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June 12, 2007

VIA ELECTRONIC FILING

The Honorable William G. Young,
 United States District Court
 for the District of Massachusetts
 One Courthouse Way
 Boston, Massachusetts 02210

Re: *Amgen Inc. v. F. Hoffmann-LaRoche, Ltd., et al.*
Civil Action No. 05-CV-12237 WGY

Dear Judge Young:

We write today on behalf of our respective clients to advise you that, although substantial agreement has been reached, the parties have not been able to reach a stipulation regarding the meaning of the term "cells transfected or transformed with an isolated DNA sequence encoding human erythropoietin," as it appears in '868 claim 1 and the asserted claims that rely on such claim. Set forth below are the parties' respective positions with the sole point of dispute highlighted for ease of reference:

<i>"Cells transformed or transfected with An isolated DNA sequence encoding human erythropoietin"</i>	
<i>Amgen's Position</i>	<i>Roche's Position</i>
"Cells that have been genetically modified with isolated DNA containing genetic instructions for human erythropoietin or later generations of these cells that have inherited those instructions."	"Cells that have been genetically modified with isolated <u>and</u> purified DNA containing genetic instructions for human erythropoietin or later generations of these cells that have inherited those instructions."

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Amgen's Position:

The only remaining dispute between the parties with regard to the construction of the claim limitation "cells transformed or transfected with an isolated DNA sequence encoding human EPO" is whether the construction should include an *additional* requirement that the DNA be "purified." Amgen objects to Defendants attempt to introduce an additional limitation into the claim as the claim only requires that the DNA be "isolated."

In their March 5, 2007 Opening Claims Construction Memorandum, both Amgen and Defendants asserted that "transformed or transfected with an isolated DNA sequence encoding human erythropoietin" means "introduction of *purified* exogenous DNA molecules containing the genetic instructions for human erythropoietin" (emphasis added). In other words, both parties asserted that "purified" was a synonym for "isolated." At the *Markman* hearing, Defendants did an about face, arguing in the construction of the related term "isolating" (which also appears in claim 1 of the '868 patent) that it did not mean "in pure form." 4/17/07 Hearing Tr. at 93-97 Thus, at the request of defense counsel and to gain consistency with the interference record, the Court struck "recovery in pure form" from the construction of "isolating." 4/17/07 Hearing Tr. at 97-98.

Amgen is not requesting further construction of the term "isolated" at this time. If the Court, however, seeks to revisit its tentative construction of "isolating" in light of Roche's current position regarding "isolated," then Amgen would continue to advocate for a consistent construction of these related terms.

Roche's Position:

Contrary to Amgen's statement above, Roche's proposed construction for "transformed or transfected with an isolated DNA sequence encoding human erythropoietin" does not include an *additional* requirement, but rather includes the requirements set forth by Amgen during the prosecution of the '868 patent. Roche's construction of this term is supported by statements made in the prosecution history where the applicants stated this limitation referred to the *isolated and purified* DNA sequence derived from claim 2 of the '008 patent. (D.I. 313, Roche Ex. O, 2/1/94, Amendment, at 6; Roche Ex. U, '008 patent at col. 40, ll.1-3.)

Roche never did an "about face" with respect to this term, because Amgen's citation to the record deals with a *different* element of the claims, namely, "isolating...said polypeptide," and not the "isolated DNA sequence." The term "isolating said glycosylated erythropoietin polypeptide expressed by said cells therefrom" as used in claim 1 of the '868 patent was properly construed by this Court based on the statements made by Amgen during interference proceedings with the PTO. (4/17/07 Hearing Tr. at 97-98.)

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If anything, it is Amgen that is unexpectedly changing its position by refusing to recognize that the isolated DNA sequence be purified. Until now, Amgen has always maintained that this term be construed as a purified sequence, including (1) its Opening Markman brief (D.I.

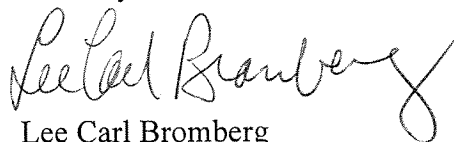
312, Appendix A, at 4); (2) its Markman Opposition (D.I. 323 at 17); (3) its proposed Markman Reply (D.I. 370 at 14); (4) its statements at the Markman hearing (4/17/07 Hearing Tr. at 101); and (5) in post hearing negotiations with Roche. Therefore, Roche respectfully requests that the Court hold Amgen to its word to require the DNA sequence of this term to be purified, especially, since both parties have recognized that it finds support in the prosecution file history.

Respectfully submitted,



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cc: Counsel of Record

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