Amgen Inc. v. F. Hoffmann-LaRoche LTD et al Doc. 923

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.	

ROCHE'S OPPOSITION TO AMGEN'S MOTION IN LIMINE NO. 7

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PRELIMINARY STATEMENT

The presentation of commercial success in front of juries is routine, and there is nothing about this case to suggest that there is any reason to make an exception and withhold relevant information from the jury in this case. Roche must be permitted to present relevant evidence of Amgen sales and profits derived from Amgen's EPOGEN® and ARANESP® products in order (1) to rebut Amgen's assertions of commercial success made in support of Amgen contentions of nonobviousness of the patents in suit; (2) to show that, in prosecuting its applications for the patents in suit, Amgen had a strong motive to deceive the USPTO, which is highly relevant to Roche's defenses of inequitable conduct; and (3) to impeach witnesses offered by Amgen and demonstrate their bias, especially where such witnesses are Amgen employees or have an interest in the success of Amgen.

Whether there is a nexus between EPOGEN®'s commercial success and the patents in suit is a disputed issue of fact, and the evidence, including Amgen's revenues and profits, shows that Amgen had achieved commercial success with EPOGEN® long before any of the patents in suit issued, and that the success of EPOGEN® is not attributable to the inventions claimed in the patents-in-suit.

Amgen, on the other hand, has made clear through its interrogatory responses and expert reports that it will present evidence, including evidence of the large revenues of EPOGEN®, in order to rebut Roche's evidence of obviousness. Amgen cannot have it both ways. Amgen cannot be allowed to present evidence of the sales of Amgen

erythropoiesis products to support an argument against obviousness if Roche is precluded from using such data to rebut Amgen claims.

Amgen seeks to have this Court deny Roche its right to rebut Amgen's contentions that there are secondary considerations of nonobviousness. The Court should not do so, but instead should admit Roche's evidence concerning Amgen sales, which is typically admissible in patent infringement cases. In the alternative, if the Court allows Amgen's motion, the Court should likewise preclude Amgen from offering proof of commercial success and related secondary considerations of nonobviousness.

FACTUAL BACKGROUND

A. No Nexus Between Commercial Success and the Patents in Suit

To rebut Amgen's contention that commercial success is indicative of non-obviousness of the Lin patents in suit, Roche may offer evidence that Amgen began marketing EPOGEN® in 1989 after receiving FDA approval, and that the product, covered only by issued claims of a patent not in suit, was an immediate commercial success. In fact, EPOGEN® sales totaled $250 million dollars in 1990. Exhibit A, Expert Report of John Lowe ¶ 58, April 6, 2007.[1] Roche will further present evidence showing that these sales were made five years before the first issuance of the patents in suit, and that, therefore, this commercial success is not attributable to these patents. Joint Pretrial Memorandum (DN 807) at 5 (stipulating that the '868 patent issued on August 15, 1995).

Specifically, from the time Amgen began marketing EPOGEN in 1989 until 1995, the year that claims of the patents in suit began to issue, the only Amgen patent that

[1] All exhibit referenced in this brief are attached to the Declaration of Kregg T. Brooks in Support of Roche's Opposition to Amgen's Motion in Limine No. 7, filed herewith.

covered EPOGEN® was U.S. Patent No. 4,703,008 ("'008 patent"), issued in 1987, which claimed, among other things, the purified DNA sequence and host cells allowing protein expression from which EPOGEN® was made. *See* Exhibit B, U.S. Patent No. 4,703,008. Furthermore, for most of the time since the patents-in-suit issued until the present, the '008 patent was also in effect. Because practicing the '008 parent patent is required for practicing the patents-in-suit, the '008 patent blocked anyone but Amgen from practicing the patents-in-suit. For example, no one except Amgen could produce the product of claim 3 of U.S. Patent No. 5,547,933 (claiming a product of the expression of EPO using cells transfected with a DNA sequence encoding EPO) due to the '008 patent. Exhibit C, U.S. Patent No. 5,547, 933. Courts have repeatedly held that commercial success is given little if any weight towards non-obviousness of claimed inventions when that success is attributed to something else, such as a prior patent, or other economic or commercial factors unrelated to the patents-in-suit. *See Merck & Co. v. Teva Pharms., Inc.*, 395 F.3d 1364, 1377 (Fed. Cir. 1995) (evidence of commercial success unconvincing to show nonobviousness of weekly-dosed osteoporosis drug, where the patentee Merck had a patent (not in suit) covering osteoporosis drugs, which a weekly dosage drug would necessarily infringe); *Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d 1371, 1383 (Fed. Cir. 2005) (reversing finding of non-obviousness, directing lower court to consider *Merck* holding that evidence of commercial success provides a "weak inference" of non-obviousness if prior patents prevent others from competing to reach the solution embodied in the at-issue claims); *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996) ("Huang simply has not carried his burden to prove that a nexus existed between any commercial success and the novel features claimed in the application.").

Amgen has indicated it will offer evidence of "secondary considerations," including commercial success of its patented products, to attempt to show nonobviousness of its patents in suit, notwithstanding the lack of nexus with the patents in suit. For example, Amgen may offer the testimony of witnesses, such as Dennis Fenton, who are longtime Amgen employees with knowledge of Amgen's revenues and profits. *See* Amgen's Proposed Supplemental Memorandum Regarding Defendants' Motion to Preclude Testimony from Belatedly Disclosed Fact Witnesses (DN 870-2), at 2 n. 4 (disclosing that Amgen may offer Dr. Fenton's testimony as to commercial success of EPOGEN®). In addition, Amgen's expert Dr. Harvey S. Lodish may offer testimony as to the huge sales of EPOGEN® to support Amgen's nonobviousness arguments. Exhibit D, Rebuttal Expert Report of Harvey S. Lodish ¶ 313, May 11, 2007.

B. Amgen Sales Also Are Relevant to Amgen's Motive to Commit Inequitable Conduct

To prove its case of inequitable conduct before the jury, Roche will present compelling evidence to the jury that Amgen, in prosecuting the patents-in-suit before the USPTO, intentionally misrepresented, omitted and/or buried material information. Roche also may present evidence attesting to the volume of sales of Amgen's erythropoiesis products, as proof that Amgen had a compelling financial motive to deceive the USPTO.

Much of the prosecution of the patents in suit occurred after Amgen had begun marketing EPOGEN® in 1989. Defendants' Second Supplemental Response to Amgen's Interrogatory No. 26, May 1, 2007, at 89-90 (quoted in Brief in Support of Motion in Limine No. 7 (DN 846) at 2). The evidence of Amgen's sales tends to show that Amgen had intent to deceive the USPTO as demonstrated, in part, by a strong financial motive to protect the huge sales of EPOGEN® and ARANESP®, which were being generated while

the patents in suit were being prosecuted and which would be generated for many years thereafter.

On the other side, Amgen will support its arguments of validity, infringement, and lack of inequitable conduct by offering the testimony of witnesses, many of whom are employees of Amgen or have other ties to Amgen, and thus have a stake in Amgen's continuing success and dominance of this market segment. The extent to which this bias may influence the testimony of these witnesses may, in part, be demonstrated by the enormous sales and profit of Amgen's EPOGEN® and ARANESP® products. Thus, such evidence is relevant if Roche wishes to examine an Amgen witness with respect to bias.

ARGUMENT

"[A]ll relevant evidence is admissible." FRE 402. Relevant evidence is evidence "having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." FRE 401. As discussed below, evidence of Amgen's profits and revenues derived from EPOGEN® and ARANESP® products easily meets this minimal standard. *See Fitzgerald v. Expressway Sewer Const., Inc.*, 177 F.3d 71, 75 (1st Cir. 1999) ("Under federal evidentiary standards, the relevancy hurdle is low. . . .").

Further, it is Amgen which has the heavy burden to show that such relevant evidence should be excluded because of unfair prejudice. Although relevant evidence may be excluded "if it's probative value is *substantially* outweighed by the danger of *unfair* prejudice," it is not enough that evidence would be prejudicial; it must be unfairly prejudicial. FRE 403 (emphasis added). Further, even if there is proof of such unfair prejudice, it must be balanced against the probative value of the evidence. *Fitzgerald*,

177 F.3d at 75 (Even if there is risk of prejudice, the court "must balance it against the evidence's probative worth, and exclude the evidence only when (and if) the discerned risk substantially outweighs the anticipated value.") Because, as demonstrated below, evidence of Roche's revenues and profits is highly relevant and Amgen cannot show that it would be unfairly prejudiced by its admission, the Court should not exclude this evidence.

A. Roche Has the Right to Present Evidence Concerning the Sales of EPOGEN® to Rebut Amgen's Evidence of Such Sales

Roche intends to argue that the claims of the patents in suit are obvious over an extensive number of prior art references. In so doing, Roche may present evidence to show a nexus is lacking between the commercial success of Amgen's EPOGEN® and the inventions of the patents in suit, in order to rebut Amgen's arguments that secondary considerations, such as long-felt need or commercial success, support a determination of nonobviousness. Proof of such a nexus is essential to any reliance on "commercial success" as evidence of nonobviousness. *Pfaff v. Wells Electronics, Inc.*, 124 F.3d 1429, 1439 (Fed. Cir. 1997) (In order to overcome obviousness conclusion, patentee must demonstrate "nexus between merits of invention and evidence of secondary considerations").

Roche can show such a nexus is lacking. Amgen began marketing EPOGEN® in 1989, a full six years before the first of the patents in suit issued, but after Amgen's U.S. Patent No. 4,703,008 (the "'008 patent") issued in 1987. Defendants' Second Supplemental Response to Amgen's Interrogatory No. 26, May 1, 2007, at 89-90 (quoted in Brief in Support of Motion in Limine No. 7 (DN 846) at 2). Thus, Roche will offer evidence to show that EPOGEN® was so successful from the time it was first marketed

because of the technology subject of the claims of the '008 patent (the DNA sequence encoding erythropoietin), which Roche is not accused of infringing and which covered EPOGEN® during the six years before the claims of the patent in suit even issued. This evidence rebuts Amgen's contention that it was the technology subject to the patents in suit that was responsible for the commercial success of EPOGEN®. *See Syntex (U.S.A.) LLC,* 407 F.3d at 1383; *In re Huang*, 100 F.3d at 140; *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1540 (Fed. Cir. 1983) ("A nexus is required between the merits of *the claimed invention* and the evidence offered, if that evidence is to be given substantial weight en route to conclusion on the obviousness issue.") (emphasis added). The fact that the patent claims in suit were not in existence during this six year period of Amgen's huge sales of and profits from EPOGEN® is a strong rebuttal to Amgen's contentions that the subject matter claimed in the patents-in-suit contributed to the commercial success of EPOGEN®, or that this subject matter filled a long-felt need. Thus, this evidence of Amgen's sales is relevant and admissible.

In addition, Amgen EPOGEN® sales are not proof of commercial success of the subject matter of the patents in suit because the '008 patent (not in issue) blocked anyone from attempting to practice the subject matter of the claims in suit from six years before these claims issued and throughout almost the entire period that the patents in suit were in effect. Exhibit B. As the Federal Circuit has held, "Because market entry by others was precluded [by a patent not in suit], the inference of non-obviousness . . . from evidence of commercial success [of the patented product], is weak . . . [and] not enough to show the claims at bar are patentably distinct . . ." *Merck & Co.*395 F.3d at 1377;

Syntex (U.S.A.) LLC, 407 F.3d at1383 (Fed. Cir. 2005) ("Assuming that the active ingredient in the formulation [subject of the patent in suit] was previously patented, the commercial success of [the commercial embodiment of the patent in suit] may heavily derive from subject matter that does not on the whole contribute to the patentable distinctiveness of these claims. In such a case, the trial court should carefully consider whether the nexus requirement of our law is satisfied.")

In addition, it is grossly unfair for Amgen to ask the Court to preclude Roche from offering sales data to rebut Amgen's contentions of secondary considerations while Amgen seeks to remain free to offer the same sales data on the same issue. Amgen has stated it may offer evidence of its sales and revenues, including through Amgen's expert Dr. Lodish, despite Amgen's protestation that this issue is "beyond dispute." Exhibit D, ¶ 313. Also, many of Amgen's witnesses, such as Dr. Fu-Kuen Lin and Dennis Fenton are longtime Amgen employees, and Amgen may attempt to rely on these individuals to testify as to the profits and revenues of Amgen's EPOGEN® product. *See* DN 870-2 at 2 n. 4 (disclosing that Amgen may offer the testimony of Dr. Fenton on the issue of the commercial success of EPOGEN®).

The Court should either permit both parties to offer evidence of Amgen profits and revenues as relevant evidence on the exact same issue of commercial success or the Court should preclude both parties from doing so. Thus, in the alternative, if the Court decides to preclude Roche from offering Amgen sales and profits evidence in Roche's defense, Roche asks the Court likewise to preclude Amgen from offering such evidence as secondary indicia of nonobviousness.

B. The Importance to Amgen of EPO Product Sales is Evidence of Motive Relevant to Amgen's Intent to Deceive the PTO

Evidence of Amgen's sales and profits derived from its EPOGEN® and ARANESP® products is highly relevant and important to a jury determining whether Amgen's patents are unenforceable due to inequitable conduct. Such a finding requires that Roche prove by clear and convincing evidence that (1) Amgen breached its duty of candor to the USPTO, and that (2) in so doing, Amgen acted with intent to deceive. *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1186, 1190 (Fed. Cir. 2006).

It is well recognized that direct evidence of a patentee's intent is rare, and that intent is generally proven by facts and circumstances surrounding the patent's prosecution. *Merck & Co., Inc. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418, 1422 (Fed. Cir. 1989) ("[i]ntent need not, and rarely can, be proven by direct evidence."); *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1354 (Fed. Cir. 2005) ("intent to deceive is generally inferred from the facts and circumstances surrounding a knowing failure to disclose material information."). Thus, any evidence showing that the patentee had motive for its breach of candor to the USPTO is highly relevant to the patentee's intent, and is important for the jury to consider.

Amgen's prosecution of the patents-in-suit continued long after it began successfully selling EPOGEN® beginning in 1989. Defendants' Second Supplemental Response to Amgen's Interrogatory No. 26, May 1, 2007, at 89 (quoted in Brief in Support of Motion in Limine No. 7 (DN 846) at 2); Joint Pretrial Memorandum (DN 807) at 5 (stipulation that patents in suit issued from August 15, 1995 to September 21, 1999). Thus, the success of EPOGEN® certainly provided a motive for Amgen to deceive the PTO, and such a motive is in turn probative of whether Amgen acted with intent to

deceive the USPTO. It is well established that financial motive is probative of intent to deceive the USPTO. *See Sony Corp. of Am. v. Soundview Corp. of Am.*, No. 3:00 CV 754, 2001 WL 1772920, *2-3 (D. Conn. Oct. 23, 2001) (finding relevant evidence of patentee's attorneys' financial interest in patent in determination of inequitable conduct because it "could lead to the inference that they were impelled or incited to act in accordance with [an] intent to deceive"). The large market for erythropoiesis drugs, and the importance to Amgen of maintaining dominance of the market for such drugs certainly support a strong motive to withhold evidence to assure successful prosecution of patent claims aimed at protecting such sales.

C. The Jury Should Hear Evidence, Such as the Sales of EPOGEN and ARANESP, that Could Influence the Testimony of Amgen's Witnesses

It also is important for the jury to be allowed to consider, in connection with all other evidence relevant to the witnesses' credibility, evidence concerning the sales of EPOGEN® and ARANESP®, and whether the testimony of Amgen's witnesses may be biased because of the importance, to Amgen's financial well-being, of protecting such sales.

"Bias on the part of a witness is an allowable and established ground for inquiry on cross-examination under the Federal Rules of Evidence." *U.S. v. Akitoye*, 923 F.2d 221, 224 (1st Cir. 1991). The First Circuit, as well as other circuits, recognize that "certain relationships and circumstances impair the impartiality of a witness and . . . that a witness who is not impartial may-sometimes consciously but perhaps unwittingly-shade his testimony in favor of or against one of the parties." *Id*. at 224-225. Because these courts believe that "objectivity is always material to the assessment of credibility," the

courts are "hospitable to the point of liberality in admitting evidence relevant to a witness' bias." *Id*. at 225.

Such bias can come from the employment relationship of the witness with the party, which has a financial interest in the suit. *Thurber Corp. v. Fairchild Motor Corp.*, 269 F.2d 841, 845 (5th Cir. 1959) (fact was relevant that testifying witnesses were employees of party that faced liability as indemnor in patent suit). Further, it is well accepted that the financial interest of the *party itself* is relevant to whether the employee-witness is biased. *Id*. ("[T]he financial interest of the witness' employer may be shown to connect the chain.")

The witness list supplied by Amgen in the Joint Pretrial Memorandum (DN 807, Exhibit E) discloses a number of witnesses who are current employees of Amgen (*e.g.* Steven Elliott), former employees (*e.g.* Dr. Fu-Kuen Lin), current and former counsel for Amgen (*e.g.* Michael Borun), or collaborators (*e.g.* Dr. Eugene Goldwasser). Many of these witnesses may have a bias in favor of Amgen, either through a direct financial interest, or an interest as an employee in Amgen's continued success and dominance in the area of erythropoeisis drugs. Further, the evidence of Amgen's sales shows that Amgen's interest in maintaining its hold on the erythropoiesis drug market is significant. It is self-evident that these interests would affect the judgment of a witness who shared these interests. *Thurber*, 269 F.2d at 845.

Because the evidence of Amgen erythropoeisis drug sales is important evidence, which bears on the credibility of Amgen's witnesses, and may support an inference of bias, such evidence is relevant and should not be excluded from the jury.

D. The Probative Value of Amgen's Sales Evidence is Not Outweighed by Unfair Prejudice

Because, as demonstrated above, Amgen's sales and profits are highly relevant under FRE 402, Amgen has the heavy burden of showing that this relevance is substantially outweighed by unfair prejudice. *Fitzgerald*, 177 F.3d at 75. Evidence of revenues and profits of the patentee's products, however, typically is introduced to the jury in patent cases, despite Amgen's arguments that its sales of its products in issue would somehow influence the jury unfairly to side with Roche. Such evidence is not only relevant to substantive claims, but also as background, so that the jury has a complete understanding of the factual context of the case including what is at stake, and the consequences of their decisions. The defendant is entitled to a jury with knowledge of the complete context of the dispute and its importance.

Neither does the absence of damages issues in this case make Amgen's sales irrelevant, nor make introduction of such sales and profits evidence unfairly prejudicial. Any balancing of the relevance of this evidence against its prejudicial impact strongly favors admissibility. Amgen can offer no credible evidence of unfair prejudice other than an unfounded and patronizing assumption that the jury would be prejudiced against a company such as Amgen earning profits from its inventions.[2]

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[2] Likewise, Amgen's reliance on *LaPlante v. Am. Honda Motor Co.*, 27 F.3d 731 (1st Cir. 1994) is misplaced. *LaPlante* concerned an individual plaintiff who brought a personal injury suit against a large corporation. The admission of defendant Honda's profits on the product in issue caused the First Circuit concern because of the possibility that the jury would tend to unfairly favor the individual at the expense of the large corporation. *Id*. at 740. Indeed, the district court had given a limiting instruction to the jury, "warning against equalizing wealth between rich and poor." *Id.* In the instant case, however, there is no such concern because both Amgen and Roche are large corporations, and there is no reason to assume that Amgen's sales information will unfairly prejudice the jury.

CONCLUSION

For the foregoing reasons, evidence of Amgen's revenues and profits derived from the sales of EPOGEN® and ARANESP® is relevant and not unfairly prejudicial, and Amgen's motion to exclude this evidence should be denied.

Dated: August 31, 2007
Boston, Massachusetts

Respectfully submitted,

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