

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

_____)	
AMGEN INC.,)	
)	
Plaintiff,)	
)	
v.)	
)	CIVIL ACTION No.: 05-CV-12237WGY
F. HOFFMANN-LA ROCHE LTD)	
ROCHE DIAGNOSTICS GmbH)	
and HOFFMANN-LA ROCHE INC.)	
)	
Defendants.)	
_____)	

MEMORANDUM IN SUPPORT OF ROCHE’S EMERGENCY MOTION TO STRIKE PORTIONS OF EIGHT EXHIBITS CONTAINING ROCHE MANUFACTURING TRADE SECRETS THAT ARE NOT NECESSARY FOR AMGEN’S INFRINGEMENT MOTIONS OR IN THE ALTERNATIVE TO SEAL THESE SELECT EXHIBITS

Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. respectfully request that the Court strike portions of eight (8) exhibits filed in connection with Amgen’s infringement summary judgment papers because they contain critical Roche trade secret manufacturing information that is irrelevant and unnecessary to the Court’s ruling. In particular, Exhibits 5, 8, 9, 43, 45, 55, and 63 to the Scott Declaration¹, and Exhibit 1 to the Galvin Declaration² (collectively, “the Exhibits”) contain hundreds of pages of technical manufacturing information that is of great value to Roche, which would allow competitors to duplicate, among other things, Roche’s cell lines, its proprietary growth media, and its process

¹ Declaration of Katie J.L. Scott in Support of Amgen Inc.’s Motion for Summary Judgment of Infringement of ‘422 Claim 1, ‘933 Claim 3, and ‘698 Claim 4 (Docket No. 514). These exhibits were submitted for *in camera* review on June 15, 2007.

² Declaration of Robert M. Galvin in Support of Amgen Inc.’s Reply in Support of Its Motion for Summary Judgment of Infringement of ‘422 Claim 1, ‘933 Claim 3, and ‘698 Claim 4 (Docket No. 665). These exhibits were submitted for *in camera* review on July 9, 2007.

for synthesizing and purifying CERA. Amgen only cites to a couple of pages from each document, and even then only to support general propositions that are already supported by other documents without the level of detail that would destroy Roche's trade secrets in its proprietary manufacturing process.

Roche has a great deal of valuable trade secret information that is implicated by this lawsuit. Unlike Amgen, however, Roche's participation isn't voluntary. Although Roche understands that, due to the public nature of this proceeding, some of its sensitive internal information may inevitably be disclosed, it would be fundamentally unfair to destroy the value of these most sensitive trade secrets when they are not even relevant or necessary to the motions before the Court. Arthur R. Miller, *Confidentiality, Protective Orders, and Public Access to the Courts*, 105 Harv. L. Rev. 427, 470 (1991) ("A business entity caught up in litigation simply must assume the risk of disclosure; its best — indeed, its only — hope of protecting its property is the court's willingness to exert its full authority to prevent further dissemination of the information.").

Furthermore, in an effort to even further limit this motion to only the most critical and unnecessary documents, Roche has agreed to allow Amgen to file certain, less sensitive pages that Amgen relies upon in the public record. Thus, Roche's motion to strike is limited to the following pages of the Exhibits:

Scott Ex. 5	Entire document except ITC-R-BLA-00004178 and ITC-R-BLA-00004200
Scott Ex. 8	Entire document except ITC-R-BLA-00004667
Scott Ex. 9	Entire document except ITC-R-BLA-00004987
Scott Ex. 43	Entire document except R000081253, R000081258
Scott Ex. 45	ITC-R-00050628–50639, R000466990–991

Scott Ex. 55	ITC-R-00050551-50580
Scott Ex. 63	Tables 11, 12 and Figure 13 from ITC-R-00091007-00091009
Galvin Ex. 1	Pages 213, 215-17

In the alternative, if the Court determines that any of the Exhibits are necessary for its decision on the underlying summary judgment motions, Roche respectfully requests that the Court reconsider its denial of the motion to seal for these select few highly sensitive documents. Amgen has not opposed the filing of these documents under seal.

I. The Trade Secret Portions of the Exhibits are Not Relevant or Necessary to Amgen's Motions

The Exhibits should be struck before their public disclosure destroys Roche's manufacturing trade secrets because the highly detailed technical information contained in these documents is irrelevant and unnecessary for Amgen's motions. *See Ramsdell v. Bowles*, 64 F.3d 5, 7 (1st Cir. 1995) (district court properly granted defendant's motion to strike plaintiff's summary judgment opposition papers, because, among other things, plaintiff's opposition was "replete with immaterial, irrelevant and prejudicial statements."); *Lexington Ins. Co. v. Virginia Sur. Co., Inc.*, 486 F.Supp.2d 173, 174 (D.Mass. 2007) (Stearns J.) (granting motion to strike exhibits to a motion for summary judgment that were not necessary to the Court's decision).

Roche would be harmed by the public release of these documents because of the extreme level of detail they contain regarding the trade secret phases of Roche's manufacturing process. Information at this level of detail, however, is simply not necessary or relevant to the motions pending before the Court, because, for example, nothing turns the precise formulation of the buffers Roche uses to purify CERA or the precise orientation and sequencing of the cDNA fragments in the proprietary vector Roche uses to create its cell line. Neither Amgen nor Roche

require information at this level of detail to support their arguments, and the Court similarly does not need to review these documents to render its decision.

Indeed, Amgen does not cite the Exhibits for the detailed technical manufacturing information that predominates them, but rather for general propositions that could be and are supported by any number of less sensitive documents. For Example, Exhibit 5 to the Scott Declaration is over two hundred pages in length, and within those two hundred pages, it contains a complete overview of the proprietary processes that Roche uses to synthesize and purify CERA. *See* Batcha Decl. ¶ 12.³ Amgen, however, only cites to approximately five of those two hundred pages, and even then only to support general propositions, such as the fact that Roche purchases the peg reagent from a third party or that “Roche makes recombinant human erythropoietin in Germany, which it calls ‘epoetin beta.’” *See* Lodish Decl. ¶ 49; Amgen’s 56.1 Statement ¶ 1. These general statements could be and are supported by any number of other less sensitive documents that are already in the record, such as Scott Exhibit 3 (“epoetin beta starting material is manufactured in Penzberg. . . The PEG reagent is commercially available through NEKTAR, formerly known as shearwater, Corp.”).⁴ Thus, Roche should not be forced to disclose in detail its proprietary step-by-step process for synthesizing and purifying CERA to the public because its competitive rival seeks to use a handful of pages to support general propositions.

The most egregious abuse, however, is found in Paragraph 49 of the Lodish declaration, where Amgen cites to all 200 pages of Scott Exhibit 5 for the proposition that “[t]he PEG reagent used to make peg-EPO – methoxy-30 kDa PEG-SBA (“PEG-SBA”) – is a reagent commercially produced and supplied by a U.S.-based company, Nektar Therapeutics.” It is simply

³ Declaration of Susan Batcha in Support of Roche’s Motion to Seal (Docket No. 563).

unnecessary to teach the world in detail the steps required to make CERA to support this general proposition.

Additionally, Roche should not lose its manufacturing trade secrets when Amgen's reliance on the Exhibits is expressly cumulative with other evidence offered by Amgen. For example, in Paragraph 11 of Amgen's 56.1 Statement, Amgen supports its contention about Roche's DN2-3alpha3 cell line with citations to three exhibits, including Scott Exhibit 9. Here, Scott Exhibit 9, which is a hyper-detailed description of the proprietary process by which Roche genetically engineered its cell line, is merely cumulative with the other citations, all of which state the same general point.

Finally, the Court should strike any portions of these sensitive documents that Amgen does not cite to at all. For example, the first page of Scott Exhibit 45 is cited once in Amgen papers (Lodish Decl. ¶ 51 n.33), and no other pages are cited at all. The page Amgen cites contains no sensitive information (and thus Roche has agreed to its disclosure), but later pages in the document do contain trade secrets regarding which particular isoforms Roche uses to produce CERA.⁵ This later, trade secret information is not necessary or even relevant to the portions of Exhibit 45 cited by Amgen, so the Court should strike these, and any other pages in the Exhibits, which are not relied upon by Amgen.

The examples given above are illustrative of why the Exhibits are irrelevant and unnecessary for the Court's determination of the motions presently before it, and therefore should be struck before Roche is prejudiced and irreparably harmed by the public disclosure of

⁴ Scott Ex. 3 at ITC-R-BLA-0000249.

⁵ Roche also notes that the last two pages of Exhibit 45, R000466990-91, are not from the same document or even from the same document production as the rest of the exhibit (the other pages in this Exhibit are from the "ITC-R" production). These pages, which presumably were included in error, are not even relevant to the other pages in Exhibit 45, let alone relevant to Amgen's underlying motions.

its critically important trade secrets. For the further convenience of the Court, Roche has prepared a table as Appendix A, which catalogues why each of Amgen's citations to these highly sensitive documents are not required by the Court, and therefore, why they should not be filed in the public record.

Roche should not be irreparably harmed by the detailed public disclosure of these highly sensitive documents, which disclose its entire manufacturing process, especially when the detailed information they contain is not necessary or relevant to the matters before the Court. Thus, Roche respectfully requests that the Exhibits be struck before they are filed in the public record.

II. The Public Disclosure of the Manufacturing Trade Secrets Contained in the Exhibits Would Irreparably Harm Roche by Destroying Its Substantial Investment in Developing CERA

Although Roche has a great deal of competitively sensitive information that is implicated by Amgen's summary judgment papers, it has limited its present motion to strike to only those documents that are absolutely essential to Roche's ability to profit on its years of research and development of CERA. The trade secret information in these select documents contains sufficient detail regarding Roche's step-by-step manufacturing process to allow Roche's competitors to duplicate, among other things, Roche's cell lines, its proprietary growth media, its process for synthesizing CERA, and its purification process. In other words, these documents contain all the information one would need to make cells identical to Roche's, and to manufacture CERA as Roche would. The public disclosure of this information at this level of detail to Roche's competitors (who are not burdened by millions of dollars of overhead from development costs), would destroy Roche's ability to profit from the drug it developed.

The secret formulas and secret manufacturing processes contained in these select few Exhibits are classic trade secrets. *See In re Gabapentin Patent Litigation*, 312 F. Supp. 2d 653, 659 (D.N.J. 2004) (“Issues in patent cases of this type are, by definition, secret. They implicate classic trade secrets. Secret formulas, the disclosure of which could result in millions or even billions of dollars being lost. Cases like this are what confidentiality orders are designed for.”); M.G.L. ch. 266 § 30(4) (trade secrets include “anything tangible or intangible or electronically kept or stored, which constitutes, represents, evidences, or records a secret scientific, technical, . . . production, . . . design, process, procedure, formula, invention or improvement.”).

Scott Exhibit 5 is an excerpt from Roche’s BLA entitled *Description of Manufacturing Process and Process Controls*. This document is, in effect, the step-by-step “recipe” for CERA, and contains highly detailed technical information regarding the full scope of the manufacturing process. For example, this document contains such highly sensitive information such as the precise ratio of the various reagents introduced during the manufacturing process, detailed descriptions of the manufacturing techniques used, and the precise method of synthesizing and purifying CERA. In addition, this document contains detailed and highly sensitive information regarding Roche’s control and testing methods that it uses to insure that the finished product meets specifications. Given that this document was required to have a level of detail necessary to effectively “teach” the FDA how CERA is made in order to gain approval, it could easily be used by Roche’s competitors, including generic drug manufacturers for the same purpose, which would effectively destroy Roche’s ability to profit from its years of research and development of CERA.

Scott Exhibit 8 is an excerpt from Roche’s BLA entitled *Summary of the Fermentation and Harvest Process*, which contains highly detailed technical information regarding the

manufacture of the starting material epoetin beta. In particular, this document gives the specific chemical formulation of the medium in which Roche's erythropoietin-producing cells are cultured at various phases of manufacturing. Roche has spent a great deal of time and resources optimizing and perfecting the precise chemical formulations contained in this document. *See* Batcha Decl. ¶ 16. This optimized media gives Roche a significant competitive advantage by allowing increased yield and potency of the starting material for epoetin beta. The disclosure of Exhibit 8, however, would destroy this advantage by teaching Roche's competitors how to make cell-culture media identical to that used by Roche.

Scott Exhibit 9 is an excerpt from Roche's BLA entitled *Control of Materials: Raw Materials Use for the Epoetin Beta Fermentation*. This documents contains a highly detailed description of the creation of the proprietary cell line that it uses to produce the epoetin beta starting material. In particular, it contains a detailed, step-by-step discussion of how Roche created the proprietary vector it used to genetically engineer host cells to produce epoetin beta starting material, which includes specific details regarding the sequencing specific composition of the particular DNA fragments that Roche included in the vector to achieve particular effects. This information in this document is kept in the utmost secrecy because, in effect, it contains all the necessary information for Roche's competitors or generic drug manufactures to create a cell line that is identical to Roche's proprietary cell line. Consequently, the public disclosure of this document would cause irreparable harm to Roche. *See* Batcha Decl. ¶ 17.

Moreover, Scott Exhibit 43 contains technical trade secret information regarding Roche's methods of purifying CERA, as well as early discovery into the effectiveness of different PEG-reagents which has never been made public. Amgen does not rely on this document for this

sensitive internal information, and thus these pages should be struck before Roche's trade secrets are revealed. *See* Appendix A.

Finally, Scott Exhibits 45, 55, and 63, and Galvin Exhibit 1 all contain technical trade secret information regarding the synthesis, yield, and purity of the manufacturing process for CERA, as well as Roche's confidential testing methodology and results relating to the chemical structure and synthesis of CERA. Of most importance, these documents disclose the identities of the isoforms that Roche selects for the synthesis of CERA. This information has never been made public, and the particular identities of these isoforms are not relevant to Amgen's motion, as indeed, Amgen cites none of the pages Roche moves to strike. *See* Appendix A.

Thus, the Court should strike the Exhibits because they are highly prejudicial to Roche's ability to profit from CERA. The Exhibits would teach one of skill in the art how to make Roche's proprietary cell line (Exhibit 5), how best to ferment and harvest those cells (Exhibit 8), what isoforms of the starting material to select (Scott Exhibits 45, 55, 63, Galvin Exhibit 1), and how to synthesize CERA and purify the finished product. Thus, this trade secret information is everything a competitor needs to make Roche's proprietary drug for itself. Thus, since these exhibits are not necessary or relevant to the motions before the Court, the Court should strike these Exhibits before their public disclosure irreparably harms Roche.

III. In the Alternative, the Court Should Allow these Select Highly Sensitive Documents to be Filed Under Seal

As detailed above, the Exhibits contain confidential trade secret information, the continued secrecy of which is critical to Roche's ability to profit from its years of research and millions of dollars of development costs for CERA. If these detailed manufacturing documents are publicly released, generic drug manufacturers and other competitors will have everything they need to know to make copy Roche's drug, irreparably harming Roche's ability to sell this

product. Thus, if the Court denies Roche's motion to strike as to any portion of the Exhibit, Roche respectfully requests that they be accepted for filing under seal.

Dated: July 13, 2007
Boston, Massachusetts

Respectfully submitted,

F. HOFFMANN-LA ROCHE LTD,
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/s/ Keith E. Toms

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