## IN THE UNITED STATES DISTRICT COURT IN AND FOR THE DISTRICT OF DELAWARE

THE JOHNS HOPKINS UNIVERSITY, : CIVIL ACTION A Maryland Corporation, BAXTER HEALTHCARE CORPORATION,: A Delaware Corporation, and BECTON DICKINSON AND COMPANY, a New Jersey Corporation,

Plaintiffs

ν.

CELLPRO, A Delaware Corporation,

Defendant

NO. 94-105 (RRM)

Wilmington, Delaware Wednesday, April 30, 1997 10:30 o'clock, a.m.

BEFORE: HONORABLE RODERICK R. McKELVIE, U.S.D.C.J.

## APPEARANCES:

POTTER, ANDERSON & CORROON BY: WILLIAM J. MARSDEN, JR., ESQ.

Counsel for Plaintiffs

Leonard A. Dibbs and Valerie J. Gunning, Official Court Reporters Multi-Page™

Page 4 APPEARABORS (Continued): THE COURT: Actually, I was going to do 2 FOLEY, BOAG & BLIGT 2 the opposite. 3 DOUALD R. MARR. \$50. 404 PETER B. ELLIS ESQ. (Boston, Massachusetts) 3 MR. WARE: You want to hear the whole thing? THE COURT: No. I thought I'd pick a couple 5 just to talk about where we are with them. ROBERT H. SALLEHBECK, KSQ., I know that the subject of the injunction is б Associate Gaseral Counsel Becton Dickinson & Company going to be the meat of any argument we have today. Let's see if we can clear some of the other 8 9 issues up first. 10 PREDERICE 6. SAVACE, ESQ., Associate General Counsel Office of the Vice President and General Counsel Johan Boptins University 10 MR. WARE: All right. 11 THE COURT: And then come back. 11 12 12 But people won't leave today without getting 13 meel for Plaistiff Becton Dickinson a chance to walk through all of the issues on the and COMPARY injunction. 15 15 But let's talk about - I guess we've got CONTROLLY, MOVE, LODGE & BUTE BY: GERARD M. O'ROUREE, \$30 and 16 the marking defense. We've got Beverly documents. We've 17 W. RICHARD PORTES, ESQ. 18 18 Why don't we talk about misuse for a minute? 19 19 Who wants to talk about that defense and where it is? 24 COM A. BLOCHBERG, 250., JEROLO B. REILLY, 830. MR. BLOOMBERG: I'm happy to address that, 20 JEROLD B. REILLY, ESQ. and MARCE G. CHAPMEN, ESQ. 21 MARCE 6. CHAPGE, RSQ. (Los Angeles, California) 21 your Honor. 22 22 THE COURT: Good. Okay. 23 Counsel for Defendant CellPro 23 MR. BLOOMBERG: As we indicated in our brief with respect to misuse, in order for judgment to be final, 25 a claim must be fully adjudicated. And while the claims Page 3 Page 5 1 of the patents here involved have been found to be valid PROCEEDINGS 2 2 and infringed, nevertheless, there's an issue as to 3 3 whether or not those claims are unenforceable because of 4 (Proceedings commenced at 10:30 a.m.) misuse. 5 Under 35 United States Code 271, Subpart (d), 5 Subpart (5), the statute sets out that misuse or an THE COURT: Okary. We're ready to get 6 7 illegal extension of a patent right by reason of started. 8 MR. WARE: May I begin, your Honor? conditioning a license of rights to a patent on the acquisition of rights in another patent where the patent 9 THE COURT: Sure. 10 A few final papers slipped through last owner has market power in the relevant market is a 11 night that I have not yet read, but you should assume defense. 11 And that's the situation here. Almost a 12 I've read everything. 12 13 MR. WARE: We always do, your Honor. textbook example of misuse is contained in Defendant's 14 THE COURT: I remember walking past some of 14 Exhibit No. 709. 15 them last night. 15 Your Honor will recall that that is a letter 16 MR. WARE: We like to think in the middle of 16 dated April 15th, 1992 from Baxter, where they indicated 17 the night there's a reason why we're there. 17 that they were no longer interested in granting a THE COURT: I thought what we'd do is a 18 license with a running royalty rate and a lump-sum 18 19 variation on pick a topic. payment, but wanted from CellPro exclusive rights to MR. WARE: The suggestion that I had was that CellPro's patents in Europe and Japan and nonexclusive 20 21 we begin generally the subject of the injunction, where 21 rights in North America. 22 there are, I think, the most issues to discuss, and that 22 THE COURT: How do you propose to resolve 23 we perhaps address some of the issues separately and 23 this issue? 24 both sides be heard on them, and then move on to 24 MR. BLOOMBERG: I would propose that discovery 25 be taken on the matter and that it be tried before a jury. 25 another point. There are a number of discrete issues.

Page 6 Page 8 THE COURT: Mr. Ware? I've read the briefing 1 issue that we truly believe could not survive a Rule 11 2 motion. 2 on the topic. MR. WARE: Well, we have not actually briefed THE COURT: Well, are you in a position - I 3 the substance of the topic. I think there was brief 4 mean, do you know what you're moving for summary judgment comment on it in the injunction brief that we filed. on? As far as where this is, the patent misuse 6 MR. WARE: Yes. 7 THE COURT: What the facts are that they'll 7 issue was, in fact, stayed by agreement of the parties, 8 and what we would propose to do, if CellPro is unwilling 8 be relying on? 9 MR. WARE: Yes. I think that there are 9 to withdraw this defense, is we would propose to set a several points here that need to be kept in mind. 10 briefing schedule and we will brief it. We think it can 10 11 11 very easily be disposed of as a matter of law. In the first place, as I understand it, and 12 based upon what Mr. Bloomberg just said, in addition to 12 THE COURT: You mean brief a summary the hand-guards-type defense, which I assume Mr. 13 judgment? 14 Bloomberg would agree, in light of the Court's rulings. MR. WARE: Yes. A summary judgment briefing 14 15 schedule. 15 doesn't survive as a patent misuse defense, but, in THE COURT: The parties agree to defer the 16 addition, this argument -- the patent-misuse argument 16 17 seems to be based entirely on an April 15th letter from 17 presentation of the defense. 18 Was that in response to my comment that I 18 Baxter to CellPro, which the Court will recall from the 19 trial, in which Baxter simply made a proposal that the 19 would otherwise shoot it into outer space, or what does 20 license include distribution of CellPro's products in 20 the agreement require? 21 MR. WARE: The original agreement was, I 21 Europe. 22 22 think - the original agreement was crafted at the very And the statement that Mr. Bloomberg just 23 made about conditioning anything on rights under CellPro 23 beginning of the case, probably even before there had 24 patents is nowhere contained in that letter and it has 24 been hearings before the Court. And at that time I 25 never been suggested in five years of litigation until 25 think that the thinking was probably on the part of Page 7 Page 9

1 both parties that, to the extent that the parties can 2 avoid the unnecessary cost of antitrust-type discovery 3 and proceed with the patents, that they ought to do so. Moreover, at least at that time, as I recall 5 it, the patent misuse defense was, in substance, a 6 hand-guards-type defense. And so, therefore, if the 7 patents were found to be valid, there would be nothing 8 left of the defense. And that's a further reason that

9 we contend now that there is no justification for going 10 forward with this defense in light of the Court's

11 findings.

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12 But I think that what was contemplated at the 13 time, or at least as the stay was written, the entire 14 patent case was to be resolved and disposed of before 15 dealing with the patent misuse issue, since CellPro has 16 now raised an objection to entry of permanent -- entry 17 of a permanent injunction as part of a final judgment, 18 because technically its patent misuse is pending.

We would like to dispose of the patent misuse 20 defense so that there will be no question about the 21 Court's entry of final judgment, including a permanent 22 injunction.

23 THE COURT: All right.

MR. WARE: We certainly do not think it would 24 be appropriate to open up antitrust-like discovery on an 1 this day that that had anything to do with it.

2 But, very briefly, we find no legal support 3 for the proposition that a licensee, such as Baxter, 4 cannot ask for distribution as part of a proposal for 5 the -- that is, distribution of the licensed product 6 itself, a product that an infringer could not sell in 7 the United States or could not export under any circumstances. 9

Secondly, as the Court is aware, this proposal never came to fruition and defenses such as this do not come up when the other party rejects the 12 proposal. And the parties move on in their negotiation.

13 One does not go back and reconstruct 14 negotiations to find one proposal made on one day that 15 was not accepted and turn that into a patent misuse 16 defense. This is a proposal that never happened. 17

And, thirdly, as the Court is aware from 18 the trial, on July 15th, 1992, Baxter reiterated its 19 earlier offer of a pure patent license. That is, it 20 said, essentially, We thought you were interested in 21 talking to us about distribution, which is certainly 22 supported by the evidence in this case, but if you're 23 not interested in talking to us about distribution,

24 fine. You can have the license that we offered in the 25 first place.

And the law is absolutely clear that, even 2 if there were misuse, that a purging of that misuse 3 takes away the defense entirely. So what we're talking about is a three-month 5 period in April that was -- certainly, if there was any 6 misuse, was purged by July, when CellPro was given an opportunity on the same terms that were offered before

8 to take a pure patent license. CellPro declined.

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There is no patent misuse under those circumstances, and that's a purely legal conclusion that the Court can draw based on undisputed facts. 11

12 THE COURT: And what discovery would you want 13 to take?

MR. BLOOMBERG: We would want discovery with 15 respect to the preparation of this April 15th letter. The 16 authorship, the review of the letter, approval of the 17 letter, comments with respect to the letter, documents 18 regarding business plans or financial plans with respect 19 to the countries affected by the conditioning of the 20 license.

21 As to the issue raised by Mr. Ware regarding 22 this so-called purge letter, which I believe is Defendant's Trial Exhibit No. 637, I think the date is 24 July 22nd, rather than July 15th, 1992.

Your Honor will recall that there was a --

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MR. BLOOMBERG: Yes. To the extent Mr. Ware

wants to raise an issue of this purpe letter, it seems to

me it would be appropriate to find out if those terms

were really made available to CellPro. And as I say, Mr.

Murdock's testimony is that when CellPro and Baxter met.

they were not.

THE COURT: And so when we talk about discovery, I had in mind discovery relating to those

communications, as opposed to getting in and rolling

around inside Baxter as to these matters. What

additional discovery do you need with regard to those

two communications?

13 MR. BLOOMBERG: Beyond what I've already 14 identified?

15 THE COURT: Right.

MR. BLOOMBERG: The only other issues that I 16 think discovery would bear on this particular misuse would 17 relate to the market power and the relevant market as 19 conditions of 35 United States Code 271(d)(5).

20 THE COURT: So have you deposed the people

21 who - the author of the letter, for example? 22

MR. BLOOMBERG: We have taken his deposition.

23 THE COURT: Have you deposed people that 24 participated in the meetings?

MR. BLOOMBERG: No, we have not.

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I shortly thereafter, there was a meeting between Baxter 2 and CellPro representatives, and Mr. Murdock has testified 3 in court that at that meeting the terms of the so-called

4 purge letter were not made available to CellPro, so we

would want discovery with respect to that meeting as well. 6

I think there would also --

THE COURT: It sounds like what Mr. Ware is 7 8 saying is it's almost a 12(b)(6) motion. And that is you can identify the letter and say that's the basis for your claim. But you can't identify any other facts that would 11 show misuse that would be communications to your client.

12 In other words, I know you want to go 13 upstream from the letter, but how would that be relevant to establishing a claim if you can't show those matters 15 were communicated to your client?

16 MR. BLOOMBERG: 1 think there were actually 17 two communications, your Honor. There was a meeting, I believe, in Southern California at a Baxter facility where the same representations were made orally, and then, as I understand it, from Mr. Murdock's testimony, the

21 substance of that correspondence was confirmed in this 22 letter.

THE COURT: And so wouldn't discovery, at 23 least in the first instance, go to what was communicated to CellPro and what was said in response to that?

1 MR. WARE: Your Honor, just a couple points. First of all, we would be prepared by the end 3 of next week to file a summary judgment brief and it would be a proper summary judgment type issue that we would argue, and we would like the opportunity to do that rather than permit CellPro to start taking discovery on market power and everything else that you hear about in antitrust cases, which are very time-consuming and expensive.

There is absolutely no law that exists that says someone making a proposal thereby engages in patent 12 misuse.

13 And I think we ought to have an opportunity to try to have this resolved as a legal matter before going 14 15 into discovery.

16 THE COURT: Okay. Let's pick another topic. 17

Documents relating to Beverly.

18 MR. BLOOMBERG: This issue, I think, your

19 Honor, relates to dialogue between Dr. Beverly and the 20 plaintiffs with respect to our inequitable-conduct claim.

21 THE COURT: Okay.

22 MR. BLOOMBERG: As I understand it, much of

23 these documents have been asserted to be work product or attorney/client, and we don't think it's appropriate to

make that claim in connection with a third party.

Page 14 Page 16 THE COURT: What's the matter in issue? What 1 rather have them be reviewing a permanent injunction. 2 is it that is still open that these documents are 2 THE COURT: If I simply enter the order now 3 relevant to? 3 for the injunction, took the word "permanent" out, just 4 said order for injunction, partial stay of injunction, MR. BLOOMBERG: Well, in view of your Honor's 5 ruling on inequitable conduct, I'm not certain that it 5 that would be an appealable order? 6 is -- that it remains a viable issue in the case. But MR. WARE: I believe so. that was the purpose of our seeking those documents --7 THE COURT: And the case would then go up, THE COURT: All right. 8 presumably go up. 8 9 MR. BLOOMBERG: - is they bore on 9 MR. WARE: Yes. 10 inequitable conduct. 10 And under 1291(a), I think, And so I think 11 THE COURT: All right. Let's move to the 11 that - I think it would be helpful to anybody reviewing 12 topic of motion for - let's move to the three issues 12 the record in this case to have the benefit of the 13 together. That is, the motion for injunction, the motion 13 Court's further thoughts on some of the issues that 14 for enhanced damages, and the application for an award 14 are before it now. 15 THE COURT: See, that's what I was wondering 15 of fees. 16 about the relationship of the timing of the injunction 16 17 and whether or not plaintiffs would prefer to defer the 18 entry of the injunction until I have a chance to write 18 19 something on the subject of fees and enhanced damages. 19 20 And I take it that's what you are saying: 20 21 Is you would rather wait until I can get something 21 22 written on that? 22 23 23 MR. WARE: Yes. I think we're perhaps 24 24 being presumptuous, but we hope that could be in some 25 reasonable time frame. And I do think it would be Page 15 Page 17 i helpful to the Court of Appeals to have the benefit of i THE COURT (Continuing): If final judgment 2 the Court's written decision. 3 is going to be defened until I can deal with this 3 THE COURT: All right. 4 question of misuse, what happens to your application for MR. WARE: There's a sort of a procedural 5 an injunction? Do you want a preliminary injunction? 5 piece of the attorneys' fee application that we might just discuss briefly -6 MR. WARE: Ithink that, since we're all here. 7 THE COURT: Sure. 7 MR WARE: - because, as we're going 8 we'd like to argue a, but I think we would like a 9 permanent injunction. And I think it makes more sense, 9 through some of these items, to get them out of the way. 10 10 because I think the patent misuse issue can be disposed I think the issues are pretty 11 of quickly. And I con't see what the advantage is, 11 straightforward, as far as the Court's authority to 12 particularly given a stay we've proposed. award fees. And I think that the issue that we seek There is nothing that can't be addressed in 13 some guidance from the Court on has to do with the 13 14 submissions that the Court wants to see, in terms of 14 permanent injunction. Insofar as we have proposed that 15 any stay be conditioned on certain payments from 15 the backup information. We have provided to the Court 16 CellPro, we've asked that those payments be made based 16 in the application a detailed breakdown by lawyer, by

18 rates.

23 like that.

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17 on sales retroactively to March 12 anyway.

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23 difference.

So I don't wink a brief delay in entering

And I thinkthat we would rather have the --

19 the injunction will affect that. And we have generally
20 accepted the proposition of a stay on the terms proposed,

21 such that, again, I don't think a matter of a couple of 22 weeks or so or a few weeks is going to make much

if this is going to not the Federal Circuit, we'd

17 time period of hours. And we have provided the billing

20 Court detailed, daily time reports of lawyers, and we 21 have not submitted to the Court at this time actual hard

22 copies of individual invoices for transcripts and things

25 based upon an itemization of the types of different

We have not at this time submitted to the

We have provided the Court a - subtotals

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I costs that we're seeking. There's no indication in 2 the papers submitted by CellPro that there is objection 3 in concept to the particular types of expenses that we 4 are seeking. And as to the time detail, we have a couple 5 of concerns.

We have the concern that the time detail 7 itself contains information that we regard as 8 confidential work product, and we're reluctant to 9 provide it to opposing counsel, although we are not in 10 the least reluctant to provide it to the Court in 11 camera.

We also had requested some time ago from 13 CellPro the equivalent information from Lyon & Lyon, 14 and that was refused. It seems to us that if Lyon -15 if CellPro is proposing to object specifically to the 16 number of hours spent in a time period or whatever, 17 that we would be entitled to see the time spent by 18 their lawyers as well, that that would be at least a 19 relevant piece of evidence.

It seems to us that CellPro -- from reading 21 the opposition brief, that CellPro's objection really is 22 not -- does not have anything to do with the time spent 23 on the case. The only substantive objection was the 24 suggestion that the billing rates ought to be 25 Wilmington billing rates, rather than national billing

1 requesting are considerably - they're considerably less

2 than what the plaintiffs actually paid, they are, we

3 believe, considerably less than what CellPro paid to its

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4 lawyers, that we really just should not have to make that

5 information available to CellPro.

But that's why we seek guidance.

THE COURT: Do you want to say something?

8 MR. BLOOMBERG: Well, I think that in order

9 for us to properly evaluate their application, we need to

see the supporting documentation, which we have not seen.

As to Mr. Ware's comments regarding our

12 billings, our understanding is that the standard is the

13 local fee rates, as opposed to rates in California.

14 As to Mr. Ware's comments that, as to the 15 willfulness, we were able to prevent plaintiffs from 16 taking discovery based upon attorney/client and work

17 product.

18 Your Honor will recall that much of our 19 documentation that was clearly work product or attorney/client was found to be waived and made 21 available to the plaintiffs.

THE COURT: I have a couple thoughts.

23 My understanding is that at the moment, with 24 the application for fees pending - and, actually, with

25 my invitation to plaintiffs to file the application.

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1 rates.

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2 CellPro has refused our request that they 3 provide information concerning Lyon and Lyon's billing 4 rates. We think that the billing rates are very much 5 in line with national firms engaged in the sort of 6 practice. But we're a little bit unsure as to what to 7 do at this point. We want to give the Court whatever 8 information it feels it needs to be able to make - to 9 review the request.

And if that sort of detailed daily report is 11 something that the Court wants to go through over a 12 period of five years, again, we are happy to do it. But 13 we do have this concern about disclosure of all of the 14 details of every potential witness we ever talked to or 15 every issue we looked into or what-have-you.

16 And there was really a parallel situation 17 earlier in this case, when we sought discovery from 18 Lyon & Lyon with respect to the willfulness issue. And 19 we were not permitted to see any of their internal 20 records, really for the same reason. They were 21 concerned about work product.

And so it seems to us that, in light of that, 23 and in light of CellPro's refusal to provide the 24 information with respect to Lyon and Lyon's time, and in view of the fact also that the fees, we think, that we're

1 that it's on my plate to resolve before the case goes 2 up.

6 that I cannot do that.

3 I'd sort of prefer to find a procedural way to send the case up and do a final review of this issue 5 if and when it comes back affirmed. But if I cannot do

7 There are a couple of advantages to doing it 8 that way. One advantage to doing it that way is that at 9 that point I think people -- we could have more of an

10 open review of the issue of fees and time put in and

11 comparison, and we could do it in the context - I don't

12 know whether the Federal Circuit has a separate provision 13 for an award of fees or whether they remand it to the

14 District Court to take care of that issue, but the costs.

15 and fees on appeal can then be added in with less concern.

16 And I can even refer to a Master or somebody like that to 17 review it.

If I cannot -- if I cannot put it off, and 18 19 if plaintiffs don't want me to put it off until the case

20 goes up, then what I'm inclined to do is the following:

21 I can tell you right now I'll apply a national standard

22 to the award for the calculation of fees and costs, as

23 opposed to a local Delaware standard, in part because I 24 don't want to restrain the national Bar with the high

25 Delaware rates that are billed.

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Second, what I will do is the following: 2 I'll take the information that the plaintiffs have given 3 me as their best shot. I will review it, to see whether 4 I think it is adequate. If I have any particular 5 questions, I will let people know promptly in time to get information back to me.

CellPro can review what it is that the plaintiffs have submitted and raise specific questions. if they want to, by category, by topic.

But if there is a specific review, I am going 10 11 to need to look at what is reasonable. And one way of 12 looking at what's reasonable is looking at what CellPro 13 did, in terms of their defense. That is, it was 14 unreasonable to spend eight hours to prepare for that 15 deposition. I'll look and see what the records of 16 Lyon & Lyon show.

So it's going to have to be an issue where. 18 if there's a challenge to the fees, it needs to be identified, either by CellPro or by me in my review.

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And I know that there are lots of categories 21 of areas where there's reasonable arguments that this 22 shouldn't be included, this should be included. And I 23 am open to hear argument on it. But if it's going to 24 get into the files, I will find a way to get into the 25 files to get it satisfied or find a way to articulate to

1 look at it and sec?

MR. WARE: Why don't we look at it and why don't we perhaps communicate back to the Court based on the comments the Court has made what we think makes sense to do at this point.

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THE COURT: When you look, you'll find a wonderful opinion by the Third Circuit on the types of attorneys' fees in civil rights cases that says that when you have a civil rights case, and you settle it, and the defendant gives to the -- gets from the plaintiff a general release of all claims, including claims relating to attorneys' fees, that's not a waiver of attorneys' fees under the Civil Rights Law.

MR. WARE: I think I remember that case. THE COURT: I don't think many people in the Bar know that, but the plaintiffs' bar likes to get a case, get all the money they can, settle, say they waive our claim for fees and then fees for fees under the Civil Rights Law. Not many Circuit Judges write opinions that

bury those type of problems in the law, but we had a few in the Third Circuit that did for a while. In any event, look at it. See what you want to do. I'm going to leave the bench today and assume

that I have on my plate the subject of an application

for fees and costs and the subject of enhanced damages 2 and I'll begin working on it. I'll be applying the

standards that I would otherwise apply to it.

To the extent that CellPro raises damages with regard -- awarding fees for appropriateness of certain matters, I looked at the briefing. I didn't notice in the briefing there were many issues that I

thought raised particular factual problems, but I'll

look. And if CellPro wants to go back and look at it again, that's fine with me. I am interested in getting

the right result here.

12 But I have in the past, and frequently, when a party objects to a rate, I say, fine. So tell me your rate. Then I have some indication of reasonable -- all right. So that's where we are on 16 that

17 And I raise all that in part because I thought, one, and I'm sure plaintiffs have thought about this, one way to go would be to simply enter the injunction, and let people go up to the Federal Circuit in the context of a decision that basically 22 says, this implements the jury's decision.

23 We've got some other issues to take care of here, but there's no reason to delay the case going up. But if the plaintiffs want me to write out on the issue

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1 the Appeals Court, to the extent that I award fees, what 2 I did and why I did it.

3 MR. WARE: Would there be any merit to the 4 idea of addressing, or making a determination about whether fees are to be awarded and under what statutes without actually calculating them and having it go up 7 that way?

8 THE COURT: That's why God invented lawyers. Judges don't know the answer to anything. They just pick what you say, until Exxon came along, and then I 11 had to come up with my own independent view. I would 12 have thought there are mechanisms to do that. That is, 13 I intend to award.

14 On the other hand, if, was the Appeals Court, 15 I might say, Look - well, if you go look at the world about what happens with fee applications, my general sense is that what happens is the case gets tried. 18 Party makes an application for fees. The Trial Court 19 puts it in its pocket. It goes up on appeal. It gets 20 affirmed. If it gets affirmed, it comes back and the 21 Trial Court resolves all of the issues about fees. Our 22 local rule has a specific provision about the time 23 period for filing fee applications, and I thought it

came down from the Appeals Court. But why don't you

24 was within a certain number of days after the decision

1 of enhanced damages and the award of attorneys' fees, 2 I'll do that, too. I will assume, unless you apply 3 otherwise -MR. WARE: That's our present thinking. 5 Yes. 6 THE COURT: Okay. On the subject of the terms of the proposed

8 permanent injunction, I have read the briefing. I 9 think I understand the positions of the parties. I 10 think they are pretty clear. I am happy to hear II argument, if people want to supplement what they've 12 already said in the briefing. But I don't know that 13 I had any particular questions. I've just got some 14 reading to do, to solve certain questions I've got. 15 MR. WARE: Let me just ponder that for a 16 minute.

17 (Pause while Mr. Ware and Mr. Ellis 18 conferred.)

20 Honor, would be just highlighting a few of the issues that are maybe most highly contested, and making sure 22 that we have anticipated any questions that the Court might have, and certainly responding to anything further 24 that CellPro has to say on the point.

MR. BLOOMBERG: With your Honor's permission,

MR. WARE: What we are thinking about, your

1 injunction that I might comment on briefly is the

proposed two-year injunction with respect to sales in

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- Europe. And there, of course, is a stay of that. But
- 4 I think that the emphasis really is on a couple of
- points. One is that this is a remedy for infringement
- in the United States, and it is really not very different
- from the very typical sort of trade secret injunction,
- which typically are worldwide, when somebody has
- 9 misappropriated a trade secret, and thereby acquired for
- themselves a head start in a market. And their having
- done so is very destructive of the marketplace for the
- licensed patent for the patent-holder or the
- 13 licensee.

14 And so it is very common to enter that sort of injunction. That's what that's about. 15

16 In terms of the mandatory injunction, the 17 repatriation of the 12.8 hybridoma we think is vital.

We have addressed in the papers the 18 conclusion that CellPro clearly did infringe in the 19

United States through its ongoing use of the 12.8 21 hybridoma after the issuance of the patent,

22 This is a situation where, by CellPro's

attempt to evade the United States patent laws by sending hybridoma cells to Canada in the midst of

litigation, the patent-holders have been deprived of

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1 Mr. Riley would argue the injunction on behalf of CellPro.

THE COURT: Fine.

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3 MR. REILLY: If I may stay here until he's finished, your Honor. I might want to take notes. 4

5 THE COURT: Whatever you want.

MR. WARE: Okay. As the Court is aware, 7 the injunction is structured to include essentially four

8 elements, one being a prohibitory injunction, one being

a mandatory injunction, the third being a temporary stay, and the fourth, which I guess is part of the temporary

stay, relates to calculation of payments of incremental

12 profit during the stay.

I don't think I need to say very much about 14 the prohibitory injunction, other than to emphasize that 15 it is key we believe that there be one. That the end 16 point must be an injunction here. And, in the absence of an injunction, the value of patent rights would be very greatly diminished and would become very difficult for inventors and non-profit institutions, such as Johns Hopkins University, to be able to license out their

- 21 patents. And there certainly is no exception for
- infringement that happens to involve medical products.
- There are injunctions entered all the time against
- infringing medical devices. 24

The other aspect of the prohibitory

1 rights that they would otherwise have had.

2 They would have had the right, upon a finding

3 of infringement, to request destruction of the

infringing hybridoma, in which case it could not have

been sent to Canada.

They could have requested, and the Court would properly have entered an injunction against

exporting the infringing hybridoma.

So they were deprived of those rights. And 10 to remedy that, the Court must require them to bring it 11 back to the United States.

12 It's really no different than a party that 13 sends out or smuggles out of the United States stolen goods. They are still within the possession and control - not possession, but control of the infringer, and they ought to be brought back.

We even know, by reason of the filings that 17 have been made most recently, that CellPro itself recognized that the operation in Canada was really a sham and that, as soon as the jury verdict came down in

the first trial, CellPro ceased manufacturing abroad. 21 They had no real intention of manufacturing there.

The mandatory injunction also includes a 23 24 destruction order. I think, ultimately, the plaintiffs

are entitled to it.

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The plaintiffs should not be in a position	1	
2 where they have to police all of the activities of	2	THE COURT: What's the evidentiary record on
3 CellPro regarding 12.8. It is very easy to clone	3	the shipping of the 12.8 hybridoma to Canada?
4 hybridoma cells and ship them out of the United States.	4	MR. WARE: There had been summary judgment
5 We shouldn't have to be guarding that. We shouldn't have	5	briefing in 1985 on the issue, and there was deposition
6 to learn that at some point in the future that, all of a	6	testimony of a Mr. Bordinaro from CellPro that had been
7 sudden, people are being supplied with 12.8 antibody from	7	submitted to the Court at the time and Mr. Bordinaro,
8 the Cayman Islands or somewhere else.	8	in fact, submitted a declaration.
9	9	There are certain facts that are undisputed,
0	10	including the fact that it was in 1993 that CellPro
1	11	shipped the hybridoma to Canada. And the various facts
2	12	on which we - the various facts we have pointed to in
3	13	terms of CellPro's maintenance and use of the 12.8
4	14	antibody in the United States after the patent issued
5	15	and before the cells were shipped to Canada are also
6	16	undisputed. That is, they come out of Mr. Bordinaro's
7	17	deposition.
8	18	So that's really the basis of the
9	19	evidentiary record, then.
0	20	Mr. Bordinaro acknowledged that the that
1	21	although CellPro first cloned the cells that they
22	22	obtained from the Fred Hutchinson Cancer Research
3	23	Institute in - I believe it's early 1990, that the
4	24	cell bank that they made out of those cells was not
25	1	even released for use until - I believe it was in '91
Page 31	-	Page
1		or '92. Maybe even in '93, but sometime after the
2 MR. WARE (Continuing): And so we think that	2	patent issued, because there's a whole series of steps
3 that's an appropriate order ultimately.	3	of quality-control testing and things that have to be
4 However, in view of the stay that we seek,	4	done before you can release it.
5 that will not come to pass in the near term.	5	But, again, it's based on the evidence
6 What I might suggest, because I think there	6	that both documentary and deposition testimony of
7 are enough differences here that - I might suggest that	7	Mr. Bordinaro.
8 we hear from Mr. Reilly on those aspects of the	8	THE COURT: All right.
9 injunction before turning to the stay, because otherwise,	9	MR. REILLY: Good morning, your Honor.
0 I will have kind of a long presentation here.	10	THE COURT: Good morning.
1	11	MR. RETILY: Let me start with the
2	1	injunctions, request for repatriation of hybridoma in
3	1	Canada. This was summary judgment briefed in 1995. I
	13	think what happened is the trial crept up on us and it
14	14	
15	15	was never argued. It's briefed a lot more thoroughly in
16	116	1995. I would refer the Court to DI-158, 159, 249 and
	1	269 was the briefing on that.
	17	<u> </u>
18	17 18	We have a rather different interpretation of
18 19	17 18 19	We have a rather different interpretation of Mr. Bordinaro's testimony. The facts, as I understand
18 19 20	17 18	We have a rather different interpretation of Mr. Bordinaro's testimony. The facts, as I understand them, is that — and this much is certainly undisputed —
18 19 20	17 18 19	We have a rather different interpretation of Mr. Bordinaro's testimony. The facts, as I understand them, is that — and this much is certainly undisputed —
17 18 19 20 21	17 18 19 20	We have a rather different interpretation of Mr. Bordinaro's testimony. The facts, as I understand them, is that — and this much is certainly undisputed — the 12.8 antibody was discovered before the '204 patent issued.
18 19 20 21 22	17 18 19 20 21	We have a rather different interpretation of Mr. Bordinaro's testimony. The facts, as I understand them, is that — and this much is certainly undisputed — the 12.8 antibody was discovered before the '204 patent issued.  There were six vials shipped to Canada.
18 19 20 21	17 18 19 20 21 22 23 24	We have a rather different interpretation of Mr. Bordinaro's testimony. The facts, as I understand them, is that — and this much is certainly undisputed — the 12.8 antibody was discovered before the '204 patent issued.

1 with, except to keep them cold so they would not die, 2 until a time in 1993, when they were sent to Canada.

Simply put, CellPro's position is that the 4 hybridoma is not an infringing product because, even if 5 it is within the claims of the patent, the patent

6 didn't issue until subsequently.

It's sort of like the parable of the 8 widgets, if I may say, your Honor. If you make a 9 bushel basket full of widgets and you have them there 10 and then one subsequent day I get a patents issued to 11 me that reads on the widgets, they do not become 12 infringing widgets. We know that because Section 271(a) 13 tells us that. He who makes, uses or sells during the --14 in the United States during the term of the patent 15 infringes and not otherwise.

So a device or a product that is made before 16 17 a patent issued does not become an infringing product if 18 the patent issues.

19 If you thereafter use it or sell it, those 20 are acts of infringements.

21 But, certainly, you would be perfectly 22 within your legal rights to store your widgets for 17 years or until I fail to pay my maintenance fee or 24 something or my patent is declared invalid.

3 around, and the mere act of shipping it out of the

Simply storing a product that was made

Page 35

1 before a patent issued does not turn that product into 2 something that infringes. The mere act of keeping it

4 country, are not acts of infringement. And we do cite 5 law on that. If you didn't want to keep your widgets in 7 the United States for 17 years until my patent expired,

8 you could ship them to Canada. And if I had no patent rights in Canada, you could just sell them in Canada, 10 and that would not be an act of infringement.

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And, again, what tells us that is 271(a), 12 which says that he who, within the term of the patent 13 in the United States, makes, uses or sells, infringes 14 the patent.

The case that plaintiffs have cited for the 16 point that mere storage constitutes an infringing act is what I call the howitzer case. It's the Olson case. 18 Very strange case. And I think it's sui generis. It 19 dealt with howitzers. And the Court says the use of 20 howitzers in peacetime is to just sit around and be a 21 deterrent, so their storage is use.

The other distinguishing fact about that case is the howitzers were made during the term of the patent. The 12.8 antibody was discovered before the patent issued. So the mere fact of shipping the

I hybridoma to Canada, the mere fact of storing it in its 2 frozen state before it went to Canada cannot be acts of

3 infringement.

There's no act of infringement that has been committed with respect to those six frozen vials in

Canada. They were thawed out after and used in Canada,

but not in the United States. It's simply our position there has been no act of infringement with respect to

those vials. Plaintiffs have called this an evasion of

10 the U.S. patent laws, but it's no more of an evasion

11 than if I moved to Switzerland and lawfully pay my taxes

12 in Switzerland. Once I move out of the country and

13 don't have any activities here that tax is due on, it's

14 certainly not an evasion of the U.S. tax laws.

15 So I think plaintiffs' position just 16 basically violates the principle of territoriality of the patent laws and there's no basis to repatriate that 18 hybridoma.

19 The other thing I should mention is that 20 CellPro does not really own it free and clear. The

21 hybridoma is licensed from the Fred Hutchinson Cancer

22 Center and there's provision in the license agreement

23 that if the -- the license ever terminates, CellPro

24 would have to return any of the remaining stock of 25 the hybridoma to the Fred Hutchinson Cancer Center.

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The other point I would make, your Honor, 2 is that to actually round up the hybridoms and kill it

3 would be as one clinician said to me when I mentioned

4 this, it would be like killing Einstein.

This is not the situation where someone 6 makes a bunch of Rolex watch knock-offs and they call a press conference and hire a steam roller and flatten 8 the watches.

A hybridoma, as your Honor well knows, is 10 a unique, living organism. You can never get another

11 one like it as a practical matter. And if it were

12 ordered destroyed then, as a practical matter, neither

13 CellPro nor anyone else could begin using it again when

the patent expires or is ultimately found invalid or for

any other reason becomes unenforceable.

16 Something made before a patent begins, there ought to at least be a right to store it until the patent 18 term is over. And I think that the law should be clear

on that, and that to actually order this hybridoma

destroyed really would be a great loss to science and

way, way beyond the bounds of, I think, anything that

the Court should fairly do, even if there were an act

23 of infringement here, which there hasn't been.

24 THE COURT: During the discovery, was there 25 discovery of documents about the motive that CellPro had

Page 38 Page 40 1 cited in our reply brief. It's called Amgen versus 1 and communications that related to the decision to ship 2 the hybridoma to Canada? 2 Ellenex (phonetic) that actually does involve frozen 3 cell lines, oddly enough, in Bothel (phonetic), MR. WARE: Well, there was discovery of Washington, a different company. The decision was 4 communications from Lyon & Lyon to CellPro. This was a 5 written by Judge Dimmick, who was the original Judge 5 scheme that was devised by CellPro and its lawyers, and 6 CellPro -6 in the declaratory action brought in Washington. And so one thing we do know if this case had 7 THE COURT: Were these documents withheld as 7 8 not left Washington and if that's where it was in 1993. 8 privileged? MR. WARE: They were produced. that Judge Dimmick's view would have been that the very 10 maintenance of the cell line that is described by THE COURT: They were produced? 11 11 CellPro is, in fact, an infringing use. MR WARE: Yes. 12 THE COURT: And they are in the summary 12 And so, had we stayed in Washington, I'm 13 judgment briefing? 13 sure that Judge Dimmick would have been quite prepared to enjoin the shipment of those cells out of the MR. WARE: I don't think so. I don't think 14 15 so. 15 Washington. 16 I don't know - well, no, I don't think so. 16 What is also different about this is that 17 the notion that's presented here is that these are just 17 THE COURT: Can you provide them? 18 a bunch of different vials, and that the particular vial 18 MR. WARE: Yes. We can provide them. 19 THE COURT: To the extent there are documents that they sent to Canada itself wasn't thawed and tested. 20 that may shed some lights on CellPro's intent at the 20 But a hybridoma is a hybridoma. And that's 21 how a hybridoma is stored. It's stored in a bunch of 21 time. I'd be interested in seeing them.

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I do want to emphasize that, as Mr. Reilly 2 said, CellPro is a licensee from the Fred Hutchinson. 3 Nobody is talking about destroying the Fred Hutchinson's 4 12.8 hybridoma. These are simply cells that were cloned 5 off of the hybridoma at Fred Hutchinson.

MR. WARE: Yes. Now, there was no

23 discovery, that is whether we deposed Mr. Bloomberg,

24 for example, I don't think we went into those. But

25 those documents themselves do exist.

And our point is simply that CellPro should 7 not be permitted to continue to be in possession of 8 hybridoma cells, because it is just very easy to ship 9 them out of the country.

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10 So -- but we are not talking about killing 11 some living thing that can never be reproduced, because 12 that's exactly the point of all of the cells in the 13 freezer at Fred Hutchinson. You can simply clone more 14 off of them.

15 I think also that what Mr. Riley is missing 16 in his discussion of widgets is that these aren't 17 widgets, and what you do with a hybridoma is you store 18 it and you test it from time to time so as to be able 19 to replenish your stock.

20 And so that is the use. Putting hybridoma 21 into service is basically putting it into the freezer 22 and pulling cells out from time to time and doing 23 quality-control testing. So it's a very different 24 situation from widgets.

And there's an interesting case that is

22 vials. And so you cannot simply say that every time you 23 pull one off, that you are -- that that had nothing to

When you do quality-control testing of the

1 hybridoma, you're testing cells in a particular vial,

2 because the results of that test tell you something 3 about all of the cells. And so you can't just say

24 do with the 12.8 hybridoma.

4 there are billions of cells, and so we only tested

5 these cells and we sent these cells. I mean, the

6 patent covers a hybridoma, and that's what a hybridoma

7 is. It's a whole lot of cells that have been closed

8 that are all identical that are sitting in the freezer

9 in vials. So...

10 MR REILLY: Your Honor, the patent - what 11 right is secured by a patent is what we need to focus 12 on. The patent doesn't really cover a hybridoma. The 13 patent covers the right to exclude others from making,

14 using and selling the hybridoma in the United States

15 during the term of the patent. That is exactly what

16 the patent covers, or is what it has been ruled to cover

17 by the Court.

And, again, the fact that this hybridoma was 18 19 made before the patent issued and that the particular 20 six vials that were shipped to Canada just remained in 21 the frozen state since before the patent issued until

22 1993, when they were shipped up to Canada, they simply

23 were not used in the United States.

As for your Honor's question about what 24 25 CellPro's motive is in shipping them to Canada, I would

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Page 42 Page 44 1 first suggest to your Honor that that is irrelevant. 1 this case. They have had a jury award them damages 2 The only thing relevant is that Canada is not the 2 based on their sales in Europe. 3 United States and 271(a) says that you've got to be in The section of the patent statute that deals 4 the United States to infringe. 4 with injunctions speaks of the injunction as being a Beyond that, your Honor, there is --5 remedy to prevent infringement. Selling a stem cell antibody, making a stem THE COURT: It sounds like a good business 7 opportunity, if somebody could rent a hospital ship and 7 cell antibody product in Europe, where the plaintiffs have 8 become some kind of a freezer bank, stay off the coast. no patent coverage and concede that they can't now get We hold it while you litigate? any, is not an infringement of the U.S. patent law. 10 MR. WARE: We hold, you litigate. And if the court were to enter an injunction 11 MR REILLY: They don't have to hold it. 11 granting that relief, the Court would really be giving 12 them a remedy that they have already had a damages remedy 12 They can use it to their heart's content in any country 13 for. The whole idea of a reasonable royalty damage claim 13 but the United States is my point. 14 THE COURT: A lot of Caribbean countries. 14 is to compensate the plaintiffs for past sales. 15 It's too hot down there. That's why you picked Canada. 15 We are now talking really about future 16 MR. REILLY: There is some evidence that we 16 conduct. And I think that the -- the injunction can't 17 recently submitted on CellPro's intent. 17 really enjoin something that's not an act of infringement. 18 On the question of -- of intent, we did 18 And to take an antibody that is wholly 19 submit a declaration of Dr. Tarnowski (phonetic) with 19 developed in Europe, or to taken 12.8 antibody that has 20 CellPro, who reports that the hybridoma, after it got 20 never been in the United States during the term of this 21 to Canada, was thawed out and was used to make 21 patent, simply would not be an infringement of the U.S. 22 biotinylated 12.8 antibody, which was not sold into the 22 patent laws. 23 U.S., I believe, but it was sold in Europe. 23 The other point on that, your Honor -- and 24 So the biotinylated 12.8 was made from the 24 we've briefed this - is the whole question of 25 hybridoma in Canada for sale in Europe which, again, 25 international comity and the extraterritorial effects Page 43 Page 45 1 is lawful, given the territorial scope of the United 1 of patent laws, we have a declaration we filed from Mr. 2 States patent. 2 Colin Overbury, who is a high official of the European 3 The next point that Mr. Ware -3 Commission, that talks about the effect that 4 extraterritorial enforcement of U.S. patent laws would THE COURT: You could call that ship Patent Pending. 5 have on the important antitrust and competition policies 6 MR. REILLY: You could. 6 of the European union. And he opines that this is 7 THE COURT: Go ahead. I'm sorry. 7 something that would implicate the comity issues and it MR. REILLY: The next point that Mr. Ware 8 could provoke international retaliation. raised, your Honor, was about the two-year prohibitory 9 The other thing I would say, to go on about 10 injunction in Europe. 10 these trade secret cases, is that they really, really 11 As we read that proposal, it would forbid 11 are distinguishable, when you consider the difference 12 CellPro from making any stem cell antibody product in 12 between what a trade secret is and what a patent is. 13 Europe, even if the antibody was 12.8 that had never Trade secrets are creatures of state law. 13 14 even been in the United States during the term of the 14 The cases are cases the plaintiff cites, where the Court 15 patent, or even if it had been some other antibody. 15 is sitting in diversity and applying state law. Trade 16 And the idea is a head-start injunction. 16 secrets aren't necessarily territorial in scope. You 17 I think it's - let me get to my notes for 17 can come in and steal somebody's trade secret and you're 18 still a thief. If you come into the United States and 18 a moment. 19 (Pause.) 19 see somebody's patented device in operation, you are 20 MR REILLY: I think it's telling, your 20 free to take it with you and use it anywhere where he 21 does not have patent coverage. 21 Honor, that there are no patent cases that are cited in support of this notion that you can have a head-start 22 I would say, too, that the -- there's an 23 injunction as a remedy for past patent infringement. 23 international network of cooperating patent laws that 24 24 really finds no counterpart in trade secret law. The remedy for past patent infringement is the remedy that the plaintiffs have already had in 25 Trade secret law is basically a state common-law thing

Page 46 Page 48 I that recently has been -- relatively recently has been 2 codified in some states. 2 MR REILLY (Continuing): So there are Whereas you look in the patent laws, and the 3 extremely large and significant differences between 4 U.S. patent laws are carefully tailored to intermesh the nature and scope of the right that patent confers 5 with international patent laws. There are -- wherein and the right that trade secret protection confers. 6 all countries respect the territoriality of each The right that trade secret protection 7 other's patent laws and expect that they will not confers is simply a right to prevent people from, you 8 apply extraterritorially. know, invading your secret and igniting it. The right 9 And to render -- issue an injunction in a that patents confers is a right to exclude others for 10 patent case that has extraterritorial effects that a limited term in a limited place that in this case does 11 would say to CellPro, Even though your activities in not include Europe. 12 Europe do not infringe any U.S. patent and can't, 12 So, for all these reasons, we think that 13 because they're beyond the territorial scope of that 13 the trade secret cases are totally inapt. There's a patent, still we are enjoining you for patent law good reason why they cite trade secret cases and not 15 reasons. patent cases. And there are serious issues of 16 That would be an extraterritorial international comity that would be implicated if that 17 enforcement in a situation where you've got a rather kind of an injunction were issued. 18 complex international scheme of rights, all countries -18 MR. WARE: I think I have about three or 19 each country understands that its own patent laws are 19 four very quick comments. 20 20 territorial. And the way the European union would be First, on the trade secret cases, it's 21 if these plaintiffs wanted patent protection in Europe 21 actually interesting. Trade secret law is a creature to prevent their business competitors from selling a of state - of the states, not federal, and those trade stem cell antibody product in Europe, they should have secrets are, in many cases, not even recognized in many 24 gotten patent production here. foreign countries, and yet certainly courts in the 25 United States feel perfectly able to enter orders like Page 47 Page 49 1 1 this and would certainly similarly feel comfortable 2 MR. REILLY (Continuing): They did not fill 2 entering an order against a United States company that 3 the requirement to get patent protection in Europe, so 3 steals trade secrets in the United States and ships they have not got it. So free competition is what products out, or ships confidential work papers or 5 should obtain. scientific technical papers out. 6 Trade secrets are worldwide. And trade secret They could be ordered to bring them back 7 is a potentially - I should not say infinite, but even if they had shipped them to - I was going to say 8 indefinite duration. As long as it remains a secret, it China, which maybe does not recognize them, or even if 9 is entitled to trade secret protection. they've got them on that offshore tender someplace. 10 By the same token, if you reverse engineer a 10 THE COURT: Even if they take them to Spain 11 trade secret -- if you make something that tastes just and Germany and they used to work for Ford Motor 12 like Coca-Cola without cracking the safe and getting the Company. 13 Coca-Cola formula, then you are perfectly legal to do 13 MR. WARE: These things do happen from time 14 that. 14 to time. 15 And the United States courts do exercise 15 16 16 their authority to provide remedies that are meaningful 17 remedies for past violations. 18 18 And the Federal Circuit has made clear on 19 a number of occasions that it is perfectly within the 20 authority of a District Court to enter injunctions that 21 not only prevent future infringement, but that remedy 22 past infringement, that will have an impact in the

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future if not remedied.

And that's what's going on here. There have
been injunctions entered even in medical cases where an

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Multi-Page™ Page 52 1 infringer has been ordered to destroy clinical data that 1 they are doing the manufacturing in the United States. 2 was generated through infringement. That's the Pfizer 2 in Bothel, Washington, and that what we're actually 3 case. And the data itself is not infringing, but it's 3 talking about is an injunction that will have - will, 4 a remedy that was granted. in the end, amount only to enjoining them from And we are not asking for that particular 5 exporting goods from the United States. 6 remedy, but we are asking for remedy for conduct in the There's no evidence that they have any 7 United States that unfairly impacts the future other plans anyway. So in terms of the impact of this 8 development of Baxter's business in Europe as a result injunction, it may be only United States activities of the head start. anyway. 10 So I guess I'd move on now to the stay of 10 MR. REILLY: Well, your Honor, I would 11 the injunction. 11 invite Mr. Ware to withdraw that part of his proposal 12 MR. REILLY: If I may just respond to that 12 that would call for an injunction in Europe. That's why 13 we have this issue. 13 very briefly, your Honor... THE COURT: Yes. 14 MR. WARE: But if you are manufacturing in 14 the United States, you can't even raise this point. 15 15 MR REILLY: Again, for past infringement, 16 they've already had their remedy. They've now gotten 16 MR. REILLY: All right. I think my problem, 17 the verdict for damages on a reasonable royalty theory. 17 your Honor, is that the injunction, the proposed 18 injunction, as written, would forbid CellPro for two The other point to keep in mind about this 18 19 head start injunction in Europe is that the logic of years from making any stem cell antibody product in 20 such an injunction I think has not really been Europe, regardless of where they got the antibody. And 21 if they didn't get it in the United States during the supported in the proof. Plaintiffs assert in their 22 briefs that, but for infringement in the United 22 term of the patent, it simply does not infringe.

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1 recently-filed declaration demonstrates that CellPro 2 could have, and did, for a while, manufacture the 3 biotinylated antibody in Europe. 4 And the reason why he stopped was that we won the trial in 1995. 5 6 And so the logic kind of breaks down that, 7 but for this infringement, we never would have gotten a 8 head start in Europe. We could have manufactured 9 outside the United States, and that's perfectly proper and encouraged by the laws of other countries. 01 11 So I think the basic premise is - really 12 isn't there, whereas, again, in a trade secret case, it 13 is there, because, by definition, when you steal a 14 trade secret and exploit the trade secret, you're 15 getting some kind of a head start from the trade secret 16 that you couldn't have gotten without the trade secret. 17 CellPro could have gotten the same head start by 18 manufacturing outside the United States, which they would have if they had thought there was any reason to do it. And, indeed, they did for a while. 20 21 MR. WARE: Yes. The interesting thing about 22 this argument is that CellPro has never actually told 23 us in opposing this injunction what they actually plan to do, as far as foreign manufacturing and sales. I believe what's going on is actually that 25

23 States, we would never have gotten going in Europe.

25 that that is true. And, in fact, Dr. Tarnowski's

It's nowhere been proved on this record

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1 its business competitor has not seen fit to get himself patent protection, such as in Europe. I can't represent to the court that CellPro 4 right now, today, is starting manufacturing operations in Europe. They may be. They may not be. I just don't know the answer to that question. But they certainly ought to be welcome to do it. And the plaintiffs are proposing a form of injunction that would prohibit them to do it, even though it wouldn't be an infringing act if they did do it. That's my 11 problem. 12 THE COURT: All right. 13 MR. WARE: If we can move on to the stay ... 14 THE COURT: All right. 15 MR. WARE: I think that, analytically, it helps to sort of subdivide the stay into several areas. One is United States versus the rest of the world and what we have proposed is different in the United States from in the rest of the world. 20 And the second is subdivision between 21 CellPro's commercial sales of its device for the rather limited FDA approval, approved indication that it has versus the clinical trials. 23 24 And then within the clinical trials.

25 there's really a subdivision as between clinical trials

And what CellPro may do later, I mean,

24 certainly, it is a business option for any company that

25 is blocked under U.S. patent law to manufacture where

1 that are ongoing and have been approved by the FDA, and

2 the applicable IRB, and clinical trials that simply

3 might be proposed at some point in the future.

I think, as to commercial sales in the United

5 States, there's not a whole lot that needs to be said,

6 except to come back in a few minutes to the issue of the

o except to come back in a few infinites to the issue of the

7 incremental profit payment on those sales. But I don't

8 think there's any serious objection to the scope of the

9 stay and the terms of the stay with respect to

10 commercial sales.

The thrust of CellPro's objections relates
to clinical trials. And as we have made clear in the
papers that we have filed, it was never the plaintiffs'
intention to preclude CellPro from continuing to supply
those clinicians who are engaged in FDA-approved
clinical trials.

We do believe, however, that there is no reason why CellPro should be able to conduct clinical

19 trials indefinitely, that is to start new clinical

20 trials, because in that realm, there are two products

21 available to a clinician, neither of which currently

22 has FDA approval with respect to the particular uses

23 in the clinical trials.

24 If CellPro had FDA approval, they couldn't 25 be doing clinical trials. And so CellPro's device is 1 more disruptive to permit an infringer providing

2 infringing products.

The arguments presented by CellPro in

its filing last week are principally -- principally

5 amount to disparagement of Baxter's product.

6 And we have filed a motion to strike those

7 declarations. We do not think that it is proper for

8 the Court to consider ex-parte declarations filed

9 post-trial. Those deponents have never -- declarants

10 have never been deposed or cross-examined. They were

11 not identified in the pretrial order. The facts on

2 which they rely were not identified in the pretrial

13 order. And as the Shyley (phonetic) case indicates,

14 in a case involving Lyon & Lyon itself, this is not a

15 proper way to decide the scope of an injunction.

We have, nevertheless, submitted on behalf of the plaintiffs some declarations on very short notice, which I think makes clear that the Baxter device

19 is a -- is an entirely acceptable device that clinicians,

20 in fact, use. It's installed in more than 40 cites

21 around the United States and Canada, at some of the

22 most prestigious institutions, hospitals and other

23 institutions. Clinicians are very satisfied with it.

24 It works well.

In fact, it has comparisons - in

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1 every bit as much experimental in that particular 2 indication as is Baxter's.

And the concern here is that these are —

this is a situation where CellPro, if permitted to

continue forever doing these clinical trials with the

SC device, could make it extremely difficult for

Baxter to ever establish a market for a commercial

market, because I'm sure clinicians are quite content

9 to continue to receive supplies for free or at a very

10 reduced cost. And these are situations where there's

11 absolutely no reason why the clinician cannot specify

12 the Baxter Isolex device in a future trial.

So we are not proposing that they must substitute the device in a current trial. But — so think it's appropriate to draw that distinction. And I think that, really, in terms of the public interest, if anything, it is more disruptive, if

17 interest, if anything, it is more disciplive, if 18 you're looking down the road to the future to a trial

18 you're looking down the road to the future to a trial
19 that hasn't even been proposed to the FDA yet, that it

20 is really even more disruptive for the clinicians

21 themselves and the hospitals themselves to embark upon

22 clinical trials using a product that ultimately will

23 be enjoined from use.

And so, therefore, just as Judge Farnan indicated in the Critikon case, it can be actually 1 comparisons with CellPro's device, it has been shown to

2 work, to provide better results and to be every bit as

3 casy to use, if not more so.

So the Court certainly should not deal
with this issue of a stay based upon the assumptions that

6 the plaintiffs or a licensed party under the patents has

nothing to offer that will address the medical need.

So what we have tried to do is we have tried to craft a stay that will assure that there is no patient

0 who will be deprived of access to the inventions that

11 Dr. Civin made at Johns Hopkins University. But this

12 needs to be a transition period. It cannot go on

13 forever.

14 I anticipate from CellPro's papers that
15 the argument is now being asserted that as to the

16 clinical trials, that somehow the injunction can't cover

17 them because of Section 271(e). And I remind the Court

18 that, at the last hearing we had on March 13th, counsel

19 for plaintiff stood up and acknowledged that there was

20 no Section 271(e) in the -- defense in the case. It was 21 not raised by CellPro in the answer. It was not raised

2 in the pretrial order.

CellPro would have had to prove that the
particular supplies of products to institutions engaged

in clinical trials were actually exempt under Section

Multi-Page™ Page 58 Page 60 1 271(e). That's a burden that they did not undertake. sale or selling the SEPRATE SC except 1 2 And, therefore, they cannot now complain that an 2 for use in clinical trials meeting the 3 injunction will encompass sales or supply of products 3 requirements of the exception stated 4 that somehow they might have proven to be exempt under in," and then they cite 271(e)(1) and 5 Section 271(e). 5 271(e)(3). In fact, as we indicated in our papers, we do 6 So it certainly was in the issues that 7 not think that they could have made that -- met that were stated. 8 burden of proof in any event, because that exemption is 8 As to whether the parties were expected to 9 a very narrow one that relates to uses that are solely -put in all their proof relevant to the injunction at 10 solely for developing FDA information, and CellPro the trial, I would remind the Court of a couple of things. The plaintiff successfully moved for an order 11 certainly could not say when it makes the 12.8 antibody in limine, which forbade CellPro to do anything that 12 that it is doing so solely for purposes of FDA reporting 13 requirements, because it has a commercial device. The would intimate to the jury that there even might be an injunction in this case. 14 commercial device is on sale in the United States and 15 in Europe. 15 So we couldn't very well put in all our 16 But, in any event, that issue simply is not 16 proof relevant to the injunction issue at the trial in 17 before the Court and it is a red herring. light of the motion in limine. 18 Furthermore, the injunction, proposed form of 18 I think that it might make sense to stop now. 19 I have some comments on the incremental profit and I have 19 injunction, was something we never saw until after the trial, and all kinds of issues that it raises, such as 20 a few more comments -- although I think we pretty much 20 21 covered the European sales issues. But I think I will what would be the public health impacts, the impacts on 22 stop right now. 22 CellPro to have this \$2,000 per unit price, to have a 23 23 prospective two-year injunction in Europe, and a host THE COURT: Okay. 24 MR. REILLY: Your Honor, if I may respond to 24 of other issues that pop out at you when you read the 25 that, I think what counsel was alluding to for part of 25 proposed injunction, but not before, couldn't possibly Page 61

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2 trial.

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1 have been fairly expected to have been addressed at

And I think the last time the Court really

went on record as to what it expected to be done about

5 the injunction and how it saw this issue being handled

1 the time was the paper we recently received wherein 2 the plaintiffs have moved to strike our declarations 3 that deal with issues, including the 271(e)(1) issue. As to the late service point, Mr. Ware didn't 5 get into it, and perhaps neither should I, but I 6 understand that the Fed Ex people failed to come and pick 7 up the declarations and get them to Boston on the night 8 when they were left for Fed Ex to get them. 9 Local counsel received them timely. Counsel 10 in Boston received them a day late. And to the extent 11 that there's any innuendo in the brief that this was 12 deliberate, I understand that Mr. Powers, our local 13 counsel, is prepared to explain how this all happened, if 14 the Court wants to hear about it. 15 As for the point about 271(e)(1) not being 16 in the pretrial order, it was in the pretrial order, and 17 the plaintiffs themselves put it there. 18 If one goes to plaintiffs' statement of 19 issue of law No. 9, which is found under Pages 9 - at 20 Pages 9 and 10 under Tab 3 of the pretrial order, they 21 frame the injunction issue thus: Quote, "Whether plaintiffs are 22

entitled to an injunction prohibiting

CellPro" - "CellPro from importing,

exporting making using offering for

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6 was at a hearing. Before the last trial - I have a 7 February 21st, 1995 transcript and at Page 29 of that, 8 Lines 2 through 14, the Court said, and again I'm 9 quoting: 10 "Here's what I think I will do. 11 I am generally familiar with the case 12 law that talks about situations where 13 a Court may not grant an injunction 14 because of the public interest in having 15 health care products on the market. I 16 think what I will do is simply defer the 17 discovery on that. If we get a jury

verdict, and the plaintiffs pop up and say, Judge, enter an injunction today, we can then have a discussion about what further information CellPro may want in order to oppose the entry of an injunction at that point. We may know at that point where the FDA is on these products."

And your Honor goes on with other comments

1 along those lines.

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2 I think it's pretty clear from that - and we certainly understood -- that the court contemplated some separate determination preceded by discovery of some kind on the exact form and scope that any injunction might take. That's a fair way to handle it. That's how we thought it would happen. That is how we expected it to happen. 8

And, indeed, it is really the only way that it can happen, given the order in limine that prevented any kind of meaningful ventilation of the injunction 12 issues during the jury trial.

13 And when we weren't yet on notice of the proposed injunction, the details of the proposed 14 injunction they would seek. And a lot of very 15 important objections go to those details.

17 So that answers their motion to strike the 18 declarations. I think the declarations are fairly in 19 the case.

Now, if I may move on to the substance of 21 it, counsel calls the 271(e)(1) issue a red herring. It 22 is not, for several reasons. The most fundamental of them is the 271(e)(1), when you read it together with 24 271(e)(3), imposes an explicit limitation on judicial power. (e)(3) says no injunction, or other relief,

1 enrich the stem cells with the use of other antibody to

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enrich or deplete for other kinds of cells. And those are being FDA tested right now.

And under 271(e)(1), CellPro has a perfect right prospectively to do that.

To counsel's point that we somehow waived the right to rely on 271(e ) by not asserting it as a damage defense, I think that view misapprehends the difference between prospective remedies and retrospective remedies.

10 Damages is a retrospective remedy. That's for what you've already done. And from the fact that CellPro chose not to argue that a portion of its past sales were FDA exempt should in no way foreclose CellPro from arguing that if, in the future, it wants to do 15 things that are FDA exempt, it can.

16 The prospective aspect of this has nothing to do with the retrospective aspect of it. On the face of their own statement of issues of law, the plaintiffs acknowledge that 271(e) is the immovable object here. 20 An injunction that does not make allowance for 271(e) 21 exempt uses is an injunction that is on its face overbroad and I think unlawful.

I just don't think that the Court could sign 24 it in the form in which plaintiffs propose it without running afoul of two 71.

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Page 65

1 may be granted which would prohibit the making, using, 2 selling or offering to sell in the United States a 3 patented invention solely for reasons related to FDA approval.

5 It's kind of a rare thing, I think, in 6 federal statutes where you have one section saying the Court can issue injunctions and then you have a separate and more specific section saying the injunction may not forbid this. 9

So it's - patent rights are creatures of statute and the remedies that can be granted are 11 12 limited by statute. And in this case Congress has determined that it simply is not an act of infringement to use someone's patented technology for purposes of 14 getting your FDA approvals ready. 15

For that reason, it would, I think, be -16 17 it would be violative of 271(e)(3) if the Court were to 18 enter the injunction in the form that plaintiffs request, because as long as something is a bona fide 20 FDA study that is aimed at either what is called a 21 label expansion, to get an approval to sell the device and advertise it for another use, another indication, or 23 a new device approval - and CellPro, as we point out 24 in our declarations, has some second-generation devices 25 that would combine the use of the 12.8 antibody to

something that can be debated later. But an injunction that says you can't make any uses that - that says you may make uses that are 271(c)(1) exempt is certainly, I think, what it would have to say. The injunction would have to carve out that exception if an injunction were entered at all.

Now, just what is a 271(e)(1) exempt use is

And the fact that CellPro has a commercial product I don't think is sufficient as a matter of law to support a conclusion that there can be no conceivable 11 use of that product that would be exempt,

We have in approximately 20 of our clinicians' declarations and also in the declaration of Dr. Cindy Jacobs, who's CellPro's Director of Clinical Research, we talk about a number of studies that are going on, 50 or 60. I think, in the United States alone at this point, and in some Europe that are under IDE's and are for the purpose of gathering data to either do a label expansion or to get a new device approval. 20

Page 66 Page 68 1 to drawing the line at present - presently under way 2 MR. REILLY (Continuing): Those are not 2 trials. Under the law, it simply is not an act of 3 commercial sales. They can be made at a commercial 3 infringement, and it cannot be enjoined if a company uses 4 price. There is an FDA regulation and it is Mr. David the patented technology to seek FDA approvals. 5 Weed's declaration that gets into this. He is the This was debated in Congress and the 6 person who is the former Deputy Counsel, I think, of the 6 plaintiffs' side lost on that question. It's simply 7 FDA. He explains that when you supply medical devices exempt and you can't read it out of the law. It is a 8 in support of a clinical trial, you can sell them at limitation on judicial power. 9 retail. You can at most charge only a cost recovery 9 One more point that I wanted to make on that. 10 price. 10 Just on the point of why the injunction will be overbroad 11 on its face if it failed to make allowance for 271(e)(1) 12 12 exempt activities, there are a number of things that 13 13 CellPro would have to do to support its FDA trials, 14 14 whether it was making a commercial product in the 15 15 United States or not. 16 16 And, as I understand the injunction, it would 17 prevent CellPro, at least after Baxter got an FDA or some 18 18 licensee got an FDA approval, from even using the CellPro 19 19 device for its one approved application, which is bone 20 20 marrow transplantation for breast cancer. 21 21 If that use were enjoined, then just about 22 22 everything else that CellPro would be doing would be in 23 support of some kind of an IDE. 23 24 As for the notion that CellPro could somehow 25 go hog wild and just do some unlimited number of clinical Page 67 Page 69

MR. REILLY (Continuing): And as Dr. 3 Jacobs' declaration explains, some of the doctors expect 4 reduced-priced goods or they won't participate in trials 5 and some of the patients can't afford it unless the 6 devices are supplied cheaper or free. Now, I think Mr. Ware has basically conceded

8 that point. I see that his revised form of injunction, 9 at least for present clinical trials, that is once 10 already under way, would exempt from this \$2,000 per 11 unit sold royalty rate any CellPro disposables that 12 are supplied in connection with these FDA trials.

I think that is correct, and that's how it 14 has to be. I think anything else would run afoul of 15 271(e)(1). 1

13

24 permits.

So the main point, your Honor, is that a 17 large amount of the uses of the CellPro device that are 18 going on presently are in support of -- either CellPro-19 sponsored or investigator-sponsored investigational 20 device exempt uses that have been cleared with the FDA. 21 and these are uses being made for the purpose of 22 either petting a label expansion or getting a new 23 device approval, and it's exactly what 271(e)(1)

There's absolutely no basis in law or in logic

1 trials for some bad-faith reason, I think the best answer

- 2 to that is that's a problem for the FDA; it's not a
- 3 problem for this Court.
- And the FDA has ways to deal with that.
- Again, I would refer the Court to Mr. Wida's declaration,
- 6 which I think makes the point, and Dr. Jacobs' does also:
- 7 That the FDA does not let you use clinical trials just to
- 8 get out there and do commercial distribution. They won't
- let you charge a commercial price. They won't let you
- 10 test market. They won't let you advertise the product
- 11 for that use. And they want to know that it's real
- 12 science that you are doing, and they want to see your
- 13 protocol.

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14 And once you have your IDE, you'd better not depart from the protocol. You'd better treat only

- the patients who say you'll treat and only the way you'll
- 17 say you'll treat them, and you'd better also comply with
- 18 all the reporting and data-gathering requirements,
- 19 because the purpose of an IDE is not to be some kind of 20 a blind for commercial sales.
- And, in fact, the FDA can, and does, revoke 21
- 22 IDE permissions if it sees someone is using them as a
- 23 blind for commercialization. I think that's something
- 24 the FDA can police and this Court does not have to.
  - MR. WARE: It seems like this is a good

1 moment to jump in. 2 MR. REILLY: I think it is. 3 THE COURT: All right. MR. WARE: Okay. Well, several comments. First, as a sort of procedural posture, I think at the time the statement in the pretrial order that counsel referred to was done, I think that plaintiffs thought that perhaps it was CellPro's intention to raise this. But they did not. They made 10 it clear they were not. 11

They even provided, with respect to damages, 12 they provided a statement of all of the revenue received 13 from SC - the SC device, which quite explicitly included 14 the cost of recovery sales as well, and did not assert a 15 271(c) defense.

16 Mr. Reilly suggested that, while there's a 17 big difference between damages and a future injunction, 18 but what they actually did was they did not assert the 19 defense as to liability either. And that statement is actually made in a brief that was filed in this court on March 13th, 1997. And we cite it in our brief.

22 They stated, We have not asserted a 271(e) defense to liability or damages.

24 If you are going to take the position that particular sales and uses of your product are

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I they should all be subject to the injunction.

2 It is also not enough to simply recite the 3 phrase clinical trial and say that they're exempt. There

4 is a serious factual issue about the 271(e) exemption

5 because of the use of the phrase "solely" in the statute.

6 which would be read out of it entirely under Mr. Reilly's 7 argument.

So that there are real issues that would have to actually have been presented and tried to - for 10 CellPro to establish that certain types of sales were 11 noninfringing and protected under Section 271(e).

The suggestion that certain sales or uses of 12 13 the device must be for 271(e) purposes, because they're 14 being used in clinical trials, overlooks the fact that 15 that isn't the point - or that's certainly not the first 16 point, when CellPro has infringed. CellPro has 17 infringed the '204 patent when it has made the 12.8 18 antibody. And when it makes the 12.8 antibody, it 19 certainly cannot say that its infringement at is solely for seeking FDA approval.

But that defense is not in the case and it 22 certainly was never contemplated in the pretrial order 23 and it certainly was never discussed with this Court 24 before the trial in March that we were then going to have 25 another trial after the completion of that trial at which

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1 noninfringing by reason of 271(e), you would be asserting

a defense to liability. That defense was not asserted,

3 so that -- so that all of the types of trials that are

going on now were treated by CellPro as no different from

the commercial sales, and there simply is no basis, legal

6 or factual, in the circumstances to then take the

position that, well, all those sales are noninfringing

8 under 271(e) and, therefore, the Court can't enter an

9 injunction.

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10 The approach that Mr. Reilly is suggesting is 11 one that the Federal Circuit has said is improper. In 12 the Eli Lilly V. Medtronic case, or one of the Eli Lilly 13 versus Medtronic cases, which we cite in our brief, the 14 Court said that you don't just - you don't enter an 15 injunction that says that it's subject to whatever 16 271(e) exemption there might be. That is an issue that's a liability issue. And so that the defendant 18 has to actually prove that particular sales are sales that are noninfringing under 271(e).

So if that does not happen, they get enjoined. Those sales have been found to be infringing sales

23 There was no exception in the Court's determination that CellPro was infringing for any particular types of sales. They are all infringing and Page 7.

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1 there would then be testimony and evidence presented in 2 order to establish a 271(e) defense that would go to the 3 scope of the injunction. That was never discussed, never

4 contemplated. And CellPro made its choice when it decided

5 not to raise a 271(e) defense.

I think it recognized that it would have a very difficult time establishing a 271(c) defense, and it did not choose to do that.

9 THE COURT: Why? Why would it have a 10 difficult time?

11 MR. WARE: Because of the "solely" language 12 in the statute. It is - there is only an exemption 13 where the infringement that is done is infringement

14 solely for purposes of meeting FDA requirements. And 15 that simply is not the case here, because they have -

16 they make the 12.8 antibody for all kinds of purposes

17 and uses which have nothing to do with FDA approval;

18 i.e., selling the product commercially in the United

19 States and in Europe.

20 So - but, in any event, it's a question 21 of fact. It's one that has to be determined as a 22 liability question. And if a party does not raise it,

23 they are not entitled to come in afterwards and raise 24 it. And they are not entitled, then, to -- when an

25 injunction is entered, to then say, Well, now, every

time that we're accused of violating the injunction, we
 have to come in and have a factual determination of
 whether or not that particular activity was infringing
 because of 271(e).
 That's exactly what the Federal Circuit said

5 That's exactly what the Federal Circuit said
6 they did not want to have happen and that issues that go
7 to liability of whether a party is infringing or is
8 exempt from infringement under 271(e), that's supposed to
9 be tried as part of liability. And if a party waives
10 that defense, it is not in the case.

11 As far as the future trials, too, the other 12 thing I wanted to suggest is -- I mean, the point of --13 to the extent that there -- let me back up.

The point of the statute was to — to allow
a certain — certain activities sort of in the period
before the patent expired. We're talking about a patent
that expires ten years from now. And clinical trials
that CellPro might start at this time are certainly not
ones that are designed to put it in a position to offer
a product when the patent expires.

And there is a serious disruption and harm
to Baxter by permitting CellPro, in effect, to just
indefinitely engage in clinical trials.

And so that's why we're talking about an injunction that the — the injunction on its face would

1 safe and effective for that use. It's still

2 experimental.

And so, as we pointed out in our papers, for those clinical trials, the Baxter product and the

5 CellPro product are both in the same boat.

Something came across my desk yesterday that
I would like to bring to the Court's attention, because
it relates to this very argument that CellPro made, that
gits own FDA approval gives it some special availability
to clinicians. And this is a letter that I was unaware

11 of until yesterday that was written to CellPro by the

12 FDA earlier this year that is highly critical of

13 CellPro's actions in promoting its product to doctors

14 for other than its approved use.

15 And it actually told CellPro that what it
16 was doing was misbranding the product, that it was
17 making misrepresentations about the product, that it
18 was making statements that are regarded by the FDA to
19 be false and misleading.

20 And I would like to submit that to the
21 Court (handing document to the court).
22 THE COURT: Do you want to identify the date
23 and author?
24 MR. WARE: Yes.

25 MR. REILLY: Your Honor, I would object to it,

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cover all of these activities. We're then talking about
 the scope of the stay from that injunction. And we do
 not think that the Court is required, or should enter
 such a broad stay as to really eliminate for the next
 ten years any serious effect of the permanent injunction.
 So that's a different — that's the

One other thing I wanted to say, I was pleased to hear actually Mr. Reilly's comment about the limitations on the approved use of the CellPro product and his acknowledgment that offering that product for uses other than the limited approved use that he referred to is improper.

7 difference there.

14 A considerable amount of time was —
15 considerable amount of space in CellPro's declarations
16 that it filed and in its opposing brief were devoted to
17 the argument that, because CellPro had an approved
18 product, that somehow that made it much more appropriate
19 than the Baxter product, even for uses that were not the
20 approved uses.

And that argument runs directly into the
FDA's very strict limitation on what an approved use is.
And anything other than what the FDA has authorized as
the approved use is an experimental use as to which no
decision has been made by the FDA as to whether it is

1 first for lack of notice, and, secondly, as irrelevant to 2 any question that's before the Court.

(Mr. Ware handed document to Mr. Reilly.)
 MR. WARE: Just for the record, this is a

5 letter - I can't read the date. It appears to be

6 January something, 1987. And just so there's no

7 mystery about where --8 THE COURT: '977

MR. WARE: 1997. January 1997 from the FDA

10 to Monica Krieger of CellPro. She is the chief

11 regulatory person. This letter was sent to Baxter's

12 Law Department anonymously from someone at CellPro who

13 evidently believed that the conduct of CellPro in this

14 regard was, indeed, inappropriate. And I just learned15 of this letter yesterday.

16 But I think that that should be in the record

17 because I think that the record presents a very

18 misleading argument with respect to the - the

availability of the CellPro device to be used for so-called off-label purposes. That appears in several of

21 the declarations, including Mr. Wida's declaration, I

22 believe.

And so from the FDA's perspective, that's not the case. It's not appropriate. And so any such use needs to be under an authorized IDE, just as does

Page 78 Page 80 1 currently any use of the Baxter device. 2 And so that's -- that's why. I think, that it MR. REILLY (Continuing): And once a device 3 is important, as we look down the road towards future is FDA-approved for one indication, it may be sold in clinical trials, to recognize that these are two products, interstate commerce. 5 either one of which can be specified by a clinician for < Once it is sold in interstate commerce. 6 a clinical trial, and that there is -- there is no public any physician within the bounds of state law and 7 health concern of the nature raised by CellPro with professional ethics may make the judgment that it ought to be used to treat a certain patient in a certain way, 8 respect to its current clinical trials when we are focusing on the future. as long as it's not advertised for that use, as long as the doctor doesn't basically proceed on other than an 10 So I think what I would -- I think it would 11 make sense to turn to a few comments about the one-by-one medical judgment basis. Off-label uses are 12 incremental profit calculation. permitted. 12 And I would refer the Court to the 13 MR. REILLY: If I may just respond to some 13 14 of these points briefly... declaration of Mr. Wida, the former Deputy Counsel of the FDA. Paragraph 7, specifically, talks about 15 This letter, your Honor, as I understand it, off-label uses. And it says, off-label uses are 16 CellPro put around a Christmas card. They had on it a allowed. And they're quite common. The difference is 17 drawing by some little child whose life had been saved if you have an unapproved device that's not approved for 18 by the CellPro device. And there was a little any indication, it may not move in interstate commerce biographical blurb about the kid on the back of the Christmas card that said what the child had been for the treatment of human patients at all, except as successfully treated for. And it was off-label use. And part of a clinical trial. 22 So that physicians are relatively free to -22 the FDA felt that that was inappropriate. 23 23 for humanitarian reasons, make an off-label use of an FDA-approved device on a particular patient in 24 25 particular circumstances. The FDA does not disapprove Page 79 Page 81 that. They would disapprove it if he advertised that MR. REILLY (Continuing): As I understand it, 2 he was doing that. But that's where it goes. And I mean that's 3 just because I think the record is in a very confusing state about this. where it stops. And so there is a significant advantage to having a device that's FDA-approved from one Off-label use is something that the FDA does 6 indication. And, in fact, we have among our declarations 6 not control. Advertising of a medical product in interstate commerce for an off-label use is something Dr. Wida's - Mr. Wida's declaration explains at great length why it is that the idea that Baxter, with just a 8 that the FDA controls. The FDA does not, however, patchwork quilt of IDE's and no FDA approval for any regulate the practice of medicine. 10 indication, cannot fill the gap in patient care 11 11 availability. 12 12 That would happen if the CellPro device were 13 frozen at the number of columns that CellPro had in use 13 14 as of March 12, which is what their injunction proposes. 15 That March 12 date is a scant three months after CellPro 15 16 16 got its FDA approval. 17 I think there is something like 50 or 60 17 18 sites in the United States that have CellPro devices 18 19 19 right now. And there are a lot more cancer patients 20 and a lot more places than that. 20 So this business about off-label use and 21 22 whether Baxter and CellPro are in the same boat, other 22 23 than for the indicated use, I think is an important thing 23 24 to dwell on for a moment, because it is just absolutely 24

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25 infeasible that Baxter, without an FDA approval, could

1 completely satisfy the needs of patients for treatment. 2 There are very, very significant constraints 3 on the ability of physicians to make choices in patient 4 treatment when they've got only an unapproved device to work with.

6 Several of our declarants make the point 7 that off-label use is a big -- a big advantage. Ease 8 of recruitment of patients is an advantage of having a -- an FDA-approved device.

10 Ease of getting insurance reimbursement 11 without which some patients couldn't be treated is -12 is something that's mentioned by Dr. Anderson and also 13 by Dr. Sender in his declaration, and also by Mr. Wida.

14 The ease of getting new IDE's approved, if 15 your device has already been found safe and effective 16 for one application, is quite significant. I think 17 eight or nine of our clinician declarants have remarked 18 on the fact that it's easier to get IDE's approved in 19 your institutional review board and your hospital, 20 university, and also by the FDA, if you can say this has been found safe and effective by the FDA for at least 22 this one application. 23

So the point of all this, and I think Mr. Ware has gotten - fairly gotten into it by this 25 letter - the point of it is that you just can't - it 1 briefing. I don't think that's a real issue, as far as

2 the commercial sales.

And as far as everything else that CellPro is talking about, they are talking about their own uses

of their product under IDE's, not under approved

6 usage - uses, and in areas where the -- the FDA has not concluded that CellPro's device is safe and effective

8 for use.

So I think we're just, you know, we're 10 talking about IDE situations that - I mean, that's

11 what we're talking about when we're talking about the

12 stay. This off-label use is - I think our point is this 13 is not something - this is not a basis on which the

14 Court should tailor the stay of the injunction in order

15 to specially encourage off-label use of CellPro's

16 product, because it's something that, while the FDA may

17 not have the authority to regulate on individual doctors'

18 use of it, it certainly does disapprove of it, and that's

not a good basis for an injunction or a stay of an

injunction, to encourage that.

THE COURT: Stop just for a minute. I need 22 to take a break or stop.

23 How much longer do you think you'll be? 24 MR. WARE: Very short. I think, really, the last thing that I wanted to address very shortly was

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1 is unrealistic to think, it is totally impractical to

2 think, that if CellPro remained frozen at the number of

3 devices and places in the United States as of March

4 12th, that Baxter, with no FDA approval, could go in

5 there and completely fill the market.

6

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It can't. It cannot sell its device 7 commercially. It cannot advertise its device. And IDE's 8 are not -- they are not a stopgap for commercial sales.

9 I think Mr. Wida's declaration makes that very, very

10 clear. There would be a shortfall in filling the needs 11 of patients for care if - if CellPro were frozen at

12 the number of devices it's now got in place.

MR. WARE: There's just a couple of brief 14 points.

15 CeliPro actually provided us no data at all 16 about the number of sites they were in. And I think 17 that it is entirely conjecture on the part of Mr. 18 Reilly's part that those sites cannot somehow fill the needs for patient care.

19 20 Bone marrow transplants aren't performed in 21 every little local hospital. They are performed in 22 transplant centers. And it's not clear to me that there are even are a whole lot more transplant centers in the 24 United States, which is one reason I think there was essentially no comment on this issue in CellPro's

I just the incremental profit point.

THE COURT: All right. Why don't we talk

about that real quick, then I'm going to need to go.

MR. WARE: OKMY.

THE COURT: If anybody has to say anything

they want to say, feel free to write me.

MR WARE: I think, first of all, just

conceptually, it's important to underscore our point here, which is that anything other than payment to the

plaintiffs of incremental profit allows CellPro to

benefit from its willful infringement, and we don't

12 think that should be permitted.

So I think what the - so I think the concept is entirely appropriate, and I have not really 15 heard much argument from CeliPro as to why it isn't.

What we're mostly arguing about here is the 16 17 floor that we proposed simply to avoid all of the kinds 18 of - all of the kinds of accounting games that can be played once you give somebody the ability to calculate 20 their incremental profit.

And I am sure CellPro would, if we had no 21 22 floor at all, it's quite clear from Mr. Simpson's 23 affidavit, that they would say we lose money on every sale but I guess hope to make it up with the volume. 24

And I think beyond that, what I'd like to

Page 86 Page 88 1 do is -- do you want very briefly -- there are just a 1 conversations with Mr. Culver, who is the CPO of -- the 2 couple -- there are a few things that we just picked up 2 CFO of CellPro. 3 that are I think just worth mentioning, although if the Now, if we, so to speak, criticize the 4 Court prefer that we do it by letter, we can. But they Simpson declaration, which it is very -- incidentally, very easy to do, then they will come back. They'll 5 have to do with the calculations that Mr. Simpson did. 6 And I think we can show the Court why those calculations play around with the figures again. We still won't have are so off base that they should not be considered at the figures that they are relying on. 7 The only point we are trying to make, your 8 all as a basis for establishing a floor for this -- for Honor, is - in that letter - and it's already addressed this incremental profit calculation. 10 But if the Court would prefer that we do that in part in Dr. Hausman's declaration, which had to be prepared. We only got their papers last week. Is that II in writing, we can do that. the figures are not trustworthy because they are very 12 THE COURT: Realistically, what will happen is 13 I will go back and reread the transcript of what was said, sciective. 14 when I've got Simpson in mind and exactly what went on For example, they are loading an entire year's worth of manufacturing costs and selling costs 15 with it. It may be just as easy for you to read the 16 letter. I've got another argument coming up at 2:00 into a year when they only had partial revenues in the U.S.. They're comparing apples and oranges. 17 that I need to get focused on. They're also loading the entire costs of 18 So if you don't mind, I'm happy to have you 18 making all 12.8 profits, including the big devices 19 write a supplemental paper, if you don't mind. I'd just themselves, on to the cost of the disposable units. as soon get it done that way, if that's all right. But these are issues we can point out. Simply to say 21 MR. WARE: Yes. the Court shouldn't rely on them, but I don't think 22 THE COURT: I saw you all carrying a disk they should now be offered an opportunity, so to speak, 23 around. I take it that's probably a disk of the order 24 to fix what Mr. Simpson has done while still depriving of the form of injunction? 25 us of the information on which he is relying. 25 MR. WARE: Would that be helpful? Page 87 Page 89 THE COURT: All right. THE COURT: There's no harm in passing it MR. REILLY: Your Honor, I think what 2 up. probably would be appropriate would be some discovery on 3 MR. BLOOMBERG: I have two very brief the question of whether the injunction - and if it were points, your Honor, one with respect to misuse. not stayed, would bust CellPro. I think the issue is 5 THE COURT: Surc. MR. BLOOMBERG: Will we be allowed to take actually broader than that. discovery on that topic, your Honor? There was nothing stealth or sneaky about Mr. Simpson's declaration. The reason why it had to be THE COURT: I think what I am going to do is put together on such short notice is that this \$2,000 9 have plaintiffs file their motion for summary judgment, per unit figure that the plaintiffs came up with and stay discovery on it, and then during the briefing, if put in their proposed injunction was something never you can identify for me what facts you believe you mentioned at trial, never put in the pretrial order, would obtain during discovery as you would under Rule 56, and seemed to be kind of picked out of the air. in any event. And then we'll see where we are. 13 14 MR. BLOOMBERG: Fine. 14 And I think, really, there's a broader issue And the last point, once we see the letter here as to whether the terms of the injunction would 16 shut down CellPro. And it goes beyond the \$2,000 per that they are submitting with respect to Mr. Simpson, may item. And I would think if we're going to go any 17 we file some response if we think it's appropriate? MR. ELLIS: Your Honor, I don't think that's farther with this, there probably ought to be a hearing 18

quite fair, because they elected to file Mr. Simpson's

Mr. Simpson extrapolated his data.

23 figures that are taken from what is described as

22

declaration without disclosing the documents from which

Mr. Simpson's declaration is arrangement of

unaudited financial statements of CellPro that have not

25 been provided to us. And based on undisclosed hearsay

on the economic impact. And you cannot really talk about that until you know what the scope of the

MR. WARE: Well, our view is that that

23 hearing was today, and we are not inclined to continue 24 this indefinitely. We've made a suggestion to the

25 Court. They've had their chance to respond to it. We

injunction is going to be.

22

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1	hope that the Court will take our views into	1	(Court recessed at 12:37 p.m.)	•
2	consideration and we're anxious to have the Court	2	•••	
3	resolve the issue.	3		
4	THE COURT: Well, back to the question, if	4		
5	you all are going to submit a paper on Simpson, then	5		
6	they can respond.	6		
7	If you are not going to submit something,	7		
8	then I will just let the record sit the way it is,	8		
9	unless somebody tries to lob something in.	9		
10	MR. WARE: Then let me say this: I think	10		
11	that Dr. Hausman's affidavit adequately sets out our	11		
12	points, if I can add one more simply, which is that as	12		
13	we looked at their all calculations today, this morning,	13		
14	what we saw is that when they calculated the per-unit	14		
15	costs of the disposables, they did it based on sales,	15		
16	or based on manufacturing something like 4600 units.	16		
17	They actually sold and compared it to about	17		
18	2300 units. So they figured out the cost of making and	18		
19	· ·			
1	building an inventory for twice the number of product	19		
20	that they actually sold and then they said that that is	20		
21	the per-unit cost that should be considered.	21		
22	So that's one point we wanted to add to what	22		
	we said before. But, unless I'm mistaken, I'll speak with	23		
24	Mr. Ellis. I think probably we were going to underscore	24		
25	points that are in Dr. Hausman's affidavit and it's	25		
	Page 91			
1	probably not necessary to go into it further.			
2	THE COURT: Well, actually, what I was also			
3	going to say is it may not be something that anybody			
4	wants to hear. I see the injunction as an equitable			
5	remedy and a remedy where I have to try to get it right:			
6	And if somebody shows me today, next year, two years from			
7	now that it's not right, I may have to keep tinkering			
8	with it and until I do it.			
9	And if it means I enter an injunction that			
10	misses the target a little bit and I go back and re-do			
11	it later, I'll go back and re-do it later. And I may			
12	appoint somebody to go back out and give me some			
13	accurate numbers and have them do it.			
14	But we'll see.			
15	MR. WARE: Thank you very much, your Honor.			
16	THE COURT: All right. I think what's going			
17	to happen is the next thing I will see is a motion for			
18	summary judgment on patent misuse and I will get working			
19	on issues on my plate, including enhance - enhancement			
20	of damages, attorneys' fees and nature of the injunction.			
21	And when I receive the briefing on misuse, I			
22	take it one of the things I'll see is whether there needs			
23	to be evidentiary discovery on this subject or whether I			
24	can resolve it without further discovery.			
25	(Counsel respond "Thank you, your Honor.")			
سا	(Countries response Timine you, your florest. )			

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