UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

AMGEN'S OPPOSITION TO ROCHE'S MOTION FOR LEAVE TO FILE A SURREPLY

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I. INTRODUCTION

Amgen respectfully opposes the motion of Defendants F. Hoffman-La Roche LTD, Roche Diagnostics GmbH and Hoffman-La Roche Inc. ("Roche") for leave to file a SurReply. As set forth more fully below, Roche's proposed SurReply is premised on a succession of false factual assertions and mischaracterizations regarding the cases it cites.

II. ROCHE'S SURREPLY CONFUSES THE PRINCIPLES OF STANDING FOR DAMAGES WITH THOSE FOR DECLARATORY OR INJUNCTIVE RELIEF.

Roche's SurReply repeatedly fails to distinguish between standing for damages and standing for declaratory or injunctive relief. Roche's claim for antitrust ***damages*** arises under § 4 of the Clayton Act (15 U.S.C. § 15), which requires allegations of an actual injury in fact, that was caused by Amgen, and is the type of injury the antitrust laws were enacted to prevent.[1] In the context of the carefully regulated industry in which Roche hopes to compete, it requires FDA approval to sell peg-EPO in the United States. Because Roche does not have that approval, it can point to no injury in fact caused by Amgen that is of the type protected by the antitrust laws. And that is why Roche lacks standing to bring a claim for antitrust damages.

At the most, Roche could perhaps bring a claim for declaratory relief to redress an imminent ***future*** harm, or a claim for injunctive relief under § 16 of the Clayton Act to redress a ***threatened*** harm**,** but, as shown below, Roche's counterclaims also fail to allege the facts required to support a claim for either declaratory or injunctive relief.

A. Roche does not allege facts sufficient for a damages claim or a claim for injunctive relief.

Two circuit courts have considered the issue of antitrust standing in a regulated industry, and both have recognized, as Amgen asserts, that the need for regulatory approval to enter and

[1] *City of Pittsburg v. West Penn Power Co*., 147 F.3d 256, 264-69 (3d Cir. 1998); *Andrx Pharma., Inc. v. Biovail Corp*., 256 F.3d 799, 805-06 (D.C. Cir. 2001).

compete in a given market can break the causal connection required to establish an antitrust injury in fact.[2] As shown below, Roche's SurReply fails to address significant facts in both of these cases. In *City of Pittsburg,* the Third Circuit held that the absence of regulatory approval to compete in a regulated industry breaks the causal connection and prevents any claim for ***either*** damages ***or*** injunctive relief. The requirement in *City of Pittsburg* that an electrical provider obtain a PUC certificate prior to entering the market precluded a damages claim:

> [T]here is no way for the court to determine what 'damages' were sustained. We cannot assume the existence of a PUC certificate for the purposes of assessing damages. Thus, the damages alleged by the City are not simply difficult to measure, but their occurrence would, in fact, be impossible to prove. The injury averred by the City is simply too speculative to permit relief under the antitrust laws.[3]

In addition, the PUC regulatory requirement also prevented a claim for injunctive relief:

> Section 16 of the Clayton Act does permit injunctive relief 'against threatened loss or damage.'. . . . However, we agree with the reasoning of the district court that the threatened loss 'is contingent on the PUC permitting competition within the City in the first instance' . . . . Allegheny Power was not legally able to provide power in the Redevelopment Zones and we do not know whether the PUC would ever have granted the permission for it to do so.[4]

Roche's argument that *City of Pittsburg* is inapt because the defendant had withdrawn its request for regulatory approval is simply incorrect.[5] The Court clearly laid out the facts central to its decision, and does not mention this fact at all.[6]

In *Andrx*, the D.C. Circuit similarly held that the absence of FDA approval to market and sell a regulated drug would ordinarily break the causal connection needed to state a claim for

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[2] *City of Pittsburg*, 147 F.3d at 264-69; *Andrx*, 256 F.3d at 805-06.

[3] *City of Pittsburg*, 147 F.3d at 269.

[4] *City of Pittsburg*, 147 F.3d at 267.

[5] Roche's 12/22/06 SurReply to Amgen's Reply Brief in Supp. of its Mot. to Dismiss at 3, Docket No. 190 [hereinafter "Roche's SurReply Br."].

antitrust damages. Significantly, the regulatory scheme at issue in *Andrx*—generic drugs—is very different from the regulatory scheme at issue here. In the context of generic drug competition, a listed pioneer drug supplier may forestall the FDA approval and market entry of generic competitors simply by filing a suit for patent infringement.[7] In addition, a first generic applicant may forestall the FDA approval and market entry of a second generic applicant simply by delaying its own market entry.[8] Thus, contrary to the facts presented here, a patentee can cause a delay in FDA approval and market entry of a would-be generic competitor simply by filing an infringement suit. It can also delay the entry of a second generic applicant by securing the agreement of the first generic applicant not to enter the market, irrespective of its FDA approval to do so. And that is precisely what happened in *Andrx*.

In *Andrx,* a second generic applicant, Biovail, argued that its market entry had been delayed by an agreement between the pioneer patentee (Hoechst Marion Roussel) and the first generic applicant (Andrx) to delay Andrx's market entry even after Andrx had obtained FDA approval to enter the market. Under the agreement, HMR agreed to pay Andrx $10 million for each quarter that Andrx postponed its market entry after FDA approval.[9] Biovail brought suit alleging that the HMR/Andrx agreement was an unlawful restraint of trade that precluded or delayed Biovail's market entry, and sought damages under § 4 of the Clayton Act.

Because Biovail's complaint did not allege that FDA approval of its own ANDA

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[6] *City of Pittsburg*, 147 F.3d at 265.

[7] 21 U.S.C. § 355 (j)(5)(B)(iii); *Andrx*, 256 F.3d at 802.

[8] The first applicant to file an ANDA seeking permission to make and sell a generic version of a patented drug is awarded a 180-day exclusivity period, which runs from the date the first generic applicant commences commercial sale of its generic drug. By delaying the commercial sale of its generic drug, the first generic applicant can keep other generic applicants off the market. *See Andrx*, 256 F.3d at 802, 804.

[9] *Andrx*, 256 F.3d at 804.

application was probable and imminent, the District Court dismissed with prejudice Biovail's antitrust claim for damages.[10] On appeal, the D.C. Circuit agreed that Biovail's complaint failed to allege facts establishing that FDA approval of its ANDA was probable or that defendants' alleged conduct had caused an antitrust injury to Biovail. It therefore affirmed the district court's dismissal.[11] However, because the Court of Appeals concluded that Biovail could allege facts establishing that FDA approval was probable, and that a collusive agreement between HMR and Andrx had in fact caused a delay in Biovail's market entry, it reversed the dismissal with prejudice and remanded with leave to amend the complaint. Noting that the district court had not been informed that the FDA had in fact approved Biovail's ANDA prior to the dismissal,[12] the Court of Appeals reasoned that Biovail could establish that it was the collusive agreement between HMR and Andrx, not the absence of FDA approval, that had delayed its market entry, and that it therefore had standing to seek antitrust damages for that delay.[13]

In addition, in the context of a claim for injunctive relief, the Court pointed to the fact that the FDA had approved Biovail's ANDA, and reasoned that Biovail could amend its complaint to allege that FDA approval was "probable."[14] In discussing the availability of injunctive relief,[15] the Court stated that "even before the FDA approved Biovail's ANDA, Biovail could have alleged its intent and preparedness to enter the market by claiming that FDA

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[10] *Andrx Pharma., Inc. v. Friedman*, 83 F. Supp. 2d 179, 183-85 (D.D.C. 2000) (discussing only a claim for damages and finding lack of standing).

[11] *Andrx Pharma., Inc. v. Biovail Corp.*, 256 F.3d 799, 806-808 (D.C. Cir. 2001).

[12] *Id.* at 807, 804 (explaining that tentative approval of Biovail's ANDA occurred in October 1999, and final approval occurred on December 23, 1999).

[13] *Id*. at 815-16.

[14] *Id*. at 808.

[15] *Id*. at 808 ("[Section 16] authorizes injunctive relief upon the demonstration of threatened injury.") (internal citations omitted).

approval was probable."[16] However, Roche fails to point out that the Court went on, in the same paragraph, to explain "Biovail has (in its motion for reconsideration) alluded to facts – FDA approval and intent to enter the market – that may entitle it to relief."[17] Thus, the Court was clearly relying on more than a bare allegation of "intent" or "anticipation" to plead facts sufficient to demonstrate an objective basis to believe that Biovail's need for regulatory approval would not preclude its market entry. And its analysis was based on a claim for injunctive relief to redress a threatened ***future*** harm, not a damages claim for a present injury in fact.

Roche's allegations are a far cry from the facts of *Andrx*. Roche alleges no facts demonstrating that its market entry has been or is now delayed or precluded by any act of Amgen rather than its unfulfilled need for FDA approval. Here, just as in *City of Pittsburgh* and *Andrx,* Roche's unmet need for regulatory approval breaks any casual connection between the alleged acts of Amgen and any past or current antitrust injury to Roche.

Similarly deficient is Roche's claim for declaratory relief.[18] To seek declaratory relief, Roche's allegations must establish that FDA approval is both probable and imminent. Its original and amended counterclaims do neither. The only allegation that even arguably relates to the topic is that Roche "[a]nticipat[es] FDA approval for CERA"[19] which falls far short of an allegation that FDA approval is both "probable and imminent." Roche's stubborn refusal to correct this deficiency is simply a transparent

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[16] *Id*. at 808. *See* Roche's SurReply Br. at 1.

[17] *Id*. at 808.

[18] As noted in Amgen's opening memorandum, Roche's Counterclaims assert no prayer for injunctive relief. *See* Amgen's 11/27/06 Mem. in Supp. of its Mot. to Dismiss at 3, Docket No. 151.

[19] Roche's 11/06/06 Answer to Am. Compl. and Countercls., Counterclaims at ¶ 50, Docket No. 140 [hereinafter "Roche's Answer or Roche's Counterclaims"].

attempt to preserve its ability to contest the jurisdictional basis for Amgen's declaratory judgment claim – imminent infringing sales or uses – while simultaneously seeking declaratory jurisdiction to adjudicate claims whose alleged injury is predicated on such non-exempt sales and uses.

The ANDA case on which Roche relies – *Xechem*[20] – for its argument that FDA approval is not required to establish antitrust injury in a case where fraudulent procurement of a patent is alleged is not only inapposite, but illustrates the fallacy of Roche's argument. In the context of an ANDA application, a patentee's institution of a suit for patent infringement automatically delays FDA approval by 30 months. Thus, the fraudulent procurement or sham enforcement of such patents arguably causes an antitrust injury, because it necessarily results in a 30 month delay in market entry irrespective of any action by FDA. Here, however, Amgen's suit to enforce its patents causes no such delay in FDA review or approval of Roche's BLA, and that is why Roche's assertion of litigation expenses alone does not and cannot constitute antitrust injury.

B. Roche's counterclaims also fail to allege that Roche is prepared for market entry.

In *Amtrol v.Vent-Rite Valve,* this Court carefully surveyed the type of preparations that would establish the requisite "intent and preparation" for market entry to establish standing under the antitrust laws: distribution of marketing brochures, direct customer solicitations, inventory build-up, and provision of marketing samples to customers.[21] Amgen alleged in its Amended Complaint that Roche has been making preparations to market and sell peg-EPO in the United States, including hiring key sales and marketing personnel and contacting potential

[20] *Xechem, Inc. v. Bristol-Myers Squibb Co.,* 274 F. Supp. 2d 937, 944 (N.D. Ill. 2003), *rev'd* 372 F.3d 899 (7th Cir. 2004).

[21] *Amtrol, Inc. v. Vent-Rite Valve Corp.*, 646 F. Supp. 1168, 1178 (D. Mass. 1986).

customers.[22] Yet Roche's Answer and Amended Answer ***deny*** any preparations to enter the market, including all of the preparations alleged by Amgen, and nowhere do Roche's Counterclaims allege such preparatory activities.[23] Thus Roche has not alleged, and in fact denies, that it is prepared to enter the market.

III. ROCHE'S LITIGATION EXPENSES DO NOT ESTABLISH STANDING.

Both *Handgards* and *Kearney* are inapposite here because they involved actual competitors in markets that had no regulatory barriers to entry or competition.[24] Consequently, the sham enforcement of fraudulently procured patents necessarily affected the targets' on-going ability to compete in the markets in which they already competed. Nonetheless, Roche continues to rely on these decisions without confronting the factual differences that render their holdings inapplicable here.[25]

In addition, Roche still misapprehends the facts and thus the holding of *CVD*. In *CVD,* a giant corporation (Raytheon) threatened a former employee with trade secret litigation, the expense of which would have vitiated the former employee's ability to compete against Raytheon as planned.[26] The allegations in *CVD* that the burden of defending Raytheon's threatened litigation would foreclose the former employee's ability to compete were both plausible and central to the Court's holding that the imposition of such threatened expenses on

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[22] Amgen's 4/25/06 Am. Compl. for Declaratory J. of Infringement ¶ 29, Docket No. 52.

[23] Roche's Answer ¶ 29; Roche's 12/08/06 Mem. in Opp'n to Amgen's Mot. to Strike, Docket No. 161, accompanying Ex. B Roche's Proposed First Am. Answer and Countercl. ¶ 29.

[24] *Handgards, Inc. v. Ethicon, Inc*., 601 F.2d 986 (9th Cir. 1979); *Kearney & Trecker Corp. v. Cincinnati Milacron, Inc*., 562 F.2d 365 (6th Cir. 1977). *See* Amgen's 12/18/06 Reply Br. in Supp. of its Mot. to Dismiss at 6, Docket No. 182. Amgen will not re-state that argument here.

[25] Roche's citation to *United States v. Microsoft Corp*., 253 F.3d 34 (D.C. Cir. 2001) is similarly inapposite, as that case also involved a competitor who did not face any regulatory obstacle to market participation. *See* Roche's SurReply Br. at 4-5.

[26] *CVD, Inc v. Raytheon Co.,* 769 F.2d 842, 858 (1st Cir. 1985).

the former employee would have precluded competition and resulted in antitrust injury. By contrast, Roche does not allege, nor could it, that litigation expenses alone will cause it to abandon the market.

Roche now concedes that its allegations of "litigation expenses" cannot establish antitrust injury or standing for any claims other than its sham litigation, *Walker Process*, and state law claims.[27] Case law supports that even if this Court concludes that litigation expenses alone establish standing to bring *Walker Process* or sham claims, such expenses do not establish standing for Roche's Third, Forth and Fifth counterclaims.[28] As the district court explained in *Novo Nordisk*:

> Defendant argues that plaintiffs lack standing to assert an antitrust claim because ***without FDA marketing approval***, plaintiffs are in no position to allege any interference by defendant with plaintiffs' ability to receive income from prospective sales of its human growth hormone product. Defendant cites to *National Ass'n of Pharmaceutical Mfrs., Inc. v. Ayerst Lab*., 850 F.2d 904, 913 (2d Cir. 1988) for this proposition. ***However, plaintiffs' complaint does not allege this sort of antitrust injury***. Rather, the complaint alleges as the antitrust injury the costs incurred in connection with defending a litigation in which a patentee attempts to enforce patents that are invalid and unenforceable.[29]

Without FDA approval, Roche lacks standing to bring Sherman Act claims.

WHEREFORE Amgen respectfully requests that Roche's Motion for Leave to File a SurReply be Denied.

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[27] Roche's SurReply Br. at 4 n.3.

[28] *Novo Nordisk of North Am., Inc. v. Genetech, Inc*., 885 F. Supp. 522 (S.D.N.Y. 1995).

[29] *Novo Nordisk*, 885 F. Supp. at 524-25 (emphases added).

Respectfully Submitted,

AMGEN INC.,
By its attorneys,

/s/ Michael R. Gottfried

D. DENNIS ALLEGRETTI (BBO#545511)
MICHAEL R. GOTTFRIED (BBO#542156)
DUANE MORRIS LLP
470 Atlantic Avenue, Suite 500
Boston, MA 02210
Telephone: (617) 289-9200
Facsimile: (617) 289-9201

LLOYD R. DAY, JR.
DAY CASEBEER
MADRID & BATCHELDER LLP
20300 Stevens Creek Boulevard, Suite 400
Cupertino, CA 95014
Telephone: (408) 873-0110
Facsimile: (408) 873-0220

WILLIAM GAEDE III
McDERMOTT WILL & EMERY
3150 Porter Drive
Palo Alto, CA 94304
Telephone: (650) 813-5000
Facsimile: (650) 813-5100

MICHAEL F. BORUN
KEVIN M. FLOWERS
MARSHALL, GERSTEIN & BORUN LLP
233 South Wacker Drive
6300 Sears Tower
Chicago IL 60606
Telephone: (312) 474-6300
Facsimile: (312) 474-0448

Of Counsel:

STUART L. WATT
WENDY A. WHITEFORD
MONIQUE L. CORDRAY
DARRELL G. DOTSON
MARYSUSAN HOWARD
KIMBERLIN L. MORLEY
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320-1789
(805) 447-5000

December 26, 2006

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 December 26, 2006.

/s/ Michael R. Gottfried
Michael R. Gottfried