

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

AMGEN, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 05 CV 12237 WGY
	)	
F. HOFFMANN-LAROCHE LTD.,	)	
a Swiss Company, ROCHE DIAGNOSTICS	)	
GMBH, a German Company, and	)	
HOFFMANN LAROCHE INC., a New	)	
Jersey Corporation,	)	
	)	
Defendants.	)	

**AMGEN’S OPPOSITION TO ROCHE’S MOTION *IN LIMINE* TO  
PRECLUDE AMGEN FROM CONFUSING THE JURY WITH STATEMENTS  
MADE IN EARLIER FOREIGN PROCEEDINGS [DOCKET NO. 822]**

**I. INTRODUCTION**

After arguing for more than a decade in many courts and patent offices around the world that the art was so lacking that even with the disclosure of Dr. Lin’s patent in hand a person of ordinary skill in the art could not repeat Lin’s inventions by isolating the EPO DNA and expressing it in a mammalian cell, the Roche defendants now ask the Court to ignore their previous admissions so that they can take entirely inconsistent positions here in asserting that Dr. Lin’s inventions are obvious. Specifically, Roche and their predecessors in interest argued in the foreign actions that there was no enriched cell source from which to clone the EPO DNA (a position based on the decision in the U.S. Chugai litigation) and that it was difficult to express the EPO DNA in mammalian cells. Now, in this Court, Roche and their experts argue that there were cells available that would serve as enriched sources of EPO mRNA from which the human EPO gene could be easily cloned, and that with the DNA in hand, it would be routine to express

it in mammalian cells. Under FRE 801(d)(2), Amgen is entitled to present the jury with the evidence of previous Roche admissions, such that Roche's motion should be denied.

There are a number of Roche statements of fact from the U.K. litigation and other foreign actions involving Dr. Lin's patents which are relevant to the issues and positions taken by Roche in this case. These facially inconsistent Roche statements are admissible under FRE 801(d)(2)(A) or (B), which statute does not restrict their use at trial. That there may be differences in British and American patent law does not preclude the admissibility of Roche's prior inconsistent statements which are factual admissions and not legal conclusions.

Roche's motion gives but one example of a statement it made in the U.K. proceeding that Roche contends would be misleading to the jury, the one example concerns the phrase "common general knowledge," because it alleges it was made in a different legal context, and then tries to use this one example to springboard into a request for a blanket exclusion order. Amgen believes that even this statement constitutes a factual admission and thus may be introduced by Amgen at trial, but there are many additional relevant, purely factual admissions made by Roche in the foreign patent proceeding which Roche fails to disclose. These prior admission of Roche are directly relevant to the issues in this case and directly rebut Roche's arguments of obviousness.

## **II. ARGUMENT**

### **A. Roche's Prior Statements are Admissible in this Litigation as Admissions of a Party Opponent under FRE 801(d)(2)(A) or (B)**

As stated in FRE 801(d)(2), an admission by a party opponent is not hearsay and is admissible when the admission is (A) the party's own statement, in either an individual or a representative capacity or (B) a statement of which the party has manifested an adoption or belief in its truth. There is no foreign patent litigation exception under FRE 801(d)(2); nor does FRE

801(d)(2) require the context of the party opponent's statement to be explained by the party offering the statement.

For example, during the U.K. litigation, Roche took the position that "the major problem facing a skilled person who wanted to obtain human EPO DNA was the absence of a suitable tissue source of human EPO mRNA from which a cDNA library could be constructed."<sup>1</sup> Now, before this Court, Roche is taking the opposite position: that Amgen's claims-in-suit are obvious because suitable tissue sources of human EPO mRNA existed from which a cDNA library could be constructed.<sup>2</sup> Regardless of their context Amgen is permitted to confront Roche with their previous factual statements made before a foreign court.<sup>3</sup> Amgen is entitled to make Roche's prior position on the lack of a suitable tissue source for human EPO mRNA known to the jury to assist the jury in assessing Roche's theory of obviousness and the credibility of their witnesses now that Roche assert that such tissue sources were available.

Yet another example is that Roche argued in the U.K. litigation that gene synthesis was very difficult at the time of Dr. Lin's inventions. In this case, Roche and their experts argue the exact opposite: that at the time of Dr. Lin's inventions, gene synthesis was obvious, i.e., that it would have been obvious to obtain the protein sequence of EPO, synthesize a DNA encoding it, attach a heterologous signal peptide to the gene, and express the construct in a mammalian cell to obtain *in vivo* biologically active EPO.<sup>4</sup> Roche's expert Dr. Fromm has asserted that synthesizing genes was routine as of 1983: "In my opinion, assuming that the amino acid

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<sup>1</sup> *The Roche Parties' Skeleton Argument on the '605 Patent* [Roche Motion Exh. A], submitted in the U.K. Chancery Division, Patent Court proceedings CH 1993-K-No. 937 and CH 1993 B-No. 5442, at ¶ 19. *See also id.* at ¶¶ 55-58.

<sup>2</sup> Lowe 4/6/07 Expert Report ¶¶ 30-53 and ¶¶ 61-94; Kellems 4/6/07 Expert Report ¶¶ 31-82; and Lowe 5/8/07 Second Supplemental Expert Report ¶¶ 8-30.

<sup>3</sup> *See* 1972 Advisory Committee Notes for FRE 801, Note To Subdivision (d)(2) *Admissions*.

<sup>4</sup> Fromm 4/6/2007 Expert Report.

sequence of EPO was known by October 1983, the Alton reference teaches all the steps necessary to synthesize large fragments of the EPO gene which could then be assembled using the known techniques in the art. Separate DNA fragments could be joined together to create a synthetic gene of less than 800 base pairs if needed, using the techniques available in the art.”<sup>5</sup> Two of the experts that Roche has indicated will testify at trial, Drs. Kadesch and Lowe, have attempted to incorporate this opinion of Dr. Fromm into their expert reports.

Contrary to what Roche’s experts will apparently seek to testify to at trial, Roche previously admitted in the U.K. litigation that the techniques of gene synthesis were not within the skill and knowledge of the skilled person even by the end of 1984:<sup>6</sup> “by the end of 1984 no one had expressed a synthetic gene in a mammalian cell. The work required of the skilled person by the Amgen parties—synthesis of a 500+ base pair gene and expression in a mammalian cell—would have been considered pioneering even for a specialist team in 1984.”<sup>7</sup> Amgen is entitled to present this inconsistent prior statement to the jury so they can assess how to evaluate Roche’s theory of obviousness.

As a final example from the U.K. litigation, Roche argued that it would have required undue experimentation to practice Dr. Lin’s inventions, *i.e.*, six months of effort and experimentation after obtaining the EPO gene to express EPO from CHO cells.<sup>8</sup> This is directly contrary to Roche’s argument in this case that the prior art taught that the EPO gene could be “routinely transferred into CHO or COS cells using one of the many gene transfer methods such

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<sup>5</sup> Fromm 4/6/2007 Expert Report at ¶ 38.

<sup>6</sup> *The Roche Parties’ Skeleton Argument on the ‘605 Patent* [Roche Motion Exh. A.] at ¶¶ 20, 71 and 72.

<sup>7</sup> *Id.* at ¶ 72 (internal citations omitted).

<sup>8</sup> *Id.* at ¶¶ 92 and 93.

as calcium phosphate for either transient or stable transformation when accompanied by a selectable marker gene.”<sup>9</sup>

For purposes of admissibility under FRE 801(d)(2), it is irrelevant that Roche made these prior inconsistent statements in foreign proceedings. The above examples of inconsistent statements are instances where Roche was discussing the facts as it understood them to be. The facts are stated as being true by Roche independent of any patent law arguments. Amgen is entitled to present factual admissions made by Roche in foreign proceedings.

**B. The “Common General Knowledge” Standard for Enablement under British Law is Encompassed by a “Person of Ordinary Skill in the Art” Standard under U.S. Obviousness Law**

In their Motion Memorandum [Docket No. 823], Roche argues that their statements in the U.K. proceeding regarding “common general knowledge” were specific to the patent enablement inquiry under British law and not probative to the obviousness inquiry before this Court.<sup>10</sup> For purposes of a §103 obviousness inquiry under U.S. patent law, the person of ordinary skill in the art is presumed to know all relevant prior art.<sup>11</sup> For purposes of an enablement inquiry under British law, the person of ordinary skill in the art is presumed to know all relevant prior art that is generally known and accepted without question by the bulk of those who are engaged in that particular art.<sup>12</sup> Taken together, the “common general knowledge” required in the U.K. is necessarily subsumed within the “all relevant prior art” that a person of ordinary skill is presumed to know under §103.

Therefore, Roche’s statements in the U.K. proceeding related to “common general knowledge” are a relevant part of the knowledge that a person of ordinary skill in the art would

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<sup>9</sup> 5/11/2007 Fromm Expert Report at ¶ 70.

<sup>10</sup> Roche’s Motion at pp. 5-6.

<sup>11</sup> *Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985).

<sup>12</sup> *Beloit Tech. Inc. v. Valmet Paper Mach. Inc.* [1997] RPC 489, 494-95 (U.K.).

have for a §103 obviousness inquiry here. Roche's prior statements in the U.K. litigation are probative on the question of obviousness in this case and are admissible in this litigation under FRE 801(d)(2).

**C. The Jury is Entitled to Hear Roche's Prior Inconsistent Statements and Decide for Themselves the Merits of Roche's Invalidity Arguments**

Under FRE 403, relevant evidence may be excluded if the probative value is substantially outweighed by the risk of confusing or misleading the jury.<sup>13</sup> As discussed above, Roche's prior inconsistent statements are highly relevant to and probative of the §103 obviousness arguments that Roche is making in this case. Roche contends that without context and explanation, their prior inconsistent statements will confuse or mislead a jury.<sup>14</sup> Roche's explanation regarding the inconsistencies between their prior and current positions may be confusing, but the prior statements themselves will not confuse or mislead a jury. If Roche chooses to explain their inconsistent statements by trying to describe the "arcane distinctions"<sup>15</sup> between U.S. and British patent law, then it is Roche's burden to make the distinction clear to the jury. This Court should not exclude highly relevant, probative, and admissible inconsistent statements by a party opponent just because Roche's justification for those statements may be "arcane."

**III. CONCLUSION**

For the foregoing reasons, Amgen requests that this Court deny Roche's motion to preclude Amgen from using statements Roche made in earlier foreign proceedings.

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<sup>13</sup> FRE 403.

<sup>14</sup> Roche's Motion Memorandum [Docket No. 823] at pp. 7-8.

<sup>15</sup> *Id.* at p. 7.

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 August 30, 2007.

/s/ Michael R. Gottfried  
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