

**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.)	
_____)	

**AMGEN INC.'S OPPOSITION TO ROCHE'S EMERGENCY MOTION
TO STRIKE PORTIONS OF EIGHT EXHIBITS RELIED ON IN SUPPORT OF
AMGEN'S MOTION FOR SUMMARY JUDGMENT OF INFRINGEMENT**

I. INTRODUCTION

Roche's motion to strike is an end-run around this Court's July 3 Order denying its motion to seal on precisely these same eight documents. Tacitly conceding that it is unable to meet the threshold requirements for a motion for reconsideration, Roche now makes this second attempt through the present vehicle of a motion to strike. However, the consequences of Roche's end-run are potentially grievous for Amgen since Roche is seeking to exclude relevant and necessary infringement evidence relied upon by Amgen in its motion for summary judgment. Because Amgen's exhibits are both necessary and relevant, Roche's motion to strike should be denied.

II. THE COURT HAS ALREADY DENIED ROCHE'S MOTION TO SEAL PRECISELY THE SAME EXHIBITS

On June 28, 2007, Roche filed a motion to seal on each of the documents that is the subject of its present motion. (Docket No. 559) The Court considered Roche's motion and more than 35 pages of three supporting declarations and determined that none of the exhibits at issue warranted trade secret protection.

Displeased with the Court's ruling, and having no basis on which to move to reconsider, Roche is trying to have another bite at the apple by moving to strike precisely the same exhibits that were the subject of its motion to seal (Docket No. 559). The import, though, of Roche's motion to strike is much more insidious than a straightforward motion to seal because it would require Amgen to present and the Court to decide summary judgment of infringement on less than a full record. Having already considered and ruled on the same eight exhibits in the appropriate context of a motion to seal, the Court should deny Roche's present motion that merely rehashes its prior motion but also seeks to deprive Amgen (and the Court) of seeking summary adjudication of infringement on an abridged record.

III. THE EXHIBITS AT ISSUE ARE BOTH RELEVANT AND NECESSARY TO AMGEN'S MOTION FOR SUMMARY JUDGMENT OF INFRINGEMENT

Roche's motion to strike is based on false premise that the eight exhibits cited are both irrelevant and unnecessary to the Court's ruling on Amgen's motion for summary judgment of infringement.¹ In its accompanying Appendix (Docket No. 722), Roche misinforms the Court that many of the eight exhibits are "cumulative." Roche is incorrect.

While many of the exhibits may be used together with other pieces of evidence to establish predicate facts for infringement, none of these documents is duplicative.² Moreover, each of the eight exhibits at issue is directly relevant to determining infringement of the patents-in-suit.

Exhibit 5 to the Scott Declaration (Docket No. 514) is relevant to Roche's manufacturing of peg-EPO.³ In particular, Amgen cites Exhibit 5 (already narrowed to six pages in total) for the propositions that Roche makes recombinant human erythropoietin (epoetin beta) in Germany, that epoetin beta is a starting material for peg-EPO, and that pegylation is a conventional process and known technique for extending the half-life of recombinant protein drugs. (56.1 Statement

¹ Roche's Memorandum in Support of Its Motion to Strike at 1, 3 (Docket No. 722).

² But even if Amgen's exhibits included cumulative citations, this would be both appropriate and necessary in the context of summary judgment to show the absence of a genuine issue of material fact or that no reasonable jury could find that every limitation is not met. *See Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed. Cir. 1998) ("[A] literal infringement issue is properly decided upon summary judgment when no genuine issue of material fact exists, in particular, when no reasonable jury could find that every limitation recited in the properly construed claim either is or is not found in the accused device."); *see also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251-52 (1986) ("The Court has said that summary judgment should be granted where the evidence is such that it 'would require a directed verdict for the moving party.' . . . In essence, though, the inquiry under each is the same: whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law.").

³ Notably, Roche fails to inform the Court that Amgen agreed pursuant to the meet and confer process that Scott Declaration, Exhibit 5 (Docket No. 514) would be reduced to six pages. Instead, Roche mischaracterized the number of pages at issue in its motion and made Exhibit 5 (pre-narrowing) the centerpiece of its motion to strike. *See* Declaration of Deborah E. Fishman in Support of Amgen's Opposition to Roche's Motion to Strike (hereafter "Fishman Decl.") at ¶¶ 9, 11.

¶¶1, 5, 39-40 (Docket No. 512)). These are important and relevant facts for infringement of Amgen's process claims and the "materially changed" issue.

Scott Declaration, Exhibit 8 (Docket No. 514) describes Roche's process for growing cells in culture and the process for isolating and purifying EPO therefrom. Exhibit 8 is necessary to show that erythropoietin is purified or isolated from mammalian cells grown in culture ('422 claim 1, '698 claim 6) and that "suitable nutrient conditions" are used ('698 claim 6). Roche disputes these facts (Roche's Response to Amgen's 56.1 Statement ¶¶14-16 (Docket No. 512)), yet seeks to strike this relevant evidence.

Roche also seeks to strike numerous pages from Exhibit 9 to the Scott Declaration (Docket No. 514) that were explicitly cited in Amgen's 56.1 Statement and the Lodish Declaration (Docket Nos. 512, 513). Exhibit 9 describes the construction and components of the vector, the sequence of the EPO DNA, and the host cells used by Roche. These facts are all relevant and necessary to show infringement of '933 claim 3 and '698 claim 6.

Scott Declaration, Exhibit 43 (Docket No. 514) is likewise necessary and relevant to show that the EPO in peg-EPO has the same amino acid sequence as EPO, that peg-EPO is comprised of EPO, and that peg-EPO is a "derivative" of EPO. (56.1 Statement ¶¶ 22, 26-27, 41 (Docket No. 512)). Exhibit 43 also describes the preparation of the EPO starting material, including the fact that it is "purified." (Scott Declaration, Exhibit 43 at R000081246 (Docket No. 514)).

Scott Declaration, Exhibit 45 (Docket No. 514) was cited to by Dr. Lodish at ¶51 (Docket No. 513) for the purpose of describing the reaction products of the pegylation reaction and is not duplicative of the other cited documents because it is the only documents relied on in Amgen's summary judgment briefing that concisely summarizes this relevant information.

Scott Declaration, Exhibit 55 (Docket No. 514) was cited by Amgen in its 56.1 statement

at ¶22 (Docket No. 512) and quoted in the text of Amgen's Reply brief at p.5 (Docket No. 664)) for the proposition that EPO and the EPO in peg-EPO have the same composition. These facts are both important and relevant to infringement of both Amgen's product and process claims.

Roche also seeks to strike from Scott Declaration, Exhibit 63 (Docket No. 514) a Figure 13 that is expressly referred to in ¶ 28 of Amgen's 56.1 Statement (Docket No. 512). Figure 13 shows that the carbohydrate structures for EPO are not altered by pegylation. Table 12, which Roche also seeks to strike, is necessary to understand and interpret Figure 13. Thus, both Table 12 and Figure 13 are relevant and necessary to showing the similarity in composition – and in particular the carbohydrate composition – of EPO and the EPO in peg-EPO.

In addition to the seven exhibits in the Scott Declaration described above, Roche also moves to strike pages 213, and 215-17 of Galvin Declaration, Exhibit 1 (Docket No. 665). Those pages provide the data that supports page 209 of the same exhibit (ITC-R-BLA-00004232 (Docket No. 665)) and that Amgen expressly relies on in its Reply brief (Reply at 6 n.18 (Docket No. 664)). Roche says that it wants to strike pages 213 and 215-217 because they contain the identity of the isoforms of peg-EPO (Roche's Memo at 9 (Docket No. 722)). Yet Roche does not seek to strike other pages of the same exhibit (*e.g.* page 209) that would disclose the identity of the isoforms in any event. Pages 213 and 215-217 of Exhibit 1 to the Galvin Declaration are relevant and support Amgen's motion for summary judgment and should not be stricken.

Because each of the eight exhibits that are the subject of Roche's motion are both relevant and necessary to Amgen's motion for summary judgment of infringement, Roche's motion to strike should be denied.

IV. AMGEN HAS MADE GOOD FAITH EFFORTS TO LIMIT THE DISCLOSURE OF ROCHE CONFIDENTIAL INFORMATION

Even before ever filing its Motion for Summary Judgment of Infringement, Amgen made a good faith effort to limit the disclosure of non-essential Roche confidential information. After

preparing its infringement summary judgment papers, counsel for Amgen undertook a process to eliminate any unnecessary or duplicative exhibits.⁴ In addition to winnowing away its total number of exhibits, Amgen's counsel also culled out of its exhibits unnecessary or duplicative information, as is reflected by the amalgam of page ranges within a single exhibit.⁵ In the end, Amgen reduced the exhibits to its summary judgment motion by more than 20-plus exhibits and hundreds of pages of text before filing it with the Court.⁶

Nonetheless, Roche filed a motion to seal on a number of the exhibits relied on in Amgen's infringement summary judgment filing and, in particular, on the eight exhibits at issue in the present motion. After the Court denied the parties' respective motions to seal on July 3, Roche suggested that the parties reach a negotiated compromise to limit the disclosure of each party's information into the public record.⁷ While Amgen cooperated with Roche in this effort, at all times Amgen made clear that it would work to eliminate duplicative or extraneous confidential information, it would not alter its briefs nor would it ask the Court to rule on a diminished or incomplete record.⁸

For the past week, Amgen's counsel has met and conferred on a near-daily basis with Roche regarding its confidential infringement information. But the parties reached an impasse when Roche insisted that Amgen withdraw virtually all of its Exhibits 8 and 9 to the Scott declaration (Docket No. 514).⁹ Roche sought to eliminate all but a single page of Exhibit 8, notwithstanding the fact that Exhibit 8 is cited in eleven separate places in Amgen's summary

⁴ See Declaration of Teresa E. Garcia in Support of Amgen's Opposition to Roche's Motion to Strike (hereafter "Garcia Decl.") at ¶¶ 11-12.

⁵ Garcia Decl., ¶¶ 6-10

⁶ Garcia Decl., ¶¶ 5-6, 11

⁷ Fishman Decl., ¶ 4.

⁸ Fishman Decl., ¶ 5.

⁹ Fishman Decl., ¶ 10.

judgment briefing. Likewise, Roche proposed excising all but a single page of Exhibit 9, notwithstanding the fact that it is cited fifteen times in support of Amgen's Memorandum of Law and supporting papers places in Amgen's summary judgment briefing including in its Memorandum of Law.

Exhibits 8 and 9 to the Scott Declaration (Docket No. 514) each contain unique, non-duplicative evidence of infringement and had been previously tailored to remove extraneous Roche confidential information. As discussed above, Exhibit 8 describes Roche's process for growing cells in culture and for isolating and purifying EPO therefrom. Since Roche disputes these facts, Exhibit 8 is necessary and relevant to showing infringement of '422 Claim 1 and '698 Claim 6. Likewise, Exhibit 9 describes the construction and components of the vector, the sequence of the EPO DNA, and the host cells used by Roche, which is relevant and necessary to showing infringement of '933 Claim 3 and '698 Claim 6. Amgen refused to withdraw these exhibits, which had already been limited to the actual pages cited in the briefing, because doing so would have undermined Amgen's motion for summary judgment.

When Amgen refused to withdraw virtually the entirety of Scott Declaration, Exhibits 8 and 9 (Docket No. 514), Roche called off negotiations.¹⁰ Amgen offered to continue negotiations and provided Roche with written assurance that it would not disclose Roche's confidential information without affording Roche an opportunity to file a motion for reconsideration.¹¹ Even so, less than an hour after the parties' had met and conferred on the subject, Roche filed its memorandum in support of its present motion to strike.¹²

V. CONCLUSION

For all of the foregoing reasons, Amgen respectfully requests that the Court deny Roche's

¹⁰ Fishman Decl., ¶ 10.

¹¹ Fishman Decl., ¶ 8.

¹² Fishman Decl., ¶ 10.

emergency motion to strike portions of eight of the exhibits relied on in support of Amgen's Motion for Summary Judgment of Infringement.

Respectfully Submitted,

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July 16, 2007

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the Electronic Case Filing (ECF) system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non registered participants on the above date.

/s/ Michael R. Gottfried

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