IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ZYMOGENETICS, INC., a Washington Corporation, Plaintiff, v. BRISTOL-MYERS SQUIBB CO., a Delaware Corporation, and DOES 1 through 100, Defendants.	)	C.A. No. 06-500-SLR **PUBLIC VERSION**

DECLARATION OF MEGHAN A. WHARTON IN SUPPORT OF ZYMOGENETICS, INC.'S OPPOSITION TO BRISTOL-MYERS SQUIBB CO.'S MOTION FOR SUMMARY JUDGMENT OF NO WILLFULNESS

Philip A. Rovner (#3215)
POTTER ANDERSON & CORROON LLP
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Attorneys for Plaintiff
ZymoGenetics, Inc.

OF COUNSEL:

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Lisa Kobialka
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(650) 590-0700

Dated: August 18, 2008
Public Version: August 25, 2008

I, MEGHAN WHARTON, declare:

1. I am an attorney with the law firm of King & Spalding LLP, counsel of record for Plaintiff ZymoGenetics, Inc. I have personal knowledge of the facts set forth in this declaration and can testify competently to those facts.

2. Attached hereto as Exhibit 1 is a true and correct copy of letter from Michael Kuran of ZymoGenetics, Inc. to Stephen McAndrew of Bristol-Myers Squibb Co. dated January 17, 2001, bearing Bates Nos. ZG 038157-59.

3. Attached hereto as Exhibit 2 is a true and correct copy of pages 1, 6-7 and 22 of Bristol-Myers Squibb Company's Supplemental Objections and Responses to ZymoGenetics, Inc.'s Interrogatories Nos. 3, 4, 9, 13, 14, 17 and 18 dated September 17, 2007.

4. Attached hereto as Exhibit 3 is a true and correct copy of pages 1 and 5-6 of Bristol-Myers Squibb Company's Objections and Responses to ZymoGenetics, Inc.'s Interrogatories Nos. (Nos. 15-16) dated April 16, 2007.

5. Attached hereto as Exhibit 4 is a true and correct copy of pages 1, 6 and 8 of ZymoGenetics, Inc.'s First Set of Interrogatories to Bristol-Myers Squibb Co. dated October 31, 2006.

6. Attached hereto as Exhibit 5 is a true and correct copy of excerpts from Bristol-Myers Squibb Company's Objections and Responses to ZymoGenetics, Inc.'s First Set of Interrogatories (Nos. 1-14) dated January 5, 2007.

7. Attached hereto as Exhibit 6 is a true and correct copy of pages 1-5, 18-25 and 42-45 of the transcript of the October 4, 2007 telephone conference before United States Magistrate Judge the Honorable Mary Pat Thynge.

8. Attached hereto as Exhibit 7 is a true and correct copy of pages 1-5 and 14-27 of the transcript of the November 8, 2007 telephone conference before United States Magistrate Judge the Honorable Mary Pat Thynge.

9. Attached hereto as Exhibit 8 is a true and correct copy of pages 1-5 and 130-33 of the transcript of the June 29, 2008 hearing before United States District Court Judge the Honorable Sue L. Robinson.

10. Attached hereto as Exhibit 9 is a true and correct copy of excerpts from the prosecution histories of ZymoGenetics' Patents Nos. 5,843,725 and 6,018,026 bearing Bates Nos. ZG000340-49, ZG000745, ZG001230-38 and ZG001646.

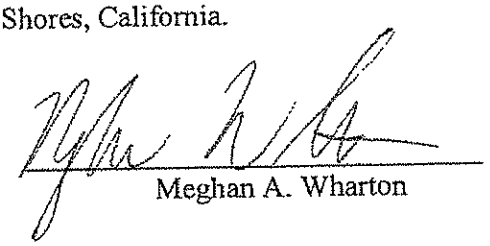
11. Attached hereto as Exhibit 10 is a true and correct copy of pages 71-72 from the transcript of the deposition of Dr. David E. Smolin taken July 18, 2007.

12. Attached hereto as Exhibit 11 is a true and correct copy of page 25 from Bristol-Myers Squibb Co.'s Form 10-K Annual Report for the fiscal year ended December 31, 2004.

13. Attached hereto as Exhibit 12 is a true and correct copy of a Bristol-Myers Squibb Co. document entitled "List of INDs and BLAs, BMS-188667" bearing Bates No. BMS004275246.

I declare under penalty of perjury under the laws of the State of California and the United States that each of the above statements is true and correct.

Executed on August 18, 2008 in Redwood Shores, California.



Meghan A. Wharton

EXHIBIT 1

THIS EXHIBIT HAS BEEN REDACTED IN ITS ENTIRETY

EXHIBIT 2

THIS EXHIBIT HAS BEEN REDACTED IN ITS ENTIRETY

EXHIBIT 3

THIS EXHIBIT HAS BEEN REDACTED IN ITS ENTIRETY

EXHIBIT 4

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ZYMOGENETICS, INC., a Washington Corporation,	)	
Plaintiff,	)	Civil Action No. 06-500-KAJ
v.	)	
BRISTOL-MYERS SQUIBB CO., a Delaware Corporation, and DOES 1 through 100,	)	
Defendants.	)	

ZYMOGENETICS, INC.'S
FIRST SET OF INTERROGATORIES TO BRISTOL-MYERS SQUIBB CO.

Pursuant to Fed. R. Civ. P. 33, ZymoGenetics, Inc. ("ZymoGenetics") requests that Bristol-Myers Squibb Co. ("Bristol") answer the following interrogatories in accordance with the following Definitions and Instructions within thirty (30) days after the service of these interrogatories. These interrogatories shall be deemed continuing, and Bristol shall serve promptly upon ZymoGenetics supplemental answers in accordance with Federal Rule of Civil Procedure 26(e) and the Local Rules of the District of Delaware as Bristol acquires additional knowledge or information relating to these interrogatories.

INTERROGATORY NO. 3:

Describe in detail when and under what circumstances you first became aware of the existence of each of the Patents-in-Suit or the applications that resulted in each of the Patents-in-Suit, what actions you took upon becoming aware of each of the Patents-in-Suit or applications, the identity of all persons with knowledge of such facts and circumstances, and the identity of all documents reflecting such facts and circumstances.

INTERROGATORY NO. 4:

Separately for each BRISTOL FUSION PROTEIN PRODUCT, identify each person who was involved in the development, design, manufacture, FDA approval, marketing, distribution, sale, or licensing of such product, and describe in detail the role that each such person played in the development, design, manufacture, FDA approval, marketing, distribution, sale, or licensing of the compound.

INTERROGATORY NO. 5:

Identify the date of first design and date of first production for each BRISTOL FUSION PROTEIN PRODUCT.

INTERROGATORY NO. 6:

Describe in detail the steps taken to construct the vector(s) for each BRISTOL FUSION PROTEIN PRODUCT.

INTERROGATORY NO. 7:

Describe in detail the steps taken to express the protein(s) comprising BRISTOL FUSION PROTEIN PRODUCT.

INTERROGATORY NO. 14:

Identify all persons having knowledge of the facts that support your contentions in your Answer and Counterclaims and, for each such person, state the entire factual basis for that person's knowledge.

POTTER ANDERSON & CORROON LLP

OF COUNSEL:

Paul J. Andre
Perkins Coie LLP
101 Jefferson Drive
Menlo Park, California 94025-1114
(650) 838-4300

By _____
Philip A. Rovner (#3215)
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Dated: October 31, 2006
759190

Attorneys for Plaintiff
ZymoGenetics, Inc.

EXHIBIT 5

THIS EXHIBIT HAS BEEN REDACTED IN ITS ENTIRETY

EXHIBIT 6

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

- - -

ZYMOGENETICS, INC., a Washington corporation,

Plaintiff,

v

BRISTOL-MYERS SQUIBB CO., a Delaware corporation, and DOES 1 THROUGH 100,

Defendants.

CIVIL ACTION

NO. 06-500 (***)

- - -

Wilmington, Delaware
Thursday, October 4, 2007 at 11:00 a.m.
TELEPHONE CONFERENCE

- - -

BEFORE: HONORABLE MARY PAT THYNGE, U.S. MAGISTRATE JUDGE

- - -

APPEARANCES:

POTTER ANDERSON & CORROON
BY: PHILIP A. ROVNER, ESQ.

and

PERKINS COIE, LLP
BY: PAUL J. ANDRE, ESQ.
(Menlo Park, California)

Counsel for Plaintiff

Brian P. Gaffigan
Registered Merit Reporter

APPEARANCES: (Continued)

RICHARDS, LAYTON & FINGER, P.A.
BY: FREDERICK L. COTTRELL, III, ESQ.

and

FITZPATRICK CELLA HARPER & SCINTO
BY: CHRISTOPHER P. BORELLO, ESQ., and
COLLEEN TRACY, ESQ.
(New York, New York)

Counsel for Defendants

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P R O C E E D I N G S

(REPORTER'S NOTE: The following telephone conference was held in chambers, beginning at 11:00 a.m.)

THE COURT: Good morning, this is Judge Thynge.

MR. COTTRELL: Good morning, Your Honor.

MR. ROVNER: Good morning, Your Honor.

THE COURT: Who do I have on the line for plaintiff, ZymoGenetics?

MR. ROVNER: Good morning, Your Honor. This is Phil Rovner, and with me on the line is Paul Andre from Perkins Coie.

MR. ANDRE: Good morning, Your Honor.

THE COURT: Good morning.

And who is on the line for Bristol-Myers?

MR. COTTRELL: Good morning, Your Honor. In Wilmington, Fred Cottrell; and my co-counsel from the Fitzpatrick firm are on, Colleen Tracy and Chris Borello.

THE COURT: All right. Good morning to all of you.

I just want to remind you, counsel, before you speak to please identify who you are for the purposes of the record.

Now, I understand that there is a dispute between the parties, the documents that I have reviewed are found at DI 105 and 106. I'm unaware of anything else. Why don't we get this addressed. It appears to me it's Bristol-Myers initiated this, so ...

MR. COTTRELL: It is, Your Honor. Fred Cottrell. With Your Honor's permission, I'll address it and either Colleen or Chris may chime in. Then if we get through this quickly, there is one other issue not in the letters that we would like to raise the parties have discussed, but if Your Honor doesn't have time, we understand. We can do it another day.

The first issue, Your Honor, is fairly discrete. As you know, on September 21st, you entered a modified scheduling order in this case which set the end of fact discovery for October 12th, and then the parties get in

expert reports, expert discovery, hopefully a Markman hearing and a summary judgment hearing but, of course, Your Honor put an asterisk there that that may move depending on who the judge is at the time or who the judge isn't at that time.

THE COURT: Yes.

MR. COTTRELL: So that is where we are, procedurally. And this discrete issue was simply when Bristol-Myers should elect to identify any opinions of counsel and to go forward with discovery on that to rebut the charge of willfulness that Zymo has made.

What we could do, Your Honor, but we haven't because we've tried to reach a compromise position with Zymo through our meet and confer, what we could do is simply move to bifurcate at the very least willfulness out, if not damages. Your Honor suggested that recently or raised that possibility recently in our Honeywell/Universal case, and I think the parties are actually submitting a few things on that issue right now.

But by way of compromise, we said what we would propose, what Bristol-Myers would propose is that after the Markman decision comes out, then Bristol would decide whether to rely on advice of counsel, produce and allow discovery. So this isn't a question of either we don't think any discovery should ever go forward or we think it

should be bifurcated out. We've tried to sort of find a middle ground.

And the reasons, I think there are two or three good reasons:

The first is we alluded to in our letter we believe that Zymo's position on infringement really hasn't been solidified yet. It eventually will need to be, particularly through expert reports, but we don't think it has been solidified as much as it could.

The second, and Your Honor knows about this case, I'm sure, and the court is acutely aware of this case, the Seagate case came down from the Federal Circuit which changed not only the test for willfulness but what kind of discovery could be had. It was in front of Judge Robinson a few weeks ago and she said at least she is still wrestling with what to do with it in the context of willfulness.

As we suggested in our letter, there is really a two-part test now for willfulness. The first is, really, has there been a high likelihood of infringement shown? And we won't know that until, of course, after Markman and summary judgment, and even then we may not know that. But the point is before we get to the second part of the test, which is the subjective views of the alleged infringer where advice of counsel may be relevant, we sort of think it would make sense under Seagate to wait until after Markman before

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MR. COTTRELL: Your Honor, claim construction briefing begins February of '08. And it says here rebuttal briefs on March 21st, '08. Yes, that is claim construction. And I think summary judgment is about parallel.

THE COURT: Okay.

MR. ANDRE: And, Your Honor, just one more data point. This is Paul Andre. I'm sorry. One more data point that I wanted to mention is that the clock is ticking against us because our patent expires in two years from this month.

THE COURT: All right.

MR. ANDRE: So, October of 2009 our patents expire. And I know that the endgame here is to make the clock tick as long as possible to get the things to the end of their life before we ever get any decision on the merits of the case. This is a very common issue that comes up in patent infringement cases. I don't understand, if this is something they wanted to raise with Judge Jordan when we were doing the scheduling order, we should have done so then.

I actually do have a case in front of Judge Sleet with Mr. Rovner and Judge Sleet does require such a disclosure during fact discovery and then claim construction occurs thereafter. So this is not something that I think is out of the ordinary. I don't believe Seagate really

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changed the timing of the reliance on opinion-of-counsel defense.

THE COURT: Well, I do think Seagate changed the standard and that could influence the timing, but I will agree with you that Seagate was not, and nor was it expected to be addressed to the ins and outs of discovery. And as I said, that little footnote 5, I love when the Fed Circuit does it, "We leave it to the future cases to further develop the application of this standard," and give little or no guidance and then just tell us later on when we're wrong. But I do think that disclosure of the opinions of counsel should happen. My expectation of that is it's not going to be done within the time frame that you presently have for fact discovery.

I also recognize that it is highly unlikely, even under the new Seagate standard, I put it probably in the less than one percentile, that a defendant realistically could expect to have a willfulness argument be or lack of willfulness be necessarily an argument for summary judgment because it's potentially so factually intense under both the objective and subjective inquiry.

Having said that, I expect the disclosure to occur and the question is the timing of it. I don't look at this as being such an absolute necessary matter. I certainly also leave out there that if you want to tee up an

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issue on bifurcation, you can. But I do feel that discovery should occur on this. The discovery should occur on this and have it completed roughly 45 days or so before the due date begins for claim construction, the filing of claim construction, in that time frame.

I recognize that there could be quite a bit of discovery in this area. But then again, as I said before, I don't think it's generally an appropriate issue for summary judgment. So as I say, I can't remember in February when the date is. I think you said mid February, so 45 days would bring you close to the end of December or in that time frame to get that discovery done and completed.

MR. ROVNER: Your Honor, this is Phil Rovner. Thank you. I just wanted to get some clarification.

If discovery is to be done within some time I guess in December, early December, when would the opinions have to be disclosed? Assuming if discovery on willful infringement would end on December 1, let's say, how much beforehand would we be able to get those opinions?

THE COURT: I would suggest 45 days before that.

MR. ROVNER: So ...

THE COURT: I firmly believe the amount of discovery that is necessary on this can be taken in that time period.

MR. ROVNER: I guess 45 days would be some time

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in mid-to-late October to give us time to complete discovery around December 1.

THE COURT: If it falls like that.

MR. ROVNER: Okay.

THE COURT: As I said --

MR. ROVNER: Briefing on claim construction is due on February 22nd, so we'll count 45 days back from there. So basically the opinions have to be disclosed about 90 days prior to February 22nd.

THE COURT: Yes.

MR. ROVNER: We can work out the dates from there, I think.

THE COURT: Yes, that's my rough. These are my rough estimates that I'm giving. And my hope is that by that time, you have got some more information, but the decision will be made as to whether opinion of counsel will be disclosed.

MR. COTTRELL: And, Your Honor, it's Fred Cottrell. I'd certainly want to speak with my colleagues about the possibility of bifurcation.

THE COURT: I understand.

MR. COTTRELL: If we do that, would you like a formal process or more sort of along the lines I think what we did or are doing in Honeywell, sort of smaller submissions?

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THE COURT: Refresh my recollection, Fred, as to what we're doing in that.
MR. COTTRELL: I think we almost had, not letters but --
THE COURT: Well, like letter briefs.
MR. COTTRELL: -- page limited kind of submissions. The number 10 sticks in my mind for page limits.
THE COURT: It may be 10, 10. Did I give you opening, answering and reply?
MR. COTTRELL: I think. All I have is the amended scheduling order that was submitted yesterday, Your Honor. I don't have the procedure for the bifurcation issue.
THE COURT: And this is horrible, I can't remember, but I do remember it being abbreviated.
MR. COTTRELL: Yes, I believe it --
THE COURT: And I would prefer an abbreviated arrangement because I again feel the bifurcation issue is something that can be handled in less rather than more.
MR. COTTRELL: I agree, Your Honor. So I would like the opportunity to consult with my colleagues. And then if we decide to do it, perhaps we can speak with Zymo about at least a procedural schedule. I'm sure they'll oppose to the substance of it.

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THE COURT: That's fine. And if you can't come to an agreement on that, get back in touch with me and we'll have a little chat. And that is an issue that I can decide without your consent because it's nondispositive.
MR. COTTRELL: Yes, Your Honor. That's my understanding.
THE COURT: Yes, you still have the right to not like it and take appropriate steps.
MR. ROVNER: Your Honor, Phil Rovner. I'm a little concerned by what was mentioned. I don't want to get into a situation where when we hang-up the phone that when we try to put together an order saying that opinions of counsel will be due by the middle to end of October that they say, well, we're going to file a bifurcation motion so we're not going to give that to you.
THE COURT: Well, and they may very well do that, Phil. And what I promise you, if that happens, we may end up having a tete-a-tete with everybody so you get an oral opinion from me as to whether there is going to be bifurcation by phone.
MR. ROVNER: Okay.
THE COURT: I will try to do it so that is addressed earlier rather than later, so that is another reason why I would probably prefer the abbreviated submissions and expedited submissions.

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MR. COTTRELL: We understand, Your Honor. Thank you.
THE COURT: Okay. It can almost be done in letter format, but I happen to prefer the double spacing for reading purposes. It's just easier to read.
All right. Thank you, counsel.
MR. ROVNER: Your Honor?
THE COURT: Yes.
MR. ROVNER: There was one other issue.
THE COURT: I'm sorry. That's right, yes.
MR. ROVNER: We have the mediation rescheduling.
THE COURT: Oh, yes. That was another reason why I had this.
Could you please get me my two calendars, the one on the desk and the other one?
I know that the mediation was cancelled, and my recollection was that it was cancelled at the request I think of both sides.
MR. ROVNER: Actually, it was the defendant who wanted it rescheduled.
THE COURT: Okay. I didn't know whether it made any sense to reschedule it and the timing of when the rescheduling should occur. I need some assistance from counsel in that regard because I don't know necessarily the interest level or the desire to mediate at this point

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and when that desire may be more better evaluated to determine.
MR. ANDRE: Your Honor, this is Paul Andre. I believe what was the issue to postpone the last mediation was that Bristol believed it would be better to complete expert discovery prior to mediation. Therefore, it would put mediation some time early in 2008, January of 2008.
THE COURT: All right.
MS. TRACY: Your Honor, this is Colleen Tracy for Bristol-Myers Squibb. That was Bristol's thinking. You get through expert discovery because we, as yet, do not have ZymoGenetics' proposed claim construction or their infringement contentions. We'd like to have that. And then after the close of expert discovery on January 3rd, we'd like to revisit mediation with Your Honor.
THE COURT: Well, do you want me to schedule? Is it the wish for me to reserve a date now?
MS. TRACY: Yes, Your Honor. We would like to set something aside in your calendar after the close of expert discovery so that we can mediate, potentially.
THE COURT: Well, right now, Thursday, the 24th of January is available on my calendar.
MS. TRACY: That is fine with Bristol, Your Honor.
THE COURT: I was hoping maybe that gave enough

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approximately 200,000 pages of documents for their 33(d) response to our basis of infringement or noninfringement. And it pretty much was, it was over 100-some-odd boxes of documents that we can derive the answer from. So I just want to make sure we are not precluded from raising that issue, if this does come up down the road again.

THE COURT: Absolutely not. As I said to you, it has application to both sides of this fence. It is not unusual for me to see -- and I'm not saying it necessarily happened in this case -- that exactly happening, using Rule 33, using the rules of discovery by being able to produce documents, essentially just dumping everything on the one side and saying here, this answers the interrogatory. Go find it. I don't think that is an appropriate way to identify what documents are actually pertinent to the issue that was asked in the interrogatory. And it depends on how the interrogatory was, what the interrogatory asks, but at the same time I generally do not find it appropriate. It's buried some place.

MS. TRACY: Your Honor?

THE COURT: Yes, Colleen. Did you want to say something?

MS. TRACY: I'm sorry, Your Honor. I have a few quick points. First of all, I sort of agree with Mr. Andre's assessment of Bristol's interrogatory responses,

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and I think that we've specified, document by document, what we contend supports our infringement contention and we have strived to not do a dump on ZymoGenetics.

THE COURT: Well, let me put it this way, Colleen. The issue is not before me right now so I'm not addressing it. I think all Mr. Andre was asking me, Paul was asking me was if they have some concerns about that, are they precluded from raising it? And they're not precluded from raising it. I'm just pointing out what the ruling is today equally applies to both of you, that's all.

MS. TRACY: Understood, Your Honor. And the last point I wanted to make is the witness that was lately identified by Zymo with respect to reduction to practice is going forward next week, so we would like ZymoGenetics' specific citations, they're narrowing of the 5,000 pages of laboratory notebooks that they cited prior to that deposition.

THE COURT: Well, I think that would be expected. And my understanding is that that had been done, or had it not been done?

MR. ANDRE: Your Honor, the pages that are between January 5th, 1988 and January 18th, 1989 will be identified to counsel if not by close of tomorrow, then first thing Monday morning.

THE COURT: And when is the deposition?

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MR. ANDRE: It's next --

MS. TRACY: Thursday.

MR. ANDRE: -- Thursday.

THE COURT: It should give you enough time. It really should because I know there is a boatload of people on this phone call for these issues, and I'm sure there is a boatload of people behind you looking up all this stuff and reviewing it.

MR. ANDRE: Your Honor, that should be no problem from Zymo's side. Thank you.

MS. TRACY: Yes. And if I understand Your Honor's order, with respect to the witnesses that have already been deposed, once ZymoGenetics has narrowed their support, that documentary support, we'll look at that. And if there are no depositions that are necessary, then that's the way it will be, but there may be a need to take some additional depositions.

THE COURT: And I expect both of you to be very discriminatory in that regard.

MS. TRACY: Yes, Your Honor.

THE COURT: Okay?

MR. ANDRE: Thank you, Your Honor.

THE COURT: Thank you. I'll get an order out. Oh, no. I will wait to hear from you, counsel, regarding the mediation before I issue a new order on it. And it will

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probably just be a brief order telling you the new date and time and the new date for the submissions. And as I said, what the court has ruled, the transcript will serve as an order of the court and on the other issues that were ruled on today.

(The attorneys respond, "Thank you, Your Honor.")

THE COURT: All right. Have a great day; weekend, too. Good-bye now.

(Telephone conference ends at 12:00 p.m.)

EXHIBIT 7

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

- - -

ZYMOGENETICS, INC., a Washington corporation,	:	CIVIL ACTION
Plaintiff,	:	
v	:	
BRISTOL-MYERS SQUIBB CO., a Delaware corporation, and DOES 1 THROUGH 100,	:	
Defendants.	:	NO. 06-500 (***)

- - -

Wilmington, Delaware
Thursday, November 8, 2007 at 4:00 p.m.
TELEPHONE CONFERENCE

- - -

BEFORE: HONORABLE MARY PAT THYNGE, U.S. MAGISTRATE JUDGE

- - -

APPEARANCES:

POTTER ANDERSON & CORROON, LLP
BY: PHILIP A. ROVNER, ESQ.

and

PERKINS COIE, LLP
BY: PAUL J. ANDRE, ESQ.
(Menlo Park, California)

Counsel for Plaintiff

Brian P. Gaffigan
Registered Merit Reporter

APPEARANCES: (Continued)

RICHARDS, LAYTON & FINGER, P.A.
BY: KELLY E. FARNAN, ESQ.

and

FITZPATRICK CELLA HARPER & SCINTO
BY: CHRISTOPHER P. BORELLO, ESQ., and
COLLEEN TRACY, ESQ.
(New York, New York)

Counsel for Defendants

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PROCEEDINGS

(REPORTER'S NOTE: The following telephone conference was held in chambers, beginning at 4:00 p.m.)

THE COURT: Good afternoon, this is Judge Thynge.

MS. FARNAN: Good afternoon, Your Honor.

MR. ROVNER: Good afternoon, Your Honor.

THE COURT: Who do I have on the line for ZymoGenetics, please?

MR. ROVNER: Your Honor, for the plaintiff ZymoGenetics, it's Phil Rovner; and Paul Andre is with me.

THE COURT: All right. And who is on the line on behalf of Bristol-Myers?

MS. FARNAN: Your Honor, for Bristol-Myers, it's Kelly Farnan. I also have on the line Colleen Tracy and Chris Borello, my co-counsel.

THE COURT: I'm writing the names down. That's why it's taking a little while.

Counsel, the reason I have you on the line is to talk about the matter that you teed up to me concerning bifurcation of the issue of willfulness and any potential enhanced damage stemming from that, including the discovery relating to that. And I'm assuming you are also asking for bifurcation of damages basically, too. Is that correct?

MS. FARNAN: Your Honor, this is Kelly Farnan on behalf of Bristol-Myers. In our application, I did not did not ask for the bifurcation of damages.

THE COURT: It's just a bifurcation of willfulness.

MS. FARNAN: Yes.

THE COURT: All right. Why don't you give me your very brief thoughts on this. I realize that you had the chance to sort of mini-brief it to me but give me the best highlights of your discussion.

MS. FARNAN: Sure. Your Honor, on behalf of Bristol-Myers, it's Kelly Farnan. And I think the best highlights of our discussion are, of course, Seagate set forth a new standard for willfulness and I think it's a

standard that lends itself to bifurcation. Not only did the Federal Circuit set forth a new two-part test but in that change, it changed the burden of proof to clear and convincing.

Now, as a practical matter, willfulness may never be an issue in this case, but if it does become an issue, the Federal Circuit recognized that an alleged infringer shouldn't be forced to make the decision of whether to waive the attorney-client privilege unless necessary and that bifurcation was an appropriate method to deal with the timing of the disclosure of the attorney-client privilege. In this case, if infringement validity and willfulness all go to trial before the same jury, you are having the jury consider certain issues on a preponderance of the evidence standard and other issues under clear and convincing. The courts have previously bifurcated issues under the risk of jury confusion. I think the risk is even greater added two separate burdens of proof. So in light of this heightened standard, Bristol-Myers does not believe all the issues should go to trial all at once and that in conjunction with that, that infringement and validity should go to trial first and that Bristol should be entitled to wait to decide to waive the attorney-client privilege until after infringement and validity have been decided.

Now, ZymoGenetics has argued it would be a waste of resources to conduct two trials but if infringement and validity are decided, I think the parties can work out an efficient way to, first of all, complete their discovery on willfulness and then to present willfulness in a streamlined way. The prejudice to Bristol-Myers of waiving the attorney-client privilege, if unnecessary, I think would outweigh any inconvenience.

I think those are the highlights of our argument but if Your Honor has any questions, I'm certainly willing to answer them.

THE COURT: All right. Thank you.

MR. ANDRE: Your Honor, this is Paul Andre for ZymoGenetics. In a nutshell, our argument is based on Bristol's logic, every single patent case would be bifurcating willfulness, and that means you would have to have two jury trials for every single case. Because the Seagate case, it doesn't support the fact that you should bifurcate. In fact, it is quite the opposite. It actually states that the issue of willfulness will be determined by the record developed in the infringement case so under this idea of bifurcating, having two different jury trials, two different juries, you just go back in and reprove infringement once again to show the willfulness issue. Seagate just doesn't propose bifurcating cases.

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except for maybe Chief Judge Sleet, there is a time, though, for filing motions for summary judgment. That is consistent among all the judges. That timing of those motions for summary judgment are dependent upon and varies from judge to judge.

But in the second, if everything is bifurcated, the discovery on it and the trial, then you follow-up with your infringement and validity trial with discovery going on, whether there is willfulness, and then potentially a round of briefing on whether plaintiff has met the objectively reckless standard. And then maybe you get to trial on the issue of willfulness. So explain to me if you think that I'm completely wrong, that that type of process may end up.

MS. FARNAN: So you are suggesting briefing on the threshold and not necessarily a summary judgment of willful infringement?

THE COURT: Well, I'm saying I can see more, I can see summary judgment on a willful infringement, and I have seen it enough times. I have seen the issue. But what you are suggesting is there is going to be, it's going to be in the second part. So we have done one round of summary judgment motions, we've gone through a trial on these points. We wait around, take some more discovery afterwards and we end up with another round of summary judgment, and I

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can see it potentially breaking down that the summary judgments motions can be on willfulness totally or they can be on willfulness, on whether or not the plaintiffs met the objective standard.

MS. FARNAN: I think on whether or not plaintiffs met the objective standard, I mean, I think Mr. Andre's suggestion is that that should be dealt with in the middle of trial so I think that is actually going to be more onerous. This may make more sense to deal with that in an orderly fashion because at some point that standard has to be met and making that determination in the middle of trial and determining whether or not to send evidence of advice of trial in front of a jury, I think it's probably more appropriate to do it more orderly. So I think while that does slightly increase the court's workload, I think it is maybe a more orderly way to proceed.

And with respect to summary judgment on willfulness, you don't often see, or maybe you have seen a lot, I haven't often seen summary judgments on willful infringement but I guess that is sort of a problem with a two-part test is to the extent that happens and I guess that is something that the parties will have to be reasonable and try not to bring too many issues before the court.

THE COURT: Paul, what type of discovery do you see occurring in this case on willfulness?

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MR. ANDRE: Well, Your Honor, I'm not sure.

THE COURT: Let's make an assumption there is an opinion of counsel out there.

MR. ANDRE: Okay. You decide whether there is opinion of counsel or not.

THE COURT: Let's assume there is opinion of counsel. It's not only there is opinion of counsel, you have to make the other assumption they will produce it.

MR. ANDRE: Okay.

THE COURT: They will waive attorney-client privilege in that regard.

MR. ANDRE: Sure. I imagine what we would want to know is what -- because as Knorr Bremse said, the opinion of counsel is just one of many factors you look into to determine the reasonableness of the company. And what we would probably want to find out is what are they relying upon, how they were going to use it, the opinion of counsel, and any other affirmative defenses to that claim. We don't know what those affirmative defenses are at that point on discovery into it. If it was opinion of counsel, we obviously would want to take discovery into the reliance upon opinion of counsel, whether opinion of counsel was competent or not. We'd have to look into it. If it was competent, maybe we wouldn't need to take the deposition of the attorney who prepared those opinions. We don't know.

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If it is a competent opinion and we don't want to take that discovery, we certainly would not do so. But you just don't know. At this point, we're trying to read the tea leaves.

THE COURT: Well, I understand. Typically, there is a game plan to some extent I would think with most counsel when they are defending or prosecuting a case and there is some idea, because you have got to have some game plan on both sides because you are saying to the court we think we can get the discovery done in X amount of time and that is done.

MR. ANDRE: Yes.

THE COURT: So there has to be some thought process in that regard, but you see potentially taking -- well, if they didn't have an opinion of counsel or more importantly they don't waive it, what type of discovery then do you see for willfulness?

MR. ANDRE: Well, I think what we want to see is what measures the company took, whether they considered the patents in trying to come up with a design-around. The other factors, the Reed factors that the court can look at that shows how a company is reasonable, and take discovery into those issues. It probably would be very limited discovery to be quite frank with you. We know that they had knowledge of these patents prior to the litigation and we have been in contact with them so we get that on record,

obviously, and we would show that the people who designed their product and continued to design working on this product did so in a reckless manner, without regard for our patent rights, our property rights.

THE COURT: So there is discovery out there that you could take to go to the objectively reckless standard.

MR. ANDRE: I believe that is correct, yes.

THE COURT: And what do you see the difference is. Beyond that, you may want to take the deposition of the attorney who gave the opinion, who provided the opinion or the attorneys who provided the opinion.

MR. ANDRE: We would want to take the attorneys who authored the opinion or opinions, depending on what the opinion looks like.

THE COURT: Sure.

MR. ANDRE: It really would be dependent. And then what we really want to focus on, the reliance by the company on those opinions, if there was a reliance. If you give an opinion, stick it in the file cabinet and never look at it, it's not very effective for an affirmative defense anyway. I think at this point, what we would want to pursue for down the road discovery would be anywhere from two-to-four depositions would be my guess and some written discovery on that.

THE COURT: You're talking about if opinion of

counsel is produced.

MR. ANDRE: Yes.

Your Honor, with respect to the administration, obviously the Federal Circuit did the district courts no favor when they said they leave it to future cases to develop an application of this standard. But that being said, surely, the administration in a trial, judges can easily bifurcate out a trial, let discovery go forth on it and the lower record, there is no proof of infringement, then you have to deal with it. You can have the same jury sit through the infringement part of the trial and the willfulness afterwards. That is one way of handling it if it's an administration problem about being orderly. I don't think there is any such issue but that would just be one of the alternatives.

As it sits now, if you were to say that every willful infringement -- like I said, I have not been in a patent case where willful infringement was not alleged, but if you are going to bifurcate every single one of them, then you do have to have two rounds of summary judgment. You have your team back up on discovery after trial and summary judgment and then another trial to a new jury and I think you will repeat a lot of information.

Even the Seagate says that the objective defined risk is determined by the record in the infringement

proceedings. So I think it would be very difficult for the patentee to say that we're not putting forward the record, the evidence of infringement so we had to go through the whole infringement process again.

THE COURT: Or the part of the record of the infringement because you would have had the court just basically telling the jury I would think at the bifurcated portion on willfulness that they're supposed to work from the assumption, which they would, that Bristol-Myers Squibb was found infringing the patent or patents. There had to be some indication in that, something along those lines, and to inform the jury either in preliminary instructions or otherwise what their responsibilities are going to be and deciding what issues they are supposed to focus their attention on.

Okay. From your standpoint, Kelly, and from, I should say, Bristol-Myers' standpoint, for the willfulness portion, for the objectively reckless standard, divorced from opinion of counsel, what do you see as the type of discovery, the type of responsibility on your part, that is, the type of individuals that could potentially object to that, or don't you know? Subject to discovery.

MS. FARNAN: I think Colleen and Chris have been more involved with discovery and they can chime in if they have anything additional, but at this point discovery is

closed, and I think the only thing that remains is whether we waive the privilege and subject any attorney-client privilege communications to discovery. So I think from our end, it would be fairly limited.

THE COURT: Okay. Well, I understand that, but I don't know. And this whole issue comes down to the fact that Bristol-Myers does not want to be put in a position of having to make a decision now about whether they are going to give up an opinion of counsel and therefore waive the attorney-client privilege. To some extent, that fear has been alleviated a little bit or concern has been alleviated a little bit in the Seagate case because I do believe that the Seagate case would have a tendency to reverse or at least severely modify the Novartis/Eon, the Eon/Novartis matter that was decided in this court and how far this waiver goes. It certainly restricted the waiver.

I also recognize that this case isn't scheduled for trial. Or if it is, it has trial dates that you may or may not have. This is not an ANDA case so it's going to be tried in front of a jury.

I also recognize that all three judges, but, in particular, Judge Robinson and Judge Farnan, have been bifurcating more cases. And I recently did what I call a semi-bifurcation because the discovery had been essentially completed and I bifurcated out willfulness and damages from

being presented to the jury in the go-around on liability. Depending upon what the jury decided on the liability phase would determine whether or not we would have any evidence presented on willfulness and any evidence presented on damages. So there has been a variety of approaches in this court in an attempt to address the concerns expressed by counsel.

What it sounds like to me, and you correct me if I'm wrong, Paul, about this, the only thing that is left on willfulness from your viewpoint I guess is the opinion of counsel aspect and whether or not you get it now and/or have you been prevented to take discovery on the other willfulness aspects? You know, other evidence of willfulness.

MR. ANDRE: At this point, Your Honor, they have not provided us. We have had issues of wilfulness and written discovery and there have been objections to that. But mostly it has focused on the opinion of counsel.

THE COURT: Yes, but I mean I'm trying to find out what are their objections to the other discovery, the other discovery outside of opinion of counsel.

MR. ANDRE: Sitting here off the top of my head, I don't know that there has been additional objections on that discovery. We have been able to discover certain issues that would factor into the showing of objective

recklessness. I think probably most of the discovery has been denied on the idea of the opinion of counsel.

THE COURT: Okay.

MS. FARNAN: Your Honor, that is my understanding as well. That it's only the waiver that is left.

THE COURT: Yes, so that is really Bristol-Myers' issue. Do we waive opinion of counsel now, and the argument that you are making about willfulness being bifurcated is really just focused on the opinion of counsel.

This is what my thought was. To the extent that discovery was not allowed or prevented or reduced on the initial objective argument that has to be obviously reached, and that is the objective recklessness, I really do think discovery should be allowed to go forward.

I am not inclined at this stage, and where this case presently is, to necessarily bifurcate willfulness because I'm not going to be the judge trying this case. That's in part a concern that I have and any decision that I make now may very well bind one of the District Court judges on this bench or a new one that starts on this bench.

My thought was also that we hold off on willfulness, hold off on opinion of counsel for now, but I would allow it to be revisited, to allow additional discovery to be taken. And I think on that point that my

decision on not bifurcating willfulness does not necessarily bind next judge, that my decision on keeping the opinion of counsel protected for now does not bind the next judge, and both parties understanding and recognizing that they have that. That ZymoGenetics would have the right to request to get opinion of counsel and to be able to take some discovery on it. As you have indicated, Paul, you think max probably four depositions and some written discovery, not much, and you revisit the issue of bifurcation because what has been said to me is there has been some discovery taken on willfulness at this point on the objective standard. I'm saying that that discovery should be allowed to go forward and get completed.

On the more subjective standard on opinion of counsel, quite frankly, I'm punting it a bit because, like I said, I'm not 100 percent certain what's Seagate's approach and what solution is going to work with the Seagate opinion, whether we stop it at the discovery level completely and then face the prospect of bifurcating every case, which I don't think is going to happen, whether we allow discovery to go forward and do whatever we need to do at trial. But to the extent that it is really left at the trial level, that is going to affect some other judge's approach to this trial and potentially limit that judge.

So those are my thoughts on this, so I make both

sides miserable.

MR. ANDRE: Your Honor, speaking for ZymoGenetics, I think that is a reasonable approach.

THE COURT: Well, you are happy because you don't have to give up your opinion of counsel right now.

MR. ANDRE: That is a reasonable approach, I think. We can wait for the discovery until we determine what judge is going to hear this case and get that judge's preference on it who is administering the trial.

THE COURT: Yes. From your standpoint, I would think, and then Bristol-Myers should be happy because they don't have to give their opinion of counsel. They're not happy I didn't bifurcate it but they didn't have to give up opinion of counsel.

MS. FARNAN: Your Honor, of course we're happy we don't have to give it up now. I just want to be clear, it's that we're going to hold off until there is another judge so discovery on that portion is stayed.

THE COURT: That is basically what it is, but I don't want one side or the other to argue, well, gee, discovery has now passed. I am carving this out because any judge who is going to get this is going to potentially pick a trial date. That date is going to be picked some time in the future. There is usually enough time to get this type of discovery, and I don't believe there is that much, on the

more subjective part of the analysis done in fairly short order, in fairly easy order.

MS. FARNAN: Your Honor, this is Kelly Farnan. Just to be clear, our position would be on the objective portion, that that has been completed and what would be left to be decided later would be our waiver and the discovery on that.

THE COURT: I'm not certain about that because, like I said, I haven't seen the discovery, Kelly, but to the extent it hasn't been responded or hasn't been finished up, I want that to be completed because I think when your motion was filed, or when it first was discussed -- the motion was filed on October 15th. I can't remember when we had our first discussion. October 4th. Was discovery closed at that time?

MS. FARNAN: Discovery closed October 12th.

THE COURT: Okay. So between the time the issue was raised and the time it's been addressed, discovery is closed.

MS. FARNAN: That's correct.

THE COURT: So there could be some. I don't know if there are any other points but that is, to me, extremely limited in any event.

MS. FARNAN: Understood.

THE COURT: Okay. So I'm not going to decide it

should be bifurcated. I really do have a concern that Seagate or its progeny, if there are going to be any progeny from it -- because I know we're not going to get any more direction from the Fed Circuit on how to try to manage our trials or our pretrial matters, because I don't think they really know how to give us any advice on that for the most part -- I just don't want to see every case now subject to bifurcation because of Seagate. I clearly don't believe that was Seagate's intent but I do think that bifurcation is appropriate and I still think it's a discretionary matter for the court, particularly the trial judge.

Okay. Thank you.

MR. ANDRE: Thank you, Your Honor.

THE COURT: Thank you very much.

MS. FARNAN: Thank you, Your Honor.

THE COURT: Take care now. Good-bye. Have a great weekend, all.

(Telephone conference ends at 4:37 p.m.)

EXHIBIT 8

THIS EXHIBIT HAS BEEN REDACTED IN ITS ENTIRETY

EXHIBIT 9

EXPRESS MAIL NO. EH314450612US

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail #EH314450612US in an envelope addressed to: Box Patent Application, Assistant Commissioner for Patents, Washington, D. C. 20231 on 11-26-97.

TOWNSEND and TOWNSEND and CREW

By Kim M. Soplen

JC169 U.S. PTO 08/980400

PATENT

Attorney Docket No. 13952A-005321US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

Andrzej Z. Sledziewski,
Lillian A. Bell, and
Wayne R. Kindsvogel

Serial No.: Unassigned

Parent Serial No. 08/477,329

Filed: Herewith
Parent Filed: June 7, 1995

For: METHODS OF PRODUCING SECRETED RECEPTOR ANALOGS AND BIOLOGICALLY ACTIVE DIMERIZED POLYPEPTIDE FUSIONS

Examiner: Unassigned
Parent Exr: C. Kaufman

Art Unit: Unassigned
Parent Art Unit: 1812

INFORMATION DISCLOSURE STATEMENT

Box Patent Application
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Applicants direct the Examiner's attention to the references below, also listed on the accompanying Form PTO-1449. This application is a divisional and relies, under 35 U.S.C. § 120, on the earlier filing date of prior application USSN 08/477,329, filed on June 7, 1995; which is a continuation of USSN 08/180,195, filed January 11, 1994, issued as U.S. Patent No. 5,567,584; which is a file wrapper continuation of USSN 07/634,510, filed December 27, 1990; which is a continuation-in-part of USSN 07/347,291, filed May 2, 1989, issued as U.S. Patent No. 5,155,027; which is a

continuation-in-part of USSN 07/146,877, filed January 22, 1988, now abandoned. The references listed on the attached form PTO-1449 were submitted to and/or cited by the Office in these prior applications and, therefore, are not required to be provided in the present application pursuant to 37 CFR 1.98(d).

The following U.S. Patents are set forth below:

U.S. Patent No. 4,766,073, issued 8/23/88
U.S. Patent No. 4,599,311, issued 7/8/86
U.S. Patent No. 4,816,567, issued 3/28/89
U.S. Patent No. 4,816,397, issued 3/28/89
U.S. Patent No. 4,474,893, issued 10/2/84
U.S. Patent No. 4,761,371, issued 8/2/88
U.S. Patent No. 5,116,964, issued 5/26/92
U.S. Patent No. 5,015,571, issued 5/14/91

The following foreign patent publications are set forth below:

EP 173 494, published 3/5/86
WO 86/01533, published 3/13/86
EP 088 994, published 9/21/83
EP 239 400, published 9/30/87
EP 162 319, published 11/27/85
EP 171 496, published 2/19/86
EP 256 654, published 2/24/88
EP 315 062, published 5/10/89
EP 116 201, published 8/22/84
EP 120 694, published 10/3/84
EP 327 369 A2, published 8/9/89
EP 244 221 A1, published 11/4/87
WO 90/06953, published 6/28/90

The following articles are set forth below:

Kuwana et al., Biochemical and Biophysical Research Communications 149(3): 960-968, 1987.

Yarden et al., Nature 323:226-232, 1986.

Hart et al., Science 240:1529-1531, 1988.
Escobedo et al., Science 240:1532-1534, 1988.
Heldin et al., EMBO J. 7:1387-1393, 1988.
Radeke et al., Nature 325:593-597, 1987.
Ebina et al., Cell 40:747-758, 1985.
Rubin et al., J. Immun. 135:3172-3177, 1985.
Ellis et al., J. Cell Biol.150:14a, 1987.
Smith et al., Science 238:1704-1707, 1987.
Livneh et al., J. Biol. Chem. 261:12490-12497, 1986.
Boni-Schnetzler and Pilch, Proc. Natl. Acad. Sci. USA 84:7832-7836, 1987.
Claesson-Welsh et al., Mol. Cell. Biol. 8:3476-3486, 1988.
Ullrich et al., Nature 309:418-425, 1984.
Ullrich et al., Nature 313:756-761, 1985.
Derynck et al., Nature 316:701-705, 1985.
Loh et al., Cell 33:85-93, 1983.
Honjo et al., Cell 18:559-568, 1979.
Alber and Kawasaki, J. Mol. Appl. Genet. 1:419-434, 1982.
Russell et al., Nature 304:652-654, 1983.
Grosschedl and Baltimore, Cell 41:885-897, 1985.
Rieter et al., Cell 22:197-207, 1980.
Treiger et al., J. Immunol. 136:4099-4105, 1986.
Roth et al., J. Cell. Biol. 102:1271-1283, 1986.
Riedel et al., Science 236:197-200, 1987.
Riedel et al., Nature 324:68-70, 1986.
Gascoigne et al., Proc. Natl. Acad. Sci. USA 84:2936-2940, 1987.
Maddon et al., Cell 47:333-348, 1986.
Maddon et al., Cell 42:93-104, 1985.

Capon et al., Nature 337:525-531, 1989.
Wood et al., Nature 314:446-449, 1985.
Carlson et al., Mol. Cell. Biol. 3:439-447, 1983.
Marx, Science 229:455-456, 1985.
Neuberger et al., Nature 312:604-609, 1984.
Oi and Morrison Biotechniques 4:214-221, 1986.
Bailon et al., Bio/Technology 5:1195-1198, 1987.
Ballou et al., J. Biol. Chem. 255:5986-5991, 1980.
Munro and Pelham, EMBO J. 3:3087-3093, 1984.
von Heijne, Nucl Acids Res. 14:4683-4690, 1986.
von Heijne, Eur. J. Biochem. 133:17-21, 1983.
Beggs, Nature:104-108, 1978.
Clarke et al., Meth. Enzym. 68:436-442, 1979.
Struhl et al., Proc. Natl. Acad. Sci. USA 76:1035-1039, 1979.
Broach et al., Gene 8:121-133, 1979.
Mariuzza and Winter, J. Biol. Chem. 264:7310-7316, 1989.
Gronwald et al., Proc. Natl. Acad. Sci. USA 85:3435-3439, 1988.
Riedel et al., Protein Engineering 1(3):237, 1987.

It is respectfully requested that the cited information be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

Applicants believe that their invention as claimed is patentable over the above references taken alone or in any combination. However, Applicants reserve the right to demonstrate that their claimed invention was made prior to any

one or more of the above-identified references. No inference should be drawn as to the pertinence of the references based on the order in which they are presented.

Applicants respectfully request that the Examiner review the foregoing references to make her own determination of the patentability of the present invention and that the references be made of record in the file of this application.

Although no fee is believed to be due, the Commissioner is hereby authorized to charge any fees necessitated by this transmittal to Townsend and Townsend Deposit Account No. 20-1430.

Respectfully submitted,

Date: November 26, 1997 By: _____
Jeffrey J. King
Reg. No. 38,515

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FORM PTO-1449 (Modified) Page 1 of 5 LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	Attorney Docket 13952A-005321US	EXPRESS MAIL NO. EH314450612US
	Applicants Andrzej Z. Sledziewski et al.	08/980,400 #4
	Filing Date November 26, 1997	Group 1646 ~~Not Assigned~~

REFERENCE DESIGNATION* U.S. PATENTS

Examiner Initial	*	Document No.	Date	Name	Class	Sub-Class
CW	AA	4,766,073	8/23/88	Murray et al.	435	172.3
	AB	4,599,311	7/8/86	Kawasaki	435	71
	AC	4,816,567	3/28/89	Cabilly et al.	530	387
	AD	4,816,397	3/28/89	Boss et al.	435	68
	AE	4,474,893	10/2/84	Reading	436	547
	AF	4,761,371	8/2/88	Bell et al.	435	68
	AG	5,116,964	5/26/92	Capon et al.	536	27
CW	AH	5,015,571	5/14/91	Niman et al.	435	7.92

FOREIGN PATENT DOCUMENTS

Examiner Initial	*	Document No.	Date	Country	Translation ?	Class
CW	AI	EP 173 494	3/5/86	EPO		
	AJ	WO 86/01533	3/13/86	PCT		
	AK	EP 088 994	9/21/83	EPO		
	AL	EP 239 400	9/30/87	EPO		
CW	AM	EP 162 319	11/27/85	EPO		

OTHER ART (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)

CW	AN	Kuwana et al., Biochemical and Biophysical Research Communications 149(3): 960-968, 1987.
	AO	Yarden et al., Nature 323:226-232, 1986.
	AP	Hart et al., Science 240:1529-1531, 1988.
CW	AQ	Escobedo et al., Science 240:1532-1534, 1988.

EXAMINER Glenn R. Kaufman	DATE CONSIDERED 9/24/98

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include a copy of this form with next communication to Applicant.

FORM PTO-1449 (Modified) Page 2 of 5 LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	Attorney Docket No. 13952A-005321US	Serial No. ~~Not Assigned~~ 08/980,400
	Applicants Andrzej Z. Sledziewski et al.	
	Filing Date November 26, 1997	Group 1646 ~~Not Assigned~~

REFERENCE DESIGNATION*

U.S. PATENTS

Examiner Initial	*	Document No.	Date	Name	Class	Sub-Class

FOREIGN PATENT DOCUMENTS

Examiner Initial	*	Document No.	Date	Country	Translation ?	Class
CMR	AR	EP 171 496	2/19/86	EPO		
	AS	EP 256 654	2/24/88	EPO		
	AT	EP 315 062	5/10/89	EPO		
	AU	EP 116 201	8/22/84	EPO		
	AV	EP 120 694	10/3/84	EPO		
	AW	EP 327 369A2	8/9/89	EPO		
	AX	EP 244 221A1	11/4/87	EPO		
CMR	AY	WO 90/06953	6/28/90	PCT		

OTHER ART (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)

CMR	AZ	Heldin et al., EMBO J. 7:1387-1393, 1988.
	BA	Radeke et al., Nature 325:593-597, 1987.
	BB	Ebina et al., Cell 40:747-758, 1985.
CMR	BC	Rubin et al., J. Immun. 135:3172-3177, 1985.
CMR	BD	Ellis et al., J. Cell Biol.150:14a, 1987.
CMR	BE	Smith et al., Science 238:1704-1707, 1987.
CMR	BF	Livneh et al., J. Biol. Chem. 261:12490-12497, 1986.

EXAMINER Claire M. Kaf	DATE CONSIDERED 9/24/98

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include a copy of this form with next communication to Applicant.

FORM PTO-1449 (Modified) Page 3 of 5 LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	Attorney Docket No. 13952A-005321US	08/980,400 Serial No. ~~Not Assigned~~
	Applicants Zndrzej Z. Sledziewski et al.	08/980,400
	Filing Date November 26, 1997	Group 1646 ~~Not Assigned~~

REFERENCE DESIGNATION*		U.S. PATENTS				
Examiner Initial	*	Document No.	Date	Name	Class	Sub-Class

FOREIGN PATENT DOCUMENTS						
Examiner Initial	*	Document No.	Date	Country	Trans-lation?	Class

OTHER ART (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)		
CW	BG	Boni-Schnetzler and Pilch, Proc. Natl. Acad. Sci. USA 84:7832-7836, 1987.
	BH	Claesson-Welsh et al., Mol. Cell. Biol. 8:3476-3486, 1988.
	BI	Ullrich et al., Nature 309:418-425, 1984.
	BJ	Ullrich et al., Nature 313:756-761, 1985.
	BK	Derynck et al., Nature 316:701-705, 1985.
	BL	Loh et al., Cell 33:85-93, 1983.
	BM	Honjo et al., Cell 18:559-568, 1979.
	BN	Alber and Kawasaki, J. Mol. Appl. Genet. 1:419-434, 1982.
	BO	Russell et al., Nature 304:652-654, 1983.
	BP	Grosschedl and Baltimore, Cell 41:885-897, 1985.
	BQ	Hieter et al., Cell 22:197-207, 1980.
	BR	Treiger et al., J. Immunol. 136:4099-4105, 1986.
CW	BS	Roth et al., J. Cell. Biol. 102:1271-1283, 1986.

EXAMINER Claire M. Kaf	DATE CONSIDERED 9/24/98

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include a copy of this form with next communication to Applicant.

FORM PTO-1449 (Modified) Page 4 of 5 LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	Attorney Docket No. 13952A-005321US	08/978,462 Serial No. ~~Not Assigned~~
	Applicants Zndrzej Z. Sledziewski et al.	
	Filing Date November 26, 1997	Group 1646 ~~Not Assigned~~

REFERENCE DESIGNATION*

U.S. PATENTS

Examiner Initial	*	Document No.	Date	Name	Class	Sub-Class

FOREIGN PATENT DOCUMENTS

Examiner Initial	*	Document No.	Date	Country	Trans-lation?	Class

OTHER ART (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)

CW	BT	Riedel et al., Science 236:197-200, 1987.
	BU	Riedel et al., Nature 324:68-70, 1986.
	BV	Gascoigne et al., Proc. Natl. Acad. Sci. USA 84:2936-2940, 1987.
	BW	Maddon et al., Cell 47:333-348, 1986.
	BX	Maddon et al., Cell 42:93-104, 1985.
	BY	Capon et al., Nature 337:525-531, 1989.
	BZ	Wood et al., Nature 314:446-449, 1985.
	CA	Carlson et al., Mol. Cell. Biol. 3:439-447, 1983.
	CB	Marx, Science 229:455-456, 1985.
	CC	Neuberger et al., Nature 312:604-609, 1984.
CW	CD	Oi and Morrison Biotechniques 4:214-221, 1986.

EXAMINER Claire M. Kaufman	DATE CONSIDERED 9/24/98

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include a copy of this form with next communication to Applicant.

FORM PTO-1449 (Modified) Page 5 of 5 LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	Attorney Docket No. 13952A-005321US	Serial No. 08/980,400 ~~Not Assigned~~
	Applicants Andrzej Z. Sledziewski et al.	
	Filing Date November 26, 1997	Group 1646 ~~Not Assigned~~

REFERENCE DESIGNATION* U.S. PATENTS

Examiner Initial	*	Document No.	Date	Name	Class	Sub-Class

OTHER ART (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)

CW	CD	Bailon et al., Bio/Technology 5:1195-1198, 1987.
	CE	Ballou et al., J. Biol. Chem. 255:5986-5991, 1980.
	CF	Munro and Pelham, EMBO J. 3:3087-3093, 1984.
	CG	von Heijne, Nucl Acids Res. 14:4683-4690, 1986.
	CH	von Heijne, Eur. J. Biochem. 133:17-21, 1983.
	CI	Beggs, Nature:104-108, 1978.
CW	CJ	Clarke et al., Meth. Enzym. 68:436-442, 1979.
CWK	CK	Struhl et al., Proc. Natl. Acad. Sci. USA 76:1035-1039, 1979.
CWK	CL	Broach et al., Gene 8:121-133, 1979.
CW	CM	Mariuzza and Winter, J. Biol. Chem. 264:7310-7316, 1989.
	CN	Gronwald et al., Proc. Natl. Acad. Sci. USA 85:3435-3439, 1988.
CW	CO	Riedel et al., Protein Engineering 1(3):237, 1987.

EXAMINER Claire M. Leff	DATE CONSIDERED 9/24/98

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include a copy of this form with next communication to Applicant.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known

Application Number	Unknown
Filing Date	Even Date Herewith
First Named Inventor	Sledziewski, Andrzej
Group Art Unit	Unknown
Examiner Name	Unknown
Attorney Docket No: 985.012USX	

US PATENT DOCUMENTS

Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	Filing Date If Appropriate
RBK	US-5,336,603	08/09/1994	Capon, Daniel J., et al.	435	69.7	08/26/1992
RBK	US-5,565,335	10/15/1996	Capon, Daniel J., et al.	435	64.7	05/02/1994
RBK	US-6,004,781	12/21/1999	Seed, Brian	435	69.7	02/04/1994

FOREIGN PATENT DOCUMENTS

Examiner Initials**	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	T²

OTHER DOCUMENTS – NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
RBK		ELLIS, LELAND, et al., "Linking functional domains of the human insulin receptor with the bacterial aspartate receptor", Proc. Natl. Acad. Sci. USA, Vol. 83, (November 1986), pp. 8137-8141	
RBK		GASCOIGNE, NICHOLAS R., et al., "Secretion of a chimeric T-cell receptor-immunoglobulin protein", Proc. Natl. Acad. Sci., Vol. 84, (May 1987), pp. 2936-2940	
RBK		RIEDEL, HEIMO, et al., "A chimeric, ligand-binding v-erbB/EGF receptor retains transforming potential", Science, Vol. 236,(April 10, 1987), pp. 197-200	
RBK		TRAUNECKER, ANDRE, et al., "Soluble CD4 molecules neutralize human immunodeficiency virus type 1", Nature, Vol. 331,(January 1988), pp. 84-86	

EXAMINER Ronald B. Kaplan DATE CONSIDERED 5/24/04

Substitute Disclosure Statement Form (PTO-1449)

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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mp
05/24/96



PATENT

I hereby certify that on the date specified below, this correspondence is being deposited with the United States Postal Service as first-class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231.

MAY 13, 1996
Date

David J. Maki

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Andrzej Z. Sledziewski, Lillian A. Bell and Wayne R. Kindsvogel
Application No.	:	08/475,458
Filed	:	June 7, 1995
For	:	METHODS OF PRODUCING SECRETED RECEPTOR ANALOGS AND BIOLOGICALLY ACTIVE DIMERIZED POLYPEPTIDE FUSIONS
Art Unit	:	1804
Docket No.	:	990008.446D5
Date	:	May 9, 1996

Assistant Commissioner for Patents
Washington, DC 20231

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MAY 23 1996

INFORMATION DISCLOSURE STATEMENT

Dear Assistant Commissioner:

In accordance with 37 C.F.R. §§ 1.56 and 1.97 through 1.98, applicants wish to make known to the Patent and Trademark Office the references set forth on the attached form PTO-1449. This application is a divisional and relies, under 35 U.S.C. § 120, on the earlier filing date of prior application USAN 08/180,195 filed on January 11, 1994; which is a file wrapper continuation of USAN 07/634,510 filed on December 27, 1990; which was a continuation-in-part of USAN 07/347,291 filed May 2, 1989; which was a continuation-in-part of USAN 07/146,877, filed January 22, 1988. The references listed on the attached form PTO-1449 were submitted to and/or cited by the Office in these prior applications and, therefore, are not required to be provided in the present application. However the following four references were not submitted to and/or cited by the Office and are submitted herewith:

- EP 327 369 A2
- EP 244 221 A1
- Gronwald et al., *Proc. Natl. Acad. Sci. USA 85*: 3435-3439, 1988.
- Riedel et al., *Protein Engineering 1*(3): 237, 1987.

As to any reference made of record on the attached form PTO-1449, applicants do not admit that it is "prior art" under 35 U.S.C. §§ 102 or 103, and specifically reserve the right to traverse or antedate any such reference, as by a showing under 37 C.F.R. § 1.131 or other method. Although the aforesaid references are made known to the Patent and Trademark Office in compliance with applicants' duty to disclose all information of which they are aware that is believed relevant to the examination of the above-identified application, applicants believe that their invention is patentable.

Please acknowledge receipt of this Information Disclosure Statement and kindly make the cited references of record in the above-identified application.

Respectfully submitted,

Andrzej Z. Slediewski et al.

SEED and BERRY LLP

David J. Maki
Registration No. 31,392

DJM:ljt
Enclosures:
Postcard
Form PTO-1449 (7 Sheets)
Copies of 4 Cited References

6300 Columbia Center
701 Fifth Avenue
Seattle, Washington 98104-7092
(206) 622-4900
Fax: (206) 682-6031

Fig 1, 2, 3, 4 Sheet 1 of 7

FORM PTO-1449 (REV.7-80) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO. 990008.446D5 | APPLICATION NO. 08/475,458

APPLICANTS Andrzej Z. Sledziewski et al.

FILING DATE June 7, 1995 | GROUP ART UNIT 1804 1812

MAIL ROOM MAY 16 1996 82 PATENT & TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
CMK	AA	4,766,073	8/23/88	Murray et al.	435	172.3	
	AB	4,599,311	7/8/86	Kawasaki	435	71	
	AC	4,816,567	3/28/89	Cabilly et al.,	530	387	
	AD	4,816,397	3/28/89	Boss et al.	435	68	
	AE	4,474,893	10/2/84	Reading	436	547	
	AF	4,761,371	8/2/88	Bell et al.	435	68	
	AG	5,116,964	5/26/92	Capon et al.	536	27	
CMK	AH	5,015,571	5/14/91	Nirman et al.	435	7.92	
	AI						
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
CMK	AL	EP 173 494	3/5/86	EPO				
	AM	WO 86/01533	3/13/86	PCT				
	AN	EP 088 994	9/21/83	EPO				
	AO	EP 239 400	9/30/87	EPO				
CMK	AP	EP 162 319	11/27/85	EPO				

OTHER PRIOR ART *(Including Author, Title, Date, Pertinent Pages, Etc.)*

CMK	AR		Kuwana et al., *Biochemical and Biophysical Research Communications 149*(3): 960-968, 1987.
CMK	AS		Yarden et al., *Nature 323*: 226-232, 1986.
CMK	AT		Hart et al., *Science 240*: 1529-1531, 1988.

EXAMINER Claire M. Kerr | DATE CONSIDERED 12/13/96

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s).

Form P-37/V11/84 I:\ltda\990008.446D\990844605.ids

Sheet 2 of 7

FORM PTO-1449 (REV.7-80) — U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.	APPLICATION NO.
990008.446DS	08/475,458

INFORMATION DISCLOSURE STATEMENT
(Use several sheets if necessary)

APPLICANTS	
Andrzej Z. Sledziewski et al.	
FILING DATE	GROUP ART UNIT
June 7, 1995	~~1804~~ 1812

MAY 16 1996 PATENT & TRADEMARK OFFICE

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	BA						
	BB						
	BC						
	BD						
	BE						
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	BI						
	BJ						
	BK						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
CMK	BL	EP 171 496	2/19/86	EPO				
	BM	EP 256 654	2/24/88	EPO				
	BN	EP 315 062	5/10/89	EPO				
	BO	EP 116 201	8/22/84	EPO				
CMK	BP	EP 120 694	10/3/84	EPO				

OTHER PRIOR ART *(Including Author, Title, Date, Pertinent Pages, Etc.)*

CMK	BR		Escobedo et al., *Science 240*: 1532-1534, 1988.
CMK	BS		Heldin et al., *EMBO J. 7*: 1387-1393, 1988.
CMK	BT		Radeke et al, *Nature 325*: 593-597, 1987.

EXAMINER	DATE CONSIDERED
Claire M. Kolb	12/13/96

* EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s).

Form PTO-1449/(REV.7-80) (Title:990008.446DS08944625.ids)

Sheet 3 of 7

FORM PTO-1449 (REV.7-80) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO. 420008.446D5

APPLICATION NO. 08/475,458

APPLICANTS Andrzej Z. Sledziewski et al.

FILING DATE June 7, 1995

GROUP ART UNIT 1804 1812

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INFORMATION DISCLOSURE STATEMENT

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U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	CA						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
CLM	CB	EP 327 369 A2	8/9/89	EPO				
CLM	CC	EP 244 221 A1	11/4/87	EPO				
CLM	CD	WO 90/06953	6/28/90	PCT				
	CE							
	CF							

OTHER PRIOR ART *(Including Author, Title, Date, Pertinent Pages, Etc.)*

CLM	CG		Ebina et al., *Cell 40*: 747-758, 1985.
CLM	CH		Rubin et al., *J.Immun. 135*: 3172-3177, 1985.
CLM	CI		Ellis et al., *J. Cell. Biol. 150*: 14a, 1987.
CLM	CJ		Smith et al., *Science 238*: 1704-1707, 1987.
	CK		Livneh et al., *J. Biol. Chem. 261*: 12490-12497, 1986.
	CL		Boni-Schnetzler and Pilch, *Proc. Natl. Acad. Sci. USA 84*: 7832-7836, 1987.
	CM		Claesson-Welsh et al., *Mol. Cell. Biol. 8*: 3476-3486, 1988.
CLM	CN		Ullrich et al., *Nature 309*: 418-425, 1984.

EXAMINER	DATE CONSIDERED
Claire M. Kosh	12/13/96

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s).

Form PT-1449/1/94 [File:\Docs\446D\P08446d5.lds]

Sheet 4 of 7

FORM PTO-1449 (REV.7-80)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

MAIL ROOM 82 MAY 16 1996 PAT. & TRADEMARK OFFICE

ATTY. DOCKET NO.	APPLICATION NO.
990008.446D5	08/475,458
APPLICANTS: Andrzej Z. Sledziewski et al.	
FILING DATE: June 7, 1995	GROUP ART UNIT: ~~1804~~ 1812

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
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FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
	DB							

OTHER PRIOR ART *(Including Author, Title, Date, Pertinent Pages, Etc.)*

CWK	DC	Ullrich et al., *Nature 313*: 756-761, 1985.
	DD	Derynck et al., *Nature 316*: 701-705, 1985.
	DE	Loh et al., *Cell 33*: 85-93, 1983.
	DF	Honjo et al., *Cell 18*: 559-568, 1979.
	DG	Alber and Kawasaki, *J. Mol. Appl. Genet. 1*: 419-434, 1982.
	DH	Russell et al., *Nature 304*: 652-654, 1983.
	DI	Grosschedl and Baltimore, *Cell 41*: 885-897, 1985.
	DJ	Hieter et al., *Cell 22*: 197-207, 1980.
	DK	Treiger et al., *J. Immunol. 136*: 4099-4105, 1986.
CWK	DL	Roth et al., *J. Cell. Biol. 102*: 1271-1283, 1986.

EXAMINER	DATE CONSIDERED
Claire M. Kenfer	12/13/96

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Form PT-37/V1/2/94 [illegible]

Sheet 5 of 7

FORM PTO-1449 (REV.7-80) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO. 990008.446D5

APPLICATION NO. 08/475,458

APPLICANTS Andrzej Z. Sledziewski et al.

FILING DATE June 7, 1995

GROUP ART UNIT ~~1804~~ 1812

MAIL ROOM MAY 16 1996 PAT. & TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
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FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
	EB							

OTHER PRIOR ART *(Including Author, Title, Date, Pertinent Pages, Etc.)*

Clmk	EC		Riedel et al., *Science 236*: 197-200, 1987.
	ED		Riedel et al., *Nature 324*: 68-70, 1986.
	EE		Gascoigne et al., *Proc. Natl. Acad. Sci. USA 84*: 2936-2940, 1987.
	EF		Maddon et al., *Cell 47*: 333-348, 1986.
	EG		Maddon et al., *Cell 42*: 93-104, 1985.
	EH		Capon et al., *Nature 337*: 525-531, 1989.
	EI		Wood et al., *Nature 314*: 446-449, 1985.
	EJ		Carlson et al., *Mol. Cell. Biol. 3*: 439-447, 1983.
	EK		Marx, *Science 229*: 455-456, 1985.
Clmk	EL		Neuberger et al., *Nature 312*: 604-609, 1984.

EXAMINER	DATE CONSIDERED
Cheri M. Kosf	12/13/96

* EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s).

Form PTO-1449 (Modified) (mod990008.446D5\990846d5.ids)

Sheet 6 of 7

FORM PTO-1449 (REV.7-80)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

MAIL ROOM 82 MAY 16 1996 PAT. & TRADEMARK OFFICE

ATTY. DOCKET NO.	APPLICATION NO.
990008.446D5	08/475,458
APPLICANTS	
Andrzej Z. Sledziewski et al.	
FILING DATE	GROUP ART UNIT
June 7, 1995	~~1804~~ 1812

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
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FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
	FB							

OTHER PRIOR ART *(Including Author, Title, Date, Pertinent Pages, Etc.)*

CMC	FC	Oi and Morrison, *Biotechniques 4*: 214-221, 1986.
	FD	Bailon et al., *Bio/Technology 5*: 1195-1198, 1987.
	FE	Ballou et al., *J. Biol. Chem. 255*: 5986-5991, 1980.
	FF	Munro and Pelham, *EMBO J. 3*: 3087-3093, 1984.
	FG	von Heijne, *Nucl Acids Res. 14*: 4683-4690, 1986.
	FH	von Heijne, *Eur. J. Biochem. 133*: 17-21, 1983.
	FI	Beggs, *Nature*: 104-108, 1978.
CMC	FJ	Clarke et al., *Meth. Enzym. 68*: 436-442, 1979.
	FK	~~Struhl et al., *Proc. Natl. Acad. Sci. USA 76*: 1035-1039, 1979.~~
	FL	~~Broach et al., *Gene 8*: 121-133, 1979.~~

EXAMINER	DATE CONSIDERED
Claire M. Le[illegible]	12/13/96

* EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s).

Form PT-27/V1/1/94 [illegible]

Sheet 7 of 7

FORM PTO-1449 (REV.7-80)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 990008.446D5	APPLICATION NO. 08/475,458
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		APPLICANTS Andrzej Z. Sledziewski et al.	
		FILING DATE June 7, 1995	GROUP ART UNIT ~~1804~~ 1812

MAY ROOM 82 MAY 16 1996 PATENT AND TRADEMARK OFFICE

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	GA						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
	GB							

OTHER PRIOR ART *(Including Author, Title, Date, Pertinent Pages, Etc.)*

CMM	GC		Mariuzza and Winter, *J. Biol. Chem. 264*: 7310-7316, 1989.
CMM	GD		Gronwald et al., *Proc. Natl. Acad. Sci. USA 85*: 3435-3439, 1988.
CMM	GE		Riedel et al., *Protein Engineering 1*(3): 237, 1987.
	GF		
	GG		
	GH		
	GI		
	GJ		
	GK		
	GL		

EXAMINER	DATE CONSIDERED
Claire M. Kolker	12/13/96

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s).

Form PT-2IDS/1449 (990008990008.446D5\9984465.jpg

PTO/SB/08A(10-01)
Approved for use through 10/31/2002 OMB 0651-0031
U.S. Patent & Trademark Office: U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449A/PTO
INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known

Application Number	Unknown
Filing Date	Even Date Herewith
First Named Inventor	Sledziewski, Andrzej
Group Art Unit	Unknown
Examiner Name	Unknown
Attorney Docket No: 985.011USX	

US PATENT DOCUMENTS

Examiner Initial*	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	Filing Date If Appropriate
RBK	US-5,336,603	08/09/1994	Capon, Daniel J., et al.	435	69.7	08/26/1992
RBK	US-5,565,335	10/15/1996	Capon, Daniel J., et al.	435	64.7	05/02/1994
RBK	US-6,004,781	12/21/1999	Seed, Brian	435	69.7	02/04/1994

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	T[2]

OTHER DOCUMENTS – NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
RBK		ELLIS, LELAND, et al., "Linking functional domains of the human insulin receptor with the bacterial aspartate receptor", Proc. Natl. Acad. Sci. USA, Vol. 83, (November 1986), pp. 8137-8141	
RBK		GASCOIGNE, NICHOLAS R., et al., "Secretion of a chimeric T-cell receptor-immunoglobulin protein", Proc. Natl. Acad. Sci., Vol. 84, (May 1987), pp. 2936-2940	
RBK		RIEDEL, HEIMO, et al., "A chimeric, ligand-binding v-erbB/EGF receptor retains transforming potential", Science, Vol. 236,(April 10, 1987), pp. 197-200	
RBK		TRAUNECKER, ANDRE, et al., "Soluble CD4 molecules neutralize human immunodeficiency virus type 1", Nature, Vol. 331,(January 1988), pp. 84-86	

EXAMINER Rachel B. Kapust DATE CONSIDERED 5/24/04

Substitute Disclosure Statement Form (PTO-1449)
[1] EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [2] Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

EXHIBIT 10

THIS EXHIBIT HAS BEEN REDACTED IN ITS ENTIRETY

EXHIBIT 11

10-K 1 d10k.htm ANNUAL REPORT FOR THE FISCAL YEAR ENDED DECEMBR 31, 2004

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2004

Commission File Number 1-1136

BRISTOL-MYERS SQUIBB COMPANY
(Exact name of registrant as specified in its charter)

Delaware	22-0790350
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

345 Park Avenue, New York, N.Y. 10154
(Address of principal executive offices)

Telephone: (212) 546-4000

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, $0.10 Par Value	New York Stock Exchange Pacific Exchange, Inc.
$2 Convertible Preferred Stock, $1 Par Value	New York Stock Exchange Pacific Exchange, Inc.

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes ☒ No ☐

The aggregate market value of the 1,951,041,834 shares of voting common equity held by non-affiliates of the registrant, computed by reference to the closing price as reported on the New York Stock Exchange, as of the last

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research efforts. These investments can take many forms, including licensing arrangements, codevelopment and comarketing agreements, copromotion arrangements and joint ventures.

Drug development is time-consuming, expensive and risky. In the development of human health products, industry practice and government regulations in the United States and most foreign countries provide for the determination of effectiveness and safety of new molecular entities through preclinical tests and controlled clinical evaluation. Before a new drug may be marketed in the United States, recorded data on preclinical and clinical experience are included in the NDA or the BLA to the FDA for the required approval. The development of certain other products is also subject to government regulations covering safety and efficacy in the United States and many foreign countries. There can be no assurance that a compound developed as a result of any program will obtain the regulatory approvals necessary for it to be marketed for any particular disease indication.

On average, only about one in ten thousand chemical compounds discovered by pharmaceutical industry researchers proves to be both medically effective and safe enough to become an approved medicine. The process from discovery to regulatory approval typically takes ten years or longer. Drug candidates can fail at any stage of the process, and even late-stage product candidates sometimes fail to receive regulatory approval. The Company believes its investments in research, both internally and in collaboration with others, have been rewarded by the number of new pharmaceutical compounds and indications it has in all stages of development.

The Company's drug discovery program includes many alliances and collaborative agreements. These agreements bring new products into the pipeline or help the Company remain on the cutting edge of technology in the search for novel medicines.

Listed below are several investigational compounds that the Company has in the later stages of development. All of these compounds are in or entering Phase II or Phase III clinical trials. Whether or not any of these investigational compounds ultimately becomes one of the Company's marketed products depends on the results of pre-clinical and clinical studies, the competitive landscape of the potential product's market and the manufacturing processes necessary to produce the potential product on a commercial scale, among other factors. The Company filed applications to the FDA for entecavir in September 2004 and muraglitazar in December 2004. The Company also filed a rolling BLA for abatacept (CTLA4Ig) under the provisions of the FDA's Continuous Marketing Application, Pilot 1 and expects that submission to be completed in early 2005. However, as noted above, there can be no assurance that the Company will seek regulatory approval of any of these compounds or that, if such approval is sought, it will be obtained. At this stage of development, the Company cannot determine all intellectual property issues or all the patent protection that may, or may not, be available for these investigational compounds. The patent coverage highlighted below does not include potential term extensions.

Abatacept	CTLA4Ig, a biological product which has been developed internally and is currently in Phase III clinical trials, is a fusion protein with novel immunosuppressive activity targeted initially at rheumatoid arthritis. Abatacept has been granted fast track status by the U.S. FDA and the Company is filing a rolling BLA for abatacept under the provisions of Continuous Marketing Application, Pilot 1. Complete Non-Clinical and Clinical sections have already been submitted to the FDA and the remaining sections will be submitted in early 2005. The Company has a series of patents covering CTLA4Ig and its method of use. The latest of the composition of matter patents expires in the United States in 2016. U.S. litigation with Repligen Corporation (Repligen) concerning the inventorship of CTLA4Ig has been concluded in favor of the Company. Repligen has received a U.S. patent that claims a use of CTLA4Ig to treat specific autoimmune diseases, including rheumatoid arthritis. For more information about this litigation, see "Item 8. Financial Statements—Note 21. Legal Proceedings and Contingencies."
Entecavir	Entecavir, which has been developed internally and is currently under regulatory review, is a potent and selective inhibitor of hepatitis B virus. The Company submitted an NDA to the FDA and a marketing authorization application to the European Medicines Evaluation Agency in October 2004. The Company has a composition of matter patent that expires in the United States in 2010.
Muraglitazar	Muraglitazar, which has been developed internally and is currently under regulatory review, is a dual PPAR agonist for the treatment of type 2 diabetes and other metabolic disorders. The Company submitted an NDA to the FDA in December 2004. The product is being codeveloped and copromoted under a collaboration agreement with Merck. The Company has a composition of matter patent which expires in the United States in 2020.
EMSAM*	EMSAM*, an investigational monoamine oxidase inhibitor administered as a transdermal patch for the

acute and maintenance treatment of patients with major depressive disorder, is being codeveloped with Somerset and has received an approvable letter from the FDA in February 2004.

EXHIBIT 12

THIS EXHIBIT HAS BEEN REDACTED IN ITS ENTIRETY

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, Philip A. Rovner, hereby certify that on August 25, 2008, the within document was filed with the Clerk of the Court using CM/ECF which will send notification of such filing(s) to the following; that the document was served on the following counsel as indicated; and that the document is available for viewing and downloading from CM/ECF.

BY HAND DELIVERY AND E-MAIL

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I hereby certify that on August 25, 2008 I have sent by E-mail the foregoing document to the following non-registered participant:

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