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2 **SANOFI-AVENTIS U.S. LLC, AVENTIS**  
**PHARMA S.A. and SANOFI,** 3:15-cv-02520-MAS-LHG  
3 **Plaintiffs,**  
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5 **-vs-**  
6 **ACCORD HEALTHCARE, INC.**  
7 **Defendant.**  
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9 **SANOFI-AVENTIS U.S. LLC, AVENTIS**  
**PHARMA S.A. and SANOFI** 3:14-cv-08081-MAS-LHG  
10 **Plaintiffs,**  
11 **-vs-**  
12 **BPI LABS, LLC and BELCHER**  
**PHARMACEUTICALS, LLC**  
13 **Defendants.**  
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15 **SANOFI-AVENTIS U.S. LLC, AVENTIS**  
**PHARMA S.A. and SANOFI** 3:15-cv-00287-MAS-LHG  
16 **Plaintiffs,** 3:15-cv-01835-MAS-LHG  
17 **-vs-**  
18 **APOTEX CORP. and APOTEX, INC.**  
19 **Defendants.**  
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*United States District Court  
Trenton, New Jersey*

1 **A P P E A R A N C E S cont'd** 4  
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Pharmaceuticals, LLC.  
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*United States District Court  
Trenton, New Jersey*

1 **SANOFI-AVENTIS U.S. LLC, AVENTIS** 3:15-cv-01863-MAS-LHG  
**PHARMA S.A. and SANOFI**  
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3 **Plaintiffs,**  
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5 **-vs-**  
6 **BRECKENRIDGE PHARMACEUTICAL, INC.**  
7 **Defendant.**  
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9 **SANOFI-AVENTIS U.S. LLC, AVENTIS** 3:15-cv-00290-MAS-LHG  
**PHARMA S.A. and SANOFI,** 3:15-cv-03392-MAS-LHG  
10 **Plaintiffs,**  
11 **-vs-**  
12 **MYLAN LABORATORIES LTD.**  
13 **Defendant.**  
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19 **B E F O R E:** HONORABLE MICHAEL A. SHIPP  
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1 THE DEPUTY COURT CLERK: All rise.  
 2 (Open court begins at 9:07 a.m.)  
 3 THE COURT: Please be seated. Good morning.  
 4 COUNSELS: Good morning, your Honor.  
 5 THE COURT: We are here today in the matter of  
 6 Sanofi-Aventis vs. Fresenius, et al, Docket Number 14-7869.  
 7 We're here today during the first part of the morning  
 8 for the tutorial, after which we will have a break, and then  
 9 we'll commence with the Markman hearing.  
 10 I'd like to do appearances. I've asked that only  
 11 those attorneys in the well enter their appearances. Everyone  
 12 else has signed in on the sign-in sheet. Your appearances  
 13 will be on the transcript and noted for the record.  
 14 So, with that being said, let me have counsel enter  
 15 their appearances.  
 16 MS. WALSH: Good morning, your Honor. Appearing on  
 17 behalf of Sanofi-Aventis, Liza Walsh and Katelyn O'Reilly from  
 18 Connell Foley. And I'm going to allow my co-counsel, William  
 19 Solander, and his associates, partners, I should say,  
 20 introduce themselves.  
 21 THE COURT: Good morning.  
 22 MR. SOLANDER: Good morning, your Honor. William  
 23 Solander, Fitzpatrick, Cella, Harper, and Scinto for Sanofi.  
 24 MR. LEONARD: Good morning, your Honor. Jason  
 25 Leonard from Fitzpatrick, Cella, Harper, and Scinto on behalf

*United States District Court  
 Trenton, New Jersey*

1 THE COURT: Good morning.  
 2 MR. JOHNSON: Good morning, your Honor. Michael  
 3 Johnson from Willkie, Farr, and Gallagher LLP on behalf of the  
 4 defendant Actavis LLC.  
 5 THE COURT: Good morning. Is that everybody?  
 6 With that being said, we're going to go ahead --  
 7 let's talk about just a few logistics here.  
 8 The way I'd like to do this morning, and hopefully we  
 9 can stick to the time schedule, what I'd like to do -- I'm  
 10 under the information that the tutorial is, roughly, one hour  
 11 and 15 minutes; is that correct?  
 12 MR. SOLANDER: It might be a little bit less than  
 13 that, your Honor, yes.  
 14 THE COURT: Less is always more in this context so...  
 15 9:15 until 10:30, I'd like to be done with the  
 16 tutorial by 10:30. After that, we'll take a 15 minute-break,  
 17 and I'd like to commence with the Markman hearing at 10:45.  
 18 We'll go from 10:45 until 12:45. We'll take a one-hour lunch,  
 19 from 12:45 to 1:45, and then we'll conclude with the back end  
 20 at 1:45 to 2:45, okay. And if we need to be a little fluid  
 21 with some of these times, if things move faster and quicker,  
 22 we can certainly do that, but going into this, that's kind of  
 23 the rough time sketch that I'm working with, okay.  
 24 Counsel.  
 25 MR. SOLANDER: Your Honor, I'm happy to start by

*United States District Court  
 Trenton, New Jersey*

1 of Sanofi.  
 2 MS. MEIER: Good morning, your Honor. Witney Meier  
 3 Fitzpatrick, Cella, Harper, and Scinto also on behalf of  
 4 Sanofi.  
 5 MS. GUHANIYOGI: Good morning, your Honor. Jayita  
 6 Guhaniyogi on behalf of Sanofi from Fitzpatrick, Cella.  
 7 THE COURT: Okay. Let me hear from defense.  
 8 MR. REED: Good morning, your Honor. Matthew Reed  
 9 from Wilson, Sonsini, Goodrich, and Rosati on behalf of the  
 10 defendant Mylan Laboratories Limited. And with me today are  
 11 my associate, Brei Gussack, and, of course, local counsel  
 12 Arnie Calmann of the Saiber law firm.  
 13 MR. CALMANN: Good morning, your Honor.  
 14 MR. WIESEN: Good morning, your Honor. Daryl Wiesen  
 15 from Goodwin Procter on behalf of Fresenius Kabi defendants.  
 16 With me is Mike Patunas from Patunas Law.  
 17 MR. PATUNAS: Good morning, your Honor.  
 18 MR. MUSGROVE: Good morning, your Honor. Kyle  
 19 Musgrove from Haynes and Boone for defendant Breckenridge  
 20 Pharmaceutical. My local Bob Fettweis is back in the well.  
 21 MR. ALUL: Good morning, your Honor. Andrew Alul  
 22 from Taft, Stettinius, and Hollister on behalf of defendants  
 23 Apotex Inc. and Apotex Corp. And with me is my colleague  
 24 Roger Kiley from Taft, Stettinius, and Hollister and my local

1 saying that we've agreed on how we're going to proceed in  
 2 terms of the order of things. We're going to do the tutorial  
 3 from the plaintiffs' perspective first, in its entirety, on  
 4 both of the subject matters of the patent. They will be split  
 5 between myself and Mr. Leonard on our side, and then the  
 6 defendants will give their tutorial in its entirety.  
 7 And then in terms of the argument, we plan to proceed  
 8 patent by patent. There's only really one term in one of the  
 9 patents so that will go first, and then we'll proceed to the  
 10 second patent and we'll go term by term through it.  
 11 So I'll speak on behalf of the plaintiffs for one  
 12 term, and then the defendants will go on the same term and  
 13 proceed that way. And I suspect the arguments will get  
 14 shorter and shorter as we go because the terms are simpler.  
 15 So, your Honor, for our tutorial this morning, I plan  
 16 first to talk a little bit about the product that's at issue  
 17 and then the technology, in general, that this product is a  
 18 member of, the taxane class of drug products, and then I'll  
 19 talk a little bit about the patents-in suit, and then we'll  
 20 talk about the specific technologies in each of the patents,  
 21 the acetone solvate patent, which is the first of the  
 22 technology which will be covered by Mr. Leonard, and then the  
 23 treatment of prostate cancer, which I'll come back and talk  
 24 about at the end.

1 in fact. Okay. Your Honor, so this is the last of the series  
2 of patents in time that Sanofi obtained regarding the  
3 cabazitaxel development project, and there are a number of  
4 disputed terms. The parties have agreed how these are going  
5 to be broken up. There's a preliminary question. The first  
6 question is whether or not the preambles should be  
7 limitations. And then there are two subsidiary questions that  
8 are if they are limitations, what do they mean? The next term  
9 is the term "administering," what does that mean? And then  
10 two related terms down at the bottom "where the cabazitaxel is  
11 in the form of an acetone solvate" and "wherein the  
12 cabazitaxel is in base form." We're going to go sort of back  
13 and forth on each one of these, and I'll start with what I  
14 consider to be a preliminary question of whether or not the  
15 preambles of the claims are limiting.

16 So, just to set the stage, let me discuss what a  
17 preamble is. So, a preamble -- your Honor, do you have these  
18 slides? I have color versions. And we're presently on slide  
19 302, which I think is the third slide in the deck.

20 THE COURT: Okay.

21 MR. SOLANDER: So, as I was saying, what is a  
22 preamble? Well, a preamble is the words of a claim that come  
23 before the term "comprising." Right there. And that term  
24 "comprising" is a claim term that's commonly used in patent  
25 drafting. There can be other terms, "consisting of,"

*United States District Court*

*Trenton, New Jersey*

1 particular limitation. If it is not a limitation we don't  
2 have to worry about proving infringement of it.

3 And the same is true for invalidity. If it is a  
4 limitation of a claim they have the burden under clear and  
5 convincing evidence to show that that limitation is taught by  
6 the prior art. And if it is not a limitation of the claim  
7 they do not have to show that that limitation is taught by the  
8 prior art. So, whether something is a limitation or not can  
9 be quite important in terms of how the trial is conducted and  
10 what things people have to be proving. So, the dispute here  
11 is whether "a method for treating" that's part of the preamble  
12 is a limitation, is part of the limitation of the entire  
13 preamble or is not. That's the dispute. We say, of course,  
14 that it is. They say that it is not.

15 So, let me just go the law. This is section 305.  
16 The case law says there's no litmus test that defines when a  
17 preamble is a limitation, when it limits the claim scope.  
18 That's black letter Federal Circuit law. But the Federal  
19 Circuit hasn't completely left us at sea. It has articulated  
20 in a number of decisions over the years that have been applied  
21 by many district courts a number of tests that one can look at  
22 to determine whether or not a preamble is limiting, and we  
23 have listed some of the pertinent ones that we'll be  
24 discussing here.

25 First, do the patentees repeatedly use the preambles

*United States District Court*

*Trenton, New Jersey*

1 "consisting essentially of." But, basically, most claims use  
2 the term "comprising." And what comes before that term is  
3 ordinarily considered the preamble, and that is shown in red  
4 up here on the board.

5 So, what is the dispute here? The dispute is  
6 highlighted on the next page. The parties agree that the  
7 portion in red starting with "a patient" and going down to  
8 "docetaxel" in both claims should be limitations of the claim.  
9 The parties disagree on whether "a method for treating" or "a  
10 method for increasing the survival of a patient" should be a  
11 limitation.

12 And let me explain what is a limitation of the claim.  
13 Let me use one that nobody disputes is a limitation. The word  
14 "cabazitaxel" that's found in the claim. What does that mean  
15 to be a limitation? It means in order to prove infringement  
16 we have to prove by a preponderance of the evidence that the  
17 defendants are using or selling cabazitaxel or telling doctors  
18 to administer cabazitaxel. We have to prove that. If they're  
19 selling some different drug -- and this isn't in dispute here,  
20 but if they were selling some different drug like Taxol or  
21 docetaxel they would not meet that limitation, and, therefore,  
22 they would not infringe the claims.

23 So, if it is a limitation, we have to prove that they  
24 infringed the claims by meeting that limitation, that whatever

1 to describe the invention in the specification or in the  
2 prosecution history? And I'll explain what that means, and  
3 I'll explain how it applies here in just a moment.

4 The second is did the patentees clearly rely on the  
5 preambles during prosecution to distinguish the claimed  
6 inventions from the prior art?

7 And the third one is do the limitations in the body  
8 of the claims rely upon and derive their antecedent basis from  
9 the preambles?

10 In our view, your Honor, all three of these tests are  
11 met by the disputed term "a method for treatment" or "a method  
12 for increasing the survival thereof," and, therefore, they  
13 should be considered limitations on the claim scope of these  
14 patents.

15 So, let me, if I could go through each one of those  
16 tests and show you the evidence, the intrinsic evidence that  
17 shows that we're right.

18 The first test is whether or not the applicants  
19 repeatedly used the preamble language to describe the  
20 fundamental characteristics of their invention. Your Honor, I  
21 have highlighted portions of the specification. This is the  
22 abstract. The invention relates to a "treatment of prostate  
23 cancer" here. Highlights that it is a method of treating  
24 prostate cancer, not a method of doing something else. That's

1 relates to" we'll see that in the case law; "invention  
2 relates" is the same as the "invention is." It is the same  
3 thing.

4 Next part of the specification now we're actually in  
5 the specification itself on columns 1 and 2. "The present  
6 invention relates to a treatment of prostate cancer." "The  
7 present invention," again, "relates to a treatment of prostate  
8 cancer in patients who have previously treated with a  
9 docetaxel-based regimen, an unmet need." So, here the  
10 specification is relating the method of treating to an unmet  
11 medical need. You don't solve an unmet medical need, unless  
12 you provide a method that treats, a method for treating a  
13 patient. That's the point. The whole point of this patent is  
14 they have identified the unmet medical need, as I discussed  
15 during the tutorial. These patients had nothing left after  
16 they were done with docetaxel, except to make them feel as  
17 comfortable as possible before they died. This gave them  
18 additional life. That was the unmet need. That is the  
19 treating -- that is what is being done to the patient. It is  
20 prolonging their life. It is treating them. That is what the  
21 claims mean. That is what they're talking about here in the  
22 specification.

23 And, again, meeting an unmet need requires an  
24 effective method for treating. Not an ineffective method, not  
25 an attempt to treat, it requires an effective method of

United States District Court

Trenton, New Jersey

1 exactly what is going on here.

2 So, let's look at the case law. This is the In Re:  
3 *Cruciferous* case. It is a very strange name for a case, but,  
4 nevertheless, it is a Federal Circuit case, and in that case  
5 they held that the term "rich in glucosinates" helps define  
6 the invention, and, therefore, the preamble was limiting. And  
7 what kind of language did they use in the specification in  
8 that case? Well, very similar language to what you just found  
9 on the slides that I just showed you. The invention relates  
10 to the production and consumption of foods which are "rich in  
11 cancer chemoprotective compounds." Those are the glucosinates  
12 at the bottom. An object of the invention is to provide foods  
13 and additives that are rich in cancer ...

14 And, so, the Federal Circuit says, the specification,  
15 therefore, indicates that the inventors believed their  
16 invention to be making food products which were rich in  
17 glucosinates, thus, the limitation was found -- the preamble  
18 language was found to be limiting.

19 Next case is the *Galderma* case, Your Honor. In this  
20 one the issue was the term "useful for the treatment of."  
21 Very similar to "method for treating." The Court found that  
22 it was a fundamental purpose of the invention to carry out --  
23 to carry out this treatment. And it further served to specify  
24 the therapeutic application of the method. And that's what we  
25 argue is happening here, Your Honor. The "method for

United States District Court

Trenton, New Jersey

1 treating.

2 Another part of the specification. "An aspect of the  
3 invention." So what does "an aspect of the invention" mean to  
4 a person reading a patent? What it means is I have an  
5 invention, I'm claiming different aspects of the invention.  
6 It is one invention, but I'm claiming different aspects of it.  
7 So I can claim a method for treatment, I can say a method for  
8 increasing the overall survival of it. One is a subset, if  
9 you will, of the former. But it is considered -- the language  
10 that people use is it is an aspect of the invention. So, the  
11 specification is talking about one aspect of the invention  
12 "comprises increasing the survival of a patient." Of course  
13 other aspects may lower the PSA, other aspects may improve the  
14 patients with respect to their tumor size. But this aspect of  
15 the invention "comprises increasing the survival of a patient"  
16 who "has previously been treated with a docetaxel-containing  
17 regimen" and the patent gives data regarding a "significant  
18 longer overall survival" and a 30 percent risk in the  
19 reduction of death.

20 So, again, the invention is being described by the  
21 applicants in the specification as actually reducing the risk  
22 of death and increasing overall survival, which in Claim 27 is  
23 the preamble language that we were asking to be a limitation.  
24 So, it meets the test. Repeated use of the preamble is to

1 treating" language in the claim is specifying that the claim  
2 must affect a therapeutic result. That's the point of the  
3 invention. That was the unmet medical need. So here the  
4 therapeutic application is the use of "the method for treating  
5 metastatic castration-resistant prostate cancer."

6 Last case on this subject, your Honor, the *Wyeth*  
7 case. The abstract says, well, here the language was in the  
8 preamble necessary -- I'm sorry. The recited property was "a  
9 ... formulation that 'provides better control of blood plasma  
10 levels than conventional tablet formulations ....'" That was  
11 the invention at issue in this case. And the term that was  
12 being construed in the preamble was a method for eliminating  
13 troughs and peaks of drug concentration in a patient's blood  
14 plasma. So, in other words, the invention that they made  
15 eliminated wide swings in the blood level of this drug. And  
16 that was contained in the preamble. So, that was the use or  
17 function of the invention that they created. And that was the  
18 method of treating in that case. That was what they were  
19 trying to achieve.

20 And the specification repeatedly emphasized that  
21 aspect of the invention, and that's what's shown up here. The  
22 invention states that "the invention is for a formulation that  
23 provides better control of blood plasma." The brief  
24 description of the invention explains "this invention provides

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