

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

Civil Action  
No. 05-12237-WGY

\* \* \* \* \*

AMGEN, INC.,

Plaintiff,

v.

F. HOFFMANN-LA ROCHE LTD,  
ROCHE DIAGNOSTICS GmbH and  
HOFFMANN-LA ROCHE, INC.,

Defendants.

\* \* \* \* \*

MOTION HEARING

BEFORE: The Honorable William G. Young,  
District Judge

APPEARANCES:

DUANE MORRIS LLP (By Michael R. Gottfried,  
Esq.), 470 Atlantic Avenue, Suite 500, Boston,  
Massachusetts 02210

- and -

DAY CASEBEER MADRID & BATCHELDER LLP  
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Plaintiff

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May 10, 2006

Page 2

1 APPEARANCES (Cont'd)

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17 Americas, New York, New York 10036-6710, on behalf

18 of Ortho Biotech Products, L.P.

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Page 3

1 THE CLERK: Calling Civil Action 05-12237, Amgen --

2 well, it isn't --

3 THE COURT: It's the same action.

4 THE CLERK: -- versus Ortho.

5 THE COURT: It's the one involving Ortho.

6 THE CLERK: Ortho.

7 THE COURT: The motion to intervene.

8 MR. ZALESIN: Yes.

9 THE COURT: And on the motion to intervene would

10 counsel identify themselves.

11 MR. DAY: Yes, your Honor.

12 Rusty Day, representing Amgen, and with me is

13 Stuart Watt and Michael Gottfried.

14 MR. ZALESIN: Good afternoon, your Honor. Steve

15 Zalesin representing Ortho, and Dan Olohan.

16 THE COURT: Thank you.

17 MS. BEN-AMI: Your Honor, my name is Leora Ben-Ami

18 and I represent Roche, along with Mr. Bromberg and Mr. Suh.

19 THE COURT: Fine, and we'll get to you.

20 MS. BEN-AMI: Thank you.

21 THE COURT: The first round -- at least it makes

22 sense to me that we ought to grapple with whether Ortho's in

23 or out; then once we have figured out Ortho in and out, we

24 can grapple with whether Amgen versus the LaRoche folks have

25 subject matter jurisdiction first and then have personal

Page 4

1 jurisdiction over the various people that they've sued.

2 That's, that's the logic.

3 So, I guess I want to turn first to Ortho.

4 And would you develop first why Ortho is a necessary party.

5 MR. ZALESIN: Certainly, your Honor. We're relying

6 on a very recently decided case by the Federal Circuit, the

7 Aspex Eyewear case.

8 THE COURT: Right. I've looked at it.

9 MR. ZALESIN: What the Federal Circuit says there

10 is that for the same policy reasons that a patent holder

11 must be joined as a party along with an exclusive licensee,

12 the exclusive licensee wants to bring suit, the inverse of

13 that should also be true that the exclusive licensee ought

14 to be joined as a party along with the patent holder.

15 THE COURT: Well, that's your inference.

16 MR. ZALESIN: Well, those more or less are the

17 words of the Federal Circuit, they say for the same policy

18 reasons. I can read you the quote if it's helpful.

19 THE COURT: But Aspex was an exclusive licensee at

20 the proper time, then Chic was not a necessary party and

21 Aspex was in fact a proper plaintiff.

22 MR. ZALESIN: That's right.

23 THE COURT: That's right. That's what they say.

24 MR. ZALESIN: That's right.

25 THE COURT: You take the negative implication of

Page 5

1 that.

2 MR. ZALESIN: Well, your Honor, I think, I think

3 they say more than that. Let me, let me get the quote that

4 I have in mind. They say that, this is a quote from the

5 Federal Circuit's opinion at Page 1344, "For the same policy

6 reasons that a patentee must be joined in any lawsuit

7 involving his or her patent there must be joinder of any

8 exclusive licensee," unquote. That quote appears at Page, I

9 was reading from Page 8 of our reply. And I think it was in

10 our opening brief also.

11 Now, they don't unpack that very much and they

12 don't go back to what the policy is. But let me tell you

13 what I understand it to be and how it affects us here.

14 The issue is duplicative lawsuits. If the

15 exclusive licensee were allowed to sue on its own then there

16 would be a risk that the patent holder and the exclusive

17 licensee could maintain separate actions, whether

18 simultaneously or seriatim, against the same infringer and

19 essentially get two bites at the apple or expose the

20 infringer, or alleged infringer to multiple suits on the

21 same accused product under the same patents because neither

22 party, both have an interest in the patent and the right to

23 sue --

24 THE COURT: Yes.

25 MR. ZALESIN: -- and neither party would be bound

Page 6

1 by the judgment against the other.

2 THE COURT: I'm familiar with that. But that's,  
3 it's not clear to me, certainly Aspex doesn't stand, doesn't  
4 hold that Ortho in the circumstances of this case is a  
5 necessary party.

6 MR. ZALESIN: Well --

7 THE COURT: That's not the holding.

8 MR. ZALESIN: I think what it holds is that  
9 whichever of the two as between the two ultimate exclusive  
10 licensees, Chic and Aspex, whichever one was the exclusive  
11 licensee as of the time the complaint was filed, and there's  
12 a discrepancy by a couple of days and they send it back for  
13 more fact finding, but whichever one of those two was the  
14 exclusive licensee was a necessary party in that case, and  
15 they can't tell on the record in front of them on appeal  
16 which one was the exclusive licensee at the time.

17 THE COURT: And that's not this case.

18 MR. ZALESIN: Right.

19 THE COURT: Another interesting aspect of Aspex is  
20 that they don't in any way suggest they're making a  
21 significant shift in the law.

22 MR. ZALESIN: I agree with your Honor. They just  
23 kind of say it matter of factly, that for the same policy  
24 reasons, et cetera. But, but if you go back to their logic  
25 and the issue is avoidance of multiplicity of suits, that

Page 7

1 same logic would hold, I believe, in our case, that Ortho  
2 should not, Ortho shouldn't have the opportunity to sue on  
3 its own in a separate or follow-on lawsuit, and Roche  
4 shouldn't have to face the possibility of being sued by  
5 either Amgen or Ortho in a separate or seriatim lawsuit.  
6 But if we're together in the same suit, Roche is protected  
7 and as we, since we have standing, there's no reason why we  
8 shouldn't be here. That's, that's more the intervention  
9 issue. But I believe that the straightforward reading, and  
10 I agree with you it's rather curt, it's rather short and  
11 they don't want unpack it very much, but it does say right  
12 on its face, it is the Federal Circuit, they are the, more  
13 or less the controlling authority on patent issues.

14 THE COURT: More rather than less. I understand.  
15 I work for them.

16 MR. ZALESIN: There you go.

17 THE COURT: But you see -- and now let's -- we'll  
18 slide over to -- I understand your argument and I understand  
19 the case with which you conjure.

20 Let's talk about Rule 24 here.

21 MR. ZALESIN: Yes.

22 THE COURT: And where I would like you to, to begin  
23 is with your license agreement with Amgen.

24 MR. ZALESIN: Yes.

25 THE COURT: Because as I read the license

Page 8

1 agreement -- well, I'll be completely transparent and you  
2 can all argue to it.

3 Absent the language of the license agreement, it  
4 looks to me like Ortho is certainly a proper party to be  
5 joined. Not, not a discretionary party, you're a proper  
6 party to be joined. Except that, except that under the  
7 license agreement it seems that you have given the right to  
8 control this lawsuit to Amgen.

9 MR. ZALESIN: I see.

10 THE COURT: And I haven't found a case, candidly,  
11 and we've looked, where if you have that right to, a right  
12 can be waived, and I read the language as waiving it.

13 Now, that's why oral argument's helpful. That's  
14 how I come on the bench. I want to hear you.

15 MR. ZALESIN: Okay. We're talking about the  
16 provision of the license agreement, I believe it's Paragraph  
17 8.02, but we'll find it in a second, in which, it sort of  
18 carves up the responsibility as between Amgen and Ortho for  
19 what's supposed to happen when there's an alleged infringer.  
20 And it says that we're supposed to talk, we're supposed to  
21 consult about the best way to go forward. Whichever party  
22 discovers the infringement is supposed to share its evidence  
23 of infringement with the other party, and then it does  
24 allocate the initial responsibility to Amgen.

25 None of the background happened in this case. I

Page 9

1 don't think that's disputed. Amgen went forward on its own.  
2 So they didn't comply with those provisions, but that's not  
3 necessarily of concern to your Honor. It may be some window  
4 in to why we don't necessarily feel that our interests are  
5 fully protected.

6 But the case that I would direct you to, your  
7 Honor, is the Ferrofluidics case against Advanced Vacuum  
8 Components from the First Circuit in 1992.

9 I'm sorry. I'm sorry. That's not the right case.  
10 I apologize. I had it flagged and -- I'm sorry, it's the  
11 Prima Tek case, Prima Tek II, LLC versus A-Roo Company, from  
12 the Federal Circuit in 2000, where the Court said, quote,  
13 "Standing to sue for infringement depends entirely on the  
14 putative plaintiff's proprietary interest in the patent, not  
15 on any contractual arrangements among the parties regarding  
16 who may sue and who will be bound by judgments."

17 So, I think that the Federal Circuit has in effect  
18 said standing is a, is a matter of patent right which  
19 depends upon whether the party that seeks to sue, whether  
20 independently or together with the patent --

21 THE COURT: Well, I'll go back and look at that  
22 case.

23 MR. ZALESIN: Sure. Okay.

24 THE COURT: But that case addresses standing.

25 MR. ZALESIN: Right.

Page 10	Page 12
<p>1 THE COURT: And as I understand the patent laws and 2 as I understand Federal Circuit jurisprudence, you can't -- 3 isn't that a case where they were saying you can't confer 4 standing by contract. That makes perfect sense. That makes 5 perfect sense. Because -- 6 MR. ZALESIN: Well -- 7 THE COURT: -- the whole concept of standing has 8 constitutional overtones. 9 MR. ZALESIN: Well -- 10 THE COURT: For my discussion, I was prepared, and 11 still am, I think, to say that you are a proper party to be 12 joined unless you gave that away in a contract. And it 13 looks like you did. 14 MR. ZALESIN: Well, first of all, standing to be 15 conferred by contract because that's what the license 16 agreement does, it creates the necessary exclusive license. 17 A license agreement is a contract, it creates an exclusive 18 license, it creates the protectable legal interests that 19 Ortho has in the enforcement of the patent and makes us a 20 proper party. 21 I think the issue that your Honor is addressing is 22 whether -- 23 THE COURT: That's right. 24 MR. ZALESIN: -- in addition to that you should 25 construe the contract in this setting to bar Ortho from</p>	<p>1 in arbitration, not in this court. If they can show some 2 damage to them from that, or want to seek an injunction in 3 arbitration against our participation -- 4 THE COURT: Oh, really? 5 MR. ZALESIN: -- they could go to arbitration and I 6 don't -- 7 THE COURT: Then maybe I should just, since you 8 people are so interested in arbitration, maybe I should say, 9 well, you, that's the justice you want, you go figure it 10 out, let the arbitrators tell me, I'll more or less confirm. 11 Are you saying that? 12 MR. ZALESIN: No, no, I'm not saying -- what I am 13 saying is that the issue of whether Ortho has standing and 14 is properly an intervenor in this case is an issue for your 15 Honor to decide. 16 THE COURT: That's what you want. 17 MR. ZALESIN: That's what I -- 18 THE COURT: And I'm saying that may turn on 19 contract. And you say, well, not you, Judge, not you, 20 arbitrators. We want arbitrators to determine the contract. 21 Well, fine. 22 MR. ZALESIN: What I'm saying, your Honor, is that 23 the issue for this Court we believe is whether Ortho has 24 standing and we're a proper party. If, if we have somehow 25 done harm to Amgen's rights under the contract then</p>
Page 11	Page 13
<p>1 participating in a case where Amgen hasn't invited us to 2 participate. 3 THE COURT: But it looks pretty clear that's what 4 you contracted for. 5 MR. ZALESIN: I would say, I would say a couple of 6 things to your Honor. First of all, if we are correct that 7 we are a necessary party under Aspex -- 8 THE COURT: I don't have to worry about that. 9 MR. ZALESIN: Okay. 10 THE COURT: I agree. 11 MR. ZALESIN: Second, I think Amgen has waived its 12 right to rely upon that language by which it gets to choose 13 whether to join us or not by failing to comply with the 14 various contractual prerequisites which is not disputed on 15 this record. They didn't contact us. They didn't discuss 16 the issue with us, et cetera. Not disputed on this record. 17 And, third, in any event, as Amgen points out in 18 its brief, and I think it's applicable here, there is an 19 arbitration clause in the contract and if Amgen is unhappy 20 that Ortho is inserting itself into this case, a patent 21 case, because Ortho has standing, and the Court is prepared 22 to find we're a proper party, then the standing issues and 23 the Rule 24 issues for this Court are satisfied. If Amgen 24 thinks that we are in breach of the contract by forcing our 25 way into a litigation where we don't belong, their remedy is</p>	<p>1 there's -- 2 THE COURT: You've made the point. I'm going to 3 stick to my time. 4 Mr. Day, on this point, or whoever's going to 5 argue. 6 MR. DAY: I will, your Honor, for Amgen. I believe 7 Roche may also want to say something and I'll try to leave 8 time for Roche. I'll try not to take all the time. 9 THE COURT: Oh. That's an interesting lineup. I 10 hadn't thought I was going to hear Roche within this time. 11 But if you -- 12 MR. DAY: I'm happy to take all the time, but they 13 filed a paper and I didn't want to squeeze them out, your 14 Honor. 15 THE COURT: Fine. 16 MS. BEN-AMI: He never wants to. 17 THE COURT: Very well. Go ahead. 18 MR. DAY: First of all, let me say with respect to 19 necessary party, if I may. I recognize the Court wants to 20 focus on the contract and I will get to the contract in a 21 moment. 22 THE COURT: But he's right, if they're a necessary 23 party that trumps contract as far as I can see. 24 MR. DAY: If they're a necessary party. Of course, 25 if they're a necessary party, they were a necessary party in</p>

<p style="text-align: right;">Page 14</p> <p>1 HMR/TKT, they never showed up. They were a necessary party 2 in Amgen v. Chugai and they never showed up. 3 THE COURT: I can't help that. My duty is to 4 adjudicate the cases in front of me. 5 MR. DAY: I understand that, your Honor. 6 But as your Honor reminds us, the holding of a case 7 is determined by its facts. And you need to look at the 8 facts. And as your Court -- as your Honor astutely took us 9 through Aspex, let's look at the facts. What was Aspex 10 doing here. And in Aspex we're dealing with licensees who 11 are exclusive licensees meaning that they have exclusive 12 license rights under the patent. They don't have a license 13 right to a product. They have exclusive rights under the 14 patent. And the rights they were granted not only included 15 the right to sell and the right to manufacture and the right 16 to use, but the right to exclude. 17 Now, Ortho has not been given those rights. Ortho 18 has not been given the right to exclude. I'll just go 19 there. And that's right where your Honor went. And you go 20 to 8.02 in the contract. Because Ortho did not get the full 21 bundle of rights under a patent, because they got a product 22 license and not a patent license. And because they do not 23 have the exclusive rights under the patent for any claim in 24 the patent, they only have the right to sell a product, 25 period. And they were not given the right to exclude. And</p>	<p style="text-align: right;">Page 16</p> <p>1 exclude. The right to exclude others from making, the right 2 to exclude others from selling, the right to exclude others 3 from using. Ortho was given a right under that patent to 4 sell, but it was not given the right to exclude. 5 THE COURT: But suppose -- and I really must 6 reflect on this because I wasn't prepared, my fault, for 7 anyone to mention arbitration. Suppose I were to say, and 8 I'm not suggesting I will, that on the issue of 9 intervention -- well, the way I see it, I've got to wrestle 10 my way through necessary party. So I do that. Let's say 11 Ortho doesn't win on that, arguably. And then I say, gee, 12 they look like a proper party to be joined under Rule 24, 13 unless of course the contract precludes them. The contract 14 says arbitrate, I'll stay my hand on this, say nothing 15 further, let them do whatever they want. They don't get to 16 arbitrate, but of course if they want an arbitration -- they 17 don't get to intervene, but if they want an arbitration 18 then -- again, I must manage the lawsuits that are before me 19 but -- 20 MR. DAY: That's their prerogative. 21 THE COURT: I understand. 22 MR. DAY: If they choose to arbitrate that's their 23 -- 24 THE COURT: You're okay with that? 25 MR. DAY: Yes, sir.</p>
<p style="text-align: right;">Page 15</p> <p>1 that was expressly bargained and negotiated between the 2 parties. Because Amgen's rights are so much broader, 3 Amgen's rights invoke so much more than Ortho was given. 4 Amgen and Ortho bargained with each other as to who would 5 have the right to enforce this patent. And the agreement 6 was reached between them that Amgen would have the right. 7 And if Amgen elected that right then Ortho, if it was 8 invited, would agree to join. If it wasn't invited it 9 wouldn't share in the costs and it wouldn't share in any 10 damages. 11 THE COURT: And it sounds like you agreed to 12 arbitrate those issues. 13 MR. DAY: Well, and then-- 14 THE COURT: If there's a dispute about that. 15 MR. DAY: We agreed, your Honor, that the contract 16 states what it states. And if there is a dispute the sole 17 remedy for that dispute of any cause arising under the 18 contract is arbitration. That's the only remedy for 19 disputes in contract. And I think, I think, your Honor, at 20 bottom, I've tried to work this through, you know, and I 21 bottom out exactly where your Honor bottoms out. 8.02 is 22 what controls here. Because 8.02 is the provision, you have 23 to look at the agreement in its entirety and you have to 24 understand that what a patent confers quintessentially, the 25 quintessential right that a patent confers is the right to</p>	<p style="text-align: right;">Page 17</p> <p>1 THE COURT: All right. I think I understand the 2 arguments. Well, now, he defers -- you had your ten 3 minutes. He defers to LaRoche here. I don't understand why 4 LaRoche wants to be heard. 5 MS. BEN-AMI: I only want to be heard about one 6 point, your Honor, and that's this Aspex case. If your 7 Honor looks at the next paragraph under joinder of -- 8 THE COURT: Beyond what I quoted? 9 MS. BEN-AMI: I think in the second paragraph it 10 says exclusive licensee with the right to sue. And so that, 11 I think that is controlling. 12 THE COURT: And your point is that here it's 13 undisputed Ortho didn't have that right. 14 MS. BEN-AMI: So there really is no necessary 15 party. 16 THE COURT: I'll take the matter under advisement. 17 Thank you. 18 Now, with the parties all in place let's -- yes. 19 And thank you very much. I appreciate your courtesy. 20 Let's turn to the issue first of subject matter 21 jurisdiction. And my first question on that issue is for 22 Mr. Day. 23 You've carefully parsed your language here and I 24 want to ask you straight out. Does Amgen claim there is, 25 today, infringement of its patents here in the United</p>

1 States?

2 MR. DAY: Yes, your Honor. What we claim is that  
3 271(e)(1) is an affirmative defense and that we know that  
4 Roche is importing into the United States and using in the  
5 United States a product that infringes our patent. Our  
6 patents. And it is their affirmative defense that all of  
7 the use of that patent, all their use of that product,  
8 excuse me, is subject to their defense. Now, that then  
9 becomes --

10 THE COURT: Their defense being this safe harbor  
11 for the regulatory --

12 MR. DAY: 271(e)(1).

13 THE COURT: -- approvals.

14 MR. DAY: Yes. That the use of a product to obtain  
15 data for submission to FDA, any reasonably, any use  
16 reasonably related.

17 THE COURT: Yes.

18 MR. DAY: I'm not parsing over the scope. You  
19 know, I think the Court got it right in HMR. I think the  
20 Court fully understands what the scope of the defense is.  
21 But it's an affirmative defense. It's a defense that Roche  
22 must make out.

23 And so, the contention is, yes, they are infringing  
24 today and there is no question that they intend to make  
25 commercial sale of this product in the future.

1 THE COURT: But they haven't done that -- well,  
2 then, let me phrase it this way. That is a direct answer  
3 and I appreciate it.

4 Why shouldn't I do what I did in the HMR case which  
5 was administratively close this until the regulatory agency  
6 approval has come out LaRoche's way --

7 MR. DAY: Yes.

8 THE COURT: -- and we have a real issue.

9 MR. DAY: Yes. For two reasons. First of all, in  
10 HMR you held that we had a real issue. You held in HMR at  
11 the time that there was a real case or controversy. You  
12 exercised your discretion to stay.

13 Now, second of all, so let's look at the facts.

14 Let's look at the circumstances in which you did that and  
15 see are they analogous to this situation. You did that at a  
16 point in time before Roche had filed an application --  
17 before, excuse me, HMR had filed an application with FDA for  
18 approval to market and sell. And, in fact, as it turned out  
19 it was more than a year prior to the time, almost two years  
20 prior to the time that HMR had filed, got around to filing a  
21 regulatory application. And you determined at that point in  
22 time that the product was still subject to change, that the  
23 manufacturing process for the product was still subject to  
24 change. And for that reason you administratively stayed it.  
25 And you pointed out, albeit, I think, a little vaguely, but

1 you pointed out that there may be a point in time prior to  
2 regulatory approval when the case should be reinstated.

3 THE COURT: Exactly. But your point here is, and I  
4 really want to hear about personal jurisdiction, so I'm  
5 going to cut you off, your point here is given the  
6 undisputed facts that are before this Court, we're much  
7 further down the process in terms of what you fear than we  
8 were with HMR.

9 MR. DAY: And I would like to make just two  
10 additional points with respect to that.

11 And the first one is if you look at the Glaxo case,  
12 which is the controlling Federal Circuit case here, the case  
13 that is closest on point, you will notice in the Glaxo case  
14 that the defendant in that case gave notice to Glaxo that  
15 they were intending to sell their product no sooner than 18  
16 months before the lawsuit was filed.

17 So they had filed an ANDA and they said they would  
18 not sell their product for at least 18 months. Nonetheless,  
19 the Federal Circuit held that there was sufficient imminence  
20 for a real case or controversy and the case went on.

21 The second point I want to make, if I may.

22 THE COURT: Very briefly.

23 MR. DAY: And I appreciate your patience.

24 The second point I want to make is that if not now,  
25 when? And that is the issue Roche has not answered. And

1 all I can take from their papers is, well, after we're  
2 approved. In other words, they want to create a safe harbor  
3 for infringement. They want to prevent Amgen from getting  
4 an adjudication of its rights.

5 THE COURT: But they do have a safe harbor, I  
6 thought, until, you say it's an affirmative defense, until,  
7 as we use a visual, until they sail out from that safe  
8 harbor.

9 MR. DAY: And then they want, at that point in time  
10 they want to say and then the lawsuit can start. So that we  
11 can, we can infringe, we can sell, we can get into the  
12 market, we can effect irreparable harm because an  
13 adjudication is not going to occur in a day, it's not going  
14 to occur in two days.

15 THE COURT: No.

16 MR. DAY: And I think your Court -- I think your  
17 Honor recognized that in HMR. Because you pointed out in  
18 HMR that there is a point in time before market approval  
19 where it may be appropriate to institute suit. And I think  
20 Glaxo specifies when that is, your Honor.

21 THE COURT: Thank you.

22 Let me hear from LaRoche, on this point now,  
23 subject matter jurisdiction.

24 And could I ask you to start where he started. He  
25 says, he posits it, and I can follow it, I'm not asking you

1 to admit you infringe, he says they're infringing now, but  
2 they have this affirmative defense, which he then proceeds  
3 to argue ought not apply here.

4 My question to you is, are you doing now, today,  
5 that of which they complain -- I'm characterizing it as  
6 infringing -- but for the fact of pending regulatory  
7 approval.

8 MS. BEN-AMI: I think to answer your question,  
9 Roche is doing clinical trials.

10 THE COURT: Yes.

11 MS. BEN-AMI: That is what Roche is doing.

12 THE COURT: So you are doing, you are doing the  
13 acts.

14 MS. BEN-AMI: We are.

15 THE COURT: But you say in complete good faith  
16 they're clinical trials.

17 MS. BEN-AMI: And, your Honor, if you look at the  
18 complaint you will see that Amgen's complaint is, the only  
19 count in the complaint is for declaratory judgment.

20 THE COURT: Oh, I've noted that.

21 MS. BEN-AMI: There is no complaint for actual  
22 infringement.

23 THE COURT: Right. And he agrees.

24 MS. BEN-AMI: And so I think that is a red herring.  
25 There is only a complaint for future infringement.

1 Declaratory judgment that when we come out of safe harbor  
2 there will be infringement, then we are squarely in the  
3 question of whether the Court can exercise declaratory  
4 judgment jurisdiction.

5 THE COURT: But you see that gets me back, though  
6 you frame it as a question of subject matter jurisdiction,  
7 that gets me back, this is, this is a new case, new parties,  
8 I treat things new, but it gets me back into that area of  
9 the law that I wrestled with before. And you use this safe  
10 harbor analogy. You say we're here in the safe harbor.

11 They may be patrolling offshore with their blockade, but  
12 we're in the safe harbor. And he says, no, no, no. At some  
13 stage they're, they're building their ships, they're arming  
14 then, and at some stage they're ready to come out, it's time  
15 for us to go into a cutting-out attack.

16 I've been reading too much Patrick O'Brian  
17 recently. But do you see what I mean?

18 MS. BEN-AMI: Yes.

19 THE COURT: And though he complains that it's  
20 vague, I do the best I can. Somewhere there's a line there.  
21 He thinks you've crossed it. You say you haven't. I think  
22 I want to suggest to you I'm not, I'm not to be heard to say  
23 that the line is a bright-line regulatory approval. It does  
24 seem to me at some stage you're gearing up, you know, you're  
25 doing your clinical testing, which has to be done in the

1 market, and I have to then grapple with are you infringing.  
2 That I suggest to you.

3 MS. BEN-AMI: Well, I don't think it can be  
4 infringement under 271(e)(1). So it's really a question,  
5 again, I come back to is it ripe for declaratory judgment.  
6 And because it is, those acts are not an infringement, they  
7 should not be able to create an actual controversy. The  
8 real issue of actual controversy, rather than advisory  
9 opinion, is when there is an imminence of an actual  
10 infringement. And let's look at where we are.

11 While Amgen put in a very carefully crafted  
12 declaration that said you get a response in ten months,  
13 that's just a response, if it happens. It could be a  
14 rejection. It could be an ask for more information, it  
15 could be anything. And the facts are, if you look at  
16 historical facts, when their Aranesp product was approved,  
17 when the Pegasys product was approved, they were both  
18 roughly about two years down the road.

19 So, we're not looking at something happening in  
20 three months or six months. And I believe there was a  
21 shipping case, your Honor, the Lang case was about building  
22 a ship, and there the Court said nine months is too far  
23 away. So, I think that your Honor needs to consider, we are  
24 far down the road still.

25 And there is a policy issue here that I would like

1 your Honor to consider. In the situation of generics where  
2 there is an ANDA, and I know your Honor is familiar with  
3 this, congress has said when you file your approval papers  
4 that will create an artificial technical act of  
5 infringement, so there can be an infringement lawsuit prior  
6 to launch. Right? Congress spoke very clearly about that.  
7 And in 271(e)(1) they took a different position which said  
8 you are safe unless you're doing something other than for  
9 clinical, something reasonably related to go to the FDA.

10 So there is a congressional split of intent to  
11 handle generics where they're copycats and they're just  
12 piggy-backing off of the other party's approval, versus a  
13 new ANDA or BLA. And I believe that congressional intent  
14 would be violated by saying once you file a BLA that's  
15 enough. If Roche were out there selling that would be a  
16 different situation. And in the TKT case, your Honor, you  
17 said, point blank, you, you have the authority at a  
18 certain point, if there's imminence, real imminence, like  
19 the product has been approved and people are about to ship  
20 it or something like that --

21 THE COURT: And you agree with that at least  
22 theoretically.

23 MS. BEN-AMI: In theory you have, you have the  
24 inherent and explicit authority just like in a regular  
25 non-pharmaceutical patent case. Imagine this as an

1 electronics case. And Amgen has a patent on a DVD player  
2 and I want to start selling DVD players. And I didn't wait  
3 two years or three years or whatever it might be. They come  
4 into court, they sue us, they ask for a preliminary  
5 injunction, and your Honor deals with it under the facts and  
6 law. And this situation shouldn't put Roche at a worse  
7 position because it has to go through FDA approvals.

8 THE COURT: But, I mean, you're hiring salespeople,  
9 you're building a manufacturing plant. That may be good  
10 business, but it certainly causes them disquiet.

11 MS. BEN-AMI: Well, we're building a manufacturing  
12 plant outside the United States which will also possibly  
13 service outside the United States. And that's a very good  
14 point, the manufacturing plant. Because for biologics  
15 getting approval with manufacturing plants is very  
16 difficult.

17 Your Honor may remember the situation where Chiron  
18 was stopped from making its vaccines, its flu vaccines,  
19 because of manufacturing plant issues. It's not a walk in  
20 the park to go ahead and do this.

21 THE COURT: What about sales personnel?

22 MS. BEN-AMI: Sales personnel are hired because  
23 they have to get doctors to work on the clinicals. The  
24 reality is that you have to get doctors to do clinical  
25 trials. And those are not acts of infringement, your Honor.

1 THE COURT: Let's, let's turn to personal  
2 jurisdiction because I cannot, I cannot keep everything  
3 cabined here. I understand my duty to address subject  
4 matter jurisdiction. But let's address personal  
5 jurisdiction. And I do think I want to go back to Mr. Day  
6 and then I'll be back to you.

7 Mr. Day, it looks to me that the stronger of your  
8 arguments on personal jurisdiction has to do with, and let  
9 me get it correct, Roche Germany, and the weaker of your  
10 arguments has to do with the other entity --

11 MR. DAY: Roche Switzerland.

12 THE COURT: -- Roche Switzerland, if we're all  
13 clear what we're talking about.

14 And I think you recognize that. So you would like  
15 a little jurisdictional discovery. Let me assume, because I  
16 may be able to handle this as matter of law, that there are  
17 a number of license agreements such as you hope to discover.

18 Would that change the analysis? Would you start  
19 there.

20 MR. DAY: It would change the analysis if as I  
21 suspect and am led to believe by Roche's website, Roche  
22 Switzerland is a sponsor of the clinical trials in  
23 Massachusetts as well as elsewhere in the United States, or  
24 if Roche Switzerland is the sponsor of the BLA that has been  
25 filed because it would then be seeking approval to make,

1 import and sell in Massachusetts an infringing product.

2 THE COURT: Now, again, I appreciate the answer.  
3 And to me it's a recognition on your part that just the data  
4 on the website's not going to be enough to establish  
5 jurisdiction, so you say let Amgen have the chance to back  
6 up that data.

7 MR. DAY: In addition --

8 THE COURT: And I guess I should posit just for the  
9 purposes of discussion that the data on the website is  
10 accurate. And you say if it is all accurate and it involves  
11 Massachusetts, as well as other states, you say you have  
12 jurisdiction under Roche Switzerland. Over Roche  
13 Switzerland.

14 MR. DAY: Yes.

15 THE COURT: More precisely, this Court does.

16 MR. DAY: Yes.

17 Now, let me add to that. Roche tells us in their  
18 reply papers that the Hoffman-LaRoche Limited that's listed  
19 on the website is actually an English company. It's a  
20 different company than the Swiss company. They don't  
21 provide us with any attestation, any declaration, any  
22 evidentiary support of that. And they leave us to guess  
23 what the internecine organizational structure and workings  
24 of all the various different Roche companies are and who's  
25 doing what where. And that's all the more reason, I

1 believe, why a limited amount of discovery to simply find  
2 out, well, if it's not the Swiss company but it's really the  
3 British company that is the proper party here, and is the  
4 party that should be joined in this lawsuit, and they could  
5 easily tell us that today if they wish, or we could discover  
6 that through limited discovery, then fine, they're the  
7 proper party.

8 I would also like to just simply point out that in  
9 addition to the clinical trials there is other activity  
10 ongoing. As the Court pointed out, not only the hiring of a  
11 sales force but the solicitation of customers to purchase  
12 Roche's product and/or to use Roche's products in a  
13 commercial setting. And the largest dialysis provider in  
14 the country happens to be a German company that is based  
15 here in Lexington, Fresenius. Their U.S. operation is based  
16 here. Are they contacted in Massachusetts or are they  
17 contacted in Switzerland or in Germany? I don't know. But  
18 the entity that appears to be the sponsor of the BLA and  
19 appears to be running the commercial organization of Roche  
20 is Roche Limited.

21 THE COURT: All right.

22 MR. DAY: And a little bit of discovery would  
23 ferret that out.

24 THE COURT: Thank you. I'll hear LaRoche on the  
25 issue of personal jurisdiction.

Page 30

1 MS. BEN-AMI: Your Honor, Roche U.S. is the sponsor  
2 of the U.S. BLA. And there is no serious dispute about  
3 that. They're looking at a website and misreading it. And  
4 I think that in fairness to open up discovery of a Swiss  
5 company for harassment of huge amounts of discovery where it  
6 is clear that Roche U.S. is --

7 THE COURT: Well, I wouldn't open it for huge  
8 amounts of discovery. How about -- would you undertake the  
9 burden of describing, I don't mean here this afternoon in  
10 open court, but among yourselves, the corporate arrangements  
11 and who's doing what?

12 MS. BEN-AMI: I think that would be manageable. We  
13 could give the sponsor page, the page that says this is  
14 being sponsored by Roche U.S. to Mr. Day.

15 THE COURT: All right. Now, I'm not asking you to  
16 concede in any way jurisdiction, but I find that helpful.

17 Now, on personal jurisdiction what do you say?

18 MS. BEN-AMI: As to Switzerland, your Honor, there  
19 are no continuous and systematic contacts, and they really  
20 do not have anything to do with this state. And it really  
21 does matter what state you're talking about. They're not in  
22 this state. They're not necessary to this case. So I'll  
23 focus on Germany, your Honor.

24 The Germans are similarly not involved with  
25 Massachusetts. And we did tell the Court that they had,

Page 31

1 their predecessor company had purchased a cell line, but  
2 that is no longer the company. The company Roche has not  
3 made payments to Massachusetts since 2003.

4 And it's important to think about that because it  
5 does tie into the motion to dismiss on subject matter  
6 jurisdiction. If this -- if Roche gets approved, and if it  
7 gets approved in two years, say, who knows what the contacts  
8 will be with this state in two years. It may be that there  
9 will be fewer contacts. There may be more contacts. And  
10 because this case is not ripe now, the Court should dismiss  
11 for personal jurisdiction now. And if there comes a point  
12 in time when the case is ripe, then the Court can look at  
13 the contacts as they exist at the time.

14 Because right now the case is not ripe. And that  
15 the German company does not supply into Massachusetts for  
16 any infringing purpose, they do not do anything like that,  
17 they only provide to Roche U.S., in New Jersey, not in  
18 Massachusetts. They don't pay here.

19 THE COURT: I follow a practice in a variety of  
20 situations, and I did it once this afternoon with the  
21 arbitration, of administratively closing cases. And that is  
22 an administrative closure. I think it's advantageous for  
23 the proper administration of this session of the Court and  
24 the maintenance of the Court's own statistics. It has  
25 the -- it's the functional equivalent of a stay. Puts

Page 32

1 everything on ice but disadvantages no one because if the  
2 circumstances change and someone is disadvantaged a motion  
3 can be made to reopen the case telling me why the  
4 administrative closure hurts.

5 Since I will not allow, at least the formal  
6 transaction costs of litigation, you can't serve  
7 interrogatories or take depositions or anything like that,  
8 your people are no worse off if I simply don't adjudicate it  
9 and administratively close the case if the corporate lineup  
10 as you sail out of the safe harbor is known at the time.

11 MS. BEN-AMI: If your Honor closes all the motions  
12 and doesn't decide anything then we'll be --

13 THE COURT: Well, my instinct is to decide what is  
14 ripe, I'm not saying I agree with you, because it's always  
15 more helpful to litigants to do the job they ask you to do  
16 than to duck them. And then as to those things that  
17 prudential value suggests I should at present duck, maybe I  
18 should duck. And everyone stays in their positions and, you  
19 know, the various commercial advantage and maybe you're  
20 discussing matters.

21 So you're okay with that?

22 MS. BEN-AMI: Except -- yes, your Honor, in  
23 general. Except that the issue of, the issue of whether  
24 there's sufficient contacts really should be decided at the  
25 time when the case is truly ripe.

Page 33

1 THE COURT: You've made that point.

2 Now, I have one other point. As the -- and this is  
3 a case management point. Let's assume that I do not stay  
4 anything, or close it, and I thrash my way through, for good  
5 or ill. I let Ortho in, I keep Ortho out, I send Ortho to,  
6 and Amgen to arbitration. Of course, if I don't find  
7 personal jurisdiction over -- but that isn't going to happen  
8 because I have Roche U.S.

9 MS. BEN-AMI: Correct, your Honor.

10 THE COURT: So somebody in your team is going to be  
11 left standing, left present even if you win across the board  
12 on what you have argued here. Unless, and even if you win  
13 on what you said, subject matter jurisdiction, the most  
14 you're going to get is an administrative closure. So the  
15 case is alive. Now -- and I've got Roche U.S. If I don't  
16 administratively close the case and I've got Roche U.S., is  
17 this a jury case?

18 MS. BEN-AMI: I don't know, your Honor.

19 THE COURT: You don't know because we haven't  
20 reached it?

21 MS. BEN-AMI: We haven't gotten that far yet.

22 MR. DAY: As the claim is currently framed it's an  
23 equitable claim, it doesn't require a jury. There's no  
24 damage claim.

25 THE COURT: I understand that. But they haven't

1 yet responded because they've moved to dismiss.  
 2 MR. DAY: That's right.  
 3 THE COURT: And you're not making a response.  
 4 And probably -- you know I like to get the business  
 5 of the Court done -- probably it's premature to hold a case  
 6 management conference until I know who's in and who's out  
 7 and I know what claims are ripe. Because if I don't think  
 8 anything's ripe we'll just put it on ice.  
 9 And you're nodding. Would you give me your name  
 10 again?  
 11 MS. BEN-AMI: I'm sorry, your Honor.  
 12 THE COURT: We're going to become very familiar  
 13 with each other --  
 14 MS. BEN-AMI: Yes, and I --  
 15 THE COURT: -- and I like to call people by their  
 16 names.  
 17 MS. BEN-AMI: My first name is Leora, L E O R A.  
 18 The last name is Ben-Ami, B E N A M I.  
 19 THE COURT: Well, Ms. Ben-Ami, you're certainly  
 20 welcome, and thank you.  
 21 MS. BEN-AMI: Thank you, your Honor.  
 22 THE COURT: And, Mr. Day, you agree with that  
 23 construct, that it's a little premature to have a case  
 24 management conference?  
 25 MR. DAY: Yes, I don't agree you should get to that

1 conclusion. But if you do get to that conclusion, I  
 2 certainly agree with that.  
 3 THE COURT: I understand your several positions.  
 4 Thank you very much. It's been very helpful, and  
 5 we'll recess.  
 6 MS. BEN-AMI: Thank you, your Honor.  
 7 THE CLERK: All rise. Court is in recess.  
 8 (Whereupon the matter concluded.)  
 9  
 10  
 11 C E R T I F I C A T E  
 12  
 13 I, Donald E. Womack, Official Court Reporter for  
 14 the United States District Court for the District of  
 15 Massachusetts, do hereby certify that the foregoing pages  
 16 are a true and accurate transcription of my shorthand notes  
 17 taken in the aforementioned matter to the best of my skill  
 18 and ability.  
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