

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

AMGEN, INC.,)
)
Plaintiff,)
)
v.) Civil Action No. 05 CV 12237 WGY
)
F. HOFFMANN-LAROCHE LTD.,)
a Swiss Company, ROCHE DIAGNOSTICS)
GMBH, a German Company, and)
HOFFMANN LAROCHE INC., a New)
Jersey Corporation,)
)
Defendants.)

**BRIEF IN SUPPORT OF AMGEN'S MOTION *IN LIMINE* NO. 12:
EXCLUDE REFERENCE TO AMGEN'S "MONOPOLY" AND THE PATENTS-IN-SUIT
AS LIMITING CONSUMER CHOICE**

I. INTRODUCTION

Although patents are sometimes loosely described as granting a “legal monopoly” to the inventor, the law is well-established that patents are not to be regarded as monopolies, and that it is improper to characterize the exercise of patent rights as monopolistic or anticompetitive behavior.¹ Thus, Amgen moves to preclude Roche from arguing or introducing evidence during infringement, validity or enforceability proceedings that Amgen’s patents-in-suit constitute “monopolies,” or that assertion of Amgen’s patent rights will constitute monopolistic or anticompetitive behavior or limit consumer choice.

Amgen is filing a companion and related Motion *In Limine* No. 6 to preclude argument or evidence regarding the fact that Amgen is seeking injunctive relief, and any argument or evidence concerning the implications of awarding such relief, including limiting consumer access to other pharmaceuticals.

II. ARGUMENT

Roche should be precluded from presenting testimony or argument regarding monopoly or consumer choice because such evidence is irrelevant to the issues of infringement, validity, and enforceability,² and poses a high risk of unfair prejudice.³

¹ See *Seymour v. Osborne*, 78 U.S. 516, 533 (1870); *U.S. v. Dubilier Condenser Corporation*, 289 U.S. 178, 186 (1933); *In re Leonard Kaplan*, 789 F.2d 1574, 1578 (Fed. Cir. 1986) (Noting that the PTO Solicitor’s brief “properly deplores [the] use of the ambiguous word ‘monopoly,’ preferring to use the more accurate and less emotion-generating expression ‘extension of patent rights’”); *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350 at 1367, 220 U.S.P.Q. (BNA) 763 at 776 (Fed. Cir. 1984) (“patent rights are not *legal monopolies* in the antitrust sense of the word”).

² FRE 402.

³ FRE 403. See *Mainland Indus., Inc. v. Standahl's Patents, Ltd.*, 799 F.2d 746, 750 (Fed. Cir. 1986) (“The decision to exclude evidence under Rule 403 is within the sound discretion of the trial judge and is a decision made on a case by case basis by balancing the probative value of the evidence against its prejudicial harm”); *E.I. du Pont de Nemours & Co. v. Berkley and Co., Inc.*, 620 F.2d 1247, 1272 (8th Cir. 1980) (“A trial judge can and should exclude evidence when convinced that it will create a danger of prejudice outweighing its probative value”).

A. Arguments about consumer choice or monopoly are irrelevant to the issues of infringement, validity, and enforceability

The Supreme Court has long held that “[l]etters patent are not to be regarded as monopolies, created by executive authority at the expense and prejudice of all the community except the persons therein named as patentees, but as public franchises granted to the inventors of new and useful improvements.”⁴ It is therefore well-established that it is improper to characterize a patent as a monopoly.

For example, in *Carl Schenck, A.G. v. Nortron Corp.*, the Federal Circuit disapproved of the defendant’s reference to “the patent monopoly” and description of the patent right as an “exception to the general rule against monopolies.” The court stated that referring to a patent as a monopoly was “an obfuscation” and “irrelevant when considering patent questions.”⁵ Similarly, in *Connell v. Sears*, the Federal Circuit criticized a district court’s use of the term “patent monopoly,” stating that such a characterization was “misdirected.”⁶

Arguments regarding monopoly or consumer choice have no probative value in the infringement inquiry. Infringement analysis is a two-step process. First, claim language is interpreted as a matter of law. Second, the accused product is compared to the claim limitations to determine whether it falls within the scope of the claim.⁷ Arguments and evidence regarding monopoly or consumer choice are not relevant to either step of the two-step inquiry, and should therefore be excluded under FRE 402.

⁴ *Seymour v. Osborne*, 78 U.S. 516, 533 (1870).

⁵ *Carl Schenck, A.G. v. Nortron Corp.*, 713 F.2d 782, 786 n.3 (Fed. Cir. 1983) (affirming holding of validity and infringement).

⁶ *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983).

⁷ *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (“An infringement analysis entails two steps. The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device accused of infringing”); *Johnson Worldwide Associates, Inc. v. Zebco Corp.*, 175 F.3d

Similarly, such arguments are irrelevant and unfairly prejudicial to validity proceedings.

What constitutes an invalid patent is governed by the patent statute.⁸ Consideration of monopoly power and consumer choice are irrelevant to the validity inquiries set forth in the statute. The Federal Circuit recognized this principle in *Jamesbury Corp. v. Litton Indus. Products, Inc.*⁹ In that case, the Federal Circuit reversed a holding of invalidity because of various errors in jury instructions, including a “legally erroneous and prejudicial” instruction that the jury has a “duty to subject the invention to careful scrutiny before endorsing [plaintiff’s] right to the patent monopoly.”¹⁰ The court reiterated that the characterization of a patent as a monopoly is “misdirected,” and stated that it is improper to “supplement the statutory body of law governing patent validity by interjecting language to the effect that the public must be ‘protected’ against a ‘monopoly’”.¹¹ Again, therefore, arguments and evidence concerning monopoly and consumer choice should be excluded as irrelevant.

Arguments and evidence concerning consumer choice and monopoly are irrelevant to the issue of enforceability. Roche has alleged that the Lin patents are unenforceable because of inequitable conduct in their prosecution. To demonstrate inequitable conduct, Roche must show clear and convincing evidence of a “failure to disclose material information, or submission of false material information, with an intent to deceive” the PTO.¹² Characterizations of a patent as

985, 988 (Fed. Cir. 1999).

⁸ *Bates v. Coe*, 98 U.S. 31, 48 (1878) (“[T]he only authority for attacking the originality or validity of the patent is that given in the act of Congress”).

⁹ *Jamesbury Corp. v. Litton Indus. Products, Inc.*, 756 F.2d 1556 (Fed. Cir. 1985) (granting patentee’s motion for JNOV with respect to validity, but noting that, in the alternative, patentee would have been entitled to new trial as a result of legal errors).

¹⁰ *Jamesbury*, 756 F.2d at 1558.

¹¹ *Jamesbury*, 756 F.2d at 1559.

¹² *Kingsdown Medical Consultants v. Hollister Inc.*, 863 F.2d 867, 872 (Fed. Cir. 1988).

a monopoly, or allegations that consumer choice is limited by the assertion of patent rights, are irrelevant and are likely to obfuscate the proper determinations of materiality and intent. Such arguments and evidence should therefore be excluded from enforceability proceedings.

B. Arguments about consumer choice or monopoly are likely to prejudice the jury into deciding against Amgen on nonlegal grounds

Under FRE 403, evidence should be excluded if it creates “undue tendency to suggest decisions on an improper basis.”¹³ Arguments that Amgen is preserving a monopoly or limiting consumer choice are pejorative and likely to mislead the jury into deciding questions of infringement or validity on nonlegal grounds, and should be excluded.

The Supreme Court has recognized that describing a patent as a monopoly is improper. In *U.S. v. Dubilier Condenser Corporation*, the Court stated that the term “monopoly” “connotes the giving of an exclusive privilege for buying, selling, working, or using a thing which the public freely enjoyed prior to the grant. Thus a monopoly takes something from the people. An inventor deprives the public of nothing which it enjoyed before his discovery, but gives something of value to the community by adding to the sum of human knowledge.”¹⁴ Thus, the Supreme Court recognized that the term “monopoly” incorrectly and improperly insinuates that a patent causes social harm.

In *Jamesbury*, the Federal Circuit disapproved of the characterization of a patentee as a “monopolist,” noting that the term is “commonly regarded as pejorative.” In that case, the court held that an instruction referring to “the patent monopoly” was “legally erroneous and prejudicial.”¹⁵ Similarly, in *Novo Nordisk A/S v. Becton Dickinson and Co.*, the Federal Circuit disapproved of the defendant’s reference to patents as monopolies that raise the price to the

¹³ *CPC Intern, Inc. v. Northbrook Excess and Surplus Ins. Co.*, 144 F.3d 35, 45 (1st Cir. 1998) (citing Notes of Advisory Committee, FRE 403).

¹⁴ *U.S. v. Dubilier Condenser Corporation*, 289 U.S. 178, 186 (1933).

public, stating that such a characterization was prejudicial to the patentee.¹⁶

As demonstrated by Supreme Court and Federal Circuit precedent, arguments concerning monopolistic behavior incorrectly and improperly suggest that patents are a social burden. This type of argument presents a danger of confusing or misleading the jury into deciding on an improper basis, and should therefore be precluded.

III. CONCLUSION

For the foregoing reasons, Amgen respectfully requests that the court preclude the following arguments and evidence during the infringement, validity and enforceability proceedings:

- a. Any reference to Amgen’s patents-in-suit as “monopolies” or that Amgen’s patent enforcement constitutes anticompetitive or monopolistic behavior;
- b. That Amgen’s patent enforcement will limit or negatively affect consumer choice.

¹⁵ *Jamesbury*, 756 F.2d at 1558.

¹⁶ *Novo Nordisk A/S v. Becton Dickinson and Co.*, 304 F.3d 1216, 1220 (Fed. Cir. 2002) (noting that defendant’s statements were unduly prejudicial, but denying motion for new trial because plaintiff did not object to statements at trial, did not request corrective jury instructions, and did not raise the issue in post-trial motions).

Respectfully Submitted,

Date: August 20, 2007

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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 and paper copies will be sent to those indicated as non-registered participants on August 20, 2007.

/s/ Michael R. Gottfried

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