

**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.)	
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**PLAINTIFF AMGEN INC.’S OPPOSITION TO DEFENDANTS’
EMERGENCY MOTION FOR TEMPORARY STAY OF
THE COURT’S DECEMBER 19, 2006 ORDER**

Defendants’ request for a temporary stay of this Court’s December 19, 2006 Order denying Defendants’ motion to file under seal should be denied because the documents at issue are not trade secrets and Defendants’ request would only serve to delay discovery. As this Court ruled, Defendants’ “Ad Hominem Conclusory Assertions” were insufficient to establish the existence of a trade secret. Defendants now seek to delay the complete filing of Amgen’s motion and accompanying documents for at least an additional three days, in contravention to the Court’s November 6 Order,¹ to give them a second bite at the proverbial apple. Any “supplement” to their original conclusory submission would be an exercise in futility.

Contrary to Defendants’ assertion, their BLA and IND documents are not rendered trade secret merely because of regulations governing FDA’s treatment of an applicant’s regulatory

¹ Docket No. 142.

filings and the lack of prior public disclosure of the documents themselves.² Defendants have publicly disclosed many of the most substantive elements of those documents. Most recently in their December 15 Motion to Compel, they publicized the components making up their peg-EPO (peg-EPO “is synthesized using polyethylene glycol polymer (PEG) and EPO as starting materials.”)³ This fact therefore cannot be considered a trade secret.⁴ Likewise, Defendants have publicly asserted that their peg-EPO is patented (as justification for their belief they do not infringe Amgen’s patents) and this patent, describing peg-EPO and the process by which it is made, is in the public domain.⁵ Finally, as acknowledged in their Emergency Motion to File Under Seal, Defendants have publicly disclosed the results and data from their Phase III studies.⁶ Peg-EPO’s structure, the process by which it is made, and the product’s activity in the clinic cannot qualify as trade secret under these circumstances either.⁷

Likewise, Defendants’ assertion that the Frazino and Dinella deposition transcripts supporting Amgen’s Motion are trade secret on the ground that the excerpts cited contain “confidential” information as to Defendants’ “confidential preparations” and “FDA approval process”⁸ is equally unsupported by the record. In the excerpt from the Franzino deposition cited

² See, e.g., Defendants’ 12/18/06 Memorandum in Support of Their Emergency Motion to File Under Seal (Docket No. 181) at 6, 8 (n. 7) (hereinafter “Emergency Motion”).

³ Docket No. 172 (Defendants’ 12/14/06 Memorandum in Support of Their Motion to Compel) at 2.

⁴ See Amgen Memo at 12-13 and n. 31 (regarding composition of peg-EPO).

⁵ See, e.g., CCBN Street Events, Event Transcript, RHHBY- Roche Conference Call – Phase II CERA Data in Renal Patients, November 17, 2003 at 1-2 (“we have recently been given a patent in the U.S.”) (attached hereto as Exhibit A); U.S. Patent No. 6,583,272 B1 (issued 6/24/03 and entitled “Erythropoietin Conjugates”) (attached hereto as Exhibit B).

⁶ See Emergency Motion at 8, n.7.

⁷ See Amgen Memo at 13, n. 32.

⁸ See Emergency Motion at 7.

by Amgen,⁹ Frazino only testified as to what peg-EPO is (a molecule comprising PEG and EPO) — which as discussed above is not trade secret — and that she worked to scale up the compound. She did not testify about the actual work she performed to accomplish the scale-up or about “confidential preparations.” Similarly, the cited excerpts from the Dinella deposition¹⁰ refer only to a colloquy between counsel over the parties’ dispute over the form of BLA produced in the ITC action (one of the issues raised in Amgen’s motion to compel) and the start of testimony regarding a “Request for Trial Material” for use in clinical trials. Those excerpts do not refer to the “FDA approval process” for peg-EPO.

Finally, the information contained in the remaining “internal Roche documents” (emails, slide decks from Roche’s Medical Affairs Team and the like) cited in Amgen’s motion are directed to either the transport of peg-EPO into the United States, dated and incomplete inventory accountings of this peg-EPO, the composition of Defendants’ “CERA” product (all of which reflect that Defendants’ internally refer to their product as “PEG-EPO” and the quantities of product shipped for use in the United States), or the identity and timing of Roche’s then planned and now on-going Phase IIIb seeding studies, at least one of which Defendants publicly announced at the November 2006 American Society of Nephrology meeting.¹¹ The publicly available information contained in these documents cannot be a trade secret.

As was the case with Defendants’ unsubstantiated assertions, mischaracterizations of the record, and *ad hominem* attack as to Amgen’s motives for filing its motion to compel in

⁹ Carter Dec., Exh.11.

¹⁰ *Id.*, Exh. 23.

¹¹ ASN Abstract PUB377 by Beserab et al., entitled “Randomized Comparison of IV C.E.R.A. (Continuous Erythropoietin Receptor Activator) and Darbepoetin Alfa (DA) at Extended Administration Intervals for the Maintenance of Hb Levels in Patients with CKD on Dialysis: Rational and Design.” (attached hereto as Exhibit C).

Defendant's original Emergency Motion, Defendants should not be allowed to further delay consideration of Amgen's Motion to Compel or discovery in this matter by their motion for temporary stay.

Dated: December 19, 2006

Respectfully Submitted,

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By its attorneys,

AMGEN INC.,

By its attorneys,

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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 December 19, 2006.

/s/ Michael R. Gottfried
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