Read in open court on 9/22/2017 nms.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC. and
AMGEN MANUFACTURING LIMITED,

Plaintiffs,

v.

HOSPIRA, INC.,

Defendant.

Civil No. 1:15-cv-839-RGA

JURY TRIAL DEMAND

FINAL JURY INSTRUCTIONS

1.2. Jurors' Duties

You have two main duties as jurors. The first one is to decide what the facts are from the evidence that you saw and heard here in court. Deciding what the facts are is your job, not mine, and nothing that I have said or done during this trial was meant to influence your decision about the facts in any way.

Your second duty is to take the law that I give you, apply it to the facts, and decide, under the appropriate burden of proof, which party should prevail on each of the issues presented. It is my job to instruct you about the law, and you are bound by the oath that you took at the beginning of the trial to follow the instructions that I give you, even if you personally disagree with them. This includes the instructions that I gave you before and during the trial, and these instructions. All of the instructions are important, and you should consider them together as a whole.

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

1.4. Consideration of Evidence

You should use your common sense in weighing the evidence. Consider the evidence in light of your everyday experience with people and events, and give it whatever weight you believe it deserves. If your experience tells you that certain evidence reasonably leads to a conclusion, you are free to reach that conclusion.

1.6. Credibility of Witnesses

You are the sole judges of each witness's credibility. You should consider each witness's means of knowledge; strength of memory; and opportunity to observe; how reasonable or unreasonable the testimony is; whether it is consistent or inconsistent; and whether it has been contradicted; the witness's biases, prejudices, or interests; the witness's manner or demeanor on the witness stand; and all circumstances that, according to the evidence, could affect the credibility of the testimony.

If you find the testimony to be contradictory, you must try to reconcile it, if reasonably possible, so as to make one harmonious story of it all. But if you cannot do this, then it is your duty and privilege to believe the portions of testimony that, in your judgment, are most believable and disregard any testimony that, in your judgment, is not believable.

In determining the weight to give to the testimony of a witness, you should ask yourself whether there was evidence tending to prove that the witness testified falsely about some important fact, or, whether there was evidence that at some other time the witness said or did something, or failed to say or do something, that was different from the testimony he or she gave at the trial. You have the right to distrust such witness's testimony in other particulars and you may reject all or some of the testimony of that witness or give it such credibility as you may think it deserves.

You should remember that a simple mistake by a witness does not necessarily mean that the witness was not telling the truth. People may tend to forget some things or remember other things inaccurately. If a witness has made a misstatement, you must consider whether it was simply an innocent lapse of memory or an intentional falsehood, and that may depend on whether it concerns an important fact or an unimportant detail.

This instruction applies to all witnesses, including expert witnesses and witnesses who provided testimony by deposition.

1.8. Exhibits and Demonstrative Exhibits

During the course of the trial, you have seen many exhibits. Many of these exhibits were admitted as evidence. Some of these admitted exhibits or portions of them have been displayed for you on a screen and you will have these admitted exhibits, whether displayed on a screen or not, in the jury room for your deliberations.

There are other exhibits (including charts and animations presented by attorneys and witnesses) that were offered to help illustrate the testimony of the various witnesses. These illustrations, called "demonstrative exhibits," have not been admitted as evidence, are not evidence, and should not be considered as evidence. Rather, it is the underlying testimony of the witness that you heard when you saw the demonstrative exhibits that is the evidence in this case.

2. THE PARTIES AND THEIR CONTENTIONS

Amgen alleges that Hospira infringed claims 1-7 of the '349 patent and claims 24 and 27 of the '298 patent when 21 batches of Hospira's epoetin drug substance were manufactured over the course of 2013-2015.

Amgen alleges that both the '349 patent and the '298 patent were infringed by the manufacture of four batches of Hospira's epoetin drug substance in 2013, six batches in 2014, and one batch in 2015. Amgen alleges that the `298 patent was also infringed by the manufacture of ten additional batches of Hospira's epoetin drug substance in 2015.

Hospira denies that it infringed any of Amgen's patent claims, asserts that its activities are protected under a "safe harbor" provision of the patent laws, and asserts that each of the asserted claims of the '298 patent is invalid, and denies that it owes Amgen any money damages.

In this case, you must decide the issues according to the instructions I give you. In general, the following are the issues you must decide:

a. Whether Amgen has proven by a preponderance of the evidence that the use of vertebrate cells and manufacturing of Hospira's epoetin product on or before May 26, 2015 infringed any of claims 1 through 7 of the '349 patent.

b. Whether Amgen has proven by a preponderance of the evidence that the manufacturing of Hospira's epoetin product on or before January 5, 2016, infringed either of claims 24 or 27 of the '298 patent.

c. Whether Hospira has proven by clear and convincing evidence that claim 24 and claim 27 of the '298 patent are anticipated or obvious, and therefore invalid.

d. Whether Hospira has proven by a preponderance of the evidence that its use of vertebrate cells and manufacturing of its epoetin drug substance are protected by the safe harbor provision of the patent laws.

3. BURDENS OF PROOF

For each issue in this case, either Amgen or Hospira bears the burden of proof, which means that it bears the burden of persuading you to find in its favor. In a patent case such as this, there are two different burdens of proof. The first is called "preponderance of the evidence." The second is called "clear and convincing evidence."

For any issue on which a party bears the burden of proof by a preponderance of the evidence, that party has carried its burden if you find that what the party claims is more likely true than not, when considered in light of all of the evidence. To put it differently, if you were to put each party's evidence on the opposite sides of a scale, the evidence supporting the party with the burden of proof would have to make the scales tip somewhat on the side of that party.

Here, Amgen has the burden of proving by a preponderance of the evidence that the manufacture of Hospira's epoetin drug substance infringed the '349 patent, infringed the '298 patent, and the amount of damages Amgen should receive to compensate it for any infringement. Hospira has the burden of proving by a preponderance of the evidence that the manufacture of Hospira epoetin drug substance is protected from infringement by the safe harbor provision of the patent laws.

For any issue on which a party bears the burden of proof by clear and convincing evidence, that party has carried its burden if you find that the party with the burden has caused you to have an abiding conviction that the truth of that party's factual contention is highly probable, when considered in light of all of the evidence. Proof by clear and convincing evidence is a higher burden than proof by a preponderance of the evidence.

Here, Hospira has the burden of proving by clear and convincing evidence that the claims of the '298 patent are invalid because the claimed method was anticipated or obvious.

4.2. Independent and Dependent Claims

Claims can be stated in two different ways in a patent. The first way a patent claim can be stated is in the form of an "independent" claim. An "independent" claim sets forth all of the requirements that must be met in order for an accused product or method to be covered by that claim, and thus infringe that claim. An independent claim is read alone to determine its scope.

In this case, claims 1 and 4 of the '349 patent and claims 24 and 27 of the '298 patent are each independent claims.

The second way a claim can be stated is in the form of a "dependent" claim. A dependent claim does not itself recite all of the requirements of the claim but instead incorporates the requirements of another claim or claims and adds its own additional requirements. In this way, the claim "depends" on another claim or claims. To determine what a dependent claim covers, it is necessary to look at both the dependent claim and any other claims from which it depends. For example, claim 2 of the '349 patent is a dependent claim of claim 1 and, as a result, claim 2 includes all the requirements of claim 1 and all the additional requirements of claim 2. Claims 2, 3, 5, 6, and 7 of the '349 patent are dependent claims. You are not being asked to consider any dependent claims in the '298 patent.

An accused product or method is only covered by, and therefore infringes, a dependent claim if the accused product or method meets all of the requirements of both the dependent claim and the claims from which the dependent claim depends. Because a dependent claim incorporates all of the features of the independent claims from which it depends, if you find that an independent claim is not infringed, then the claims that depend from that independent claim cannot be infringed.

4.4. Open Ended or "Comprising" Claims

Some of the Asserted Claims use the word "comprising."

"Comprising" is interpreted the same way as "including" or "containing." In patent claims, "comprising" means that the claims are open-ended. As such, the accused cells and methods must contain or use everything that is in the claim, but may additionally contain or use other things. Based on this explanation, if you find that Hospira's cells and methods include all of the requirements in a claim, the fact that Hospira's cells and methods may also include an additional component do not mean that the cells and methods does not infringe the claim.

5.2. Infringement

To prove infringement of a patent claim, Amgen must prove by a preponderance of the evidence, that is, that it is more likely than not, that the use of vertebrate cells and manufacture of the Hospira epoetin drug substance met all of the requirements of the patent claim. Infringement requires no more than the unauthorized making, use, sale, offer for sale, or importation of a patented invention during the time when the patent was in force. Thus, Hospira's knowledge of Amgen's patents and Hospira's intent are irrelevant to your determination of direct infringement.

To determine infringement, you must compare the accused product or method with each claim that Amgen asserts is infringed, using my instructions as to the meaning of the patent claims. A patent claim is infringed only if the vertebrate cell or method used in manufacturing Hospira's drug substance includes each and every requirement in that patent claim. If Hospira's cells or methods do not contain one or more requirements or steps recited in a claim, Hospira does not infringe that claim.

Hospira is responsible for the manufacturing activities of GlaxoSmithKline ("GSK") as they relate to Hospira's epoetin drug substance.

7. INVALIDITY

In this case, Hospira contends that claims 24 and 27 of the '298 patent are anticipated by U.S. Patent 4,667,016. Hospira also contends that claims 24 and 27 of the '298 Patent are obvious over U.S. Patent No. 4,667,016 in view of the prior art. I will explain the legal concepts of anticipation, obviousness, and prior art in a moment.

In making your determination, you must consider each of these patent claims separately and individually.

7.2. Prior Art

Under the patent laws, a person is granted a patent only if the invention claimed in the patent is new and not obvious in light of what came before. That which came before is referred to as the "prior art." In this case, the following items are prior art to the '298 patent:

- U.S. Patent No. 4,667,016;
- W.A. Lukowsky & R.H. Painter, Studies on the Role of Sialic Acid in the Physical and Biological Properties of Erythropoietin, Canadian Journal of Biochemistry, Vol. 50, 909-917 (1972); and
- Beeley, Laboratory Techniques in Biochemistry and Molecular Biology: Glycoprotein and Proteoglycan Techniques (1985).

The burden of proof on Hospira to prove that the prior art renders a claim invalid never changes regardless of whether the Examiner in the Patent Office considered the prior art reference during the prosecution of the application which matured into the '298 patent. However, if the Patent Office considered a reference, it may be more difficult for Hospira to meet its burden of proof to prove invalidity based on that reference.

patented invention that was unrecognized and unappreciated can still be an invalidating anticipating reference, provided the allegedly inherent feature was necessarily and inevitably present in the reference. Evidence outside of the prior art reference itself may be used to show that elements that are not expressly disclosed in the reference are inherent in it.

To determine the scope and content of the prior art, you must determine what prior art is reasonably pertinent to the particular problems the inventor, Dr. Strickland, faced. The person of ordinary skill in the art is presumed to be aware of all of the pertinent prior art.

I have already instructed you on how you are to determine the level of ordinary skill in the art. Once you have made that determination, you are to apply it in your determination whether the asserted claims would have been obvious.

The next factor that you must consider is the differences, if any, between the prior art and the claimed inventions. Importantly, a claim is not proved obvious merely by demonstrating that each of the elements was independently known in the prior art. Most, if not all, inventions rely on building blocks of prior art, and claimed discoveries almost of necessity will likely be combinations of what is already known. Therefore, you should consider whether a reason existed at the time of the invention that would have prompted a person of ordinary skill in the art in the relevant field to combine the known elements in the way the claimed invention does. The motivation to modify the prior art to arrive at the claimed invention need not be the same motivation that the inventor had.

In arriving at your decision on the issue of whether the claimed inventions of the '298 patent would have been obvious to a person of ordinary skill in the art, you may take into account such factors as: (1) whether the claimed invention was merely the predictable result of using prior art elements according to their known functions; (2) whether the claimed invention provides an obvious solution to a known problem in the relevant field; (3) whether the prior art teaches or suggests the desirability of combining elements claimed in the invention; (4) whether the prior art teaches away from combining elements in the claimed invention; and (5) whether it would have been obvious to try the combinations of elements, such as when there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions.

8. DAMAGES

8.1. Damages—Generally

I will now instruct you about the measure of damages. By instructing you on damages, I am not suggesting which party should win this case on any issue.

The damages you award must be adequate to compensate Amgen for any infringement you determine to have occurred. Damages are not meant to punish an infringer. Your damages award, if you reach this issue, should put Amgen in approximately the same financial position that it would have been in if the parties had reached agreement for Hospira to license the patents before the infringement began.

Amgen has the burden to prove the amount of its damages by a preponderance of the evidence. While Amgen is not required to prove the amount of its damages with mathematical precision, it must prove them with reasonable certainty.

If you find that Amgen has established infringement of a valid patent claim of the patents-in-suit, Amgen will be entitled to a reasonable royalty to compensate it for that infringement. A reasonable royalty is defined as the amount of money Amgen and Hospira would have agreed upon as a fee for Hospira using Amgen's invention before the infringement first began.

8.3. Factors for Determining a Reasonable Royalty

In determining the reasonable royalty, you should consider all the facts known and available to the parties at the time the infringement began. Some of the kinds of factors that you may consider in making your determination are:

(1) The royalties, if any, received by Amgen for the licensing of the '349 patent or the '298 patent.

(2) The nature and scope of the license, such as whether the license is non-exclusive or exclusive.

(3) The utility and advantages of the patented property over the old modes or devices, if any, that had been used for working out similar results.

(4) Amgen's established policy and program to enforce its patent rights, if any, or license its patents under special conditions to preserve its monopoly.

(5) The portion of the realizable profits that should be credited to the invention as distinguished from non-patented elements, the manufacturing process, or business risks.

(6) The commercial relationship between Amgen and Hospira, such as whether they are competitors in the same territory in the same line of business, or whether they are inventor and promoter.

(7) The duration of the patent and term of the license.

(8) The established profitability of the products made under the patents, its commercial success, and its popularity.

(9) The nature of the patented invention, the character of any commercial example of it, and the benefits to those who have used the invention.

(10) The extent to which Hospira has made use of the invention and any evidence probative of the value of that use.

8.4. Availability of Non-Infringing Alternatives

In determining a reasonable royalty, you may also consider evidence concerning the availability and cost of non-infringing alternatives to using the patented invention. A non-infringing alternative must have been available at the time of the infringement, must be acceptable in that it provides the same advantages as the patented invention, and must not infringe the patent.

9. DELIBERATION AND VERDICT

9.1. Deliberations and Verdict—Introduction

That concludes the part of my instructions explaining the rules for considering some of the testimony and evidence. Now let me finish by explaining some things about your deliberations in the jury room, and your possible verdicts.

Once you start deliberating, do not talk to the jury officer, or to me, or to anyone else except each other about the case. If you have any questions or messages, you must write them down on a piece of paper, sign them, and then give them to the jury officer. The officer will give them to me, and I will respond as soon as I can. I may have to talk to the lawyers about what you have asked, so it may take me some time to get back to you. Any questions or messages normally should be sent to me through your foreperson, who by custom of this Court is juror No. 1.

One more thing about messages. Do not ever write down or tell anyone outside of the jury how you stand on your votes. For example, do not write down or tell anyone that you are split 4-4, or 6-2, or whatever your vote happens to be. That should stay secret until you are finished.

9.3. Duty to Deliberate

Now that all the evidence is in and the arguments are completed, you are free to talk about the case in the jury room. In fact, it is your duty to talk with each other about the evidence and to make every reasonable effort you can to reach a unanimous agreement. Talk with each other, listen carefully and respectfully to each other's views, and keep an open mind as you listen to what your fellow jurors have to say. Try your best to work out your differences. Do not hesitate to change your mind if you are convinced that other jurors are right and your original position was wrong.

But do not ever change your mind just because other jurors see things differently, or just to get the case over with. In the end, your vote must be exactly that—your own vote. It is important for you to reach unanimous agreement, but only if you can do so honestly and in good conscience.

No one will be allowed to hear your discussions in the jury room, and no record will be made of what you say. So you should all feel free to speak your minds.

Listen carefully to what the other jurors have to say, and then decide for yourself.

9.5. Court Has No Opinion

Let me finish up by repeating something that I said to you earlier. Nothing that I have said or done during this trial was meant to influence your decision in any way. You must decide the case yourselves based on the evidence presented.