UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

AMGEN INC., et al.,	:	CA NO. 15-839-RGA
	:	
Plaintiffs,	:	
	:	
v.	:	May 4, 2016
	:	
HOSPIRA, INC.,	:	
	:	
Defendant,	:	1:32 o'clock p.m.
.....:		

TRANSCRIPT OF DISCOVERY DISPUTE

BEFORE THE HONORABLE RICHARD G. ANDREWS

UNITED STATES DISTRICT JUDGE

APPEARANCES:

For Plaintiffs: MORRIS, NICHOLS, ARSHT & TUNNELL

BY: MARYELLEN NOREIKA, ESQ

-and-

MARSHALL, GERSTEIN & BORUN LLP
BY: JOHN R. LABBE, ESQ

For Defendant: PROCTOR HEYMAN & ENERIO LLP
BY: DOMINICK T. GATTUSO, ESQ
-and-
WILLKIE FARR & GALLAGHER LLP
BY: THOMAS J. MELORO, ESQ

Court Reporter: LEONARD A. DIBBS
Official Court Reporter

P R O C E E D I N G S

(The proceedings occurred at 1:32 o'clock p.m. as follows:)

THE COURT: Good afternoon, everyone. Please be seated.

This is Amgen v. Hospira, Civil Action No. 15-839.

Ms. Noreika, good afternoon.

MS. NOREIKA: Good afternoon, your Honor.

I'm here representing the plaintiff with my co-counsel, John Labbe, from the Marshall Gerstein firm in Chicago.

THE COURT: All right.

MR. LABBE: Good afternoon, your Honor.

THE COURT: Good afternoon.

Nice to see your, Mr. Labbe.

Have I seen you before.

MR. LABBE: Yes. We were here for the Case Management Conference and argued the Motion to Dismiss. I was in Court for the Motion to Dismiss in February.

THE COURT: Okay. So maybe the question I should have asked is, have I heard you before?

MR. LABBE: Only briefly at the Case Management Conference.

THE COURT: Okay. All right.

Mr. Gattuso.

MR. GATTUSO: Good afternoon, your Honor.

I'm here with Tom Meloro from Willkie Farr.

MR. MELORO: Good afternoon, your honor.

THE COURT: Good afternoon, Mr. Meloro.

So I read your letters. And why don't we talk about the first thing first.

And why don't you start off, Mr. Labbe, with what exactly is it that you want to get from Hospira in terms of -- well, what is it that you want to get in the first request?

MR. LABBE: Your Honor, in our first request, we're seeking specific manufacturing information regarding the product in suit, and its manufacturing information that Hospira was required to provide to us under Paragraph(2)(a) of the BPCIA.

And under Amgen vs. Sandoz --

THE COURT: So this manufacturing information, I thought I saw something where they said something like, you want to get four products that went into their -- that were involved in, somehow or other, in their production of this biologic.

MR. LABBE: The specific information that we're seeking -- and this is one of reasons we don't think this is a fishing expedition is -- we've identified the specific information.

It's four components of their cell culture medium that we're requesting the complete ingredient list for.

And then --

THE COURT: So, cell culture medium, you know, my

knowledge of this if from 9th grade biology, that this is some kind of substance that the cell, or the precursor of the cell, exists when it's making the cell that is claimed in the patent?

MR. LABBE: That's correct, your Honor.

So the product here is a biologic, and it's a protein, and the protein is made in recombinant cells. And the cells are grown in a mixture. You might call it a soup. I think Mr. Meloro used that term in the past.

The cell culture medium is the medium in which the cells are grown. And, in the commercial process, they do this in large vats that are able to grow many cells at one time.

And, so, the cell culture medium is made up of particular components. And one thing that's --

THE COURT: And just give me like a for example kind of thing.

What kind of components would be in cell culture medium?

MR. LABBE: Well, the most common example would be amino acids. Amino acids are the building blocks of proteins. And there may be information about amino acids in the BLA, for example, but there is not complete information about everything, but other things that may be included in the cell culture medium.

THE COURT: So amino acids, things like amino acids would be in the cell culture medium.

And the reason -- and I only have the haziest knowledge of this -- for the reason why this is relevant to your patent claims is what?

MR. LABBE: It's potentially relevant to additional patents that Amgen owns.

THE COURT: Well, let's skip the additional patents, all right?

Is it relevant to the patents that you've actually asserted so far?

MR. LABBE: It may be relevant to one of the claims of the Lin patent. Claim 7 of the Lin patent that calls for a suitable cell culture conditions.

But I would like the opportunity to make the broader point here, though --

THE COURT: Well, I'll let you do that in a second.

Claim 7 of the Lin patent, because the element of that has something to do with the culture medium?

MR. LABBE: Claim 7 of the Lin patent is a processing of producing erythropoietin comprising a step of culturing, under suitable nutrient conditions, vertebrate cells according to Claims 1, 2, 3, 4, 5, and 6.

THE COURT: And so, the suitable nutrient conditions, does that maybe include the culture medium?

MR. LABBE: Correct, your Honor. So the composition of the cell culture medium would certainly fall within the scope of

relevance, in our view, to that claim.

THE COURT: Okay. So that's your narrower argument.

You have a broader argument?

MR. LABBE: Your Honor, the broader argument is that the information is relevant to this case to the extent that this is a case that Amgen has brought under the BPCIA in an effort to resolve patent disputes regarding Hospira's product in advance of the launch of the product. And that's the entire purpose of the BPCIA.

We can't know for certain what information -- what the information says without reviewing the information, as is often the case with discovery.

THE COURT: But isn't the way that goes, is that they produced their aBLA, and then you reasonably assert the patents you think might be implicated by whatever it is they told you they were doing?

MR. LABBE: Well, that leads to one important point, your Honor. That Section (2)(a) of the statute says that they are to produce their application, and such other information that describes the process or processes used to manufacture a biological product.

And that's important here, because there's a distinction between the BPCIA and Hatch-Waxman.

Under Hatch-Waxman, you can only assert a 271(E) claim of infringement based on patents regarding the product, itself,

or methods of use of the product, but under the BPCIA you can also assert patents based on the manufacture of the product.

And this is the reason that it would, A, the information exchange process requires that the applicant provide the manufacturing information as well.

And then Amgen is required --

THE COURT: I'm sorry. You said "provide the manufacturing information."

The language of the statute, which you probably have in front of you --

MR. LABBE: Yes, I do.

THE COURT: -- but it's, essentially, the aBLA and other information, or something like that?

MR. LABBE: And such other information that describes the process or processes used to manufacture the biological product that is the subject of such application.

THE COURT: Okay.

MR. LABBE: So it, specifically, requires that the information regarding manufacturing be provided.

And we did raise this issue during the information exchange process. The first three exhibits are correspondence to Hospira during the information exchange process where we said that they should provide this information.

This would have been about year ago, because it's required under the BPCIA.

And you're correct, that Amgen is required to provide a list of patents that are reasonably believed Hospira would infringe. But it's a reasonableness requirement, it's not a speculation requirement, an uninformed speculation requirement.

Amgen is not required to list patents for which it lacks information. Amgen is entitled to the information and then it can list the patents. Under Hospira's reading of the statute, it would be able to prevent Amgen from ever reviewing the information.

THE COURT: And, I'm sorry, Mr. Labbe.

In terms of the aBLA, which I think I've heard Mr. Meloro, or one of his cohorts say is 700,000 pages, or some other ridiculous number, does it describe what goes into the cell culture medium?

MR. LABBE: It does to an extent, your Honor, yes, but it does not include the information that we've requested, the specific information regarding the four components. It identifies those four components, but it doesn't provide a complete ingredient list for those four components.

And that is what we've -- and they've never pointed to a place where that information is provided in the aBLA.

We said this in our letters to them that that information is lacking. And even though the BLA may be hundreds of thousands of pages, the fact remains that it lacks this specific manufacturing information, and the statute calls for

the manufacturing information to be provided so that Amgen can assess its patent portfolio.

But they're taking advantage of this abbreviated pathway. They should also be required to follow it.

And also Amgen v. Sandoz said that you couldn't have a cause of action based on a violation 2(A). It did say that Sandoz was required and had, in fact, produced the required information during discovery.

So you can't bring a cause of action based on 2(a). And then we have the separate 8(A) issue, and that's a different issue. We can't bring a cause of action under Amgen v. Sandoz based on a 2(A) violation, but we can receive the information during discovery.

And the Federal Circuit was -- expressed a concern about the fact that the applicant could keep the information secret forever, and prevent the reference product sponsor from evaluating its manufacturing patents.

And, in that case, the Federal Circuit found that it was sufficient that the information would be provided in discovery. And so, it didn't find that a concern only because the information would be provided in discovery.

If it's not provided in discovery, Amgen would never get the information, and the whole purpose of the information exchange process would be undermined.

THE COURT: All right.

THE COURT: Mr. Meloro?

MR. MELORO: Thank you, your Honor.

The argument that Amgen sets forth really falls in the end as an attempt to argue that the BPCIA trumps Rule 26 and relevance on the discovery standards.

Counsel mentioned a narrow argument and a broader argument.

The narrow argument, I don't even think Claim 7 of the Lin patent was mentioned in their letter, but suffice it to say, that simply identifying a claim limitation that refers to a -- not even the cell culture medium in those terms, culturing under suitable nutrient conditions, doesn't place in issue, directly or indirectly at this point in the case, the identity of the four components.

THE COURT: Well, you say that, but it doesn't seem to me on its face to be ridiculous for Mr. Labbe to say that the claim language implicates what is in the cell culture medium.

Is it ridiculous, what he's saying?

MR. MELORO: I wouldn't use --

THE COURT: You can use your own words.

MR. MELORO: I'm responding to the exact phraseology of the question.

The identity of those four components is not necessary nor relevant to the infringement allegation in the case. As a matter of fact, Amgen has already provided infringement

contentions without this information, so, clearly, they're able to do it.

We have not --

THE COURT: I take it one of the things that they have said is you infringe Claim 7?

MR. MELORO: I believe they have asserted Claim 7. I don't have the contentions in front of me.

We have not even engaged in a substantive discussion with Amgen as to whether or not there will be a contest of infringement of Claim 7. The issue has not been joined on that particular contention, as it was provided, nor whether if there is going to be a contest on infringement of Claim 7, whether the identities of these four components would have anything to do with it.

THE COURT: So I don't think it's real likely that in the next two weeks you're going to say, okay, we don't contest. We infringe Claim 7.

So it's not something where I'm going to say, okay, well, we're going to wait until you make up your mind on that, which, as we all know, might be a year from now, right? That's not really much a good dodge here, is it?

MR. MELORO: Well, if that were the difference in relevance in the case, and the Court were inclined to think that there was some relevance based on Claim 7, we'd go back and have a hard discussion with our client that there just hasn't been

the opportunity or need to have a discussion with Amgen on this.

We certainly have and are serving this week invalidity contentions on this '349 patent, and so, it's conceivable that the case could end up being an invalidity case, or at least as to Claim 7 being an invalidity case only.

We don't see that there is any relevance to these four components of the Claim 7 infringement case, but if there were a difference there, that's a discussion that we haven't had with Amgen.

On the broader BPCIA question, there is no indication in the statute that Congress intended that Rule 26 relevance be somehow circumvented.

THE COURT: Well, so, I -- I saw that argument in your papers, and I think I appreciate that argument.

And, I think, Mr. Labbe is really saying that you're circumventing the statutory purpose here, and so, regardless of what Congress might have thought, and I'm sure they never contemplated the intersection of this with the Discovery Rules, or the actual -- I mean maybe they did, actually. But in terms pf how you get these things if people didn't do what the statute envisioned.

Are you, by taking this tact, defeating the purpose here?

MR. MELORO: No. In fact, it was Amgen that defeated the purpose of the statute here, because Amgen was given the

information that's in the aBLA from Hospira. And, at that point, it had the opportunity to put in play whatever patents it wanted to put in play that it thought could -- that it believed the claim of patent infringement could reasonably be asserted, and that was initially to sue on those patents.

That was simply to just hand Hospira a list of those patents, at which point, it would have been incumbent upon Hospira to provide contentions of invalidity or non-infringement on those patents.

THE COURT: Why would -- one of the things that I was at least in the back of my mind thinking about was, why would Amgen narrowly assert patents, particularly when the standard, you know, seemed to allow -- allowed them assert the patents of 3(A), probably a lot more liberally than filing a lawsuit?

MR. MELORO: Without guessing as to their particular motives here, why someone in their position might, perhaps to try to intentionally conjure up a situation where not all information requested was provided, so that an argument could be made that 2(A) was violated.

And, although, counsel made the argument today that it is not possible to bring a lawsuit for a violation of 2(A), that's not the position that Amgen took at the beginning of this litigation. The original Complaint in this case had a cause of action for a violation 2(A).

THE COURT: But -- and the Sandoz case was decided

after that?

MR. MELORO: The Sandoz case was decided in the District Court beforehand.

MR. LABBE: The Federal Circuit denied en banc review between our original Complaint and our Amended Complaint, and that was the change of circumstances that caused you to drop the 2(A).

We think under the Amgen v. Sandoz case, as it stands today -- and our cert petition is pending, actually, but as it stands today, we didn't think we could bring that cause of action, but at the time of the original Complaint, an en banc petition was pending.

MR. MELORO: And so, in the original correspondence between the parties, which was about a year ago, clearly somebody in Amgen's shoes could have been thinking that they might want to have 2(A) cause of action available to them by asking for information and not getting the information.

THE COURT: Do you have any other theories?

MR. MELORO: There's a concept of potentially getting a second bite at the apple by wanting to come into court and asserting patents the way that the patent -- the so-called patent dance works. Not every patent on the 3(A) list automatically ends up in litigation.

THE COURT: Well, presumably, because part of it is, you could give them things that wouldn't cause them to think

that it was a good idea to go forward a particular patent.

MR. MELORO: Or, even if they wanted to go forward on a particular patent, there's a negotiation about the number of patents that would be included in the first-wave lawsuit that could, conceivably, result in the plaintiff not being able to assert all the patents that they would like to assert, even if they think they have good grounds to do that in a first-wave lawsuit.

THE COURT: Do you, Mr. Labbe, have anything to add as to why a company, in the position of Amgen, might be taking conservative approaches as to what to name in their 3(A) patent list?

MR. LABBE: Well, I think it does present the reference product sponsor. It puts Amgen on the horn of a dilemma, in some respects, because there have been cases in the Hatch/Waxman context, where the brand company has been found to have listed too many patents in the Orange Book. And so, it's a reasonableness standard.

Amgen is supposed to make a reason -- a determination of what patents would reasonably be asserted based on the information that's been provided. It can't make --

THE COURT: But isn't it the case, that -- because you were talking about Congressional intent -- Congressional policy -- didn't they want to get all of this stuff out in the air, open?

You said this multiple times.

MR. LABBE: Well, to us that's the reason that the -- that the information should be provided. And this notion that we were trying to cook up a dispute is not consistent with Amgen's activities.

THE COURT: Well, so, you know, I gave Mr. Meloro a chance to say various theories. I'm not so interested in that theory, because, frankly, you know, having the right to sue under 2(A) doesn't strike me as something that a rational company would say, yeah, well that's something we would like to work towards.

But I do -- but I am wondering when -- I am just wondering why, to the extent that everybody agrees part of goal here was to get things resolved, why a company like Amgen wouldn't be a reference sponsor, let's say, wouldn't be aggressive in saying, here's all the patents that we have that might cover this, and which then gives you the right to find out more stuff, and to make a better choice about which things to go forward on, right?

MR. LABBE: Well, a listing of the patents doesn't give Amgen a right to find out more information. It would find out their contentions, but it wouldn't require them to produce the information.

The production requirement is set forth in 2(A), and then Amgen is to make a determination, a reasonable

determination, not an uninformed determination.

Under what you're putting forth, your Honor, it would mean that Amgen would never be able to assess the information for itself.

Hospira could simply say, well, we don't infringe those patents for these reasons, and never have an opportunity to assess the underlying information.

What Congress intended is that the underlying information would be available to the reference product sponsor to evaluate. And let's keep in mind that the -- when we're talking about Congressional intent, and Rule 26 -- keep in mind we have Congressional intent, and we also have the Federal Circuit's decision in Amgen v. Sandoz, which forecloses the availability of -- at least as it stands right now, as the Court ruled -- we couldn't bring a private cause of action. We couldn't do anything else to get the information, but to bring an infringement suit, and seek the information in discovery.

And the Federal Circuit felt that that was a sufficient way of addressing the issue.

THE COURT: But the information in Amgen v. Sandoz, the Federal Circuit was talking about was actually, clearly, relevant to the claims that have been made, right?

MR. LABBE: It was not. It was not.

The only patent that had been asserted was a method of treatment patent. And, nevertheless, Sandoz produced its entire

BLA, and also produced additional manufacturing information.

The point of that really is that the Court in Amgen v. Sandoz, the Federal Circuit relied on that fact. The fact that the information was then made available in discovery. It relied on that fact to --

THE COURT: But the information that was made in discovery, what was important to the Federal Circuit was not that peripheral information had been made available, but the core information relating to even though one patent, right?

MR. LABBE: No. It was all the information was made available. The entire aBLA was provided.

The important thing for the Federal Circuit, it repeatedly referred to the information under 2(A) as required information.

And from the opinion, the Court appears sympathetic to the notion that the information needs to be provided, so that infringement can't go undetected.

And, in that case, Amgen was only able to sue on a method of treatment patent, and the Federal Circuit didn't suggest that discovery should be limited to discovery that would be relevant to a method of treatment patent. In fact, that is not what Sandoz did.

In its ruling, in its opinion, the Federal Circuit really focused on that. The information was then available in discovery through an infringement suit, so that the required

information would not be withheld forever. It would eventually be provided.

And, in fact, subsequently, Amgen has amended its Complaint that case to assert at least one additional patent after the Federal Circuit ruling, and discovery continued to progress in that case.

THE COURT: So, Mr. Labbe, what kind of patent, because, presumably, all the patents that Amgen has that could conceivably cover any of this. That's not a secret to somebody like Hospira.

There are ways for them to know what patents, at least according to the PTO, are assigned to you, correct?

MR. LABBE: That's correct, your Honor.

THE COURT: So what kind of patent do you have that might cover the amino acids and the like in the cell culture medium?

MR. LABBE: Well, there's a number of cell culture patents that Amgen owns, and they would require certain ingredients.

One, for example, would require the addition of caffeine to the cell culture medium that Amgen found that that was a way to promote the production of the protein in these cells, and a number of other patents of that nature that would call for, including additional ingredients, and --

THE COURT: And the description of the culture cell

culture medium that comes in the aBLA, isn't enough to tell you whether or not any of your patents are reasonably implicated?

MR. LABBE: Correct, your Honor, without knowing the entire list of ingredients of the cell culture medium.

So, for example, one of -- this is under a Protective Order, so I'm supposed to be careful about mentioning it, but --

THE COURT: Yes, yes. Pretend like everything you're going to say here is going to be on the public record and speak accordingly.

MR. LABBE: Okay. So, you know, one ingredient X. It is a -- it's a cell culture, it's a powder that is used in making a cell culture medium, and it is probably a commercially available powder, but the ingredient list is proprietary.

And we suspect that Hospira has the complete ingredient list and that they should provide it to us.

And what exactly is in that cell culture powder, product, we don't -- we don't know. That information is not provided. There's some information about it provided in the BLA, but it's not a complete ingredient that's provided in the BLA.

So we don't know with certainty whether there are additional patents of Amgen that are implicated. Maybe there aren't. I can't say that there are, but we don't know. We weren't able to form a belief one way or the other.

THE COURT: As a matter of curiosity, if you got the --

if you got what you were seeking from them, and you said, aha, we have a couple of cell culture patents that cover this exactly, would that mean that you would be moving to amend the Complaint here, or do you have to go to through some kind of other dance under the BPCIA, or what would happen next?

MR. LABBE: We would seek leave to amend, the Complaint, your Honor. I don't think it would call for any other process under the dance at this point, because this is information that should have been provided previously.

I mean, we could take that under advisement, if there were a process to go through, but I think it would just be a matter of whether it gives us a Rule 11 basis to seek leave to amend the Complaint at this point, if it was the purpose to go through the process that Hospira should have given us the information a year ago, and then we would have included it in the process at that time.

THE COURT: I understand your position.

Do you have a thought on that question?

MR. MELORO: Yes. A couple of thoughts.

First of all, a year ago Amgen had several choices, and Hospira would submit duties if they thought they had patents that could reasonably be asserted, even if they thought that there was still information they would like to see concerning those patents. And they should have listed the patents on the 3(A) list. That was their duty at that point.

Hospira also, in the correspondence, asked Amgen, specifically, when they asked for this information.

Hospira said, no, we've complied with the statute. We've given you aBLA, which describes the manufacturing process for the product. There is nothing more required.

But if there is something that you think you need to see to evaluate a specific patent, please let us know, so we can evaluate that.

And Amgen never responded to that. They never said, well, gee, here's something that we think might be implicated, but we just don't without knowing the ingredients of component X.

That's why we want the information. They stayed silent, and, presumably, we're fishing. I don't know. Maybe they were sandbagging, but they just never responded to that.

If Amgen were in a position where it got the information it's seeking now, and then sought leave to amend, Hospira would certainly oppose such a motion, and would move to dismiss such a claim on the grounds that those patent or patents should have been on the 3(A) list, and Amgen is barred by statute from asserting patents that were not on their 3(A) list.

THE COURT: Okay. Even though -- and I can't remember, maybe I'm confusing this with something else -- if somewhere down the road, let's assume in this particular case that we have right here, right now, ends up unfavorably to Amgen. And

somewhere down the road, you get whatever approvals you need -- well, obviously, not from me, but from somebody else, and you start selling your biologic -- they can then sue you for infringement upon some other theory that they haven't advanced here, right?

MR. MELORO: I don't believe Amgen can sue on patents that should have been on their 3(A) list.

THE COURT: Is that -- or is it only patents that come in -- that they get after?

MR. MELORO: If they have patents that are after invented, so to speak, or acquired, then we could be in a different situation. But I don't -- I don't get the sense that that's what we're talking about.

THE COURT: Well, I mean, that not what we're talking about right now, but I thought there was just some second round of --

MR. LABBE: Well, your Honor, the question raises a number of different issues. But just to focus on the should have been included point.

I think -- and I'll try to limit my answer to that -- in that to the extent that Mr. Meloro is referring to Section 271(E)(6)(c), to the extent that that provision of the Patent Act creates a bar of any kind, it only creates a bar for patents that Amgen should have listed on its 3(A) list.

And it can't be said that Amgen should have listed

patents for which it lacked sufficient information to have a reasonable belief that Hospira infringed.

The process that Mr. Meloro is describing --

THE COURT: But, I mean, presumably, that would be something that would be a question of fact to be figured out at some later time, right?

MR. LABBE: I agree with that, your Honor, that it could be an issue to be decided later, but it's just not that it's entirely foreclosed. It's a question of whether it's a patent that should have been included.

And we can't -- Amgen couldn't have included a patent for which it lacked information.

And Mr. Meloro was not entirely right earlier in saying that we didn't tell them why we wanted the information. We did say in our correspondence that Amgen owned cell culture patents, and that was the reason that we were seeking the information.

It's not that Amgen has to identify the patents, and then they tell us whether they infringe. They have to give us the manufacturing information so that Amgen can then assess it. That's the process that's set forth in the BPCIA.

It's true that we didn't follow the process that Mr. Meloro set forth, but that's not the process of the BPCIA. That's a process that Hospira proposed and doesn't comport with the process set forth in the statute where they give us, Amgen, the information to assess and make a determination based on a

reasonableness standard of which patents it should list on its 3(A) list.

MR. MELORO: May I respond, your Honor?

THE COURT: Yes.

MR. MELORO: In essence, I think what Amgen's position comes down to is a back-door private right of action on what they perceive to be a violation of Section (2)(A). Hospira complied with Section (2)(A).

Amgen is saying now they believe that Hospira didn't comply with Section (2)(A) as to these four components. They have no 2(A) cause of action, but that's essentially the gravamen of what they're trying to do under the rubric Rule 26.

THE COURT: Okay. And so, just to make sure that I know what I'm ruling on here, if I think of what I'm ruling on here is a list of ingredients for the four components in the cell culture medium or some variation of that.

That's what you're looking for, Mr. Labbe?

MR. LABBE: Yes, your Honor. It's most succinctly stated in our Interrogatory No. 1.

THE COURT: Well, if you are comfortable with that --

MR. LABBE: Yes.

THE COURT: -- I don't need to --

MR. LABBE: Yes.

THE COURT: And do you agree too if that's what it says?

MR. MELORO: I'm comfortable that we think we know what he is asking for.

THE COURT: All right.

What I'm going to do is this.

I'm going to say that within two weeks, on the basis of Claim 7 being asserted, it seems to me that it is relevant, it seems to me it's proportionate, so on the narrow ground you need to provide that information.

I'm going to take a break when we get through with the FDA, and go back and look at Amgen v. Sandoz, since I looked at it before, but to see -- because I'm inclined to give you an alternate ruling one way or the other on the broader ground, too, so that you can make whatever decisions are appropriate, okay?

MR. MELORO: Thank you, your Honor.

MR. LABBE: Okay, your Honor. Thank you.

THE COURT: All right.

So, the FDA correspondence.

And so, here, as I understand it, Amgen's position is Hospira should give you every single piece of paper of any kind between them and the FDA relating to any aspects of these biologics?

MR. LABBE: I think that's right, your Honor, with respect to the product that is the subject of their aBLA.

THE COURT: All right.

And Hospira has responded, we will provide you any FDA correspondence back and forth that relates to any -- essentially, to anything that's at issue, because of the assertion of the patents against the biologic product.

Is that -- does that accurately sum up what your two positions are?

MR. LABBE: More or less. I think their position is even narrower, in my view, and that it's not just relevant to the patent -- the patent lawsuit -- but it's relevant to the specific claims of the patent is their position.

THE COURT: Okay.

MR. LABBE: In other words, it's our view that it's relevant to the patent infringement suit. And it's their view that it's not relevant to the specific claims, and, therefore, not relevant.

THE COURT: Okay. I didn't see that in their letter.

Mr. Meloro, what's your position?

MR. MELORO: Our position is that we will provide anything in the correspondence that's relevant to the patent infringement claims in the case.

THE COURT: So, the patent infringement claims, that's ...

MR. MELORO: The subject matter of the patents, essentially.

So one patent relates to cells. The other patent

relates to what are called isoforms.

THE COURT: Okay. That's helpful.

And so, why is it that you should get every single piece of paper about unrelated aspects of the biologics? Is it, essentially, as I think you said, so you'll know when they're ready to launch?

MR. LABBE: That is one reason, your Honor. That's not a improper reason. Hospira suggested that's some improper reason.

There is a Protective Order in this case, and only limited people at Amgen would know the information. It's a proper purpose to know what the timing of the lawsuit needs to be.

There's other reasons.

We know that they received what's called a complete response letter from the FDA, and that they have to make an additional submission, which they're expected to make some time in the first half this year based on public information.

We don't know what will be in there. There may be amendments to the BLA. There may be changes to the manufacturing process.

THE COURT: Well, to the extent that they change the process, and that's relevant to this lawsuit, they're going to be, for sure, in their obligation to advise you, right? That's a duty to supplement kind of thing, right?

MR. LABBE: Yes, but we think the duty to supplement goes beyond that in this case. And there could be information that could implicate additional patents. It could implicate the timing of the case.

And we mentioned that this information, in our view, is routinely provided in Hatch-Waxman cases, and we say that only because for the same reasons it's relevant in those cases, it's relevant here, it's relevant regarding what types of rejections, what type of information they're receiving from the FDA. All of that is potentially relevant. It could be relevant to a potential defense in the case.

We -- they haven't answered the Complaint yet, but we expect them to assert a clinical trial exemption. There be could information about the manufacture of their lots of the products.

THE COURT: To the extent they assert particular defenses, you know, I think attributing to Mr. Meloro that right now he's just -- right now the only thing on the table is your infringement contentions. If they expand what is at issue here, presumably that expands what -- things that he might have to provide, if there is a discussion about experimental use, or whatever it was you said.

And you say it's standard in Hatch-Waxman to produce FDA correspondence, and I would say based on discovery disputes, that it's not certainly just accepted that a hundred percent of

FDA correspondence gets produced. And, if so, I don't know why I'm having so many discovery disputes over it.

The other thing is, even the discovery disputes I have, it strikes me that, in fact, the norm, as I would define it -- I will ask my Independent experts here in a minute -- the norm, I would define it is, yes, I think it is routine that some FDA correspondence gets provided back and forth, but I think it's not routine that it is a hundred percent.

But, in any event, Ms. Noreika or Mr. Gattuso, do you have any input on what the norm is?

MS. NOREIKA: In my experience, most of the FDA correspondence is provided, and there is not usually disputes. Disputes usually come up when you have situations where there's a question as to whether it's going to effect the timing of case, or whether they're going to be changes to the product that would impact, you know, the infringement allegations, or something like that.

I'm not sure what was brought to you, your Honor, but in my cases, it's usually just provided, and there is not much fight about it.

MR. GATTUSO: Judge, I think it's not always all. It's most. And you do see it more when there is a change of manufacturing process, or things like that, which will alter the posture of the case.

THE COURT: All right.

THE COURT: All right.

So what sort of things do you imagine happening, Mr. Meloro? What kind of correspondence do you imagine not producing?

MR. MELORO: Correspondence that is unrelated to the technical aspects of the product or the manufacturing process that have bearing on the patents.

So, if there were, for example, routine correspondence that indicated the progress of the application through the FDA, but had no substantive discussion of the product or the manufacturing process.

We're dealing with two expired patents. This is very different from a Hatch-Waxman case where the patents are enforced. There's usually a 30-month stay.

THE COURT: Well, when you say two expired patents, explain that.

MR. MELORO: Both of the patents-in-suit are expired in this case, and there is no 30-month stay.

So the usual concepts of expiration of the stay, and a potential at-risk launch, and the things that happened routinely in Hatch/Waxman cases are not at issue here.

THE COURT: Wait. Let me go back.

How can expired patents be asserted against you?

MR. LABBE: We can assert expired patents, your Honor, based on previous acts of infringement. And we're seeking

damages based on earlier acts of infringement prior to the expiration of the patents.

THE COURT: But if they -- if they get permission, or whatever it is they need to launch their biologic right now, these two patents couldn't stop them?

MR. LABBE: There's a possibility of some degree of injunctive relief based on prior infringement in terms of product that has been manufactured. Based -- if the product was manufactured and infringed under the patent, there's a possibility of injunctive relief to some extent, but it wouldn't -- it wouldn't prevent them forever, that's correct, your Honor.

We also --

THE COURT: Let me just go back.

When did the second of these two expire?

MR. LABBE: The second of two expired in January of this year.

THE COURT: How long, typically, does it take to culture cells and grow them? I mean, is that a long-drawn out process or is that something that happens every 24 hours?

MR. LABBE: I don't know how long it would take from start to finish to make a batch, your Honor. But I think since January they probably could have manufactured a batch of the product, if that's what you're asking?

THE COURT: So how would back and forth with the FDA effect -- so we're not, necessarily, talking about FDA

correspondence going forward. We're talking more about FDA correspondence that already occurred or, because I'm trying to wonder how -- like if they right now we want to change the way we manufacture things, maybe that -- I don't know whether that creates some separate duty to do something, but in relation to this suit, why do you care?

MR. LABBE: Well, we're talking about both, really.

They could amend the Complaint -- they could amend their BLA, rather, in a way that would implicate other Amgen patents, and we don't -- we would be completely in the dark about that.

THE COURT: Okay. But that doesn't seem to me like this lawsuit is really about other Amgen patents, right, it's about the two you asserted?

MR. LABBE: It is about the two that we have asserted, and that's based on the information that has been provided to us to date.

If they were to make a change to their BLA that would implicate other patents, Amgen should know about those patents as well. It should be provided as part of discovery.

THE COURT: And so, FDA correspondence you want, I take it's actually kind of a going-forward basis? I mean --

MR. LABBE: Correct, your Honor. We would seek the FDA correspondence on a going-forward basis for the reasons I've stated. For the -- there was a timing information --

THE COURT: Mr. Labbe, is that actually what's in dispute, not historical FDA correspondence, but stuff that has yet to occur?

MR. LABBE: Well, both items are in dispute. The only thing that we received from them is the BLA that they produced last February a year ago. Since February they haven't produced any other FDA information.

THE COURT: And so, this FDA response letter that you seem to be quite certain that they have received, and in which they have some duty to respond to, would that actually -- would that actually be -- I guess that could be relevant to your patent infringement, because it, perhaps, talks about something they were doing before your patents expired?

MR. LABBE: Correct, your Honor. It could be, yes. We don't know what was in the complete response letter. We don't know if they were -- if they were required to change their manufacturing process. Then, perhaps, nothing that they had already manufactured at the time the patents expired, would even be relevant any more, but we don't -- we don't know that. They haven't asserted that to us, but we don't have a way to even evaluate that.

THE COURT: All right.

And, Mr. Meloro, if the FDA correspondence, I guess if it talks about something you did during the -- or, in particular, this response letter -- and I'm not asking, because

I'm not entirely sure whether -- you don't even have to admit there is a response letter -- but let's assume, hypothetically, you got a response letter.

If there was something in it that talked about whatever you were doing directly either indirectly before the patents expired, you would produce that, right?

MR. MELORO: That's correct, your Honor. If it related to the subject matter of these patents, we would produce the information.

We haven't refused -- we did receive a letter from the FDA, that's been publicly-acknowledged by the company, and we haven't refused to produce that letter.

The reason we're before your Honor today is the line that we've drawn as to how we will decide what to produce from the FDA correspondence is what Amgen is unhappy about.

THE COURT: Okay. I think the usual balance of things here is pretty significantly in favor of Hospira here, because unlike the Hatch/Waxman cases that I see where there are legitimate timing issues that impact all aspects of the litigation, they don't really seem to be at issue here, because the two patents that are asserted, as I understand it, can't effectively -- you know, I can't see them as actually having much to do with whether or not Hospira can start -- or can launch its product, and market it, or whatever.

So I don't think the -- and so, even though I

appreciate the highest degrees of confidentiality and such, it seems to me that before you even order, or before you produce that, even though I'm quite confident everyone will live up to the Protective Order, that does seem to me to be very important information to Hospira.

And so, it seems to have, essentially, no relevance to the patents that are asserted. I think the line that Hospira has drawn is the right line.

MR. LABBE: Can I just add one thing, your Honor?

I mean, we do so on the pending 8(A) issue, and I know that's subject to a Motion to Dismiss right now, but were the Court to deny that Motion to Dismiss, the issue there is whether Hospira is giving the appropriate 180-day notice before it launches its product.

And there the timing of the information would be particularly relevant, because we're in the dark right now as to when they may get approval. We don't know if they've already filed their responses, a complete response letter or not, or when -- we just don't now anything other than what they have said publicly back in the fall.

So for that issue, we think it would be particularly relevant, and I haven't focused on that, because it's subject to the Motion to Dismiss.

I would just state that for the record.

THE COURT: Okay. And, I'm sorry, Mr. Labbe, just -- I

don't mind you mentioning that just a little more, because it's not in the forefront of my mind.

MR. LABBE: Yes. So the 8(A) issue, as I was referring to it, your Honor is, we have asserted a claim in the case that is subject to the Motion to Dismiss, saying that Hospira has violated the BPCIA by refusing to give 180-days notice prior to its commercial marketing.

Under the Amgen v. Sandoz case, such a notice can only be given after Hospira receives approval from the FDA. Under the Amgen v. Sandoz case, they're then required to wait a hundred and eighty days after approval before launching the product.

And so, that's an issue that's been raised.

THE COURT: But you would -- if they get the approval, do you learn that they've gotten the approval?

MR. LABBE: I don't know. It wouldn't be public information. They would, perhaps, announce that, but we wouldn't necessarily know that they've gotten approval. They might just launch.

Now, their position is that they don't have to give us the notice. And so, if they were able go forward with that position, we wouldn't know, and we wouldn't have an opportunity to seek an injunction to prevent the launch without their waiting the statutory 180 days, but I don't know of any way that Amgen would know, unless they made a press release about it.

THE COURT: Okay. Do --

MR. LABBE: It may, at some point, become a part of the FDA website. You wouldn't know when it's about to happen to be able to come to court and seek an injunction.

MR. MELORO: I'm not a FDA expert, but I do believe that the FDA posts approvals very promptly after they are issued.

THE COURT: So, in other words, to the extent that there is a concern about the timing of things, if the FDA gave you approval, you're saying it would be public knowledge, in your opinion?

MR. MELORO: That's my understanding.

THE COURT: All right. Okay.

Well, so, I'm going to stick with what I said about the FDA.

Let me just go off and take another look at Amgen v. Sandoz, and I will be back.

(A recess was taken at this time.)

(The proceedings continued after the recess as follows:)

THE COURT: Well, thank you for your patience.

So on the broader asserted basis for discovery, I'm going to deny plaintiffs' request.

I don't think the Amgen v. Sandoz Federal Circuit case is really on point for -- not only -- it would be controlling,

obviously, if it were on point, but it's not on point. I don't think that really impacts this at all.

And, I think, looking for the cell culture medium so you can consider about asserting other patents, it's, basically, what in the pre-amendment, you know, before December, what we just called the fishing expedition, is they're even less favored after the amendments than they were before.

So, to the extent that you're interested in assessing what other patents you might have had, I don't think this is the way to do it.

So I'm going to, on the broader grounds, deny it, but that will only come into play if the narrow grounds became moot for some reason, all right?

MR. MELORO: Thank you, your Honor.

Just for clarity, on the narrower ground, the Order at this point is that the information be produced in two weeks, if the Claim 7 infringement issue is still in play?

THE COURT: Right. It seems to me to be relevant to that.

MR. MELORO: Thank you, your Honor.

MR. LABBE: I understand the Court's ruling. It puts us in a somewhat difficult position.

If we're getting the discovery, it doesn't make any difference, but because we've dropped 2(A) claim, really, in reliance on the Amgen v. Sandoz decision, I think that's a issue

that we may -- Amgen may have reevaluate.

We'll take that under consideration as to whether there are any additional --

THE COURT: Okay. Let me just say, when we were taking the recess, my law clerk was pointing out, I was asking some of these questions that I was asking today at the oral argument.

You know, after we have oral argument, usually we decide how we're going to decide it, but it takes time to write it up.

And my law clerk reminded me that among other things, we weren't in a hurry to write that up, because we thought it -- the overall oral argument topics might be effected by the appeal from this Florida case in the Federal Circuit, which I think is on 8(A)?

MR. LABBE: Correct, your Honor.

THE COURT: Apparently, I was -- well, you obviously know this -- it was argued six weeks ago or something?

MR. LABBE: It was argued. That's right. That's about right, your Honor.

THE COURT: So we're probably not going to decide that until -- we would appreciate getting the benefit of whatever the Federal Circuit might have to say about that. Maybe it will be helpful, maybe it won't.

In terms of -- and so, is it -- is it the case, though, now this case is just is kind of just in more or less a hiatus,

because you are waiting for me to decide this thing, you said you haven't answered the Complaint?

MR. MELORO: With respect to a formal answer to the Complaint, I think it was the pending motion, but we do have a schedule in place, and the parties will move through fact discovery on the two expired patents, so we're not paused in that sense.

THE COURT: Okay. All right.

Thank you. That's another thing I couldn't remember.

All right.

Normally, the transcript here serves as the Order of the Court on these things.

If you need me any further, you know how to contact me.

MR. MELORO: Thank you, your Honor.

MR. LABBE: Thank you, your Honor.

THE COURT: Thank you very much.

(The proceedings adjourned at 1:18 o'clock p.m.)

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