

**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 BIND  
AMGEN INC. TO PRIOR ADMISSIONS RELEVANT TO DOUBLE PATENTING**

By its present motion, Roche effectively asks the Court to hold the ‘868 and ‘698 patent claims invalid for obviousness-type double patenting (“ODP”) as a matter of judicial estoppel.<sup>1</sup> This is the *third* time Roche has burdened the Court and Amgen with these baseless judicial estoppel claims. Roche first made these arguments in support of its motion for summary judgment of obviousness-type double patenting, which the Court denied.<sup>2</sup> Roche pressed these points again in its August 10, 2007 “Motion *In Limine* To Preclude Amgen Inc. From Contradicting Arguments It Made In Prior Administrative and Judicial Proceedings.”<sup>3</sup> In that prior motion *in limine*, Roche sought the same relief as it does now,<sup>4</sup> based on the same legal theory (judicial estoppel)<sup>5</sup> and much of the same “evidence” (purported admissions from the *Fritsch v. Lin* interference proceedings).<sup>6</sup> In response, Amgen filed a detailed opposition demonstrating the flaws in Roche’s judicial estoppel arguments.<sup>7</sup> The Court denied Roche’s motion.<sup>8</sup> Now, Roche has filed essentially the same motion *in limine* under a different title.

To prevail on its affirmative defenses that Lin’s ‘868 and ‘698 claims-in-suit are invalid for ODP over Lin’s ‘008 patent claims, Roche must prove by clear and convincing evidence that

---

<sup>1</sup> See Roche’s Motion *In Limine* To Bind Amgen Inc. to Prior Admissions Relevant to Double Patenting (Docket Item (“D.I.”) 1036).

<sup>2</sup> See, e.g., D.I. 491, at 8-9, 19-20; D.I. 762 (Order denying motion).

<sup>3</sup> D.I. 801.

<sup>4</sup> Compare D.I. 801, at 1 (asking the Court to preclude Amgen from arguing “that the Lin process claims of the ‘868, ‘698 and ‘349 patents are not obvious over the ‘008 patent claims”) with D.I. 1036, at 1 (asking the Court to preclude Amgen from arguing “that the Lin process claims of the ‘868 and ‘698 patents are not obvious over the expired ‘008 patent claims.”).

<sup>5</sup> Compare D.I. 802, at 8-9 with D.I. 1037, at 4-5.

<sup>6</sup> Compare D.I. 802, at 4-5 (quoting as judicial estoppel evidence: Brief for Senior Party Lin (‘097 Interference), at 25-26, 57-58; *Fritsch v. Lin*, 21 U.S.P.Q.2d 1737, 1738-39 (B.P.A.I. 1991)), with D.I. 1037, at 3-4 (same).

<sup>7</sup> D.I. 867. Amgen demonstrated in its earlier opposition that Roche cannot establish either element of its judicial estoppel claim. (See *id.* at 1-14) Amgen hereby incorporates those arguments in their entirety and will provide only a brief restatement in the present opposition.

<sup>8</sup> See 9/4/07 Electronic Clerk’s Notes; 9/4/07 Trial Tr. 5:10-6:1.

the process inventions claimed in the '868 and '698 patents are patentably *indistinct* from (i.e., obvious over) the DNA and host cell inventions claimed in the '008 patent. Amgen will be filing a detailed bench memorandum and offer of proof demonstrating why these Roche "Theory No. 3" ODP defenses fail as a matter of law. Roche brings the present motion *in limine* asking the Court to ignore Amgen's evidence and to preclude Amgen under a theory of judicial estoppel from arguing "that the Lin process claims of the '868 and '698 patent are not obvious over the expired '008 patent claims."<sup>9</sup> Roche's inaccurate and incomplete analysis does not come anywhere close to justifying such an extreme result.

First, there is no inconsistency between Amgen's past positions in the *Fritsch v. Lin* interference proceedings and its present position that Lin's '868 and '698 claims are patentably distinct from Lin's '008 claims.<sup>10</sup> The interference proceedings did not involve any allegations of obviousness-type double patenting. Neither did the *Amgen v. Chugai* litigation. 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 ODP and to the patentable distinctiveness of Lin's various inventions. They do not. Roche asserts that Amgen "argue[d] that the process for making an *in vivo* biologically active recombinant EPO polypeptide . . . was obvious, routine and non-inventive."<sup>11</sup> This is both illogical and contrary to the evidence. Amgen has always contended that Dr. Lin's process claims are patentably distinct from (and not obvious over) Lin's DNA claims. Indeed, when addressing the issue of obviousness, Amgen told the interference

---

<sup>9</sup> D.I. 1036, at 1.

<sup>10</sup> See D.I. 867, at 11-13.

<sup>11</sup> D.I. 1037, at 4.

board that even with the DNA sequence in hand, the “process at best was only a wish.”<sup>12</sup>

Second, in resolving the ‘097 Interference in Amgen’s favor, the PTO did not accept or rely on any inconsistent positions by Amgen.<sup>13</sup> The PTO’s decision regarding priority expressly references arguments made by *Fritsch* in his brief and at the final hearing.<sup>14</sup> It does not make any reference to Amgen’s positions or arguments regarding priority to the Process Count. Nor does it discuss any of the arguments that Roche’s motion *in limine* seeks to preclude Amgen from making at trial. Thus, there is no risk of inconsistent determinations. Indeed, the PTO determined on multiple occasions that Lin’s process inventions *are* patentably distinct from (and not obvious over) Lin’s DNA and host cell inventions.<sup>15</sup> This is simply 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.

While most of Roche’s latest motion *in limine* is a rehash of its previous motion, which the Court denied, Roche does include a few purported admissions that were not addressed in Roche’s previous motion. It is not surprising that Roche passed on these arguments in its earlier brief, because they do not provide any basis for judicial estoppel.

For example, Roche mischaracterizes passages from Amgen’s interference brief regarding priority to create the impression that Amgen argued that there was no patentable distinction between Lin’s DNA and process inventions.<sup>16</sup> When read in context, however, it is clear that these arguments had nothing to do with patentable distinctiveness, or obviousness. The preceding paragraph — which Roche omitted from its brief — shows that Amgen argued that

---

<sup>12</sup> D.I. 803, Ex. 4, at 56.

<sup>13</sup> See D.I. 867, at 13-14.

<sup>14</sup> See *Fritsch v. Lin*, 21 U.S.P.Q.2d 1737, 1738-39 (B.P.A.I. 1991).

<sup>15</sup> See Amgen’s Bench Memorandum and Offer of Proof Regarding No Obviousness-Type Double Patenting, at Part II.B.3.

Lin was entitled to priority because this Court had already found that Lin had produced *in vivo* biologically active recombinant EPO before Fritsch had even conceived of the EPO DNA starting material necessary to practice the process invention:

The above undisputed factual summary from the District Court decision thus clearly and unequivocally shows 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, before Fritsch et al even conceived of the essential DNA sequence.<sup>17</sup>

This argument is not at all inconsistent with Amgen's position that Lin's process and DNA inventions are patentably distinct. The fact that the EPO DNA sequence is necessary to practice the process invention does not mean that the process and the DNA are the same invention, or that the process would have been obvious in light of the DNA.<sup>18</sup> Indeed, later in the same brief, Amgen argued that even with the DNA sequence in hand, the "process at best was only a wish."<sup>19</sup>

Roche also asserts the following "admission" from Amgen's '097 Interference Brief as a basis for judicial estoppel regarding ODP:

Thus, the litigation directly involved an essential feature of the process, i.e. the purified and isolated DNA sequence encoding EPO. . . . Lin submits that the Court findings establish priority for Lin as to the present count and show that the subject matter at issue is not patentable to Fritsch . . . .<sup>20</sup>

Once again, however, when these statements are considered in context it is clear that Amgen did

---

<sup>16</sup> See D.I. 1037, at 2 (quoting Brief for Senior Party Lin (D.I. 803, Ex. 4), at 47-48).

<sup>17</sup> See Brief for Senior Party Lin (D.I. 803, Ex. 4), at 46-47.

<sup>18</sup> See *generally* Amgen's Bench Memorandum and Offer of Proof Regarding No Obviousness-Type Double Patenting, at Part III.D.

<sup>19</sup> Brief for Senior Party Lin (D.I. 803, Ex. 4), at 56.

<sup>20</sup> Brief for Senior Party Lin (D.I. 803, Ex. 4), at 29 (quoted in Roche's Brief (D.I. 1037), at 3).

not argue that the DNA and process inventions were the same and that Lin should win priority to the process count merely because he had the DNA first. Rather, Amgen argued priority based on Lin's prior invention of the process count, as already determined by the courts:

Thus, the litigation directly involved an essential feature of the process, i.e. the purified and isolated DNA sequence encoding EPO. **The findings of the District Court, affirmed by the Federal Circuit, clearly show that Lin carried out the expression process using the DNA sequence to produce in vivo biologically active recombinant human EPO before Fritsch et al even conceived the DNA sequence.** Lin submits that the Court findings establish priority for Lin as to the present count and show that the subject matter at issue is not patentable to Fritsch **et al** under 35 USC 102(g) because of Lin's acknowledged prior work.<sup>21</sup>

Finally, Roche asserts that the following Amgen statement constitutes an admission that Lin's process and DNA inventions are the same:

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.<sup>22</sup>

As with the other purported "admissions" identified in Roche's brief, when read in context, this statement has a very different meaning than the one that Roche ascribes. The very next sentence — which Roche omitted — makes clear that the reason Fritsch could not logically argue that the process and DNA inventions were different was because *Fritsch* (not Amgen) had earlier argued that the DNA and process inventions represented different manifestations of the same invention:

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. **They earlier said that the subject matter at issue in Interference No. 102,096 and the present case represent "different manifestations of the same invention".**<sup>23</sup>

---

<sup>21</sup> *Id.* (bold emphasis added, underlining in original).

<sup>22</sup> Brief for Senior Party Lin (D.I. 803, Ex. 4), at 34 (quoted in Roche's Brief (D.I. 1037), at 3).

<sup>23</sup> *Id.* (emphasis added).

Thus, the “same invention” position was Fritsch’s position, not Amgen’s position. 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 a related 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 not to the “same invention”.<sup>24</sup>

Amgen’s position regarding priority to the process count did not involve any assertion that Lin’s DNA and process inventions were one in the same. Amgen’s priority position was based on this Court’s prior determination that Lin had produced *in vivo* biologically active recombinant EPO before Fritsch had even conceived of the EPO DNA necessary to practice the process invention.

As shown above and in Amgen’s prior opposition brief, Roche’s judicial estoppel arguments are baseless. The purported “admissions” identified by Roche are presented out of context in a manner that distorts Amgen’s positions. At no time has Amgen ever argued that Lin’s process inventions were patentably *indistinct* from (or obvious over) Lin’s DNA and host cell inventions. Thus, there is no basis to judicially estop Amgen from arguing that Lin’s process inventions are patentably distinct from Lin’s DNA and host cell inventions. The Court was correct to deny Roche’s previous motion *in limine* concerning the interference proceedings, and it should deny Roche’s present motion as well. The Court should decide Roche’s “Theory No. 3” ODP defenses on the merits, not as a matter of judicial estoppel.

---

<sup>24</sup> Oppositions By the Party Lin to the Preliminary Motions of the Party Fritsch et al. (D.I. 868, Ex. E), at 81, 149 (emphasis in original).

September 24, 2007

Respectfully Submitted,

AMGEN INC.,  
By its attorneys,

Of Counsel:

STUART L. WATT  
WENDY A. WHITEFORD  
MONIQUE L. CORDRAY  
DARRELL G. DOTSON  
KIMBERLIN L. MORLEY  
ERICA S. OLSON  
AMGEN INC.  
One Amgen Center Drive  
Thousand Oaks, CA 91320-1789  
(805) 447-5000

/s/ Patricia R. Rich  
D. DENNIS ALLEGRETTI (BBO#545511)  
MICHAEL R. GOTTFRIED (BBO#542156)  
PATRICIA R. RICH (BBO#640578)  
DUANE MORRIS LLP  
470 Atlantic Avenue, Suite 500  
Boston, MA 02210  
Telephone: (857) 488-4200  
Facsimile: (857) 488-4201

LLOYD R. DAY, JR. (*pro hac vice*)  
DAY CASEBEER  
MADRID & BATCHELDER LLP  
20300 Stevens Creek Boulevard, Suite 400  
Cupertino, CA 95014  
Telephone: (408) 873-0110  
Facsimile: (408) 873-0220

WILLIAM GAEDE III (*pro hac vice*)  
McDERMOTT WILL & EMERY  
3150 Porter Drive  
Palo Alto, CA 94304  
Telephone: (650) 813-5000  
Facsimile: (650) 813-5100

KEVIN M. FLOWERS (*pro hac vice*)  
MARSHALL, GERSTEIN & BORUN LLP  
233 South Wacker Drive  
6300 Sears Tower  
Chicago IL 60606  
Telephone: (312) 474-6300  
Facsimile: (312) 474-0448



**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 September 24, 2007.

/s/ Patricia R. Rich  
Patricia R. Rich