Amgen Inc. v. F. Hoffmann-LaRoche LTD et al Doc. 947

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC.,	
Plaintiff,	
v.	
F. HOFFMANN-LA ROCHE LTD; ROCHE DIAGNOSTICS GmbH; and HOFFMANN-LA ROCHE INC.,	CIVIL ACTION No.: 05-CV-12237WGY
Defendants.	

PRELIMINARY JURY INSTRUCTIONS [PROPOSED BY DEFENDANTS]

Defendants, F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc., respectfully request that the Court read the attached preliminary jury instructions to the jury prior to the commencement of trial and where noted, prior to the commencement of each new phase of trial.

These few preliminary instructions relate to the key substantive issues in the case: validity, infringement, and inequitable conduct. Given the number and complexity of issues in this case, Defendants believe that such preliminary instructions are necessary to orient the jurors to the evidence they will hear at trial.[1]

For the foregoing reasons, Defendants respectfully request that the following jury instructions be given to the jury at the commencement of trial, immediately before the opening statements.

[1] These preliminary instructions were adapted from similar instructions provided by this Court in patent cases such as *Genlyte Thomas Group, LLC v. Architectural Lighting Systems*, C.A. 05-10945 (January 22, 2007)(J. Young) and *Ethos Technologies, Inc. v. RealNetworks, Inc*, C.A. 02-11324 (March 14, 2006)(J. Young); and from acknowledged model patent instructions.

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Dated: September 2, 2007
Boston, Massachusetts

Respectfully submitted,

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

By their attorneys,

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and will be delivered to Amgen's trial counsel by electronic mail in the manner requested in the August 29, 2007, letter of Renee DuBord Brown to Thomas F. Fleming. Paper copies will be sent to those indicated as non-registered participants on September 4, 2007.

/s/ Julia Huston
Julia Huston

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PRELIMINARY JURY INSTRUCTIONS
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1. OVERVIEW[2]

Ladies and gentlemen, welcome, I want to thank you for participating in this trial, which is a true example of the democratic process in action. At this time in this courtroom there are thirteen judges. You twelve men and women are the judges of the facts. You are the only judges of the facts. That is not my function. I am the judge of the law. You are going to determine the facts in this case.

You can take notes during this case. Ms. Smith is passing out to you now notebooks and pens. Put your names on them. We will lock them up after every court session. You just carry them out with you, or leave them on the table in the jury room. Ms. Smith will collect them, lock them up, and we will give them back to you the next day. So you have the right to take notes. Now, while you are allowed to take notes, no one says you have to take notes. It's not a test. If you are one of those people who by background and life experience you get your best judgment about people by watching them very closely, no one says you have to take notes.

But this case is going to take a while and maybe you would want to keep the names of witnesses or particular things, dates or data that you think is of significance, feel free to take notes. Your notes are private to you. No one will ever see them. When the trial is over, Ms. Smith will destroy the notes. You should not pass your notes among the jurors. And the reason for that is they are not evidence of anything. They are your notes to refresh your recollection.

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[2] Model Patent Jury Instructions for the Northern District of California (2004).

We are going to be together for several weeks, I have told the lawyers and I promise you that the evidence will be concluded by October 17. We are not going to have trial every day until then, in fact we will not have trial during the week of September 17 and during the period October 5 to October 14. There may be other days on which we don't have trial during this period and Ms. Smith will tell you exactly when that is.

You can ask questions. It's a formal proceeding, so if you have a question write your question out, rip it out of your notebook, pass it down to the foreperson. Ms. Smith and I will be watching. We'll come collect it. The question will get to me and I'll read it. Now, I may not ask it. If I decide to ask the question, I may not ask it exactly as you've written it but rather will ask it or a series of questions to elicit the information in a neutral manner. All questions that you pass to me will, whether they are asked or not, will be put on Ms. Smith's bench so that the attorneys can review them.

I am now going to give you a brief overview of this case. This case involves a dispute relating to five United States patents. Before summarizing the positions of the parties and the legal issues involved in the dispute, let me take a moment to explain what a patent is and how one is obtained.

Patents are granted by the United States Patent Office (sometimes called "the Patent Office" or the "PTO"). The process of obtaining a patent is called patent prosecution. A valid United States patent gives the patent owner the right for a limited period of time to exclude others from making, using, offering to sell, or selling the patented subject matter in the United States or from importing it into the United States. Generally speaking, the term of a patent is 17 years from the date that the patent was

issued. A violation of the patent owner's rights is called infringement. The patent owner may try to enforce a patent against persons believed to be infringers by a lawsuit filed in federal court.

To obtain a patent, one must file an application with the United States Patent Office. The application includes what is called a "specification," which must contain a written description of the claimed invention telling what the invention is, how it works, how to make it and how to use it so others skilled in the field will know how to make or use it. The specification concludes with one or more numbered sentences. These are the patent "claims." When the patent is eventually granted by the Patent Office, the claims define its boundaries and give notice to the public of those boundaries.

The idea of the patent application is that, in exchange for the exclusive right to practice the invention, an inventor must teach the world how to practice the invention. The advantage of this is that when we, the public, know how an invention is performed, the public is able to learn from and use the information disclosed in the patent.[3]

During the patent application process, the patent application is reviewed by an Examiner at the Patent Office. The examiner considers, among other things, whether each claim defines an invention that is new, useful, and not obvious in view of the prior art.

But, the fact that the Patent Office grants a patent does not necessarily mean that any invention claimed in the patent, in fact, deserves the protection of a patent. Sometimes the Patent Office makes a mistake. Also, for example, the Examiner may not have had available to him or her other prior art or information that will be presented to

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[3] Transcript of Pretrial Matters, Preliminary Jury Instructions, Opening Statements and the Evidence at 26-27, *Genlyte Thomas Group, LLC v. Architectural Lighting Systems*, C.A. 05-10945 (January 22, 2007)(J. Young).

you. A person accused of infringement has the right to argue here in federal court that a claimed invention in the patent is invalid because it does not meet all the requirements for a patent.

2. SUMMARY OF THE CASE

In this case, there are five patents. Amgen owns these patents. Amgen has sued Roche claiming that Roche is practicing the claimed subject matter in these patents. In response, Roche argues that it does not infringe the patents because what Roche does is different and is not covered by the patents and that its product is so different that it could not be considered infringement.

Roche also argues that Amgen's patents are invalid and should not have been granted. Finally, Roche also argues that Amgen acted unfairly, or inequitably, in applying for these patents and that, for this reason, they are unenforceable.

We will run this trial in three phases to address each of these three issues. First, the parties will address the issue of invalidity. In this phase, Roche will have the burden of proof and so Roche will first present its case as to why it believes that Amgen's patents are invalid. Among Roche's defenses are that the patents are invalid for anticipation, obviousness, double patenting, and lack of written description. When Roche is finished presenting its case, Amgen will have the opportunity to respond.

Second, the parties will address the issue of infringement. This time, Amgen has the burden of proof and will present its case first. Roche will then have the opportunity to respond. Finally, the parties will address the issue of inequitable conduct, or whether Amgen committed misconduct in applying for the patents. Here, Roche has the burden of proof and so Roche will present its case first. Amgen will then respond. At the end of all three phases, you will then be asked to deliberate on all issues and come to a unanimous verdict.

Your job will be to decide whether the cited claims of Amgen's asserted patents have been infringed, whether those claims are invalid, and whether Amgen's conduct in applying for these patents is inequitable.

I will now talk a little bit more about patents in general and about the applicable law for each of these phases and then the lawyers will begin.

3. WHAT IS A PATENT[4]

As I stated earlier, a patent is issued by the United States Patent Office. In order to get a patent, you have to teach the world how to do what you do. The different parts of the patent go to the teaching of the patent. If you look at Tab ** in your notebooks, you will see one patent that is at issue in this case. First, you will see a seven digit number in the upper right hand corner of the patent. Patents are usually referred to by the last three numbers of the patent. For example, this patent would be referred to as the '*** patent. At the beginning of the patent, there is what is called an abstract. The abstract generally describes what the inventors believe has been invented. Then, there are a number of illustrations that show what the inventors believe they invented. Following the illustrations, you will find the section that is called the specification. The specification is designed to teach the public how to perform or make the invention. After the specification, you will find a section that contains the patent claims. This section begins with the sentence, "what is claimed is" and then continues with numbered paragraphs. The name of the game is the claim. That is, the claims define what the patent owner may exclude others from doing during the term of the patent..

It is the claim that describes what the applicant believed was its exact invention. If valid and enforceable, an inventor can only exclude others from doing what is described in these claims.

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[4] Transcript of Preliminary Jury Instructions, Opening Statements and the Evidence at 106-108, *Ethos Technologies, Inc. v. RealNetworks, Inc*, C.A. 02-11324 (March 14, 2006)(J. Young); Transcript of Pretrial Matters, Preliminary Jury Instructions, Opening Statements and the Evidence at 25-26, *Genlyte Thomas Group, LLC v. Architectural Lighting Systems*, C.A. 05-10945 (January 22, 2007)(J. Young).

4. INVALIDITY[5]

As I stated a few minutes ago, we will begin the trial with the validity phase.

As I told you earlier, a patent can only be granted to an inventor for a new, novel and nonobvious invention. And, in order to obtain a patent, one must file an application with the U. S. Patent Office. The idea of this application is that, in exchange for the exclusive right to practice the invention, an inventor must describe his claimed invention and teach the world how to practice the invention.[6] An issued patent is presumed valid.

Roche claims that Amgen's patents are invalid and that the Patent Office should not have granted Amgen these patents. Roche argues that the inventions claimed in the Amgen patents were not new or novel, but instead, that the invention was already being practiced by others, written about in publications, and patented by others. Roche also contends that the Patent Office did not have all the necessary information when evaluating the asserted claims.

Additionally, Roche claims that others were already using things so similar to Amgen's invention that Amgen's inventions were obvious and therefore, not entitled to patent protection and not valid. Roche also asserts that the claims are overbroad and deficient because they do not adequately describe the claimed invention or teach the world how to make the invention, as they are required to do.

Roche also argues that the patents are invalid as obvious, and that certain patents are invalid for double patenting. Double patenting is a doctrine that prevents an unjustified extension of the term of the right to exclude granted by a patent by allowing a

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[5] Model Patent Jury Instructions for the Northern District of California (2004).

[6] Transcript of Pretrial Matters, Preliminary Jury Instructions, Opening Statements and the Evidence at 26-27, *Genlyte Thomas Group, LLC v. Architectural Lighting Systems*, C.A. 05-10945 (January 22, 2007)(J. Young).

second later patent claiming an obvious variant of the same invention to issue to the same owner.

To prove invalidity of any patent claim for any of these reasons, Roche must persuade you by clear and convincing evidence that the claim is invalid.

5. INFRINGEMENT[7]

The second phase of the trial will address infringement. To prove infringement of any claim, Amgen must prove by a preponderance of the evidence that Roche has infringed one or more of the claims of at least one of Amgen's patents. In other words, Amgen must persuade you with proper evidence that it is more likely than not that Roche has infringed the claim.

Amgen may show either direct infringement or indirect infringement. Direct infringement refers to any infringement that is committed by Roche itself. Indirect infringement refers to instances where Roche may not infringe the patent but where Roche intentionally induces induce others to infringe the patent. In general, when I say that Amgen claims that Roche infringes its patents, what I mean is that Amgen claims that Roche is practicing the claimed subject matter in Amgen's patents.

As you will hear, Roche's product, called MIRCERA®, is approved for sale outside the United States, but is pending approval for sale in the United States. Roche argues that all of its uses in the United States to date were for reasons related to its pending approval from the FDA, if you find that this is true, then you should find that there has been no infringement.

A product directly infringes a patent if the product practices the patented subject matter described in at least one claim of the asserted patent. Deciding whether a claim has been directly infringed is a two-step process. The first step is to decide the meaning of the patent claim. I have already made this decision, and I will instruct you later as to the meaning of the asserted patent claims. The parties have presented you with a glossary of

[7] Roche anticipates that the Court may wish to provide this instruction immediately before the second phase of the trial.

the meanings of certain claim terms that you must apply in coming to your conclusion. The second step is to decide whether Roche has made, used, sold, offered for sale or imported into the United States a product covered by the asserted claim of the patent. You, the jury, make this decision. With one exception, you must consider each of the asserted claims of the patent individually, and decide whether Roche's product infringes that claim by practicing each of the requirements of the claim.

The one exception to considering claims individually concerns dependent claims. A dependent claim includes all of the requirements of a particular independent claim, plus additional requirements of its own. [Provide example from one of Amgen's patents]. As a result, if you find that an independent claim is not infringed, you must find that its dependent claims are also not infringed. On the other hand, if you find that an independent claim has been infringed, you must still separately decide whether the additional requirements of its asserted dependent claims have also been infringed.

You may also find that the product does not infringe that claim if you find that the product is so far changed in principle from the claimed subject matter described in the patent specification that persons of ordinary skill in the field would find that the product performs the required function of the invention in a substantially different way.[8] If this is the case, Roche has not literally infringed the patents.

You may recall that one way to infringe a patent is to import an item derived from a patented process into the United States. However, one is allowed to import an item into the country that is "materially changed" from the claimed subject matter in the course of

[8] *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608-9 (1950).

its conversion into the imported item.[9] Such importation does not constitute infringement, either literally or otherwise. With regard to whether or not the imported product is "materially changed," Amgen bears the burden of proof and must prove that the allegedly infringing imported product was not materially changed.[10]

[9] 35 U.S.C. § 271(g); *Eli Lilly & Co. v. Am. Cyanamid Co.*, 82 F.3d 1568, 1572 (Fed. Cir. 1996).
[10] *Genentech, Inc. v. Boehringer Mannheim GmbH,* 47 F. Supp. 2d 91, 108 (D. Mass. 1999).

6. INEQUITABLE CONDUCT[11]

In the third phase of the trial, the parties will address Roche's claims that Amgen's conduct in filing its patent applications was inequitable and therefore, that the patents are unenforceable. Roche bears the burden of proof on this issue.

As I explained earlier, after a patent application is filed, it is assigned to an Examiner, who examines the application and attempts to determine whether or not the application and the claims meet all of the requirements of the patent laws. In conducting this examination, the Examiner must consider the description of the invention in the application, which may involve highly technical subject matter, and search for and consider the prior art. The Examiner has only a limited amount of time and resources available and, therefore, must rely on information provided by the applicant with respect to the technical field of the invention and the prior art. For example, the Patent Examiner cannot do testing or confirm scientific data submitted by the applicant.

Because the United States Patent Office must rely on the patent application for information, applicants are required to prosecute patent applications with candor, good faith, and honesty. This duty of candor and good faith extends to all inventors named on a patent application, all attorneys and agents involved in preparing and prosecuting the application, and every other person involved with the prosecution of the patent application. Each individual with such a duty must disclose directly to the examiner all information known to that individual to be material. The term "information" can include prior art and factual representations made by each individual to the Patent Office. Moreover, the duty of candor and good faith requires more than just disclosing material

[11] Roche anticipates that the Court may wish to provide this instruction immediately before the third phase of the trial.

information.[12] For example, if an applicant knowingly takes advantage of an error by the Patent Office, then it would not fulfill its duty of candor and good faith.[13] Similarly, the mere submission of information does not satisfy the duty of candor and good faith where an applicant buries material information or presents the information in a manner so that the examiner would be likely to ignore it and permit the application to issue as a patent.[14]

Roche contends that Amgen may not enforce its patents because Amgen engaged in inequitable conduct before the Patent Office during the prosecution of its patents. "Inequitable conduct" refers to the failure to meet this duty of candor and good faith.

Roche bears the burden of establishing inequitable conduct by clear and convincing evidence. To determine whether the Amgen patents were obtained through inequitable conduct, you must determine that Amgen, its representatives, or someone involved in a substantial way with the prosecution of the application, withheld, buried, or misrepresented information that was material to the examination of the patent application, and that this individual or individuals acted with an intent to deceive or mislead the Patent Office.[15] You can find intent based on direct evidence but direct evidence is rare. Intent can also be inferred from the facts and surrounding circumstances, considering the

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[12] MPEP § 2001.04 (8th Ed. Rev. 5, Aug. 2006); *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1571 (Fed. Cir. 1983).

[13] *KangaROOS USA, Inc. v. Caldor, Inc.*, 778 F.2d 1571, 1576 (Fed. Cir. 1985).

[14] *See e.g. eSpeed Inc. v. BrokerTec USA LLC*, 417 F. Supp. 2d 580, 598 (D. Del. 2006)(submission made amidst more than two thousand pages of materials was a "blizzard of paper" characterized as "consistent with an intent to hide" and supporting a finding of inequitable conduct), *aff'd*, 480 F.3d 1129 (Fed. Cir. 2007); *Golden Valley Microwave Foods Inc. v. Weaver Popcorn Co., Inc.*, 837 F. Supp. 1444, 1477 (N.D. Ind. 1992) (holding duty of candor violated where applicant or attorney discloses reference "in such a way as to 'bury' it or its disclosure in a series of disclosures of less relevant prior art references, so that the examiner would be likely to ignore the entire list and permit the application to issue"), *aff'd*, 11 F.3d 1072 (Fed.Cir. 1993).

[15] AIPLA model jury instruction 11.0; *Bristol-Myers Squibb Co. v. Phone-Poulence Rorer, Inc.*, 326 F.3d 1226 (Fed. Cir. 2003); *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268 (Fed. Cir. 2001); *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253 (Fed. Cir. 1997).

totality of the circumstances, including the nature of the conduct and evidence of the absence or presence of good faith.

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