IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| ELAN PHARMA INTERNATIONAL LIMITED,<br><br>Plaintiff,<br><br>v.<br><br>ABRAXIS BIOSCIENCE, INC.,<br><br>Defendant. | ) | C.A. No. 06-438-GMS<br><br>**REDACTED – PUBLIC VERSION** |

**APPENDIX OF EXHIBITS TO DEFENDANT ABRAXIS BIOSCIENCE, INC.'S ANSWERING BRIEF IN OPPOSITION TO ELAN'S MOTION FOR (1) AN AWARD OF PREJUDGMENT INTEREST AND (2) AN ACCOUNTING OF ABRAXIS'S INFRINGING SALES SINCE JUNE 12, 2008**

OF COUNSEL:
Michael A. Jacobs
MORRISON & FOERSTER, LLP
425 Market Street
San Francisco, CA 94105-2482
(415) 268-7000

Emily A. Evans
Eric S. Walters
Erik J. Olson
Paul F. Coyne
Diana B. Kruze
MORRISON & FOERSTER, LLP
755 Page Mill Road
Palo Alto, CA 94304-1018
(650) 813-5600

Anders T. Aannestad
MORRISON & FOERSTER LLP
12531 High Bluff Drive
San Diego, California 92130
(858) 720-5100

YOUNG CONAWAY STARGATT & TAYLOR, LLP
Josy W. Ingersoll (#1088)
Elena C. Norman (#4780)
Karen E. Keller (#4489)
Michele Sheretta Budicak (#4651)
Jeffrey T. Castellano (#4837)
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, DE 19801
(302) 571-6600
jingersoll@ycst.com
enorman@ycst.com
kkeller@ycst.com
mbudicak@ycst.com
jcastellano@ycst.com

Attorneys for Defendant
ABRAXIS BIOSCIENCE, INC.

Dated: July 18, 2008

## TABLE OF CONTENTS


| Exhibit No. | Description | Date | Page Nos. |
|---|---|---|---|
| PX046 | Contract - License Agreement between Elan Pharma International Limited and Aventis Pharma SA | 12/19/2003 | B 1-46 |
| PX050 | Contract - License Agreement between Elan Pharma International Limited and F. Hoffman-La Roche Ltd and Hoffman-La Roche Inc. | 04/16/2004 | B 47-89 |
| PX063 | Contract - License Agreement between Elan Pharma International Limited, Elan Drug Delivery, Inc. and Bristol-Myers Squibb Company | 08/29/2003 | B 90-141 |
| PX064 | Contract - License Agreement between Elan Pharma International Limited and Janssen Pharmaceutica N.V. | 07/31/2003 | B 142-202 |
| | Excerpts of Trial Transcripts | 06/05-11/2008 | B 203-218 |

**CERTIFICATE OF SERVICE**

I, Karen E. Keller, Esquire, hereby certify that on July 23, 2008, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

Steven J. Balick, Esquire
ASHBY & GEDDES
500 Delaware Avenue, 8th Floor
Wilmington, DE 19801

I further certify that on July 23, 2008**,** I caused a true and correct copy of the foregoing document to be served by e-mail on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

**BY E-MAIL**

Stephen Scheve, Esquire
BAKER BOTTS L.L.P.
One Shell Plaza
910 Louisiana Street
Houston, TX 77002-4995
steve.scheve@bakerbotts.com

Paul F. Fehlner, Esquire
BAKER BOTTS L.L.P.
30 Rockefeller Plaza
New York, NY 10112-4498
paul.fehlner@bakerbotts.com

YOUNG CONAWAY STARGATT
& TAYLOR, LLP

/s/ *Karen E. Keller*
Josy W. Ingersoll (No. 1088)
jingersoll@ycst.com
Elena C. Norman (No. 4780)
enorman@ycst.com
Karen E. Keller (No. 4489)
kkeller@ycst.com
Michele Sherretta Budicak (No. 4651)
mbudicak@ycst.com
Jeffrey T. Castellano (No. 4837)
jcastellano@ycst.com
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, Delaware 19899
(302) 571-6600

*Attorneys for Defendant*
*ABRAXIS BIOSCIENCE, INC.*

# PAGES B 1 – B 202

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IN AND FOR THE DISTRICT OF DELAWARE

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| ELAN PHARMA INTERNATIONAL LIMITED, | : | Civil Action |
| Plaintiff, | : | |
| v. | : | |
| ABRAXIS BIOSCIENCE INC., | : | |
| Defendant. | : | No. 06-438-GMS |

- - -

Wilmington, Delaware
Thursday, June 5, 2008
9:30 a.m.
FOURTH DAY OF TRIAL

- - -

BEFORE: HONORABLE GREGORY M. SLEET, Chief Judge, and a Jury

APPEARANCES:

JOHN G. DAY, ESQ.
Ashby & Geddes
-and-
STEPHEN SCHEVE, ESQ.,
LINDA M. GLOVER, ESQ.,
JEFFREY SULLIVAN, ESQ.,
ROBERT RIDDLE, ESQ., and
PAUL FEHLNER, ESQ.
Baker Botts LLP
(Houston, TX)
-and-
GREGORY BOKAR, ESQ.
Counsel - Elan Drug Delivery

Counsel for Plaintiff

Page 799

the quantitative analysis that you performed, sir.
In the first chart, you made reference to something called the market approach. Could you explain that to the jury?
A. The market approach involves looking at other transactions involving similar technology, similar parties, as close to February '05 as one can get, using as close to the same economic underlying facts as one can get.
It's similar to a real estate transaction.
When I go to sell my home, one of the very first things that a real estate agent will do is see if there have been other homes in my neighborhood or close in neighborhood that have sold as well. What should be charged for my house is importantly impacted by what other homes have sold for in my neighborhood or in my town or in the broader geographic area.
So if all the homes in my neighborhood have sold, for instance, for $150,000, just by way of example, then that's pretty strong evidence that I should probably attempt to sell my home for about $150,000.
What I do is look at other homes in the neighborhood, I look at other transfers and sharing of patent rights that are similar to what we have today.
Q. Okay. Are there any types of agreements or sets of agreements that you reviewed, then, in applying this market

Page 800

approach to your analysis?
A. Yes. There are three sets of agreements. The first are Elan group agreements, agreements entered covering NanoCrystal technology to users of that technology.
The second is Abraxis licenses. The third is third-party licenses in the general industry that we are talking about but involving other parties.
Q. I bored the jury to death reading into the record various agreements. Have you reviewed all of those Elan agreements as part of your exercise, sir?
A. I have. There have been about 25 agreements that have been produced as part of this discovery. And we have reviewed all of those and summarized those in the report that, or in the reports that I have submitted in this matter.
Q. In addition to the Elan agreements, did you review any other sets of agreements?
A. Yes. I reviewed the Abraxis agreements. There were four agreements. I referred to three of them a few moments ago. Then I reviewed about 175 third-party agreements and surveys about licensing rates in a variety of industries.
Q. Let's go to the next slide then, sir, in terms of the Elan group agreements. Could you explain this slide, please?
A. Yes. Each agreement is quite lengthy. There are many

Page 801

terms to each Elan group agreement covering NanoCrystal technology. But most of them have the features that are reported here. That is, there are running royalty rates, which means five percent or four percent or eight percent. The percentage that I referred to before, when the user of the technology makes sales, it pays associated with its sales level, so five percent of sales, for instance.
So they are running royalties.
The vast bulk of the agreements also have up front or milestone payments, some as high as $35 million. In other words, there is a transfer of money up front just for the right to practice the patented inventions.
Each of the agreements covered Elan's NanoCrystal technology, or what's written here, the nanotechnology patent portfolio, so a set of rights, patents and patent applications, U.S. patents and foreign patents. A whole host of rights were given to each one of the users, which are called licensees.
Most of the licenses were related to a specific compound. So they didn't state, You can use our technology for any number of applications, but they said, for instance, that you can use our technology in anticancer applications, for instance, or in other types of very specific applications.
The last -- many of the agreements involved more

Page 802

than just what's called a naked patent license. It usually involved some kind of collaboration with Elan, the owner of the patent rights, and each one of its licensees. Sometimes it was to develop a drug, sometimes to help sell the drug, sometimes to make the drug. So, these are kind of the basic provisions that one sees in those agreements.
Q. With regard, then, to the Elan group agreements, did you perform an analysis where you looked at them in different points of time?
A. I did.
Q. What was your purpose for doing that, sir?
A. Well, I saw, there is kind of a line of demarcation in about the year 2000. There are quite a number of licenses before, which you see summarized on the screen, and quite a number of licenses afterwards, but in about an 18-month period, there wasn't much activity. So that looked like a clear line of demarcation.
More importantly, Elan didn't start receiving its first revenues associated with the licenses until the year 2002. So, at that point, it became clear to Elan and clear to the marketplace that this technology really was pretty strong and useful. So there were things that happened after 2002 in the marketplace that said, the nature of the licensing changed some.
What I did is I drew a line of demarcation at

Page 803

2002, looked at the licenses before, in this chart, and looked at the licenses after, in another chart.
Q. Let's explain this. I see, let's take the very first line, there is a company called Janssen. Can you tell the jury what that is?
A. Janssen is a pharmaceutical company, who was the first company to take a license to NanoCrystal technology. They entered a license with Elan in 1995. There were a number of provisions. But among the provisions was that Janssen would pay a ten-percent royalty. In other words, for every hundred dollars in revenues that it received off a drug it ultimately commercialized, it would pay $10 in a royalty rate.
Q. What I would like you to explain, sir, you have got these bars, some of which are pretty thin and others of which, like me, are pretty fat.
Can you explain the difference between the length of the bar and what you are trying to communicate?
A. Sure. You see the ones that are skinny, they represent a single point, that is, in the license, for instance, with Mimetex, the royalty rate was four percent. That's what that skinny little bar looks like. The fatter, or Scheve bar, represents that, or Jarosz bar, represents the -- that that license has a range of rates, that is, for instance, in the Muro license, depending on sales levels and

Page 804

depending on other milestones, the rate could be anywhere from eight to 12 percent.
So a wider line means there is a range of rates within that license.
Q. Okay. Then did you do a separate review of agreements, sir, for 2002 and after?
A. I did.
Q. What does this next chart communicate to the jury?
A. That reflects the running royalties associated with those later agreements. Remember, all I have charted in these two is just a running royalty rate. There are lots of up-front payments and milestone payments, other forms of compensation. But I wanted to only focus on the running royalties. And what I have mapped here is the running royalties associated with these later agreements, with particular focus on the kind of orange colored bars, I found those agreements to be particularly useful.
Q. Let's go, then, to our next slide. Would you then, in addition to looking at the license agreements involving Elan's NanoCrystal technology, look at license agreements that Abraxis has entered into?
A. Yes, I did.
Q. What is communicated in this slide?
A. This is a summary of one of the three licenses that I spoke of a little bit earlier, and, that is, Abraxis entered

Page 805

into an agreement with AstraZeneca in early 2006 in which AstraZeneca agreed to pay $200 million to have access to the ability to sell Abraxane. It also agreed over time, when certain events were satisfied, that it would pay $108 million, again, from AstraZeneca to Abraxis. AstraZeneca also agreed that it would share the costs with Abraxis of advertising and promoting the drug in the United States.
In other words, AstraZeneca kind of has taken over the marketing role associated with this drug because AstraZeneca, as we all know, is a well-known company. It is a very successful company. It has been around a long time and it knows how to market. So it's kind of taken over the marketing of the drug but it has paid quite a bit of money for those rights.
Abraxis has agreed, in this return, through this strategic alliance, to supply Abraxane, that is making the product and handing it to AstraZeneca, in essence, to sell, it also has agreed to pay for its activities, to pay AstraZeneca 22 percent of the money Abraxis takes in. So there is money going both ways. It's an alliance whereby AstraZeneca is helping ensure the success of Abraxane in the marketplace.
Q. This up front money, has that money been paid to Abraxis?
A. Yes. It was paid in 2006, all 200 million of it has

Page 806

been received and put to use by Abraxis.
Q. Okay. And you made mention of two other agreements. Let's provide information both for the jury and Judge Sleet here about both the Taiho and Green Cross agreements?
A. Yes. I think I made a little bit of a mistake. I apologize. The line that is drawn is not quite drawn in the right place.
I meant the line to be drawn after the second big bullet. So the top half is the Taiho agreement and the bottom half is the Green Cross agreement. I just drew the dotted line imprecisely, I apologize.
Without getting into excruciating detail, as tempting as that might be, the Taiho agreement again covers that company taking charge of selling in Japan, Green Cross allows that company to sell Abraxane in South Korea. Both those companies paid a fair amount of money up front for the rights, whether there are any sales, there may not be a single sale in Japan or South Korea, but still, $20 million is owed by Taiho and $2 million is owed by Green Cross.
Then there are some milestone payments associated with certain things that are accomplished by Abraxis, and payments can be higher, as you see in those notes, and both Taiho and Green Cross have agreed, by supplying us with Abraxane, Taiho and Green Cross have agreed to pay a fair amount in a royalty fee. Taiho has

Page 811

Q. What was the next part of your quantitative analysis to come up with a reasonable royalty rate?
A. I undertook an income approach, and that entailed looking at what the benefits and expected benefits to Abraxis have been and will be through selling Abraxane. One looks at the income, the money that Abraxis can expect to make, and apportions that associated with the contributions associated with the '363 patent.

In other words, you look at a profit pie and divvy that up, that's what the income approach is.
Q. Now, have you, yourself, published in the area, or published on the topic of this so-called profit split rule?
A. Yes. In fact, there are two forms of income approaches. One is a profit split rule and one is an incremental income approach, which I think is on the next slide.

On the profit split rule, I have published papers in that area, one a few years back that is used by quite a number of people in the area, and then I have given quite a number of presentations associated with the profit split rule. So I have done a lot of research on that topic.
Q. With regard to this particular slide, sir, what should one take away from it?
A. Without going again into all the gory tails, the expected operating profits for Abraxane are about 32 percent

Page 812

over a long-term period. Divvying that up, one-quarter or one-third to the owner of the patent says that Elan, by this particular tool, would be entitled to a royalty fee of 8.1 to 10.8 percent.
Q. Is that the range utilizing that profit split rule that you have come up with as a reasonable royalty rate?
A. Yes, using that profit split rule, using industry data with regard to expectations as to profit margins.
Q. Okay. Now, did you end your analysis at that point?
A. No, I did not.
Q. Let's go to the next slide, again, with regard to the income approach, to try and conclude or determine what would be a reasonable royalty rate.
A. I also sought to compare Abraxane gross profits and expectations as to gross profits in the February of '05 period versus Abraxis' other business.

Gross profits is revenues minus cost of goods sold. It doesn't account for selling costs and general and administrative costs. It's just how much it takes to make a product.

Its gross profit experience is shown in the darker blue bar. That's about 84 percent.

For its other business, which is largely related to hospital work and generic work, in particular, providing generic drugs, its margin is much lower. It's about 50

Page 813

percent.

So the difference is, this Abraxane was going to allow Abraxis to bump up to a new level of margins and returns.

It would make a 34.4 percent excess return by selling this product versus the other activities that it engaged in historically.
Q. What significance, then, sir, does that have in terms of your income approach to analyzing a reasonable royalty rate?
A. Well, if this were the only evidence, if we just go back one slide, if this were the only evidence, and the comments would say, Abraxis would say up to 34 percent and still get its normal margin, that is quite a substantial excess, I did not think it would be fair to do, that it would not give away all its excess, but I used this observation in figuring out a range of reasonableness?
Q. Did you create a summary of the income approach for analysis of the reasonable royalty rate?
A. Yes, I did.
Q. Is it reflected here on this next slide?
A. Yes, it is.
Q. What is the results that came out of your income approach to analyzing a reasonable royalty rate?
A. The profit split rule that I employed said 8.1 to 10.8

Page 814

percent. There were other confirmations of that in Abraxis documents. The Grand plan and the Green Cross agreements confirmed the profit rates that I was using. That says 8.1 to 10.8. The incremental income approach says as high as 34.4 percent. I thought that number was too high. I thought that wouldn't be reasonable for Abraxis to pay that or Elan to demand that.

So I pretty much eliminated what is that high end, and said, The range from the income approach is 8.1 to 10.8 percent.
Q. We have covered the market approach. We have covered the income approach. What was the third approach under your quantitative analysis?
A. It's called the cost approach. That entails looking at what other alternatives were available to Abraxis that would allow it to achieve the same ends through a different means. Could it have rolled out Abraxane using some other patented invention? An example to think about is if I could buy a Trek bicycle for $300 from Wal-Mart and Sears was offering it for $250, I never would pay $300 to Wal-Mart. I would buy the bike from Sears. I would go to the next best alternative.

So I sought to determine if there was a next best alternative available to Abraxis and I didn't see any evidence of it. In other words, I didn't see that it

Page 835

have simply superimposed on that where Mr. Musika believes the royalty rate should be and my six to eight percent, in the green and Mr. Musika is in the red.
Q. I will go to my last slide here, sir. What is, based upon your review, sir, applying all the standards that an economist would apply to the analysis that you have done, what do you conclude to be a reasonable number for calculating damages from February of 2005 up through the present in terms of the infringing revenue?
A. I believe that range is $55.2 to $75.9 million, with, I believe, the high end being the appropriate number, it's based on eight percent and based on fully considering AstraZeneca, Taiho, Green Cross, and the product sales.
Q. I may not have spoken very clearly, sir. I wanted to focus first on the first column, which is the total revenue.
Do you, sir, believe, to a reasonable degree of economic probability, that that is the appropriate number to use for purposes of calculating the appropriate damage number from February of 2005 up through the second quarter of 2008?
A. Yes, I do. I apologize, I may have misheard you before.
Q. I probably didn't speak very clearly.
A. Thank you.
That number, again, includes the product sales

Page 836

of Abraxane. It includes the AstraZeneca payments. It includes the Taiho and it includes Green Cross.
Q. If the jury were to conclude that the reasonable rate of royalty to be applied to that is eight percent, which of these numbers would be the appropriate damage number?
A. The $75.9 million number.
Q. If the jury concluded that the lower number, the six percent, would be the more appropriate royalty rate, what would be the appropriate damage number?
A. Assuming as well that the jury would exclude Green Cross and Taiho reimbursements, that number would be $55.2 million.
Q. If they applied Mr. Musika's one percent, what would be the damage number?
A. $8.1 million.
Q. Do you have an opinion, sir, as an economist, to a reasonable degree of economic probability, as to whether or not that $8.1 million figure for damages from February of 2005 through the second quarter of 2008, whether that's a reasonable figure?
A. Considering the company has generated revenues of almost a billion dollars, that $8.1 million appears to be too low.
Q. In terms of going forward, in terms of a reasonable royalty rate, for the jury to decide --

Page 837

THE COURT: Yes, sir.
MR. OLSON: Objection, Your Honor. The jury does not determine forward-going royalties legally as a matter in this case.
THE COURT: Let me see counsel.
(The following took place at sidebar.)
THE COURT: Mr. Olson, I know Judge Garth was -- you clerked for him. It is bad form to tell a judge what a jury does or does not determine, especially to do it in front of the jury. Just ask for a sidebar. I will gladly grant it.
MR. OLSON: I apologize, Your Honor.
THE COURT: Go ahead.
MR. OLSON: Your Honor, in terms of the royalty, under the law of the Federal Circuit, you determine reasonable royalty up to the date of trial. What happens thereafter is really a matter not yet fully addressed by the Federal Circuit, but there are a number of cases that it is not appropriate to leave to the jury the question of forward-going royalties, and that, rather, the determination could be made, in part, it goes again to the special verdict form at issue, it needs to be made by the Court in light of the decision of the plaintiff not to seek an injunction in this case.
I again --

Page 838

THE COURT: That's okay. Mr. Scheve, your reaction?
MR. SCHEVE: My response to that, Your Honor, is that the evidence should come in, and then depending upon the instruction, they will either be asked to come up with that number or not. And there are a number of areas, as I have come to learn, as I have come to love patent law over the last few months, that maybe the Federal Circuit is unclear whether that's for Your Honor to decide or the jury. But I wanted to get that number in so whoever decides it will have that benefit.
THE COURT: I think this is one of those situations we may be able to repair later on or address later on, as we discussed earlier.
So we have got the jury here. Let's go ahead and let them hear the evidence. I might benefit from further submissions on this. I think you are probably right. But rather than having me make that call from the hip, as we often do to the disadvantage of the process and everyone here by not letting them hear the evidence, let's let them hear it and we can take it care of it later on if necessary.
(End of sidebar conference.)
BY MR. SCHEVE:
Q. Mr. Jarosz, in terms of a going-forward reasonable

Page 847

A. No. Again, I am not a scientist. I am an economist. I don't have training in the physical sciences. So I am not able to interpret it from that perspective.

But I saw some of the representations as to what would impact an economic analysis. And I reported on that.

Q. Is it correct, sir, that on this question, which you didn't have a basis from your own knowledge --

A. I am sorry, I missed the first part of your question. I apologize. If you could start over.

Q. Sure. Is it correct that on this subject matter for which you did not have any expertise, that you did not seek out the assistance of any outside or independent technical experts?

A. I did not seek out any separate expertise. I did have a conversation or more with Dr. Liversidge. To me, he is an outsider. But I understand he is employed by Elan. I got some technical understanding through him. But I don't recall talking with anybody beyond the people we have identified on this topic.

Q. You didn't speak to any of the experts that have presented technical evidence in this case on behalf of Elan. Correct?

A. I don't believe I did.

Q. You don't have any understanding as to whether or not Abraxane contains any crystalline medicament. Is that

Page 848

correct?

A. I don't know for sure. Again, I am not a scientist.

Q. You are seeking a royalty on all the sales of Abraxane. Correct?

A. I am not seeking a royalty. I believe Elan is hoping that it gets a royalty. I am providing my expertise on what the royalty base and appropriate royalty rate should be. But it's for the jury to decide whether that was done correctly or not.

Q. So may I rephrase to say, you are recommending a royalty be paid on all the sales of Abraxane. Correct?

A. Yes.

Q. Every --

A. From February 2005 through my estimate of June 2008.

Q. Every vial from 2005 through the present. Correct?

A. Yes.

Q. And all the nanoparticles in those vials?

A. Yes.

Q. Isn't it correct -- withdrawn.

I would like to turn to another subject matter, the subject matter of the license agreements or the market approach that you discussed. That is in part derived from the Georgia-Pacific analysis as well. Correct?

A. Well, I am not exactly sure what you are asking. But at least two Georgia-Pacific factors ask one to consider

Page 849

other licensing.

Q. If I could have Slide F11.

Isn't it the case that this is a statement of the Georgia-Pacific Factor No. 2 as it relates to this case, so with the insertion of Elan and Abraxis or others, and that one of the factors is the rates paid by a licensee of Elan, Abraxis, or others for the use of other patents comparable to the '363 patent? Correct?

A. Not exactly. I think it's the rates paid by the licensee -- I forget the exact words. But putting Elan and Abraxis together, that's not the focus of Georgia-Pacific Factor 2. Georgia-Pacific Factor 2 looks at the licensee, and maybe you could show me the exact case because I don't think this is quite right, and of course it doesn't specifically talk about the '363 patent but it talks about other comparable licenses.

So I don't know if this is quite a fair representation.

Q. Is it your understanding that the intent is to try to identify comparable licenses? Correct?

A. In Georgia-Pacific 2, it is comparable licenses entered into by the licensee, as my memory goes.

Q. This was something you referred to as using other data, similar to what you referred to as the real estate circumstance. Correct?

Page 850

A. I did this analysis as part of my market approach, which was part of my quantitative analysis.

Q. Would you agree with me, if we were doing a market approach with respect to real estate, that you wouldn't want to use the price for a mansion to determine the price for a fixer-upper?

A. Probably not, although one might consider that. But it probably would be discarded if there was a huge disparity between those two pieces of property.

Q. And you agree that the hypothetical license in this case would involve only the '363 patent. Right?

A. Yes.

Q. It doesn't include any other patents?

A. Correct.

Q. It wouldn't include any know-how?

A. Correct.

Q. And know-how is unpatented technology that's nonetheless valuable to another party?

A. Yes, it can be.

Q. And it wouldn't include any manufacturing assistance?

A. That's correct.

Q. Wouldn't include any other services from Elan. Correct?

A. That's correct. These are all things that I spoke about on direct. I agree with that.

Page 851

Q. You agree that all things being equal, the transfer of a larger bundle of intellectual property rights would command a higher price than the transfer of a smaller bundle of intellectual property rights. Correct?
A. Yes. That's why I have one of the factors as a downward arrow, favoring Abraxis.
Q. And the Elan portfolio includes a complete, the complete Elan nano-technology portfolio. Correct?
A. I think it's technically called the NanoCrystal technology. But most of the licenses, if not all, include the entire portfolio, patents and patent applications.
Q. That is more patents than just the '363 patent. And foreign patents -- can I have the answer?
A. I am sorry. I was just waiting for your question. I had heard you make a statement.
Q. Let me ask it again. That's more patents than just the '363 patent. Correct?
A. Yes.
Q. And continuations in part, or other children patents. Correct?
A. Yes. Although I am not sure I have heard the term children patents, I think I know what you are referring to.
Q. It would include the know-how that is transferred. Correct?
A. Yes. Many of the licenses do.

Page 852

Q. The licenses often include manufacturing assistance. Correct?
A. Certainly some of them do. I don't recall if it is a majority.
Q. And certainly formulation assistance. Correct?
A. Some of them do, yes.
Q. You didn't limit yourself to licenses that involved the '363 patent. Correct?
A. Correct, there were no licenses that involved just the '363 patent.
Q. You didn't limit yourself to those licenses which specifically identified the '363 patent in those terms. Correct?
A. That's correct. I looked broader.
Q. If I could have Slide F008. I put up on the board a series of licenses between Elan and others that specifically identify the '363 patent. Do you recognize these as licenses that you reviewed?
A. I have not seen this chart before. It's something that I created. The licensee names all appear to be licensees of Elan. I don't know for sure whether the dates are correct and the other information. But based on my very brief look, which is in the last 60 seconds, it appears to be correct in the first column.
Q. It's correct is that these licenses include patents

Page 853

other than the '363 patent?
A. The licenses that Elan has entered include patents beyond the '363, yes.
Q. And they include this other technology or know-how. Correct?
A. They often do. And these, I don't have reason to dispute your representation is correct that these all do.
Q. Isn't it correct that none of these licenses that I have listed here have resulted in a commercial product?
A. I think that's right. I believe that's right, yes.
Q. And I have listed --
A. Although you will see all of them were entered 2003 or later. So I am not sure that it will always be the case that there was no commercial product. I believe probably work is being done as we speak at a number of these licensees. These are not old licenses. These are relatively new or modern licenses.
Q. Certainly none of those have resulted in a commercial product to date. Correct?
A. I believe that's correct, yes, not yet.
Q. Do you have any reason to disagree with the fact that the median of those license agreements is three percent?
A. I am not quite sure how you are computing the median. Let me just ask so I can answer your question.
For the EntreMed, are you considering that two

Page 854

separate observations, the six and the eight percent for Sanofi patents, is that separate, or are you averaging or median-ing thing those? I don't know how you have done this calculation precisely.
Q. If you look at every observation on the right-hand column, is it correct that if you count every observation, the median royalty rate is three percent?
A. You will have to give me a minute if you want me to do the calculation, because I haven't seen this before. Just give me one minute to do it.
(Pause.)
So we are in agreement, I think there are 22 observations. Is that right?
Q. I didn't do a count right now, sir, but that seems about right.
A. How should I handle the five to seven percent? Should I handle that as five, or seven or something else?
Q. Why don't you handle them as two observations?
A. So that is 23 observations then, is that what you are asking?
Q. That's right.
A. Okay.
(Pause.)
Yes, that appears to be the case.
Q. You put some significance when you did your analysis

Page 855

on whether or not a license agreement included a commercialized product, didn't you?
A. Yes.
Q. So I would like to show you Slide F10, please. Elan has five licenses that have resulted in currently FDA approved products. Isn't that right?
A. Ignores that's right, although it's four separate products. TriCor is with Fournier and Abbott. It's four products, five licensees.
Q. And each of these licenses with these companies includes other patents and technology beyond the '363 patent. Correct?
A. I believe that's correct, yes.
Q. They include other know-how. Correct?
A. I believe that's correct, yes.
Q. And I have again listed the running royalty rate at the right-hand side for these patents, or these license agreements. Do you see that?
A. Yes, I see that column.
Q. Do you agree with me that the median of those observations, if you take each one, is 3.5 percent?
A. You will have to give me a minute if you want me to compute that.
(Pause.)
Again, the 2 to 2.35, am I treating that as two

Page 856

observations?
Q. Why don't you.
A. Okay.
(Pause.)
I think so, but I am a little less confident because I have done it a little more quickly. Just give me one moment.
Yes, I believe 3.5 is correct. Remember, however, all the previous pages and this page, these were all in a world in which there was uncertainty associated with the strength of the patent rights, and remember the academic study says you should consider a rate to be twice as high as what one sees in real licenses.
Q. Mr. Jarosz, you had an opportunity to talk to people at Elan about their licenses before you formed your opinion. Correct?
A. Yes.
Q. And isn't it correct that at the time you formed your opinion, you did not understand Megace to be an anticancer drug? Is that right?
A. You are saying before I came to my opinion? Is that what you are asking?
Q. At the time you came to your opinion in the fall of last year. Is that correct?
A. I just don't remember. I don't have reason to dispute

Page 857

it, but I don't remember sitting here right now.
Q. Do you agree that the Green Cross license deals solely with sales of Abraxane in Korea?
A. Actually, technically it's South Korea.
Q. Otherwise, you agree with the statement?
A. Yes, I think I spoke of that earlier, an exclusive license to cell in South Korea.
Q. You agree that the Taiho agreement is exclusively or solely about sales in Japan. Correct?
A. I believe that's correct, yes.
Q. And is it your understanding, under the AstraZeneca agreement between AstraZeneca and Abraxis, that Abraxis owes certain responsibilities to AstraZeneca going forward?
A. In order to earn the 108-million-dollar milestone payments, yes. But not with regard to the 200-million-dollar up-front payment.
Q. Do you understand whether the contract provides certain obligations from Abraxis to AstraZeneca that are ongoing?
A. Yes.
Q. I would like to turn to the income approach. Isn't it correct that you previously evaluated Abraxis's profitability, at least in part, based on their actual financial results?
A. Yes. That's why you saw on the summary chart I had

Page 858

before, I had three observations under the income approach, the lowest one was associated with the actual financial performance.
Q. When you looked at the actual financial performance of Abraxane, you identified a royalty rate of between 1.7 and 2.3 percent.
A. That sounds right, although I will look at my report to confirm that if you would like me to.
Q. That's okay. I don't think I need you to.
You have identified a hypothetical profitability rate of 32 percent. Correct?
A. That's my projection as to what the long-term operating profits will be for Abraxane, 32.3 percent.
Q. That is not anywhere near what Abraxis's actual profitability has been from February of 2005 to March of 2008. Correct?
A. I don't know that I have the data to say for sure what the profits have been. But as I spoke of before, there has been negative profit performance. So 32.3 percent is certainly higher than negative profit performance.
Q. Isn't it the case that you have the certified financial reports of the company?
A. I have the 10-K's from the company.
Q. Which are certified by the officers. Correct?
A. As I understand it, yes.

Page 859

Q. And audited by the independent auditors. Correct?
A. Yes, although I don't think they report Abraxane profits.
Q. And isn't -- well, they report the profits of Abraxis. Corrects?
A. They reports the profits of the company but not of that product.
Q. Isn't it correct that Abraxane is currently the only product being sold by Abraxis?
A. It certainly is the bulk, it's at least 85 percent.
Q. And isn't it the case, sir, that Abraxis's losses during the period from January 2005 to March 2008 have been over 208 million dollars?
A. I don't recall the exact number. But there certainly have been losses, many of those associated with merger-related activities, some of those associated with operating activities.
Q. Isn't it the case in a supplemental report, March 23rd in this case, you provided a calculation that for that period Abraxis had lost 208 million dollars?
A. If you want I will turn to it. I don't think it was March I submitted a report. I think it was May.
Q. I meant to say May, if I said March.
A. You may have. If I misheard you, I apologize.
Do you want me to look at that report?

Page 860

Q. Why don't we bring it up on the screen. Supplemental Tab 4. If you will look in the total there, where there is income from operations here at the left, do you see that?
A. Yes, I do.
Q. It's for the period 2005 through March 31st, 2008. Correct?
A. Yes, for the company, not for the product, and it includes merger-related costs. I think you covered them up. I don't know if that was accidentally or not. But you see the merger-related costs that are about 180 million dollars of that.
Q. But the amount of the loss that you calculated from the SEC reports is 208 million dollars. Correct?
A. Yes. That's the amount. But again, about 170, 180 million of that is associated with merger-related activity.
Q. And your calculation of the loss as a percentage is 28 percent, correct, of revenue?
A. Yes. That's right. Again, including the merger-related costs.
Q. Compared to your 32-percent profit number. Correct?
A. I don't know what you mean by "compared with." I have an estimate over a long run of 32.3 percent operating profit for Abraxane.
MR. OLSON: No more questions, Your Honor.
THE COURT: All right. Do you have any

Page 861

questions?
MR. SCHEVE: None, Your Honor.
THE COURT: Thank you, Mr. Jarosz. You are excused.
(Witness excused.)
THE COURT: That's pretty good timing, ladies and gentlemen. Let's take our lunch break.
(Jury leaves courtroom at 12:58 p.m.)
THE COURT: We will take care of the exhibit issue. Get together with Ms. Walker.
(Luncheon recess taken.)
THE COURT: All right. Ms. Walker.
(Jury enters courtroom 2:04 p.m.)
THE COURT: All right, ladies and gentlemen. If you would take your seats.
Mr. Scheve.
MR. SCHEVE: With some regret, I would request the ability to show the deposition of Dr. Raj Selvaraj to the jury, Your Honor.
THE COURT: How long? Hopefully you will give a better estimate than you did last time.
MR. SCHEVE: The technician says 30:08 seconds.
MR. JACOBS: To complete the story, we have like two or three minutes of counter-designations.
"Question: And how would you like me to address

Page 862

you today?
"Answer: Ulagaraj Selvaraj, Ph.D.
"Question: And are you still a senior manager in the biopharmaceutical technology group at Abraxis?
"Answer: Yes, sir.
"Question: Where did you go to school?
"Answer: I went to school in Indiana.
"Question: Did you get what we call an undergraduate degree in Indiana?
"Answer: Undergraduate, Master's, and Ph.D. in India.
"Question: What was your undergraduate degree in?
"Answer: Chemistry.
"Question: Any particular discipline of chemistry?
"Answer: It was like general chemistry, physics, mathematics.
"Question: When was the first time that you began research with the application of nanotechnology to paclitaxel?
"Answer: That is in Abraxis Bioscience.
"Question: Have you reviewed the patents that are at issue in this lawsuit?
"Answer: Can you tell me what are the patents?

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

- - -

| | | |
|---|---|---|
| ELAN PHARMA INTERNATIONAL LIMITED, | : | Civil Action |
| Plaintiff, | : | |
| v. | : | |
| ABRAXIS BIOSCIENCE INC., | : | |
| Defendant. | : | No. 06-438-GMS |

- - -

Wilmington, Delaware
Wednesday, June 11, 2008
9:40 a.m.
EIGHTH DAY OF TRIAL

- - -

BEFORE: HONORABLE GREGORY M. SLEET, Chief Judge, and a Jury

APPEARANCES:

JOHN G. DAY, ESQ.
Ashby & Geddes
-and-
STEPHEN SCHEVE, ESQ.,
LINDA M. GLOVER, ESQ.,
JEFFREY SULLIVAN, ESQ.,
LISA A. CHIARINI, ESQ.,
ROBERT RIDDLE, ESQ., and
PAUL FEHLNER, ESQ.
Baker Botts LLP
(Houston, TX)
-and-
GREGORY BOKAR, ESQ.
Counsel - Elan Drug Delivery

Counsel for Plaintiff

APPEARANCES CONTINUED:

ELENA C. NORMAN, ESQ., and
MICHELLE SHERETTA BUDICAK, ESQ.
Young Conaway Stargatt & Taylor, LLP
-and-
MICHAEL A. JACOBS, ESQ.,
EMILY A. EVANS, ESQ.,
ERIC S. WALTERS, ESQ.,
DIANA KRUZE, ESQ., and
ERIK J. OLSON, ESQ.
Morrison & Foerster
(San Francisco, CA)

Counsel for Defendant

- - -

THE COURT: Good morning. Please take your seats.

We will take the JMOLs first. Other than to -- I will indicate that I have had a chance to, albeit an abbreviated opportunity to review your various positions, I have considered them. Contrary to what I announced yesterday, I will act on at least a couple of things on each side.

Largely, for the reasons articulated in various submissions, I'm not going to have time to prepare a more articulate analysis than that. I will tell you that I am going to do the following.

As to plaintiff's various JMOLs -- and I gather counsel will recognize that I am not interested in hearing argument. This is, I think, a housekeeping matter more than



anything, that Abraxis in one of its headings at Page 8 of its motion, points out that Abraxis has failed to put on certain evidence to support certain defenses. I don't think this is contested. If it is -- well, we'll see.

Obviousness, obvious type double patenting, indefiniteness, I think are the three. I think you would concede those, wouldn't you?

MR. JACOBS: Yes, Your Honor.

THE COURT: Okay. So those are out. In other words, the motion is granted.

The Court agrees with Elan that the reverse doctrine of equivalents is not supported by the law and the facts of record in this case. The Court agrees with Elan that Abraxis's defense of unclean hands is not properly submitted to the jury in this case.

Unless you can tell me why I should not so find, Mr. Jacobs, I don't see any other basis for this jury, any other damage theory for this jury to consider other than that which has been offered by Elan.

MR. JACOBS: On the theory, we agree, Your Honor.

THE COURT: So that's granted. Those are all granted.

The others are denied. Not reserved. Denied. Of course, they can be raised again.



I am going to agree, Mr. Scheve, with Mr. Jacobs that Abraxane does not infringe under the doctrine of equivalents, nor has Abraxis induced infringement or contributorily infringed. I have already decided on the reverse doctrine of equivalents issue in Elan's favor.

The remaining motions are denied.

That's JMOLs.

Any questions about any of those rulings? Do we understand where we are?

MR. SCHEVE: I am putting that question to my co-counsel, Your Honor, just to make sure that I caught it correctly.

MR. SULLIVAN: Your Honor, I have advised Mr. Scheve, and I hope correctly, that Elan will not be permitted to put on a case of doctrine of equivalents infringement.

THE COURT: That's right.

MR. SULLIVAN: Thank you, sir.

THE COURT: All right. All right. Let's take a few moments and go through these remaining disputes on the parties' proposed final general instructions.

So the first one I have is at Page 9. The parties and their contentions. I see that Abraxis objects to the bracketed language as unnecessary, argumentative, redundant, confusing.



MR. JACOBS: Your Honor, we resolved that, we think.

THE COURT: Fine.

MR. JACOBS: That is what I am told.

THE COURT: That language is going to remain?

MR. WALTERS: I apologize, Your Honor. This is an agreement reached just as we walked in the door. We have substitute language for that instruction that the parties have agreed on.

THE COURT: I would like to see it.

MR. WALTERS: It was in one of your packets. It may not have made it up there. I apologize for that.

THE COURT: It's not in any of the packets I have. I mean, I have got enough packets that it's an amazing thing that I think I have come out with the right materials. So if you want to give me the language, I will look at it.

I think in the fourth line, there is a typo issue to be referred to as paclitaxel or taxol, not "a."

As best I can tell, the change from the version that I have is in the last sentence. The version I have been provided just a moment ago reads, the last sentence, the case also involves certain questions regarding the validity and enforceability of Elan's '363 and '025 patents.

The version submitted this morning earlier

it has windows.
(Recess taken.)
(The following took place at sidebar.)
THE COURT: Ms. Walker reports that it's going to be about another hour. I don't understand that. But it is what it is.
So I am going to have Ms. Walker advise the jury, we have ordered their lunch, we have their orders, we haven't placed it yet. We will have it delivered at 11:30. I am going to tell the jury in the meantime they can go about whatever they want to do and come back at around 11:30, and hopefully we will be ready to instruct them by noon.
So you, ladies and gentlemen, should get some food, because we are going to go straight through after that.
MR. SCHEVE: Your Honor, just so I am perfectly clear and don't inject any error into my closing, when you said that contributory and inducing was out, is that out both on the literal and DOE.
THE COURT: Yes. Let me also remind you my preference, and I think the appellate courts prefer this as well, I know that counsel are loathe to interrupt during closing speeches. I prefer you do, so that we can correct any error that you perceive to be injected into the case



improper closing and if necessary I can give a curative instruction at that time.
I don't know how you practice, Mr. Jacobs, Mr. Scheve.
MR. SCHEVE: I am real loathe to do something that the jury would get upset about.
THE COURT: I will leave it to you. Judges don't want to micromanage these kinds of cases.
MR. SCHEVE: Would you prefer we ask for a sidebar?
THE COURT: Yes; Judge, may we see you at sidebar.
MR. JACOBS: If we can get a sense of ground rules. Is it okay to put the instructions on the Elmo and walk the jury through them?
THE COURT: I have no difficulty with that.
This is what I will have already told the jury. This is one of the reasons I instruct first. There is no issue about what the jury has been told is the law.
MR. JACOBS: Otherwise, of course, it's argument, and we can argue from the evidence.
THE COURT: Absolutely. To the extent there is some passing in the night, as we alluded to earlier, it may happen. We will do the best we can. It is an imperfect system, but for the most part, it works.



(End of sidebar conference.)
(Recess taken.)
THE COURT: All right. Take your seats. I understand there is one more issue. Mr. Scheve, what is it?
MR. SCHEVE: Your Honor, I raised with Mr. Jacobs, Your Honor granted the motion on the damages theory. I suggested to him that it seemed to me the only question, then, for the jury, if there is a jury question, is where between six and eight percent. Mr. Jacobs thought that maybe the ruling was different than that and suggested that we speak with you about that.
THE COURT: I think what I intended to convey in my ruling was that there is evidence from only one side on the issue of damages.
MR. JACOBS: Your Honor, when you came out and said -- there are two things here, what did I agree to and, two, what is your ruling.
When you came out and asked me if I agreed that there is only one theory of damages, I said, yes, there is only one theory.
THE COURT: There is only one set of numbers.
MR. JACOBS: Well, I think the jury doesn't have to accept because, for example, he was cross-examined on this, the jury doesn't have to accept the Elan quantification of the reasonable royalty. For example, if



the jury were to discredit Dr. Jarosz' testimony --
THE COURT: They would be free to do that.
MR. JACOBS: -- because he decided that a hundred percent of the value was associated with the Elan patents --
THE COURT: They could do that.
MR. JACOBS: Then they could go well below six or eight percent. So that the jury still has a jury question as to amount. I agree that there is only one theory of damages.
THE COURT: Mr. Scheve?
MR. SCHEVE: I would only suggest, Your Honor, if he is going to argue that there ought to be some different combination of numbers or percentages, there has been no affirmative evidence by Abraxis and, therefore, they would be arguing from something that is not in the record. So rather than disrupt his closing, I thought it would be appropriate to raise that.
THE COURT: Well, I guess Mr. Jacobs is arguing that he was able to achieve certain responses to questions asked during cross, and that those answers, as evidence, would support an argument of some type. I am just hypothesizing.
Would you disagree that if a witness in response to a question, albeit posed on cross, the question resulted

in the adducement of evidence, that that would not be appropriate?

MR. SCHEVE: Certainly, the jury is free, Your Honor, with any witness to disregard their testimony. But if in any sort of alternative, you ought to come with three percent for this reason and that reason, there is no evidence in this record upon which to suggest a different theory.

THE COURT: Let's talk about that then.

Mr. Jacobs.

MR. JACOBS: Two points. First, they put in Mr. Musika's calculation of one percent. I think I can cut through this, Your Honor. I don't intend to argue in my closing for an alternative quantification of damages.

MR. SCHEVE: I think we have resolved the dispute, Judge.

THE COURT: That's great.

Ms. Walker, you can bring the jury back.

Mr. Sullivan, compliments to you in getting these in shape.

MR. SULLIVAN: Thank you, Your Honor. And. Mrs. Walters as well.

(Jury enters courtroom at 12:27 p.m.)

THE COURT: Ladies and gentlemen, please take your seats. The time has arrived, and the Court on behalf



of the parties wishes to extend its gratitude to you for your patience.

These are best estimates sometimes we make with regard to time. Please believe me, that was our best estimate, 10:00. I apologize for any inconvenience, and there has been a tremendous inconvenience. Jury service is a, I guess, probably by some called an inconvenience. It is a duty. We deeply appreciate your assiduous attention to your duty and your indulgence.

You each have a copy of the instructions and the verdict form.

Ladies and gentlemen, now it's time for me to instruct you about the law that you must follow in deciding this case.

If you read along, you are free to do that, but it is probably just as easy for you to just watch me or to listen. But feel free, if you are more comfortable reading along. You may see from time to time a small deviation from the literal language, as just now, of the instructions, but hopefully I will not deviate in any material aspect.

I will start by reminding you about your duties as jurors and instructions you heard at the beginning of the case. I will then explain the positions of the parties and the law that you will apply in this case.

Last, I will explain the rules that you must



follow during your deliberations in the jury room, and the possible verdicts that you return.

I expect that both sides are going to talk about the verdict form that you have been provided. I am probably, therefore, not going to spend a lot of time on that. I think it is pretty self-explanatory, in any event.

Please listen carefully to everything that I have to say.

Ladies and gentlemen, remember your duties as jurors, as I explained them to you at the beginning of the case. You must decide what the facts are from the evidence you saw and heard here in this courtroom. Nothing I have said or will say should influence your determination of the facts in any way. Do not guess or speculate and do not be influenced in any way by any personal feeling of sympathy for, or prejudice against, either side in this case. All parties are entitled to the same fair and impartial consideration.

You must take the principles of law that I will now explain to you and apply them to the facts in reaching your verdict, the facts that you find.

You are bound by the oath you took to follow my instructions, even if you personally disagree with them. All of my instructions are important, including the ones that I from time to time gave you during the course of the



trial, and the preliminary instructions. You should consider them together as a whole.

I will not repeat my earlier instructions about evidence and how to weigh and consider it. You have copies of these instructions. Again, you may feel free to reference them as you need to.

Perform these duties fairly. Do not let any bias, sympathy, or prejudice that you may feel toward one side or the other influence your decision in any way.

As you know, this is a civil case in which the plaintiff, Elan, is accusing the defendant, Abraxis, of patent infringement. Elan alleges that Abraxis has infringed the asserted claims of the '363 patent. Elan has the burden of proving its allegations of patent infringement and its alleged damages by what is known as a preponderance of the evidence. That means Elan must produce evidence that, when considered in light of all the facts, leads you to believe that what Elan claims is more likely true than not.

To put it differently, if you were to put Elan's and Abraxis's evidence on opposite sides of a scale, the evidence supporting Elan's claims would have to make the scales tip somewhat to its side.

Elan also alleges that Abraxis's alleged infringement was willful. Elan must prove its claim of

Page 1691

the facts," and that offended you, please hold me responsible. Don't hold my client responsible. If I offended you in any way, I apologize for that.

This case can really be boiled down to two issues. I am going to get to what the evidence is. At the risk of going over territory you have already heard, let's just go over a few of the slides that I showed you during opening to sort of give us some bearing on what the evidence shows in this case.

You have heard about this compound called Taxol. It contains this drug that was originally derived from a yew tree. When I sit down this weekend to talk with my friends, among the things I am going to say is I met Sam Danishefsky. If there wasn't Sam Danishefsky, there wouldn't be an Abraxane. There wouldn't be the nanoparticulate formulations of paclitaxel. And we all got to meet him in this case.

He was the person who was able to synthesize this so that they could make paclitaxel, not kill all those yew trees up in the Northwest. And that allowed for the development of different formulations. The original formulation, called Taxol, which is made by Bristol Myers Squibb, is toxic, as you have heard in this case, because it contains solvents. Cremophor is a very, very toxic solvent. It is made from castor beans. It is actually more toxic

Page 1692

than Taxol itself. It requires premedication with antihistamines, and it limits the maximum-tolerated dose.

Nanoparticles, you have heard testimony, why are they beneficial when smaller means more exposed surface area? More exposed surface area means better dissolution rate. Better dissolution rate means we hope that you are going to get more of the chemical or drug into your system so that it can do what's hoped for.

What was Elan's solution? What was Dr. Liversidge's and Dr. Liversidge's solution? Reduce particle size, the stabilizer adsorbed onto the surface of the particle, to prevent clumping. We showed you an example, when we poured that stuff in the water and that stuff clumped up, that's what poorly soluble molecules do.

The hope was here that they could separate these particles in such a way that there wouldn't have to be these terrible solvents which create all sorts of problems and require premedication.

The proteins are adsorbed onto the surface of the crystalline medicament, and they function in two different ways. One is through electrical charges, and others, as Dr. Liversidge described, is sort of failing arms prevent these particles from coming together and clumping.

Adsorbed, what does it mean? It means physical contact with the surface. No penetration of the surface and

Page 1693

no chemical reaction.

Who were the people behind this? Dr. Gary Liversidge, Dr. Elaine Liversidge, you have heard about their accomplishments. Dr. Liversidge told you the thing that means the most to him is every day 1.5 million people take a compound that contains one of his inventions.

The invention claimed are particles. It's very important, ladies and gentlemen, that when you go back to do your deliberation you understand, we are not claiming that Abraxane as a product infringes. We are claiming that Abraxane contains particles and that those particles infringe.

You heard testimony in this case that there are 61 trillion particles in a bottle of Abraxane. 61 trillion is over 10,000 times the number of human beings living on this earth. And the question is, among those 61 trillion, are there more than one particle -- are there particles that embody the invention of the '363 patent and therefore infringe it?

So it's particles consisting essentially of crystalline medicament and a surface modifier essentially free of intermolecular cross-linkages. And as Judge Sleet has instructed you, the first question is below 1,000 nanometers, and the other claim is below 300 nanometers in size.

Page 1694

Now, there is a problem with putting nanoparticles in the human body, because bodies react to it. It's called an anaphylactic reaction. It can be deadly, as you heard testimony about.

My clients also patented the '025 patent, which was a method of intravenous administration to a mammal within a certain period of time, according to a certain formula for administration. My client is not before you claiming that Abraxis infringed that patent. Nonetheless, Abraxis wants you to declare this patent to be invalid.

It's not unusual in patent cases, if you have been accused of infringement, to have as an immediate response, well, your patent is no good. Therefore, I shouldn't be held liable.

When you checked in this building, you probably were asked to check your cellphone. But you weren't asked to check your common sense. As we go through and I go through the evidence with you, I am going to ask you to draw on your common sense, your common experiences in life, look at this evidence. I am going to ask you to put up experts side by side and witnesses side by side. Use your common sense, draw inferences, and reach the conclusions that we believe the evidence shows.

You will be happy to know that I am then going to go to materials up on the screen and get rid of these

Berkland tells you, it's not outcome-determinative, it is suggestive of crystallinity.

Let's go to the next studies.

Solid state NMR. This is the only picture of a car I could find on the Internet last night. If I wanted to find if there is something in that car, a nut or bolt, that infringes -- again, we are not looking at Abraxane as a product. We are saying, is there something in it that was incorporated that infringes the '363 patent? I am not going to be able to determine if those bolts infringe from just looking at the exterior of this. I recognize that inside of this there is an engine. If I look at the engine, pull it out, I am still not going to be able to see all of the parts. The only way to begin to see all of the parts is to take it apart, get it down to every little nut, bolt, screw. And if I want to find out if a couple of those pieces infringe, I am going to have to get down to that level. And that's what the solid state NMR testing was that you heard testimony about at some length in this case.

You heard from Dr. Eric Munson, in Who's Who of ssNMR on that list. He spent his entire carrier doing this. He was recently invited to the FDA to consult on solid state NMR. You heard Dr. Brittain's video say Professor Munson is one of the most qualified scientists I know of to perform solid state nuclear magnetic resonance spectrometry work.



This is his research specialty.

And even the expert for Abraxis said, Dr. Munson did that experiment. I am quite happy with his experiment. I have found no fault with his experiment.

You will recall that Dr. Atwood actually wrote a letter of recommendation when Dr. Munson was up for full professorship at the Pharmaceutical Sciences School when he was on the faculty. What did Dr. Munson teach us? He taught us that this NMR machine -- this is his actual machine in his laboratory in Lawrence, Kansas. It's a huge magnet. And he likened it to the huge magnet that's in an MRI machine. If you have ever been in an MRI machine, it is not a pleasant experience, loud, pinging sounds. But it's a huge magnet that is realigning atoms within your body, and then there is some resonance that's put to it, and it measures all of that. It is the same technology. And he further described to you it's like the advance from the old x-rays. When I was a kid, every time I went to the doctor, I don't care if I had a sore toe, they would take an x-ray of something on my body. This is a much more precise technology, entirely different, where you are looking at the atomic level, and using it to determine what are the constituent parts. What is the makeup of the molecules or the atoms within a certain substance?

Let's see here what's in the published



literature about it. As early as 1991, the ultimate characterization of a pharmaceutical material concerns the chemical environment of each atom in the compound. Again, looking at it at an atomic level. Not just taking a picture looking at the surface, but looking at the atomic level.

This information is best obtained through the use of nuclear magnetic resonance spectroscopy. With recent advances in instrumentation and computer pulse sequences, these studies can now be carried out in the solid state.

This is what we have been talking about in this case, is solid state chemistry, not liquid chemistry.

So as early as 1991 -- and you saw Dr. Munson, fairly young man. If you line this up, he has been doing this ever since this came to be recognized as the most sensitive method for characterizing the chemistry of solid materials, using it to determine if there is crystallinity.

So what happened?

You saw from the evidence that Abraxis itself separated the nanoparticles with something called a centrifuge, where you spin. What happens is the solids spin out and the liquid stays in there. Abraxis did it itself in its own experiments. They created what's called a pellet. The liquid goes to the top and the nanoparticles settle to the bottom.

What you also heard is, Abraxis has never tested



that pellet for its crystallinity. That's where the nanoparticles are, is in that pellet. We know that Dr. Berkland actually did the centrifuging for Dr. Munson's study. He did it at ten times less the centrifugal force that Abraxis uses to make sure they didn't mess up the particles, they didn't hurt their integrity.

You heard, then, that they got two different samples. They reconstituted it. They spun them. Got the nanoparticles, and then they had to dry them to make sure they didn't have some result that would be criticized because they dried it one way versus another, they dried it two ways. One was air-dried, one was freeze-dried.

Now, actually, you heard testimony from both sides about what happens when you get this data from ssNMR. Well, you have to go use a very sophisticated computer program. And it's called deconvolution. Because the question is, you get all these humps on these lines, what does it really mean? And we have created a little video here to illustrate the testimony that you heard in this case.

What has happened here is, these peaks could reflect two or more pieces of data. And what Dr. Munson found was that there was this third peak that was hidden in the data using this very sophisticated technique. When he subtracted out the other two, there was this unexplained

third, which the computer did analysis on, if I could go to the next slide, please. Dr. Munson -- this was the freeze-dried sample -- after he subtracted out these other two human beings, there was a third one there. Eight percent of the total paclitaxel within those vials of Abraxane are crystalline. Eight percent of the total. Very important number to remember. Eight percent of the total, because the issue here isn't in this case is there a certain percentage of the total. The question is are there nanoparticles, more than two, amongst 61 trillion, that are, as Judge Sleet has instructed you, that are themselves entirely crystalline. We know that eight percent of the total was crystalline, based on this definitive study. We know that in the air-dried sample, it was seven percent.

Dr. Munson testified to you that gave him some confidence that there wasn't any sort of artifacts or artifactual data that was being seen.

Single bottle of Abraxane contains over 60 trillion particles. If eight percent of those particles contain crystallinity, then over 4.8 trillion particles in a vial have a crystalline content.

If only four percent, then 2.4 trillion particles contain crystalline medicament.

The question that you have to decide, based on the evidence that you have seen here is, of those 60-plus



trillion particles, are there two or more that are particles wherein the paclitaxel is crystalline as has been construed for you by the Judge in the instructions you have been given?

Again, the law isn't, well, it doesn't infringe if it's just a few. Personally, I don't think 2.4 transitional is just a few. If it contains particles and they meet the claim limitation, then that's infringement. That's what the law is. The law allows my client and anybody else who has got a patent to seek to prevent others from using that invention. And we seek a license for the fact that, notwithstanding their best efforts, there are crystalline particles therein.

Now, Dr. Munson then offered the following opinions. Abraxane contains particles consisting essentially of 99 to 10 percent by weight of a crystalline medicament useful in treating cancer. Abraxane contains particles that meet the crystallinity claim limitation as defined by Judge Sleet.

What else do we know on this crystallinity issue?

We know that the starting material, starting paclitaxel is a white to off-white crystalline material. They start with crystals.

What else did we know? You heard Dr. Atwood,



their expert, comment on this. In the published literature since 1955, one of the most remarkable facts revealed by x-ray science is the extreme rarity of a truly amorphous state. The extreme rarity of a truly amorphous state.

You begin to add the evidence up. DSC, this is not a hundred-percent amorphous. It is the fingerprint. That testimony is not contradicted by anybody. Dr. Berkland looks at the cryo-TEM. He sees some angles and some edges. He says it's suggestive of crystallinity. We go to the definitive test, ssNMR. We know that eight percent of the total paclitaxel contained is crystalline. And Dr. Munson gave you his opinion, there are particles in there that meet the claim limitation.

Now, you heard evidence in this case about, well, wait a minute, there is this test called x-ray powder diffraction, and it shows that this is amorphous.

You saw this chart. When you go back to deliberate, I am going to ask you please to look at this real close, because the evidence really didn't focus on -- or I should say the testimony. These lines all look about the same. What's important is that you look at this scale. You remember during the testimony that this bottom line is crystalline paclitaxel, particles up to 500 microns. That is 3500 times bigger than the nanoparticles within Abraxane. 3500 times bigger.



The reason I say look at this scale, because the largest peak goes up to 7,000, just under 7,000.

You will also recall this lineup here. This is what their expert pointed to, Dr. Atwood, which was a physical mixture. They just took that raw paclitaxel, somewhere between 50 and 500 microns, up to 3500 times larger than the particles in Abraxane. And they just added albumin to it. That's all they did. They didn't reduce it in size. They just added albumin to it.

Look at the difference in the shape by just adding albumin to particles that big.

What we provide to you now is, if you chart these, no reduction in size, all you do is add albumin to these large particles. And look what happens to the line. Look at the difference in the scale. The highest peak here, when you look at it, is about 600. You remember, this one that went up to close to 6800. Look where the peak is here. Why? Why? What's the effect of albumin? What things affect x-ray powder diffraction?

Again, I am going to ask you to consider the testimony of the woman that I asked the Texas phrase to -- I shouldn't say that because I grew up someplace other than Texas. This was Katherine Melody. I said, Ms. Melody, you don't have a dog in this hunt, do you? She didn't know quite what I meant. I was trying to ask her, you are not