IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMGEN, INC., Plaintiff, v. F. HOFFMANN-LA ROCHE Ltd, a Swiss Company, ROCHE DIAGNOSTICS GmbH, a German Company and HOFFMANN-LA ROCHE INC., a New Jersey Corporation, Defendants.	Civil Action No. 05-12237 WGY U.S. District Judge Young

MEMORANDUM IN SUPPORT OF ROCHE'S MOTION *IN LIMINE* TO BIND AMGEN INC. TO PRIOR ADMISSIONS RELEVANT TO DOUBLE PATENTING

I. INTRODUCTION

Amgen should be precluded from asserting that the claims of the '868 and '698 patents are patentably distinct from the '008 claims because:

- Amgen's current assertions are directly at odds with arguments made by Amgen during Interference No. 102,097 in gaining priority over Fritsch and Genetics Institute.
- In stating its position in the '097 Interference, Amgen relied on this Court's prior findings and argued that there is "no distinction" between Lin's process claims (which issued as the '868 and '698 patents) and the '008 claims.
- Amgen admitted that "transforming and transfecting a mammalian host cell" with the DNA sequence of the '008 patent and growing under nutrient conditions "necessarily and inherently involves transcription, translation and glycosylation...to provide the *in vivo* biologically active recombinant EPO."

II. STATEMENT OF FACTS

In order to prevail in its priority contest over GI in the '097 Interference, Amgen repeatedly relied on this Court's findings in *Amgen, Inc. v. Chugai Pharm. Co.*, 13 U.S.P.Q.2d

1737 (D. Mass. 1989) to argue that there was "no distinction" between the '008 claims and Lin's process claims. Amgen should be estopped from taking an inconsistent position here.

For example, Amgen argued that this "District Court's uncontested factual findings" showed "clearly and unequivocally . . . that Lin made the invention at issue, *i.e.*, he expressed *in vivo* biologically active recombinant human EPO by a process involving culturing (or growing) a mammalian host cell transformed with the isolated EPO DNA sequence and isolating an *in vivo* biologically active expression product." (Ex. 1, Brief for Senior Party Lin (Trial Ex. SS) at 45-47).[1] Amgen continued, referencing this Court's decisions as follows:

> It is appreciated that the Court decisions use shorthand language (e.g. "expressed") concerning the preparation process rather than reciting the specific language of the present count. However, there can be ***no distinction*** between Lin's expression of *in vivo* biologically active recombinant human EPO using 293, COS cells and CHO cells and the determination of its activity as found by the Courts and the specific language of the count. Glycosylation is necessary to provide *in vivo* biological activity. This is art-recognized and the Examiner-in-Chief has noted that Fritsch et al have not challenged this. . . .Transforming or transfecting a mammalian host cell (e.g. 293, COS or CHO) with the DNA sequence of the Lin '008 patent and growing (or culturing) this transformed cell under nutrient condition ***necessarily and inherently involves transcription, translation and glycosylation*** as specified in steps (a)(i)(ii)(iii) of the Count to provide the *in vivo* biologically active recombinant EPO....This leave[s] step (b) for consideration and Lin notes that determination of the *in vivo* biological activity ***obviously*** requires isolation (b) of the product from the host cells.
>
> Fritsch et al cannot validly argue the contrary. The isolation step (b) means ***nothing more*** than separating the expressed product from the cells...and would ***obviously be necessary*** to determine the *in vivo* biological activity of the expression product.

(Ex. 1 at 47-48) (emphasis added).

Moreover, as Roche explained in a prior motion *in limine* (D.I. 802), Amgen's interference

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[1] "Ex.___" refers to the Declaration of Krista M. Rycroft in support of Roche's Motion *in Limine* to Bind Amgen Inc. to Prior Admissions Relevant to Double Patenting, filed concurrently.

brief argued, under the heading "Summary of Lin's Position":

> While the count is directed to a process for preparing *in vivo* biologically active EPO using a mammalian host cell transfected or transformed with an isolated DNA sequence encoding human EPO, and the litigation was directed to the purified and isolated DNA sequence and host cells transfected or transformed thereby, ***it is evident that these are only different manifestations of the same invention*** as acknowledged by Fritsch et al in their Motion Q here (and in Motion G in Interference No. 102,096). Clearly, the whole purpose and intent of the purified and isolated DNA sequence encoding human EPO (and host cells transfected therewith) at issue in the litigation was to express *in vivo* biologically active human EPO. Stated otherwise, the process language of the Lin patent claims ***at issue in the litigation ("encoding human EPO") is, for all intents and purposes, a description of the present count.*** One cannot be sure he has the sequence until he has successfully expressed in vivo biologically active human EPO. This involves culturing the transfected cells and isolating the expression product to determine whether or not it has the required in vivo activity. Hence, ***the priority holding in the litigation is directly on point***, notwithstanding the different statutory class of claims involved.

(Ex. 1 at 25-26) (emphasis added). Amgen later noted that the litigation in this Court "directly involved an essential feature of the process, i.e. the purified and isolated DNA sequence encoding EPO," and "Lin submits that the Court findings establish priority for Lin as to the present count [i.e. Lin's process claims] and show that the subject matter at issue is not patentable to Fritsch." (Ex. 1 at 29).

Amgen further argued that "Fritsch et al cannot logically argue in opposition to Lin's motion that the present interference involves a different invention (expression process) from that involved in the litigation" (host cells transformed with the EPO gene). (Ex. 1 at 34). According to Amgen, this Court "addressed priority of invention of Lin's '008 claims to host cells transformed with the isolated EPO gene. ***Consideration of such claims is tantamount to consideration of the present process counts, particularly in view of the District Court's findings*** of the *in vivo* biological activity of the products of host cells." (*Id.*) (emphasis added).

Finally, Amgen argued that "the isolated DNA sequence is ***the*** novel feature of the process

claims." (Ex. 1 at 57). Subsequently, referring to the isolation step in the interference count, Amgen argued that "the ***whole purpose*** of isolating the DNA sequence was to use the sequence in expression to obtain *in vivo* biologically active recombinant EPO . . . . As for the isolating step, there is ***clearly nothing separately inventive*** in this." (Ex. 1 at 58) (emphasis added).

In sum, in order to secure a victory in the '097 Interference, Amgen repeatedly relied on this Court's findings with respect to the '008 patent claims to argue that the process for making an *in vivo* biologically active recombinant EPO polypeptide — including transcription, translation, glycosylation and isolation of the polypeptide — was obvious, routine and non-inventive. Indeed the Board accepted Amgen's arguments in finding for Lin:

> With regard to the issue of prior inventorship in particular, we note that Fritsch conceded at the final hearing that ***priority in each of the related interferences turns on isolation of the EPO gene,*** i.e., determination of priority in Interference No. 102,096 is dispositive on the issue of priority in the present interference.

Fritsch v. Lin, 21 U.S.P.Q.2d 1737, 1738-39 (B.P.A.I. 1991) (emphasis added). The Board continued by "agree[ing] with Lin" that there is "no evidence that the work done at Amgen relating to the expression of the EPO gene in mammalian host cells and isolation of the resulting glycoprotein product involved anything other than the exercise of ordinary skill by practitioners in that field." *Id.* at 1739.

III. ARGUMENT

In accordance with the well-established law of the First Circuit, Amgen should be judicially estopped from now taking a position contrary to the aforementioned arguments used by Amgen to procure a favorable decision in the '097 Interference.

Judicial estoppel serves as a sanction for placing at risk the integrity of the court by "preclud[ing] a party from asserting a position in one legal proceeding which is contrary to a position it has already asserted in another." *Patriot Cinemas, Inc. v. Gen. Cinemas Corp.*, 834

F.2d 208, 212 (1st Cir. 1987); *see also Alternative Sys. Concepts, Inc. v. Synopsys, Inc.*, 374 F.3d 23, 32-33 (1st Cir. 2004). "Judicial estoppel should be employed when a litigant is 'playing fast and loose with the courts.'" *Patriot Cinemas*, 834 F.2d at 212.

Here the doctrine of judicial estoppel applies because Amgen "has adopted one position, secured a favorable decision, and then taken a contrary position in search of legal advantage." *InterGen N.V. v. Grina*, 344 F.3d 134, 144 (1st Cir. 2003); *see also Portela-Gonzalez v. Sec. of the Navy*, 109 F.3d 74, 78 (1st Cir. 1997) ("Equitable doctrines of estoppel apply in administrative and judicial fora, … and a party cannot take one position in an underlying administrative proceeding and then disclaim it in a subsequent suit…."); *Analog Devices, Inc. v. Linear Tech. Corp.*, 479 F. Supp. 2d 202, 212 (D. Mass. 2007) (applying judicial estoppel in the context of Patent Office proceedings).

This is not simply an example of Amgen "playing fast and loose" with the judicial system in general. Amgen is playing fast and loose with *this Court*. There can be no dispute that Amgen secured a favorable decision from this Court in *Amgen v. Chugai* and then repeatedly used this Court's findings to secure a legal victory in the '097 Interference based on findings and arguments that claim limitations other than the EPO DNA sequence were obvious, routine and non-inventive. Under the doctrine of judicial estoppel Amgen should be precluded from now asserting that the claims of the patents-in-suit are not routine and would not have been obvious in view of the expire '008 claims.

IV. CONCLUSION

Based on the foregoing, Roche respectfully requests that the Court bar Amgen from arguing here, contrary to the position it took in the '097 Interference:

(1) that the Lin process claims of the '868 and '698 patent are not obvious over the expired '008 patent claims;

(2) that expression of an *in vivo* biologically active recombinant EPO polypeptide confers patentability;

(3) that isolation of an *in vivo* biologically active recombinant EPO polypeptide confers patentability;

(4) that transcription confers patentability;

(5) that translation confers patentability;

(6) that glycosylation of the EPO polypeptide confers patentability; and

(7) that the asserted claims are patentable because production of a biologically active protein was an unexpected result.

Dated: September 10, 2007
Boston, Massachusetts

Respectfully submitted,

F. HOFFMANN-LA ROCHE LTD,
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