

**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 ASSERTING OUTCOMES OF PRIOR LITIGATIONS CONCERNING  
THE VALIDITY AND INFRINGEMENT OF CERTAIN CLAIMS OF THE PATENTS-  
IN-SUIT AS EVIDENCE AND ATTORNEY ARGUMENT (DOCKET NO. 804)**

## I. INTRODUCTION

The Court should deny Roche's motion *in limine* [Docket No. 804] seeking to preclude Amgen from referring to the outcomes of certain prior litigations because Amgen needs to refer to these outcomes to cite to highly relevant Roche admissions and to give proper context to the many statements about prior litigations Roche intends to make. Roche's motion *in limine* appears to ask the Court to exclude both outcomes from prior litigations and *any* reference to the prior *TKT* and unspecified foreign decisions. In the Joint Pretrial Memorandum submitted on August 10 [Docket No. 807], Roche has stated an intention to present statements at trial copied from decisions issued in prior Amgen litigations. The statements Roche intends to introduce are "findings and holdings." Amgen would be extremely prejudiced if it were not permitted to counterdesignate such statements from those same decisions or to otherwise properly put such statements in context, including itself referring to outcomes and holdings of the prior litigations.

Roche asserts that it was not a party to any of these prior litigations and thus has not had its chance to make its arguments about the patents-in-suit. While it is true that Roche was not a party to the *TKT* litigation in the U.S., Roche was a party, either directly itself or through its predecessors in interest, to almost all of the foreign litigations. Roche was the defendant in Canada where the Canadian court held Roche's product to infringe Dr. Lin's patent and rejected Roche's attacks on the validity of the Lin's product claims. Roche was the party in the U.K. proceeding that resulted again in a finding of infringement and validity of the claims asserted against Roche. Roche was the party to the Australian actions unsuccessfully challenging the validity of Dr. Lin's Australian patent. Importantly, Roche was the party to the 2001 settlement agreement that resolved the foreign litigations and included an acknowledgment of the validity and infringement of Dr. Lin's patents. These admissions directly contradict many positions that Roche is taking here, and Amgen will rely on these admissions at trial.

## II. FACTUAL BACKGROUND

In the Joint Pretrial Memorandum, Roche specifically provides a list covering *113 paragraphs* over *22 pages* of statements of “findings and holdings” from court decisions in previous lawsuits to which Amgen was a party and, to which Roche argues, Amgen should be bound.<sup>1</sup>

“In order to aid in the efficient and speedy resolution of the issues in suit Roche provides the following list of findings and holdings from previous cases by this Court and the Federal Circuit to which Amgen was a party, and therefore to which Amgen is bound, and which involved some of the same issues in suit here. Roche submits that these findings and holdings have a preclusive effect on Amgen and obviate the need to relitigate these issues.”<sup>2</sup>

In its motion *in limine*, Roche wants to bar Amgen from discussing the outcomes of the past lawsuits because the jury might be prejudiced.<sup>3</sup> However, as made plain in the Pretrial Memorandum, Roche itself intends to introduce certain of the outcomes from the previous Amgen litigations, as well as snippets from the case decisions. In particular, the list presented by Roche in the Joint Pretrial Memorandum includes statements about the indefiniteness of claim language,<sup>4</sup> the obviousness of the claimed inventions,<sup>5</sup> the anticipation of the claims,<sup>6</sup> and the lack enablement of the claims.<sup>7</sup> One of the holdings or outcomes to which Roche wants Amgen to be bound to is the holding of indefiniteness of claim 1 of the ‘933 patent.<sup>8</sup> As Roche says in the Joint Pretrial Memorandum, the court in *TKT* found claim 1 of the ‘933 patent indefinite

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<sup>1</sup> Joint Pretrial Memorandum [Docket No. 807] at pp. 40-62.

<sup>2</sup> *Id.* at p. 40.

<sup>3</sup> Roche’s Motion at p. 5.

<sup>4</sup> *Id.* at p. 41, ¶¶ 1 and 2.

<sup>5</sup> *Id.* at p. 50, ¶ 48.

<sup>6</sup> *Id.* at p. 48, ¶ 36.

<sup>7</sup> *Id.* at p. 44, ¶ 15.

<sup>8</sup> *Id.* at p. 41, ¶¶ 1 and 2.

because it was unclear which urinary erythropoietin (“EPO”) preparation should have been the standard for comparison against glycosylated EPO.<sup>9</sup>

Roche has been a party, either directly itself or through its predecessor Boehringer Mannheim, to many foreign litigations. Amgen believes the jury has a right to hear of these Roche actions and admissions. These cases involved Dr. Lin’s EPO patents in other countries around the world including the following cases:

Kirin-Amgen Inc. v. Hoffmann-LaRoche Ltd., Dkt. T-2784-07 (Fed. Ct. of Canada – Feb. 15, 1999), *affirmed* Dkt. A-155-99 (Fed. Ct. of Appeal – Dec. 20, 2000).

Kirin-Amgen v. Boehringer, Case No. 93/2620 (Court of the Hague – March 13, 1996)

Kirin-Amgen v. Boehringer / Hoechst Marion Roussel v. Kirin Amgen; CH 1993 K No. 937 and CH 1993 B No. 4552 (Chancery Division - April 11, 2001), *affirmed*, HC 1999 Nos. 02916, 02917, and 03241 (High Court – March 21, 2002).

In the Canadian decision, Roche’s EPO product was held to infringe Dr. Lin’s claims to a recombinant EPO having a higher molecular weight than urinary EPO on SDS-PAGE. Many of the same arguments Roche makes here about urinary EPO being the same as Dr. Lin’s recombinant EPO were tried and rejected by the Canadian courts. One of Roche’s scientists, Dr. Anton Hasselbeck, testified in the Canadian case and is listed as a trial witness in this case.

In the UK litigation, both Roche and TKT were defendants in that action with different claims asserted against each defendant. Again, the trial court held that Roche infringed the process claims and rejected its validity attacks. The case was later settled as part of the 2001 settlement of foreign litigations.

In the Netherlands, Roche’s predecessor in interest, Boehringer, unsuccessfully attacked the validity of Dr. Lin’s patent. argument

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<sup>9</sup> *Amgen., Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 129 (D.Mass. 2001).

It is apparent from the Joint Pretrial Memorandum that Roche intends to introduce numerous statements from prior Amgen litigations into evidence at trial. Roche's Motion, then, is asking this Court to preclude Amgen from using these decisions and Roche's acknowledgements against Roche or even explaining anything about these prior litigations while Roche would be free to assert any portions of these litigations against Amgen. Roche argues: "Moreover, Amgen should not be allowed to introduce into evidence, or show through demonstrative exhibits, any portion of the prior *TKT* and foreign decisions."<sup>10</sup> Roche's Motion is tantamount to asking this Court to allow Roche to cherry pick evidence from numerous prior litigations that appears useful to it, but not allow Amgen to explain, rebut or otherwise put in context Roche's statements by likewise referring to the litigations, including the outcomes of the litigations. Permitting Roche to succeed in this scheme would be blatantly unfair and prejudicial to Amgen.

If Roche intends to introduce and refer to evidence of prior litigations at trial, Amgen should also be able to do so, including to refer to the outcomes of the prior litigations. It would not be fair and certainly contrary to due process to permit Roche to have it both ways. Roche claims "[it] has not had, as is its right under due process law, its own full and fair opportunity to present evidence about or argue the validity or infringement of the patents-in-suit."<sup>11</sup> But Roche was a party to the foreign litigations and had its full opportunity to argue its case in those jurisdictions. Moreover, Roche willingly acknowledged the validity of Dr. Lin's patents. Roche is trying to keep this evidence from the jury without even explaining its actions to this Court. Roche is even trying to keep Amgen from having an opportunity to fairly challenge the cherry-picked evidence it intends to present at trial.

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<sup>10</sup> Roche's Motion at p. 5 (emphasis added).

<sup>11</sup> Roche's Motion at 2.

Roche argues that “[t]here is no probative value in the outcome of prior litigation and is therefore surely outweighed by the enormous potential for jury confusion.”<sup>12</sup> Yet Roche undercuts that argument by showing its intent to rely heavily on “findings and holdings” from the TKT case and some foreign litigations to prove its case at trial. Roche’s intent to rely upon 113 paragraphs of findings and holdings from prior litigations makes it necessary, as matter of fairness, for Amgen to likewise be able to quote or otherwise reference findings and holdings, including outcomes, from prior litigations.

Amgen would be greatly prejudiced by not being allowed to refer to the outcomes of prior litigations if Roche were allowed to rely on them. Under FRE 403, relevant evidence may be excluded if the probative value is substantially outweighed by the risk of unfair prejudice.<sup>13</sup> Any prejudice that exists for allowing statements from previous cases without allowing the outcomes of the previous cases is toward Amgen, not Roche. In this case, for example, Roche has made clear that it intends to refer at trial to non-asserted claims held invalid in the *TKT* litigation. Since those claims are not at issue, such prior holding is not relevant to any issue in this case and reference to that holding would be unduly prejudicial to Amgen in this action. But if Roche is permitted to present evidence of that prior holding, Amgen would suffer even more prejudice if it were not afforded the opportunity to put such findings in context, including by noting that there were many more other claims not found invalid. Absent that fundamental fairness, the jury would be told, in the one-sided fashion Roche’s Motion seeks to obtain, that *this Court* held claims invalid in the prior litigation. This scenario would likely unfairly influence the jury to likewise find the asserted claims in this case invalid, thus prejudicing Amgen not Roche.

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<sup>12</sup> Roche’s Motion at 2.

Roche mischaracterizes the *Mendenhall* case.<sup>14</sup> In *Mendenhall*, the Federal Circuit actually stated that prior outcomes, while not forming binding legal precedent, may be informative.<sup>15</sup> Amgen has the right to introduce a prior opinion of a court that has ruled on validity and the prior opinion “may be given ‘weight’ without also giving the opinion evidentiary effect on disputed underlying facts which the jury must resolve.”<sup>16</sup> The Federal Circuit also specifically noted that “a prior decision that a patent has previously survived an attack on its validity serves only to inform the district court, and this court as well, that caution must be taken in reaching a contrary legal conclusion.”<sup>17</sup> Amgen should be allowed to introduce the outcomes of prior litigations because Roche made some of the same arguments in those cases, was rejected, and acknowledged Dr. Lin’s patents. If Roche is permitted to tell the jury about many findings and holdings from previous litigations, Amgen is entitled to give the jury a well-rounded view of such litigations.

### III. CONCLUSION

For the foregoing reasons, Amgen requests that this Court deny Roche’s motion to preclude Amgen from making reference to outcomes of prior litigations at trial.

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<sup>13</sup> FRE 403.

<sup>14</sup> Roche’s Motion at 3.

<sup>15</sup> *Mendenhall v. Cedarapids*, 5 F.3d 1557, 1569 (Fed. Cir. 1993).

<sup>16</sup> *Id.*

<sup>17</sup> *Id.*

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 24, 2007.

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