UNITED STATES DISTRICT COURT
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

AMGEN INC'S OPPOSITION TO ROCHE'S MOTION *IN LIMINE* TO PRECLUDE AMGEN INC. FROM CONTRADICTING ARGUMENTS IT MADE IN PRIOR ADMINISTRATIVE AND JUDICIAL PROCEEDINGS

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I. INTRODUCTION

Roche's motion *in limine* (Docket Item ("D.I.") 801) asks the Court to preclude Amgen from responding at trial to Roche's allegations that the asserted claims of Dr. Lin's '868, '698 and '349 patents are obvious over the claims of Dr. Lin's '008 patent, because Roche interprets Amgen's statements in prior proceedings to be inconsistent with Amgen's current position. In effect, Roche's motion asks the Court to hold three of the five patents-in-suit invalid for obviousness-type double patenting ("ODP") as a matter of judicial estoppel. Roche made similar arguments, and relied on many of the same purported "admissions," in its motion for summary judgment of obviousness-type double patenting, which the Court denied. (*See, e.g.*, D.I. 491, at 8-9, 19-20; D.I. 762 (Order denying motion).) The Court should likewise deny Roche's present motion *in limine*.

During prosecution of the patents-in-suit, including during the interference proceedings that are the focus of Roche's judicial estoppel argument, Amgen maintained that Dr. Lin's process inventions were patentably distinct from (and not obvious over) Dr. Lin's DNA inventions. Now Roche contorts the interference record. Roche presents portions of Amgen's arguments regarding ***priority*** (which were based on this Court's findings that Lin cloned the EPO gene and obtained *in vivo* biologically active product before Fritsch) and argues that these statements pertain to obviousness-type double patenting. Roche is wrong. When addressing the issue of obviousness, Amgen told the interference board that even with the DNA sequence in hand, the "process at best was only a wish." Thus, as shown below, when Amgen's statements are considered in their entirety and in context, it is clear that Amgen's past and present positions are not "directly inconsistent." Amgen has always contended that Dr. Lin's process claims are patentably distinct from (and not obvious over) Dr. Lin's DNA claims; it is inconsistent with basic logic to imagine that Amgen would ever have had any reason to take a contrary position.

Moreover, the United States Patent and Trademark Office ("PTO") repeatedly determined Dr. Lin's DNA and process inventions to be patentably distinct. Thus, this is not a situation where Amgen has secured a favorable decision based on one position, and then taken a contrary position in search of a legal advantage. The only party "playing fast and loose with the courts" is Roche when it mischaracterizes Amgen's prior positions.

II. BACKGROUND REGARDING THE '097 INTERFERENCE

Interference No. 102,097 ("the '097 Interference") was one of three separate interference proceedings instituted by the PTO, at the urging of Amgen's competitor, Genetics Institute, Inc. ("GI"), to determine priority as between Lin/Amgen and Fritsch/GI to various EPO-related inventions. The '097 Interference was declared on May 9, 1989. The "Process Count"[1] of the '097 Interference was identical to claim 65 in Amgen's then-pending Application No. 07/113,179 ("the '179 application"). The '179 application later issued as U.S. Patent No. 5,441,868 ("the '868 patent").

Interference No. 102,096 ("the '096 Interference") also was declared by the PTO on May 9, 1989. The invention at issue in the '096 Interference was to "[a] purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin." *Fritsch v. Lin*, 21 U.S.P.Q.2d 1731, 1732 (B.P.A.I. 1991). This "DNA Count" of the '096 Interference was identical to claim 2 in Amgen's U.S. Patent No. 4,703,008 ("the '008 patent").

Interference No. 102,334 ("the '334 Interference") was declared by the PTO on February 9, 1990. The "Product Count"[2] of the '334 Interference was identical to claim 76 in Amgen's then-pending Application No. 07/113,178 ("the '178 application"). The '178 application later

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[1] *See Fritsch v. Lin*, 21 U.S.P.Q.2d 1737, 1738 (B.P.A.I. 1991) (setting forth the Count in the '097 Interference).

[2] *See Fritsch v. Lin*, 21 U.S.P.Q.2d 1739, 1740 (B.P.A.I. 1991) (setting forth the Count in the '334 Interference).

gave rise to U.S. Patent No. 5,547,933 ("the '933 patent").

The fact that the PTO declared three separate interferences with three separate counts indicates that the PTO considered the DNA, process, and product inventions corresponding to those counts to be patentably distinct. M.P.E.P. § 2303 (5th ed., Rev. 9, Sept. 1988) (8/24/07 Godfrey Decl., Ex. A) ("Each count shall define a separate patentable invention.") (quoting 37 C.F.R. § 1.603); *see also* 37 C.F.R. § 1.601(f) (1988) (8/24/07 Godfrey Decl., Ex. B) (same). Importantly, with respect to the subject matter of these three interferences, a determination was signed by Acting Commissioner Jeffrey Samuels, as well as Group Director John Kittle and Examiner Howard Schain, stating that, while related, "***the subject matter of the three interferences is deemed to be patentably distinct*** . . . ." (8/24/07 Godfrey Decl., Ex. C, at 2 (emphasis added).)

Fritsch and GI urged the PTO to combine the separate interferences under a single, very broad count. In making this attempt, ***Fritsch*** (not Lin or Amgen) argued to the PTO: "The interferences in terms of subject matter are essentially the same and the interferences counts are ***different manifestations of the same 'invention***.'" (8/24/07 Godfrey Decl., Ex. D, at 86, 153 (emphasis added).) Thus, the "different manifestations of the same invention" language was ***Fritsch's language***, not Amgen's language.

Amgen opposed Fritsch and GI's attempts to combine the interferences. Amgen explicitly rejected Fritsch's position that the DNA Count of the '096 Interference and the Process Count of the '097 Interference were "different manifestations of the same invention," stating in its opposition brief:

> Since Fritsch does not even attempt to supply any argument or evidence in support of the bare allegation of "same invention", it is apparent that it was not a serious contention. Suffice it to say that Lin contends that the two counts are <u>not</u> to the "same invention".

(8/24/07 Godfrey Decl., Ex. E, at 81, 149 (emphasis in original).) Elsewhere, Amgen reiterated

its position that the Process Count was not to the same invention as the DNA Count:

> Fritsch is totally confused. The present count derives from claim 65 of Lin's application. The present process count of this interference has no relation whatsoever to Fritsch reason (ii) [referring to claim 2 of the '008 patent]; it may be Fritsch has the two interferences confused.

(*Id.* at 131 (emphasis in original).) The PTO dismissed Fritsch and GI's motions to combine the interferences. (8/24/07 Godfrey Decl., Ex. F, at 5 (dismissing Motion G) and Ex. G, at 5 (dismissing Motion Q).)

Although GI failed in its bid to have the interferences combined, GI continued to press the same fundamental position throughout the interferences. Although a number of issues were litigated in the context of the interferences, the central issue was whether Fritsch or Lin was entitled to priority for the inventions in each of the three Counts. Fritsch argued for priority of inventorship for all three Counts on the basis that he had come up with a "plan" for cloning the EPO DNA before Lin's invention date, and that from that alleged conception date he had thereafter diligently reduced to practice the inventions of all three Counts. As Fritsch/GI argued:

- Since the record clearly shows that Dr. Fritsch had conceived of an operative probing technique by December 1981, the corroborated evidence of Dr. Fritsch's conception makes his invention prior to Dr. Lin's . . . . (8/24/07 Godfrey Decl., Ex. H (Fritsch's '097 Brief), at 25, Ex. I (Fritsch's '096 Brief), at 20, Ex. J (Fritsch's '334 Brief), at 24.)

- Lin cannot seriously dispute that Dr. Fritsch worked diligently to reduce his conception to practice. . . . This diligence is sufficient to establish Dr. Fritsch as the prior inventor pursuant to 35 U.S.C. § 102(g). (8/24/07 Godfrey Decl., Ex. H (Fritsch's '097 Brief), at 28, Ex. I (Fritsch's '096 Brief), at 23, Ex. J (Fritsch's '334 Brief), at 27.)

- Accordingly, as in the '096 interference, priority turns upon the first conception of the purified and isolated EPO gene. (8/24/07 Godfrey Decl., Ex. H (Fritsch's '097 Brief), at 24, Ex. J (Fritsch's '334 Brief), at 23.)

The argument that Fritsch was the first to invent an isolated and purified EPO DNA

molecule was also being advanced by GI as an invalidity defense in a co-pending district court action concerning GI's infringement of Amgen's '008 patent. *See Amgen, Inc. v. Chugai Pharm. Co.*, 13 U.S.P.Q.2d 1737, 1759 (D. Mass. 1989). On December 11, 1989, several months after the '096 and '097 Interferences had been declared, Magistrate Judge Saris in the district court action held that invention of the DNA claims required simultaneous conception and reduction to practice, and that Dr. Lin was the first to accomplish this. *Id.* at 1760-61. Specifically, the Court found that, to be the first party to conceive of an isolated and purified DNA encoding human erythropoietin, one had to actually have possession of the DNA. In so doing, the Court rejected GI's argument that a plan for how to get EPO DNA was sufficient for conception (although Amgen was found to be first in that regard as well). *Id.* at 1760-62. The Court's findings made clear that, not only had Amgen cloned the EPO gene before anyone else, but that it was also first to produce an *in vivo* biologically active EPO polypeptide. *Id.* at 1745-54. The Federal Circuit later affirmed the district court's findings and judgment regarding the '008 patent. *Amgen, Inc. v. Chugai Pharmacuetical Co.*, 927 F.2d 1200 (Fed. Cir. 1991). In summary, it was determined in the parallel infringement litigation that: (1) Lin had cloned the DNA, expressed it in cells and confirmed *in vivo* biological activity, all before Fritsch first cloned the DNA; and (2) an inventor claiming discovery of a DNA sequence was required to have actual reduction to practice, not merely conception of how to do so followed by diligent effort to reduce to practice.

These rulings established that Lin, not Fritsch, was the first to reduce to practice the EPO DNA invention claimed in the '008 patent. By the same logic, and in view of the additional findings of fact in Judge Saris' opinion, Fritsch's "plan" did not qualify as a date of conception for the Process Count either, and the facts established that Lin had reduced to practice the invention in the Process Count before Fritsch had even cloned the EPO DNA. Thus, even though the three Counts in the three interferences were patentably distinct inventions, in view of

the facts found by Judge Saris, the same legal issue was determinative of priority in all three Counts.

That is, based on the district court's findings and Fritsch's own arguments, Fritsch could never be first to invent the Process Count of the '097 Interference because he lacked the necessary starting material (the EPO DNA), because Amgen was first in the race to produce *in vivo* active EPO, and because Fritsch himself had argued, then conceded, that everything rose and fell with who was the first with respect to the DNA. *See Fritsch v. Lin*, 21 U.S.P.Q.2d 1737, 1738 (B.P.A.I. 1991) ("[W]e note that Fritsch conceded at final hearing that priority in each of the related interferences turns on isolation of the EPO gene . . . ."). In other words, because Fritsch's priority theory for the Process Count was based on his alleged earlier conception of the DNA Count, it followed that if, as the Court found, Fritsch did not have conception (let alone possession) of the subject matter defined by the DNA Count, he could not have conception or possession of the subject matter defined by the Process Count.

Amgen argued to the PTO that the district court's findings and opinion should govern the outcome in the interferences. At no time, however, did Amgen rely solely on the fact that Lin had cloned the EPO gene first to prove priority in the '097 Interference. It was not Amgen's position that the Process Count of the '097 Interference defined the same invention as, or was obvious over, the DNA Count of the '096 Interference. Instead, Amgen submitted arguments and evidence showing that in addition to obtaining the DNA first, Lin also separately satisfied all of the other elements of the Process Count. Amgen explicitly stated that the '097 Process Count was not obvious, even after Lin obtained a DNA encoding human EPO:

> - However, the Federal Circuit decision clearly confirms that the Fritsch et al position is incorrect and, in light of the Federal Circuit holding that the DNA sequence and host cells transfected therewith are unobvious, it follows that Lin's process claims should also define unobvious and patentable subject matter. The DNA sequence and host cells transformed

or transfected therewith were not available in the prior art and the process at issue could not be performed. ***Furthermore, it was not obvious that in vivo biologically active recombinant human EPO could be made by the claimed process. Until Lin obtained the sequence, Browne used it in expression and Egrie with Dukes found the product had in vivo biological activity, the process at best was only a wish.*** (D.I. 803, Ex. 4 (Lin's '097 Brief), at 55-56 (emphasis added).)

- As to why the Federal Circuit decision should govern in an application v. application interference, as here, Lin notes that the Courts' findings on the priority evidence considered in the litigation established that Lin is the prior inventor of not only the DNA sequence and host cells transformed therewith at issue in Interference No. 102,096, ***but that he had used this sequence and transformed mammalian host cells to produce in vivo biologically active recombinant human EPO***. (*Id.* at 29 (emphasis added).)

- The ***expression*** and isolation of the expression product as required to test for in vivo biological activity clearly meet the limitations of the present process count. Hence, it is not necessary to go beyond the undisputed facts as found by the District Court and left unchanged by the Federal Circuit to determine that Lin's expression and determination of in vivo biological activity of the expressed product satisfies all of the limitations of the count of the present interference and represents reduction to practice by Lin well prior to the Fritsch et al conception date. ***However, the present Lin record also includes further confirmation that the expression and testing referred to by the District Court constituted reduction to practice of the process of the count. See, for example, the testimony of Drs. Browne and Egrie that the work which they did on Lin's behalf involved all of the features of the Count (LR 30, 67, 68). Lin also confirmed this (LR 5)***. (*Id.* at 39 (emphasis added).)

- Since the Federal Circuit has found that Lin was the first to have a conception of the DNA sequence (upon reduction to practice), and ***it has not been questioned that Lin produced in vivo biologically active recombinant human EPO before Fritsch et al even conceived of the DNA sequence, it follows that Lin is entitled on the record to priority as to the present count***. The argument presented by Fritsch et al in favor of priority based on his version of a probing method for possible use (FB 21-31) totally disregard the Courts' finding that conception of the purified and isolated EPO gene did not occur until the gene was reduced to practice. ***Fritsch had no concept***

> ***of the constitution of the gene before the gene was isolated and identified. By that time, Lin had expressed recombinant human EPO and found it to have <u>in vivo</u> biological activity***. (*Id.* at 36-37 (emphasis added).)

Thus, Amgen's briefing shows that Amgen's position was that Lin produced *in vivo* biologically EPO before Fritsch had even conceived of the gene, and that the factual findings in the district court litigation had already determined this to be the case. It was never Amgen's position that everything was the same and that Amgen had the DNA first and thus Amgen should win the priority contest as to the '097 Process Count.

The PTO resolved the '097 Interference in Amgen and Lin's favor and determined that Dr. Lin was entitled to a patent containing claims corresponding to the Process Count. *Fritsch v. Lin*, 21 U.S.P.Q.2d 1737, 1739 (B.P.A.I. 1991). On the issue of priority as between Lin and Fritsch, the PTO focused on ***Fritsch's*** position, stating that "[w]e note that Fritsch conceded at final hearing that priority in each of the related interferences turns on isolation of the EPO gene, i.e., determination of priority in [the '096 Interference] is dispositive on the issue of priority in the ['097 Interference]." *Id.* at 1738-39. The PTO did not make any reference to Amgen's position or arguments regarding priority to the Process Count.

In the same decision, the PTO also held in Amgen's favor on the separate issue of Lin's inventorship under 35 U.S.C. § 102(f), rejecting Fritsch's argument that Dr. Lin "did not himself invent the subject matter" set forth in the Lin claims corresponding to the Process Count. *Id.* at 1739. The PTO expressly agreed with Amgen's position that "the expression of the EPO gene in mammalian host cells using the DNA sequence isolated by Dr. Lin was ***carried out at Lin's request and on his behalf***," and that "it is not essential for the inventor to be personally involved in carrying out process steps defined by the count where ***implementation*** of those steps does not require the exercise of inventive skill." *Id.* (emphasis added). Nowhere in Amgen's briefing or in the PTO's opinions was the issue of obviousness conflated with that of inventorship, as Roche

improperly urges this Court to do here.

The PTO's final decision in the '097 Interference did not discuss any of the five arguments that Roche's motion *in limine* seeks to preclude Amgen from making at trial.[3] But, as noted above, the PTO had previously indicated that the process inventions of the '097 Count were patentably distinct from the DNA inventions of the '096 Count.[4] The "obviousness" section of the PTO's decision focuses on (and rejects) Fritsch's flawed assertion that Lin's claims are obvious under 35 U.S.C. § 103 because, according to Fritsch, it was "obvious to try" to isolate the EPO gene in light of prior art such as the Toole et al reference. *See Fritsch v. Lin*, 21 U.S.P.Q.2d 1737, 1738-39 (B.P.A.I. 1991) (referencing *Fritsch v. Lin*, 21 U.S.P.Q.2d 1731, 1735-36 (B.P.A.I. 1991)).

After examination of the '868 patent resumed following the '097 Interference, the PTO examiner reviewed the double patenting issue and initially rejected the process claims of Lin's '868 patent as obvious over the DNA claims of Lin's '008 patent. (*See* 8/24/07 Godfrey Decl., Ex. K, at 2.) Amgen then explained to the examiner that the double patenting rejection over the '008 patent claims was improper because: (1) the expression of a glycosylated EPO product having *in vivo* biological activity was unexpected given the state of the art at the time; (2) Amgen's attempt to enforce the '008 patent in the ITC failed because the '008 patent did not

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[3] The five arguments Roche seeks to exclude are: "(1) that the Lin process claims of the '868, '698 and '349 patents are not obvious over the '008 patent claims; (2) that the use of mammalian host cells for expression of EPO confers patentability to the asserted claims of the patents-in-suit; (3) that isolation of the EPO glycoprotein product from mammalian host cell expression confers patentability to the asserted claims of the patents-in-suit; (4) that the purported differences in glycosylation linkages confers patentability to the asserted claims of the patents-in-suit; and (5) that the asserted claims are patentable because production of a biologically active protein was an 'unexpected result.'" (D.I. 802, at 11.)

[4] *See* 8/24/07 Godfrey Decl., Ex. C, at 2 (stating that, while related, "the subject matter of the three interferences is deemed to be patentably distinct . . . ."); M.P.E.P. § 2303 (5th ed., Rev. 9, Sept. 1988) (8/24/07 Godfrey Decl., Ex. A) ("Each count shall define a separate patentable invention.") (quoting 37 C.F.R. § 1.603); 37 C.F.R. § 1.601(f) (1988) (8/24/07 Godfrey Decl., Ex. B) (same).

include process claims; and (3) the PTO had already determined that the production process subject matter was patentably distinct from the DNA-related subject matter of the '008 patent claims. (*See* 8/24/07 Godfrey Decl., Ex. L.) Amgen will present this same and additional evidence at trial to rebut Roche's allegations of invalidity. After Amgen's response, the PTO issued a notice of allowability for the '868 patent. (*See* 8/24/07 Godfrey Decl., Ex. M.)

III. ARGUMENT

The doctrine of judicial estoppel is designed "to safeguard the integrity of the courts." *Alternative Sys. Concepts, Inc. v. Synopsys, Inc.*, 374 F.3d 23, 33 (1st Cir. 2004). "Courts are prone to invoke it when a litigant is playing fast and loose with the courts, and not otherwise." *InterGen N.V. v. Grina*, 344 F.3d 134, 144 (1st Cir. 2003) (internal quotations omitted).

For judicial estoppel to apply, it is "widely agreed" that "at a minimum, two conditions must be satisfied." *Alternative Sys.*, 374 F.3d at 33. First, the party's previously asserted position and presently asserted position must be "directly inconsistent, that is, mutually exclusive." *Id.*; *see also Simon v. Safelite Glass Corp.*, 128 F.3d 68, 72 (2d Cir. 1997) ("[T]here must be a true inconsistency between the statements in the two proceedings. If the statements can be reconciled there is no occasion to apply an estoppel."). Second, "the first forum [must have] *accepted* the legal or factual assertion alleged to be at odds with the position advanced in the current forum . . . ." *In re Gens*, 112 F.2d 569, 572 (1st Cir. 1997) (emphasis in original); *see also Alternative Sys.*, 374 F.3d at 33 (The party to be estopped "must have succeeded in persuading a court to accept its prior position."); *Merrill Lynch, Pierce, Fenner & Smith Inc. v. Georgiadis*, 903 F.2d 109, 114 (2d Cir. 1990) (Judicial estoppel "applies only if the party against whom the estoppel is claimed actually obtained a judgment as a result of the inconsistent position."). Together, these two conditions give the impression that "either the first court has been misled or the second court will be misled, thus raising the specter of inconsistent

determinations and endangering the integrity of the judicial process." *Alternative Sys.*, 374 F.3d at 33.

Roche's argument for judicial estoppel based on the '097 Interference fails to satisfy both essential elements of a judicial estoppel claim. As to the first element, Amgen's present position — that the asserted process claims of the '868, '698 and '349 patents are not invalid for ODP over the '008 patent claims — is not "directly inconsistent" with Amgen's positions during the '097 Interference, but rather is consistent with what Amgen argued and the PTO determined. The language from the interference briefing that Roche relies on originated with Fritsch, and Amgen cited Fritsch's own position against him as to the priority issues, ***not*** to ODP or to the patentable distinctiveness of Lin's various inventions. Other language that Roche points to pertains to a 35 U.S.C. 102(f) inventorship attack against Lin. Those statements, which focus on implementation of individual steps within the Process Count, do not address the legal doctrine of obviousness-type double patenting, which focuses on the attacked claim as a whole.

Roche's judicial estoppel argument is premised on a mischaracterization of Amgen's positions during the '097 Interference.[5] For example, as discussed above, it was Fritsch and GI's position that the DNA and Process Counts "are different manifestations of the same 'invention,'" not Amgen's position. (8/24/07 Godfrey Decl., Ex. D, at 86, 153.) Amgen expressly rejected that position: "Suffice it to say that Lin contends that the two Counts are <u>not</u> to the 'same invention.'" (8/24/07 Godfrey Decl., Ex. E, at 81, 149 (emphasis in original).) When Amgen later used the "different manifestations" language in its own brief, it did so not as an

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[5] Roche also mischaracterizes Amgen's current position to the extent that Roche suggests Amgen is arguing that individual steps or elements, such as "the use of mammalian host cells for expression of EPO," are alone sufficient to confer patentability to the asserted claims of the patents-in-suit over the '008 claims. (*See* D.I. 802, at 11 (numbers (2) – (5)).) The legal issue of whether two claims are "patentably distinct" requires comparison of the two claimed inventions ***as a whole***. *See Gen. Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1280 (Fed. Cir. 1992).

endorsement of Fritsch's position — which Amgen consistently had argued against — but rather to show that, in light of the district court's findings, priority should be awarded to Lin even under Fritsch's position (because the Court had found that Lin produced *in vivo* biologically active EPO before Fritsch had even conceived of the DNA): "Hence, the priority holding in the litigation is directly on point, ***notwithstanding the different statutory class of the claims involved***." (D.I. 803, Ex. 4, at 26 (emphasis added).)

Roche's motion, and indeed its entire ODP argument, centers on Roche's incorrect view that the "different manifestations of the same invention" statement was an admission by Amgen that the process inventions of the '097 Interference and the DNA inventions of the '096 Interference were not patentably distinct. As demonstrated by the citations to the interference record above, however, this was not Amgen's position. If it had been, Amgen would have agreed with Fritsch's motion to combine these interferences instead of opposing it. Even if the "different manifestations" language was attributable to Amgen, instead of GI's inventor Fritsch, saying that three separate categories of claimed subject matter which the PTO had already determined to be patentably distinct were "different manifestations of the same invention" for purposes of determining priority was not an admission of patentable indistinctness for purposes of ODP. Rather, in the patent world, "different manifestations" could easily be patentably distinct, for example, a genus and a species, because having one "manifestation" does not necessarily give you a "different manifestation." Because the PTO determined that Lin's process claims were patentably distinct from Lin's DNA claims both before and after the interference briefing cited by Roche, clearly the PTO did not view the statement as an admission.

Elsewhere in its brief, Roche contends that it was Amgen's position during the '097 Interference that "the process for making biologically active glycosylated EPO, would have been obvious to one of skill in the art." (D.I. 802, at 5.) This, too, is a mischaracterization of

Amgen's prior position. In the portion of the paragraph that Roche selectively omitted from its quotation, Amgen argued: "***The production process is not obvious*** but the process is properly attributable to Lin as the one who succeeded in isolating the DNA sequence and requested its use in expression to give recombinant human EPO." (D.I. 803, Ex. 4, at 58 (emphasis added).) Amgen also argued: "***Furthermore, it was not obvious that in vivo biologically active recombinant human EPO could be made by the claimed process***. Until Lin obtained the sequence, Browne used it in expression and Egrie with Dukes found the product had in vivo biological activity, ***the process at best was only a wish***." (D.I. 803, Ex. 4, at 56 (emphasis added).) Roche also altered its quotation of Amgen's interference brief to create the impression that it was Amgen's position that "the isolated DNA sequence is ***the*** novel feature of the process claims," when in reality Amgen was referring to Fritsch's position. (*Compare* D.I. 802, at 4 *with* D.I. 803, Ex. 4, at 57.)

The other purported "admissions" identified in Roche's brief are similarly presented out of context in a manner that distorts Amgen's position during the '097 Interference. As explained above, it was Amgen's position that, based on the district court's decision and factual findings regarding priority to the '008 patent, and because the DNA was necessary to practice the method recited in the '097 Process Count, Fritsch could not prevail on priority as to the Process Count. The gist of Amgen's argument was merely that Fritsch never was in possession of the DNA at any relevant time, and without the DNA Fritsch could neither conceive of, nor reduce to practice, the Process Count. This position is not "directly inconsistent" or "mutually exclusive" with Amgen's position in this litigation that the asserted process claims of the '868, '698 and '349 patents are patentably distinct from (and not obvious over) the DNA claims of the '008 patent. Thus, Roche has failed to prove the first element of its judicial estoppel claim.

Roche's motion *in limine* also fails to establish the second essential element of a judicial

estoppel claim. Because the sound bites that form the basis of Roche's argument do not accurately represent Amgen's position during the '097 Interference, Roche cannot establish that Amgen successfully persuaded the PTO to accept these allegedly inconsistent assertions and to resolve the '097 Interference in Amgen's favor as a result of these statements. As noted above, the PTO's decision regarding priority to the '097 Process Count expressly references arguments made by ***Fritsch*** in his brief and at the final hearing. *See Fritsch v. Lin*, 21 U.S.P.Q.2d 1737, 1738-39 (B.P.A.I. 1991). The decision does not make any reference to Amgen's positions or arguments regarding priority to the Process Count. Nor does the decision discuss any of the five arguments that Roche's motion *in limine* seeks to preclude Amgen from making at trial. Thus, there is no risk of inconsistent determinations.

Roche contends that "the Board specifically adopted Amgen's position that the subject matter of the '096 and '097 Interferences were all part of the 'same invention' and that the process steps of the '097 count did not involve inventive skill." (D.I. 802, at 6.) This assertion is meritless. As discussed above, the PTO repeatedly determined that the process inventions of the '097 Count are patentably distinct from the DNA inventions of the '096 Count.[6] Moreover, when the PTO later considered whether Amgen's '868 process claims should be rejected for ODP over the DNA claims in Lin's '008 patent, Amgen reiterated its position that the process claims are patentably distinct from the DNA claims, and the PTO determined that the '868 claims were allowable. (*See* 8/24/07 Godfrey Decl., Ex. K, at 2, Ex. L, Ex. M.) Thus, Roche also has failed to establish the second element of its judicial estoppel claim based on the '097 Interference.

Roche's motion *in limine* recites a hodgepodge of statements made in the context of various foreign proceedings. There is no evidence that these statements were submitted to or

relied on by the PTO during the '097 Interference. In fact, most of these statements are from documents dated several years after the end of the '097 Interference. (*See, e.g.*, D.I. 803, Ex. 6 (referencing events in 2000), Ex. 7 (dated 2004), Ex. 8 (dated 2000).) Therefore, these statements are irrelevant to Roche's argument for judicial estoppel based on the '097 Interference.

Nor do these statements from foreign proceedings provide any independent basis for judicial estoppel. The foreign statements were made during proceedings regarding foreign patents and concern issues of patentability under foreign laws. As a matter of formality, Roche has failed to establish that the claims of these foreign patents are sufficiently similar to the claims of the patents-in-suit,[7] and that the patentability standards in these foreign jurisdictions are sufficiently similar to those applicable in the present action.[8] In fact, the claims are different. As a matter of substance, nothing in the cited statements contradicts Amgen's position that its U.S. process claims are patentably distinct from the '008 patent claims. Thus, Roche cannot establish that the positions taken in these foreign proceedings are directly inconsistent with Amgen's positions in the present action.

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[6] *See supra* note 4.

[7] Some of the statements cited by Roche are not even directed to the patentability of foreign counterparts to Amgen's patents-in-suit. (*See, e.g.*, D.I. 803, Ex. 9 (concerning the patentability of claims in a European Patent owned by Genetics Institute Inc.).)

[8] *See Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 457 F.3d 1284, 1290 (Fed. Cir. 2006) ("[T]he statements made during prosecution of foreign counterparts to the '893 patent are irrelevant to claim construction because they were made in response to patentability requirements unique to Danish and European law. . . . insofar as Ranbaxy restates the same argument under the guise of judicial estoppel, we are not persuaded."); *Heidelberger Druckmaschinen AG v. Hantscho Commercial Prods., Inc.*, 21 F.3d 1068, 1072 n.2 (Fed. Cir. 1994) ("We take notice of the fact that the theories and laws of patentability vary from country to country, as do examination practices."); *Astra Aktiebolag v. Andrx Pharms., Inc.*, 222 F. Supp. 2d 423, 578 n.96 (S.D.N.Y. 2002) ("[D]ifferences in the realities of patent litigation in the United Kingdom or different legal standards for publication could well be the cause of that position. Without supporting evidence about the relevant patent law, evidentiary standards and burdens of proof, and without knowing the tactical decisions that were made during trial, the court finds that the statement has no value for this court in deciding whether TC-5 or Up-to-Date are prior art under United States law.").

Indeed, Roche again mischaracterizes the positions Amgen was taking. In the opposition proceedings to Genetics Institute's European Patent No. 0 411 678, Amgen argued that GI's patent which claimed recombinant EPO having O-linked glycosylation lacked novelty ***based on the disclosure of Dr. Lin***, because Lin disclosed the production of EPO in the very same CHO cells used and disclosed in GI's patent. In other words, Amgen's statement that "[t]he particular type of glycosylation linkages was simply a result of the type of host cell used to produce the recombinant erythropoietin" (D.I. 803, Ex. 9, ¶ 1) showed that Lin, not GI, was the first to invent recombinant EPO having O-linked glycosylation because CHO cells have the ability to attach O-linked carbohydrate to proteins. The cited statement says nothing to contradict, and actually supports, Amgen's position that it was unexpected that CHO cells or other vertebrate cells grown in culture would produce a glycosylated EPO having *in vivo* biological activity, because glycosylation is cell type specific as Amgen stated. Roche misapplies the law of obviousness-type double patenting when it tries to use Dr. Lin's specification as support for its arguments. What was only known ***after*** Dr. Lin's patented achievements is not relevant to obviousness-type double patenting.

With regard to the other statements from foreign proceedings that Roche presents out of context, none of them addresses, let alone contradicts, Amgen's position that Lin's process claims are patentably distinct under U.S. law from Lin's DNA claims, and that expression of *in vivo* biologically active EPO in vertebrate cells was unexpected. For example, Roche's cited excerpt from Dr. Brenner's expert report in the UK proceedings says nothing about the inventions corresponding to the U.S. claims of the patents-in-suit, and more specifically, says nothing about expressing an *in vivo* biologically active product. (*See* D.I. 803, Ex. 8, ¶ 66.) In the paragraph immediately following the one quoted by Roche, Dr. Brenner puts Dr. Lin's achievements in perspective: "If someone could not obtain an EPO clone and achieve expression

of EPO ***with the information presented in [Dr. Lin's] '605 Patent***, I would seriously question whether that individual was capable of doing his/her job properly." (*See id.* at ¶ 67.)

As for the statements in Amgen's opening submissions during the UK proceedings, it is true that the EPO DNA is a "blueprint" for the polypeptide backbone of the protein and is the "essential genetic information" to produce recombinant EPO. It is also true that given the disclosure of Dr. Lin's patents, "the rest of the world is then enabled to use that information to secure expression of that which was not previously available – namely, recombinant EPO – and thereby secure the therapeutic benefits which have served to transform the lives of hundreds of thousands of patients who would otherwise be severely anemic." (D.I. 803, Ex. 6, ¶ 30.) There can be no doubt that Dr. Lin's claimed inventions are fully enabled by the patent disclosure. In fact, Roche's arguments of lack of enablement of Dr. Lin's UK patent failed in the UK courts. As the U.S. courts have also found, given the teaching of Dr. Lin's patents, a person of ordinary skill in the art could produce recombinant EPO regardless of whether a specific plasmid recited in the examples of Dr. Lin's patents was literally made available by deposit or otherwise.

In sum, Roche has failed to establish that Amgen's positions in the foreign actions contradict Amgen's positions in the present case, let alone establish the requirements for judicial estoppel on the issue of whether Lin's process claims are patentably distinct under U.S. law from Lin's '008 claims.

IV. CONCLUSION

Roche's motion *in limine* effectively asks the Court to hold three of the five patents-in-suit invalid for ODP as a matter of judicial estoppel. For the reasons explained above, Roche's inaccurate and incomplete analysis does not come anywhere close to justifying such an extreme result, and the Court should deny Roche's motion *in limine* (D.I. 801).

Respectfully Submitted,

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CERTIFICATE OF SERVICE

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

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