THE COURT: Did I say claims?

MR. DANE: You just said claims.

THE COURT: I meant patents.

MR. DANE: Okay. Thank you.

And, your Honor, I raise this because I have run into this exact situation in another case with regard to claim narrowing. We eliminated a claim because we thought it was relatively redundant and not all that necessary. After we eliminated it, the other side introduced a 112 defense and said that the claim that we left did not have appropriate support. If we had left in the other claim, they never would have the 112 argument.

So our being put to the position before getting into validity reports or anything like that puts us a little bit at risk of some moving around in terms of validity arguments. So I would only ask if we reduce our claims, that we have some vehicle, if that were to happen again -- I'm not saying it would happen here, but if we see that one of our cuts caused an invalidity argument to come into the case, if we didn't think it would have, that at least the Court entertain our ability to come to the Court and suggest maybe that that be reintroduced.

THE COURT: Absolutely. I mean, this is not supposed to make it so that folks can play games. It's

supposed to make the process more meaningful. So, yes.

MR. DANE: Thank you.

And when would your Honor like us to propose to the other side a reduction of the patents?

THE COURT: When is your first expert? It has to be done --

MR. DANE: July 2nd is the date of the initial expert reports.

THE COURT: Then not a whole lot of time. What's that, about two weeks?

MR. DANE: A little over two weeks.

THE COURT: Well, I would think you'd want to exchange that within -- well, we've got to talk about prior art references. If you are going to be getting their invalidity opening report at the same time you're providing the opening infringement report, then it seems to me that they both have to be commensurately narrowed.

So whether in a week you provide your eight patents with the associated claims and a week after that, or we come up with a number -- I don't know whether you need to know which prior art references, but certainly, they need to know what patents and claims. We just need to get a number. I don't know what that is, so let me talk to them.

MR. DANE: All right. And if your Honor is suggesting a week, we can make sure that we get that done in

time to let them know --

THE COURT: All right.

MR. DANE: -- what our next cut would be.

THE COURT: All right. Thank you.

So anyone with some ideas about how many prior art references with eight patents would be a reasonable number?

MS. CARLAN: Your Honor, with respect to the eight patents, I know that we have in our chart what's listed as 210 references. We're not going to trial on 210 references. We expect, of course, we can say already, you know, we know with eight patents, that would certainly go down by at least half, and we're in the process of reducing those now with our expert reports and working with our experts.

So I think our proposal would be to hear exactly what patents and what claims we're being given by plaintiff as a proposal and give them a number based upon that.

THE COURT: Well, my only problem is, if the plaintiff thinks it's a too high number, then I'm in the business of meeting with you all before your expert reports.

So --

MS. CARLAN: So with respect to eight patents, I mean, we can certainly commit right now, that's half. That would certainly take the prior art down by half, no

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question. And depending upon which ones are left, even further reduced.

THE COURT: Well, when you talk about a trial, it would be unusual to have more than five prior art references. Now, they might end up in different combinations, so it makes more, but I'm going to have you all aim at five prior art references per patent. If you really think you can't do it, then you can come back to me, but it just strikes me that -- and I don't know how different the claims are.

So --

MS. CARLAN: We'll take a look at that, your Honor.

THE COURT: All right.

MS. CARLAN: And if there's some real concerns, we'll bring it to your attention. But we'll strive for that.

I just want to make sure that we're talking about the references that are going to be -- we're not talking about background references, for example. Ben Franklin used colchicine, cite. We're not talking about those references?

THE COURT: No, we're not.

MS. CARLAN: Great. Okay. Then I think the defendants will work to get it. We'll look at that number,

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we'll work towards that number with eight patents in mind.

THE COURT: And, quite frankly, if we're talking about 40, I'm not sure it has to be five per patent. It can be 40, and you might have three and however that works out. But I would think -- well, between 40 and 50. All right? How is that?

MS. CARLAN: Yes, your Honor.

THE COURT: All right.

MS. CARLAN: Thank you.

THE COURT: All right. All right. Now, you are free to agree to anything else you want to as long as you agree, but as long as you don't agree, then I will throw out more or less random guidelines to get this case to a manageable size.

Are there any other issues that we should yet talk about? Yes, sir?

MR. DANE: Your Honor, there's one issue. It involves some Par specific highly confidential information, so it's not appropriate for me to raise it in open court. I don't know if there's a possibility of a sidebar or -- I know the Court hates to clear the courtroom.

THE COURT: Well, we can use it as the last issue and everyone can clear except people representing Par. Are there any other issues besides this one?

MR. DANE: Not from Takeda's perspective.

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THE COURT: From any other defendants?

MR. GOGGIN: No, your Honor.

MR. NOONAN: No, your Honor.

THE COURT: I will ask everyone to leave except those lawyers associated with Par, and I thank you for your time this afternoon.

MS. SHARP: Thank you, your Honor.

THE COURT: Thank you.

***(The following portion of the transcript is transcribed under seal.)

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[redacted]

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[redacted]

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MR. DANE: We will do that.

THE COURT: All right.

MR. DANE: And, your Honor, assuming that we remain where we are at the conclusion of that process, would the Court allow us to submit letter briefs?

THE COURT: Sure.

MR. DANE: Thank you.

THE COURT: I will get to them when I get to them, but you can certainly file paper if you want.

MR. DANE: Thank you.

THE COURT: All right. Is there anything else, counsel?

MR. DANE: No.

THE COURT: I thank you for your time this afternoon.

(Court recessed at 5:15 p.m.)

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WORD INDEX

REDACTED IN ITS ENTIRETY