

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

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

**MEMORANDUM IN SUPPORT OF
AMGEN’S MOTION FOR A PERMANENT INJUNCTION OR, IN THE
ALTERNATIVE, LEAVE TO SUPPLEMENT
ITS COMPLAINT UNDER FED. R. CIV. PROC. 15(d)**

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I. INTRODUCTION

On October 23, 2007 the jury returned its verdict in favor of Amgen, finding that Roche's importation of peg-EPO would infringe each asserted claim of Amgen's patents, and that Roche had failed to prove that any claim of any Amgen patent was invalid. Since that date, Amgen has diligently sought the entry of a permanent injunction to restrain future infringement by Roche, and Amgen continues to believe that a permanent injunction is the appropriate remedy in this case as detailed in Amgen's previous filings.¹

On November 14, 2007, after the trial of this matter, Roche announced that the FDA had approved Roche's application to market and sell peg-EPO in the United States. On February 28, 2008 Roche informed the Court and Amgen that it would commence commercial sale and non-exempt use of peg-EPO in the United States unless enjoined from doing so by the Court. The Court promptly entered a preliminary injunction restraining such conduct by Roche. At the same time, the Court stated that it was continuing to weigh the public interest and might subsequently modify its order to remove the restraint against commercial sale and non-exempt use if Roche agreed to certain conditions, including the payment of a 22.5% royalty to Amgen on sales made by Roche.

If the Court modifies the existing injunction to remove its restraint against Roche's future infringement, or denies the permanent injunctive relief Amgen has requested, Amgen respectfully moves the Court under Fed. R. Civ. Proc. 15(d) for leave to supplement its Complaint to claim damages under 35 U.S.C. §§ 271(a) and 284 resulting from such future infringement. Amgen requests that it be granted 60 days from Roche's first commercial sale of peg-EPO in the United States to file such a supplemental Complaint. The modification proposed

¹ See Amgen Inc.'s Br. in Supp. of Permanent Injunctive Relief (D.N. 1679); Amgen's Post-Trial Br. for the Remedy Phase and Resp. to Defs.' January 28, 2008 Proposal (D.N. 1656); Mem. in Supp. of Amgen's Request for a Permanent Injunction (D.N. 1578).

by the Court would subject Amgen to continuing irreparable harm and fail to compensate Amgen for the damages it will suffer if Roche imports peg-EPO for sale or non-exempt use in the United States.²

Ironically, Amgen's claim for declaratory judgment was brought to prevent the very harm that will befall Amgen if the injunction Amgen has requested is denied. But the denial of injunctive relief cannot strip Amgen of its statutory and constitutional right to damages, as measured by the profits Amgen will lose, if Roche continues to infringe Amgen's patents. Although an award of lost profits cannot adequately compensate Amgen for the irreparable harm it would suffer in such circumstances, Amgen is entitled to claim and recover the damages it will suffer from Roche's future infringement, and the Seventh Amendment guarantees Amgen's right to a trial by jury on that claim. To date, neither party has been afforded the opportunity to discover or present evidence regarding the damages Amgen will suffer in such circumstances.

If the Court modifies the preliminary injunction to remove its restraint against future infringement, or denies the permanent injunction sought by Amgen, supplementation of the existing complaint to add Amgen's claim for damages provides the most efficient and judicious process for adjudicating Amgen's claim. When Amgen filed its original and amended complaints in this action, Roche had not yet obtained FDA approval to market and sell its infringing peg-EPO product in the United States. If the Court modifies its injunction or denies the permanent injunction Amgen has requested, Amgen's supplemental claim for damages would be based entirely on post-trial events and, for that reason, could not have been brought previously. Nothing in the prior proceedings of this case would unfairly prejudice Roche's defense of Amgen's claim to damages. Indeed, supplementation of the current complaint would provide the most efficient forum for the discovery and adjudication of Amgen's claim for

² Amgen Inc.'s Br. in Supp. of Permanent Injunctive Relief (D.N. 1679).

damages and would best serve the interests of judicial economy.

II. IF ROCHE IS NOT PERMANENTLY ENJOINED, AMGEN WILL HAVE A CLAIM FOR DAMAGES

A. IF ROCHE IS NOT PERMANENTLY ENJOINED AND ENTERS THE MARKET, AMGEN WILL BE ENTITLED TO DAMAGES.

Since the jury returned its verdict on liability, Amgen has diligently sought a hearing on the propriety of injunctive relief and entry of a permanent injunction. On November 14, 2007, after the jury had rendered its verdict on Amgen's pending claims, Roche announced that the FDA had approved its application to promote and sell peg-EPO in the United States. On February 28, 2008, Roche informed the Court that it would no longer self-enjoin and would commence infringing sales in the immediate future, whereupon the Court preliminarily enjoined Roche from doing so. At the same time, the Court suggested that it might modify its preliminary injunction to remove the restraint against Roche's importation for sale and/or non-exempt use if Roche agreed to pay Amgen a 22.5% royalty on its U.S. sales of peg-EPO.

If the Court were to make such a modification, Roche has indicated that it will import peg-EPO for non-exempt use and sale in the United States. Amgen would thereupon be entitled to recover its damages pursuant to 35 U.S.C. § 284. Section 284 provides, in relevant part:

Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.

When the damages are not found by a jury, the court shall assess them. In either event the court may increase the damages up to three times the amount found or assessed.³

In *Aro Manufacturing Co. v. Convertible Top Replacement Co.*, the Supreme Court held that the statutory damages to which a patentee is entitled are measured by the difference between the profits that a patentee would have made but for the accused infringement, and the reduced

profits the patentee actually makes due to the infringing conduct.⁴ In addressing the statutory right to damages created under § 284, the Court held that

[t]he question to be asked in determining damages is “how much had the Patent Holder and Licensee suffered by the infringement. And that question [is] primarily: had the Infringer not infringed, what would Patent Holder-Licensee have made?”⁵

Twenty years later, in *General Motors Corp. v. Devex Corp.*, the Court went on to hold that the “overriding purpose” of § 284 is to afford patent owners “complete compensation.”⁶ As the Court observed, in enacting § 284, “Congress sought to ensure that the patent owner would in fact receive full compensation for ‘any damages’ he suffered as a result of the infringement.”⁷

Nothing in the Supreme Court’s holding in *eBay v. MercExchange*⁸ suggests that a patentee loses its right to damages if an injunction is denied. Nor does anything in *eBay* grant courts the power to order a patentee to share its patent-derived profits with an infringer or disturb the Seventh Amendment right of patentees to a trial by jury of the damages that result from the infringement of their patents. And nothing in *eBay* addresses the measure of a patentee’s damages if an injunction is denied, much less overrules the long-settled law of *Aro Mfg. Co.* and *General Motors* establishing the right of patentees, such as Amgen, to recover the profits they lose when a defendant infringes their patents.

Where, as here, Roche would sell its infringing product in direct competition with Amgen’s patented product, the law is clear that Amgen is entitled to recover the profits it will lose as a result of Roche’s importation for sale or non-exempt use. “[W]e have held that the

³ 35 U.S.C. § 284.

⁴ *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 507 (1964).

⁵ *Id.* (quoting *Livesay Window Co. v. Livesay Industries, Inc.*, 251 F.2d 469, 471 (5th Cir. 1958)).

⁶ *Gen. Motors Corp. v. Devex Corp.*, 461 U.S. 648, 655 (1983).

⁷ *Id.* at 654-55 (citing H.R. Rep. No. 1587, 79th Cong., 2d Sess. at 1 (1946); S. Rep. No. 1503, 79th Cong., 2d Sess. at 2 (1946)).

⁸ *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006).

general rule for determining actual damages to a patentee that is itself producing the patented item is to *determine the sales and profits lost* to the patentee because of the infringement.”⁹

Those damages properly include the profits that Amgen loses on sales displaced by Roche, the profits that Amgen loses on sales made by Amgen at prices eroded by Roche’s competition, and the profits that Amgen loses by reason of its increased expenses to compete with Roche.¹⁰

Indeed, even Roche’s remedies expert, Dr. Steven Schwartz, acknowledged this fundamental precept, testifying at deposition that Amgen would be entitled to each of these components of damages if Roche made infringing sales of peg-EPO in the United States.¹¹

Moreover, because Roche’s product has been held to infringe Amgen’s valid and enforceable patents, any importation for sale or non-exempt use in the United States would constitute willful infringement, entitling Amgen to enhanced damages and attorneys fees.¹²

⁹ *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1545 (Fed. Cir. 1995); *see also Grain Processing Corp. v. Am. Maize-Prods. Co.*, 185 F.3d 1341, 1349 (Fed. Cir. 1999) (stating that § 284 requires full compensation, which “includes any foreseeable lost profits the patent owner can prove”). As discussed in Amgen Inc.’s Br. in Supp. of Permanent Injunctive Relief (D.N. 1679), the Federal Circuit’s recent decision in *Paice LLC v. Toyota Motor Corp.*, 504 F.3d 1293 (Fed. Cir. 2007), does not address a situation in which the patentee’s business depends on its practice of the claimed invention, and is therefore inapplicable to circumstances where, as here, lost profits from infringing competition provides the proper measure of a patentee’s damages. Moreover, the patentee’s claim for past damages was presented to and decided by the jury, and the only remaining issue was whether and to what extent that award should apply to the patentee’s future damages. Unlike the patentee in *Paice*, Amgen has had no opportunity to present its claim for damages to a jury.

¹⁰ *Lam, Inc. v. Johns-Manville Corp.*, 718 F.2d 1056, 1065 (Fed. Cir. 1983); *Minco, Inc. v. Combustion Eng’g, Inc.*, 95 F.3d 1109, 1118 (Fed. Cir. 1996); *see also Crystal Semiconductor Corp. v. Tritech Microelectronics Int’l, Inc.*, 246 F.3d 1336, 1353-61 (Fed. Cir. 2001).

¹¹ 6/7/07 Schwartz Dep. Tr. at 118:23-122:16 (discussing that Amgen’s damages, if Roche is allowed onto the market, are all tied, directly or indirectly, to Amgen’s lost profits); *id.* at 128:6-129:8 (stating that lost profits is the appropriate measure of damages in the situation where the patentee is manufacturing and selling its patented invention); *id.* at 131:24-136:17 (stating that lost profits include profits lost by Amgen on its sales because of price erosion) (the Schwartz deposition testimony cited herein was submitted to the Court by Amgen as remedy-related deposition designations on 12/14/07).

¹² 35 U.S.C. §§ 284, 285.

B. A ROYALTY ON ROCHE'S SALES WILL NOT COMPENSATE AMGEN FOR ITS DAMAGES

If the Court modifies the current injunction to remove its restraint against infringing sales on the condition, *inter alia*, that Roche pay Amgen a 22.5% royalty on Roche's U.S. sales, the royalty paid by Roche will not compensate Amgen for the damages it will suffer as a result of Roche's importation for sale and non-exempt use. By law, Amgen is entitled to recover its damages as measured by the profits it loses as a result of Roche's infringing sales. Amgen is also entitled to a trial by jury of its damages claim. A royalty fixed by the Court without respect to the profits lost by Amgen does not compensate Amgen for the damages it will suffer.

For example, if Roche were to sell peg-EPO at EPOGEN's ASP, the royalty rate proposed by the Court would award Amgen approximately one-fourth of the compensation Amgen otherwise would have received had it made the sale itself. Specifically, a 22.5% royalty on sales made by Roche does not begin to compensate Amgen for the 89% to 90% operating profit Amgen would lose on each sale made by Roche. Nor does it provide any compensation to Amgen for the sales it would lose as a result of non-exempt uses of peg-EPO that do not entail sales of Roche's product. Nor would it compensate Amgen for the profits Amgen would lose on the sales Amgen makes at eroded prices, or the resulting diminution in Roche royalty payments as prices decline, if – as Roche contends¹³ – its market entry will drive Amgen's prices down. Nor does the Court's proposal account for the increased costs Amgen would likely incur by manufacturing and selling a lower volume of product in competition with Roche.

C. AMGEN IS ENTITLED TO A TRIAL BY JURY ON ITS CLAIM FOR DAMAGES.

Amgen's statutory claim for damages constitutes a legal claim to which Amgen is

¹³ *See, e.g.*, Roche's Mem. in Supp. of this Court Modifying the Preliminary Injunction and Satisfying the Court's Conditions to Have MIRCERA Available for American Patients (D.N. 1684) at 21. Note that Dr. Bernheim testified that given CMS's ASP system, it is unlikely that Amgen would compete on price if Roche enters the market. 12/5/07 Hr'g Tr. at 255:10-257:5 (Bernheim).

entitled to trial by jury. The Seventh Amendment to the United States Constitution guarantees litigants the right to a jury trial “[i]n Suits at common law.” In determining whether a statutory claim entails a right to trial by jury, the Supreme Court applies a two prong test:

First, we compare the statutory action to 18th-century actions brought in the courts of England prior to the merger of the courts of law and equity. Second, we examine the remedy sought and determine whether it is legal or equitable in nature.¹⁴

Where, as here, the newly added claim would seek statutory damages for infringement of a statutory right, the Seventh Amendment guarantees Amgen’s right to trial by jury.¹⁵

To date, neither Amgen nor Roche has been afforded an opportunity to discover evidence regarding the damages Amgen will suffer if Roche imports and sells peg-EPO, let alone present that evidence to a jury. If the Court modifies the present injunction and Roche imports peg-EPO for sale or non-exempt use in the United States, Amgen is entitled to present evidence to prove the magnitude of its damages. Accordingly, if permanent injunctive relief is denied, Amgen also requests the Court to bifurcate the trial of its damages claim and enter final judgment on the remaining claims-in-suit that have already been adjudicated so that each party may take whatever appeals therefrom may be appropriate.

D. SUPPLEMENTATION UNDER RULE 15(d) IS APPROPRIATE WHEN POST-FILING EVENTS WARRANT A NEW CLAIM AND NEW RELIEF.

Where, as here, events occurring after the original complaint give rise to an additional claim between the same parties, Fed. R. Civ. P. 15(d) authorizes a plaintiff to supplement its complaint to plead new or additional claims arising from such subsequent events:

Supplemental Pleadings. On motion and reasonable notice, the court may, on just terms, permit a party to serve a supplemental pleading *setting out any transaction, occurrence, or event that happened after*

¹⁴ *Tull v. United States*, 481 U.S. 412, 417-18 (1987) (citations omitted).

¹⁵ *In re Lockwood*, 50 F.3d 966, 980 (Fed. Cir. 1995); *Feltner v. Columbia Pictures Television, Inc.*, 523 U.S. 340, 353-54 (1998).

*the date of the pleading to be supplemented.*¹⁶

“The purpose of Rule 15(d) is to promote as complete an adjudication of the dispute between the parties as possible by allowing the addition of claims which arise after the initial pleadings are filed.”¹⁷ In particular, Rule 15(d) allows a plaintiff to seek further relief where, as here, events occurring subsequent to the original complaint justify such relief.¹⁸

Leave to file a supplemental complaint is freely given when supplementation will provide a means to achieve a prompt and efficient resolution of the entire controversy between the parties. “Supplemental pleadings should be freely granted where it will promote the economic and speedy disposition of the entire controversy between the parties, will not cause undue delay or trial inconvenience, and will not prejudice the rights of any of the other parties to the action.”¹⁹ “Liberality is the rule in permitting supplemental pleadings.”²⁰ Indeed, “as a general

¹⁶ Fed. R. Civ. P. 15(d) (emphasis added); *see also United States v. Russell*, 241 F.2d 879, 882 (1st Cir. 1957).

¹⁷ *William Inglis & Sons Baking Co. v. ITT Cont'l Baking Co.*, 668 F.2d 1014, 1057 (9th Cir. 1981); *see also Intrepid v. Pollock*, 907 F.2d 1125, 1129 (Fed. Cir. 1990) (“Rule 15(d) unequivocally allows supplementing a complaint with a count based on later events.”) (citing *Griffin v. County School Board of Prince Edward County*, 377 U.S. 218, 227 (1964)); *Structural Systems, Inc. v. Sulfaro*, 692 F. Supp. 34, 36 (D. Mass. 1988) (new claim added via supplemental complaint); *First Savings Bank, F.S.B. v. U.S. Bancorp*, 184 F.R.D. 363, 367-68 (D. Kan. 1998) (“A party may supplement its complaint by adding new claims to the action ‘when subsequent events make it necessary to do so.’” (quoting 3 James Wm. Moore et al., *Moore’s Federal Practice* § 15.30, at 15-107 (3d ed. 1997))).

¹⁸ *See, e.g., City of Texarkana v. Ark. La. Gas Co.*, 306 U.S. 188, 203 (1939) (“setting up facts subsequently occurring which justify other or further relief is proper”); *see also Owens-Illinois, Inc. v. Lake Shore Land Co.*, 610 F.2d 1185, 1188 (3rd Cir. 1979) (“One of the intended uses of a supplemental pleading is to change the nature of the relief initially requested”); *Ebel v. Drum*, 55 F. Supp. 186, 188 (D. Mass. 1944).

¹⁹ *Boston Police Superior Officers Fed’n. v. Jordan*, No. 83-3396-MA, 1984 U.S. Dist. LEXIS 19036, at *1-2 (D. Mass. Feb. 29, 1984) (citing *Rowe v. U.S. Fidelity & Guar. Co.*, 421 F.2d 937 (4th Cir. 1970); *West v. Sullivan*, No. 84-3883, 1990 U.S. Dist. LEXIS 9924, at *10 n.8 (E.D. Pa. July 26, 1990) (“A supplemental pleading . . . enables a court to award complete relief in one action and avoid the cost and delay of separate actions.”); *Winslow v. Comm’r, Me. Dep’t of Human Servs.*, 139 F.R.D. 15, 17 (D. Me. 1991).

²⁰ *Structural Systems, Inc. v. Sulfaro*, 692 F. Supp. 34, 36 (D. Mass. 1988).

rule, applications for leave to file a supplemental pleading are normally granted.”²¹ Moreover, motions for supplementation can be brought at any time while an action is before the district court.²²

E. SUPPLEMENTATION OF AMGEN’S COMPLAINT TO ADD A CLAIM FOR DAMAGES WOULD NOT UNFAIRLY PREJUDICE ROCHE.

Because Amgen’s supplemental claim for damages would be based entirely on post-trial events, it could not have been brought previously. Roche would be no more prejudiced by the filing of a supplemental complaint in this action than it would be by the filing of a new complaint seeking damages for its post-trial infringement in a separate action.²³ Under either approach, Roche will have its day in Court. Nothing in the prior proceedings of this case would unfairly prejudice Roche’s defense of Amgen’s claim to damages, nor would supplementation delay interlocutory appeal of the Court’s injunctive remedy. Supplementation of the current complaint with any newly arising claim is the most “economic and speedy” route to final disposition of the dispute between the parties, particularly given the prodigious investment of time and energy already made by the Court in this matter.

Notably, both parties will benefit from a prompt ruling on this motion if the Court were to modify the existing injunction or deny Amgen’s request for entry of a permanent injunction. In such circumstances, Roche would have a better understanding of the risks it faces by launching peg-EPO and willfully infringing Amgen’s patents, and both parties would have a more complete record on any appeal of the Court’s disposition of Amgen’s request for

²¹ *Stewart v. Shelby Tissue, Inc.*, 189 F.R.D. 357, 362 (W.D. Tenn. 1999) (citing *McHenry v. Ford Motor Co.*, 269 F.2d 18, 25 (6th Cir. 1959)).

²² *Id.* (citing 6A Charles Alan Wright et al., *Federal Practice & Procedure* § 1509 (2d ed. 1990)).

²³ *See, e.g., Otis Elevator Co. v. 570 Bldg. Corp.*, 35 F. Supp. 348, 348-49 (E.D.N.Y. 1940) (finding adjudicated infringer not prejudiced by allowing supplemental complaint alleging patent infringement after decree and injunction entered so long as infringer had day in court, and noting that “granting of this motion is in the interest of expedition, economy, and a speedy disposition

permanent injunctive relief.

III. CONCLUSION

Amgen respectfully requests the Court to enter a permanent injunction consistent with the preliminary injunction currently in place. A permanent injunction is the only remedy that can adequately protect Amgen against the irreparable harm that Roche's importation for sale and non-exempt use would cause.²⁴ Should the Court decide to modify its injunction as outlined in its February 29th Order, Amgen respectfully requests the Court to grant Amgen leave to file a supplemental complaint stating a claim for damages resulting from Roche's importation for sale or non-exempt use of peg-EPO in the United States. Although an award of lost profits cannot adequately compensate Amgen for the harm it would suffer as a result of such conduct by Roche, it would provide a more just and correct measure of Amgen's damages than the royalty fixed by the Court. Finally, Amgen also requests the Court to bifurcate the trial of its damages claim and enter final judgment on the remaining claims-in-suit that have already been adjudicated so that each party may take whatever appeals therefrom may be appropriate.

of the controversy").

²⁴ Although Amgen did not pray for damages in its Complaint, it consistently reserved the right to do so if necessary. *See, e.g.*, Joint Pretrial Mem. (D.N. 807) at 2 ("Amgen will not seek actual or enhanced damages for defendants' actual or threatened infringement of the claims-in-suit occurring prior to the commencement of trial, but *reserves the right to seek damages for any activities of Roche subsequent to the commencement of trial of this matter.*") (emphasis added).

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