

DAY CASEBEER
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September 3, 2007

VIA ELECTRONIC CASE FILING SYSTEM

The Honorable William G. Young
District Judge for the District of Massachusetts
John Joseph Moakley U.S. Courthouse
1 Courthouse Way
Boston, MA 02210

Re: *Amgen Inc. v. F. Hoffman-Roche, Ltd., et al.*
Civil Action No: 05-12237-WGY

Dear Judge Young:

We write to raise with Your Honor issues that we believe would be useful to consider prior to the commencement of trial on Tuesday.

Motions in Limine

We have Mr. Bromberg's letter to you of Saturday asking that, in advance of the commencement of the validity phase of trial this coming week, you consider certain motions *in limine* bearing on the evidence to be presented during that phase.

Amgen respectfully makes a similar request, namely that you consider and decide the Amgen motions *in limine* set forth in the attached table. We believe that resolution of the identified Amgen motions will serve to eliminate irrelevant, prejudicial, confusing or otherwise improper evidence from the opening statement and the validity phase, and thus materially impact the presentation of evidence to the jury during the validity phase of trial.

The urgency of resolving certain of Amgen's motions *in limine* was made evident at 9 p.m. last night when we received the graphics Roche intends to use in its opening statement. Several of the slides implicate the motions *in limine* identified in the attached table, and others are made moot and irrelevant by the Court's recent orders granting certain of Amgen's motions for summary judgment. In particular:

Slide 4: This slide refers to Roche's argument that cloning the EPO gene was obvious in 1983, which is the subject of Amgen's Motion *in limine* No. 17, to Exclude Roche from Presenting Evidence to Challenge the Non-Obviousness of the DNA Sequence Encoding for Human

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Erythropoietin in 1983, Docket No. 876; it refers to the duration of Amgen's patent protection (see discussion pertaining to Slide 23 below); and it refers to Roche's argument about standards for use in the radioimmunoassay recited in the '349 patent claims, an issue on which Amgen was granted summary judgment.

Slide 8: This slide also refers to standards for use in the radioimmunoassay recited in the '349 claims, an issue on which Amgen was granted summary judgment.

Slide 9: This slide depicts Amgen's EPOGEN® sales from 1989 through 1995, which is the subject of Amgen's Motion *in limine* No. 7, to Exclude Roche from Referencing the Profits or Revenues from Amgen's EPOGEN® and ARANESP® Products, Docket No. 845.

Slide 16: This slide depicts alleged EPO-producing cell lines prior to Dr. Lin's patent filing dates, in support of Roche's argument that cloning the EPO gene was obvious, which is the subject of Amgen's Motion *in limine* No. 17, to Exclude Roche from Presenting Evidence to Challenge the Non-Obviousness of the DNA Sequence Encoding for Human Erythropoietin in 1983, Docket No. 876.

Slide 23: This slide presents a chronology of the expiration dates of the '008 patent and the patents-in-suit, in support of Roche's argument that Amgen's period of patent protection extends too long, which is the subject matter of Amgen's Motion *in limine* No. 20, to Preclude Roche from Making Statements Regarding the Duration of Amgen's Patent Protection, Docket No. 886. Roche's depiction is also in support of its argument that the patents-in-suit are invalid for obviousness-type double patenting over the '008 patent, an issue upon which Amgen's motion for summary judgment was granted.¹

In addition, Roche Slides 17 and 19 depict alleged facts which are without foundation because there is no witness identified by Roche who can lay such a foundation. Roche Slide 24, reciting supposed accolades to Roche for its alleged commitment to its employees and the community, is irrelevant to any issue before this Court, much less any validity issue.

We will meet and confer with Roche this afternoon regarding the disputed slides, but anticipate requiring Your Honor's assistance with these issues on Tuesday.

We also request that Roche's motion *in limine* to preclude the testimony of Amgen witness Nancy Spaeth be addressed before opening statements on validity, in that we anticipate that issue

¹ Other Roche opening statement graphics may be subject to objection, and Amgen reserves its right in that regard. Copies of the Roche opening statement graphics referenced in this letter are enclosed.

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arising during opening statements. Amgen will file its opposition to that motion today, September 3, 2007.

We understand that the numerous motions *in limine* filed to date by both parties impose a large burden on the Court, and we deeply appreciate the Court's willingness to devote the time to resolve these issues.

Jury Trial and Trial Phasing Issues

We seek the Court's guidance prior to trial with respect to the particular phases of trial in which Your Honor expects the jury to hear certain disputed evidence, and the particular issues at trial for which the jury will be sitting as the trier of fact or in an advisory capacity.

As Your Honor may recall, Amgen believes that this matter should not properly be resolved by a jury, and especially as to issues such as obviousness-type double patenting and inequitable conduct, which we believe are issues of law for the Court. Amgen also believes that the Court's manner of phasing the case, such that Roche proceeds first on validity issues, is unduly prejudicial to Amgen. With Your Honor's permission we will renew those objections on Tuesday.

Other Issues

Roche has filed a 90 page trial brief listing dozens of issue that could not possibly be tried in the time allotted. Amgen invited Roche to meet and confer in an effort to identify and narrow the issues to be tried, but Roche has thus far refused to respond to that proposal.

In that same regard, Roche has identified a number of issues in its trial brief that it has not previously focused on during the fact discovery and expert phases of the case. Such issues include:

- Roche asserted in its trial brief the issue of its good-faith belief that its peg-EPO product is non-infringing.² Inasmuch as Amgen seeks no remedies for past infringement and does not allege willful infringement, the issue is not relevant to any issue before the Court. Moreover, Roche provided no discovery on this issue, refusing to produce any opinions as to validity or infringement. Amgen has filed a motion to exclude the testimony of George Johnston, a Roche in-house counsel anticipated to testify on Roche's alleged good-faith beliefs.
- Following the Court's grant of Amgen's Motion for Summary Judgment, Roche seeks to circumvent the effect of that order by asserting obviousness-type double patenting

² Roche Trial Brief, section C,1, p. 12

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defenses that none of its ODP experts addressed. Roche now contends that the '933, '422 and '349 asserted claims are invalid for obviousness-type double patenting over claims in the '868 or '698 patents.³ Amgen will file an emergency motion to exclude these additional obviousness-type double patenting defenses, because they were not properly disclosed during discovery and are barred by 35 U.S.C. §121.

The multitude of issues introduced by Roche, together with issues newly focused on, leaves Amgen unable to predict with any certainty the defenses it and its witnesses will have to address at trial. The assistance of the Court in ascertaining and narrowing the issues to be tried, either before trial or during its first week, would be most helpful and appreciated.

With respect to the '698 patent, Amgen notified Roche in an August 2, 2007 letter that it would not be proceeding against Roche on claims 4 and 5 (although Amgen is still proceeding on claims 6-9 of that patent). Although Roche acknowledged Amgen's notice in its Pre-Trial Brief at footnote 7, page 18, statements in that same brief make clear that Roche will still assert invalidity of claims 4 and 5 (Roche Pre-Trial Brief at pages 44-49). Amgen will file a motion to forestall that unnecessary expenditure of the Court's time and resources.

In addition, Roche continues to assert that it is entitled to call 11 trial experts, notwithstanding the parties' agreement, which is reflected in the Court's electronic notes from the Scheduling Conference/Case Management Conference held on June 6, 2007, that each side agreed they would be limited to 10 trial experts. Accordingly, Amgen requests the Court's assistance with resolving this matter.

Finally, Amgen understands that Your Honor has sequestered witnesses during the taking of evidence. Amgen requests that the inventor, Dr. Lin, be permitted to attend the opening statements for the purpose of being introduced to the jury. Also, Roche has listed several Amgen attorneys, including Mr. Watt, Mr. Odre and Mr. Borun, as potential witnesses, and Amgen requests that these attorneys not be sequestered and be allowed to be present in the courtroom during the taking of evidence. Mr. Watt and Mr. Borun have been attorneys of record in this case since its inception and Mr. Watt is Amgen's Vice President Law and Intellectual Property Officer.

³ Roche Trial Brief, section B, 3, C.8, F.2, pp. 34, 40-41, 50.

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Thank you for your consideration of these issues.

Very truly yours,

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/s/ Craig H. Casebeer

Craig H. Casebeer

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Docket No.	Amgen's Motions <i>in Limine</i>
824	Exclude Roche from Referring to its Own Patent on Pegylated Erythropoietin (Amgen's MIL No. 1)
839	Exclude Reference to Amgen's Request for Injunctive Relief (Amgen's MIL No. 6)
845	Exclude Roche from Referencing the Profits or Revenues from Amgen's EPOGEN® and ARANESP® Products (Amgen's MIL No. 7)
847	Exclude Reference to Amgen's "Monopoly" and the Patents-in-suit as Limiting Consumer Choice (Amgen's MIL No. 12)
865	Exclude Sofocleous Testimony Regarding the Competence of the Examination Process in the U.S. PTO (Amgen's MIL No. 16)
876	Exclude Roche from Presenting Evidence to Challenge the Non-Obviousness of the DNA Sequence Encoding for Human Erythropoietin in 1983 (Amgen's MIL No. 17)
889	Preclude Roche from Referring to Government Funding of Dr. Goldwasser's Research and from Arguing that Dr. Goldwasser's Research Should Not Have Been Shared with Amgen (Amgen's MIL No. 18)
886	Preclude Roche from Making Statements Regarding the Duration of Amgen's Patent Protection (Amgen's MIL No. 20)
921	Exclude Introduction of Opinions or Supporting Evidence Not Previously Identified in Expert Reports (Amgen's MIL No. 21)
921	Preclude Roche from Introducing, Including in its Validity Opening, Testimony, Evidence or Argument on Pegylation During the Validity Phase of the Trial and to Exclude any Proffered Testimony of Dr. Robert Langer During the Trial (Amgen's MIL No. 22)
Docket No.	Roche's Motion <i>in Limine</i>
873	Preclude Testimony of Proposed Amgen Witness Nancy Spaeth

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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/ Patricia R. Rich

Patricia R. Rich