

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

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

**AMGEN’S MOTION *IN LIMINE* TO PRECLUDE ROCHE FROM UNDERMINING  
THE COURT’S PRIOR RULINGS AND UNDULY PREJUDICING AMGEN BY  
ARGUING ITS ODP-RELATED INEQUITABLE CONDUCT THEORY TO THE JURY**

The Court properly determined that obviousness-type double patenting (“ODP”) issues are to be tried to the Court, and not to the Jury. The Court also instructed the parties not to raise the outcome of prior judicial and PTO proceedings before the Jury. Now, Roche apparently seeks to try an inequitable conduct theory to the Jury that necessarily will require substantial discussion of obviousness-type double patenting, as well as the substance and outcomes of the *Fritsch v. Lin* interference proceedings, the Chugai ITC proceeding, and the *Amgen v. Chugai* case. Litigation of these issues before the Jury would be contrary to the Court’s conduct of the trial to date and highly confusing for the Jury. It would also be an inefficient use of judicial resources and would create the risk of inconsistent factual determinations, because the Court already heard the same evidence and likely will make the same determinations in the context of the ODP portion of this case. Consequently, Amgen respectfully requests that the Court require that Roche’s ODP-related inequitable conduct theory be tried to the Bench, rather than to the

Jury.

One of Roche's three remaining inequitable conduct theories<sup>1</sup> substantially overlaps with Roche's obviousness-type double patenting invalidity defense. Specifically, Roche contends that Amgen committed inequitable conduct by failing to disclose to the Examiner positions Roche alleges Amgen had previously taken during the *Fritsch v. Lin* interference proceedings.<sup>2</sup> According to Roche, those prior positions were inconsistent with the arguments Amgen made during prosecution to overcome a rejection of Lin's process claims for ODP over the '008 patent claims, and therefore should have been disclosed.<sup>3</sup> The alleged prior inconsistent statements that Roche relies on as the basis for this inequitable conduct theory are the same statements that Roche relies on for its argument that Amgen should be judicially estopped from contesting that Lin's process claims are invalid for ODP over the '008 patent claims.<sup>4</sup> In both instances, Roche argues that it was Amgen's position during the interference proceedings that Lin's process and DNA inventions were "only different manifestations of the same invention."<sup>5</sup> And in both instances, Roche argues that this statement is inconsistent with Amgen's subsequent argument of

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<sup>1</sup> Roche's other two remaining inequitable conduct theories are discussed in Amgen's Motion and Supporting Memorandum Requesting That This Court Try Roche's Inequitable Conduct Defenses (Docket Item ("D.I.") 1341).

<sup>2</sup> See Defendants' First Amended Answer (D.I. 344), at ¶¶ 43-44, 47-48; Roche's Opposition to Amgen's Motion for Summary Judgment of No Inequitable Conduct (D.I. 633), at 7-8. The entirety of Roche's ODP-related inequitable conduct allegations is set forth at ¶¶ 38-53 of Roche's First Amended Answer (D.I. 344). As explained in Amgen's separate motion *in limine*, Roche's attempt to cast Amgen's legal arguments to the Examiner as misrepresentations of material fact must also be rejected because the Federal Circuit has made clear that legal argument cannot constitute a misrepresentation of material fact for inequitable conduct purposes. See *Young v. Lumenis, Inc.*, 492 F.3d 1336, 1349 (Fed. Cir. 2007); *Azko N.V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1481 (Fed. Cir. 1996).

<sup>3</sup> *Id.*; see, e.g., D.I. 633, at 8 ("Amgen's attorneys statements in the Interference are *per se* material because they actually contradict the very arguments Amgen relied on during subsequent prosecution of the '179 application.") (emphasis in original).

<sup>4</sup> Compare D.I. 344, at ¶¶ 47-48 with D.I. 802, at 3-4 (identifying same purported prior admissions as bases for ODP-related inequitable conduct and judicial estoppel-based ODP).

<sup>5</sup> Compare D.I. 344, at ¶ 47 with D.I. 802, at 4.

no obviousness-type double patenting.<sup>6</sup>

Because Roche's ODP-related inequitable conduct theory is premised on the same core set of allegations as Roche's judicial estoppel-based theory of ODP, the same evidence is relevant to both defenses, and many of the same factual determinations are required to resolve each defense. In both instances, the fact-finder must assess (1) the PTO's determination of patentable distinctiveness in setting up the three separate interferences, (2) the positions argued by Amgen and GI during the *Fritsch v. Lin* interference proceedings, (3) the Board's decisions in the three interferences, and (4) the court decision in the *Amgen v. Chugai* case.<sup>7</sup> Indeed, Roche's Amended Answer quotes an excerpt from Amgen's interference brief concerning the *Chugai* litigation<sup>8</sup> as an example of a prior statement that Roche contends was inconsistent and should have been disclosed to the Examiner.<sup>9</sup> Finally, for both of these Roche defenses, the fact-finder must assess Amgen's argument of no obviousness-type double patenting — which is substantially similar in the present litigation as it was during prosecution of the patents-in-suit — and determine whether that argument is inconsistent with Amgen's previous positions during the interference proceedings.

The Court, not the Jury, should make these determinations — both for purposes of Roche's ODP defense *and* its ODP-related inequitable conduct defense. First, the Court has already received the relevant evidence, as well as multiple rounds of related briefing and oral

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<sup>6</sup> Compare D.I. 344, at ¶ 47 with D.I. 802, at 1.

<sup>7</sup> Amgen explained the relevance of these prior proceedings during the ODP hearings and related briefing. See 10/1/07 ODP Hearing Tr. 64:13-69:2; 10/4/07 ODP Hearing Tr. 137:15-138:17; Amgen Inc.'s Opp. to Roche's Mot. *In Limine* To Preclude Amgen Inc. From Contradicting Arguments It Made in Prior Administrative and Judicial Proceedings (D.I. 867), at 2-9 and 10-14; Amgen Inc.'s Opp. to Roche's Mot. *In Limine* To Bind Amgen Inc. to Prior Admissions Relevant to Double Patenting (D.I. 1122), at 1-6.

<sup>8</sup> *Amgen, Inc. v. Chugai Pharms. Co.*, 13 U.S.P.Q.2d 1737 (D. Mass. 1989), *aff'd* 927 F.2d 1200 (Fed. Cir. 1991).

<sup>9</sup> See Defendants' First Amended Answer (D.I. 344), at ¶ 48.

argument, in the context of the ODP hearing.<sup>10</sup> If the Court were to decide Roche's overlapping ODP-related inequitable conduct defense, there would be no need for the parties to re-introduce the same evidence and rehash the same arguments in the jury proceeding. This would conserve judicial resources. Equally important, it would eliminate the risk of inconsistent judgments, which might otherwise occur if the Court and the Jury were both required to make separate determinations regarding the substance of Amgen's interference and ODP positions and whether or not the two were inconsistent.

Second, as explained above, if Roche's ODP-related inequitable conduct defense were tried to the Jury, the Jury necessarily would be required to grapple with detailed information concerning ODP issues, as well as the substance and outcome of prior administrative and judicial proceedings. The Court previously instructed that the Jury was not to be exposed to such information.<sup>11</sup>

Third, irrespective of whether information concerning ODP issues and prior proceedings might be more relevant in the inequitable conduct phase of the jury case than it was during the validity phase, sudden introduction of these issues on the final day of evidence would be extremely confusing for the Jury. The risk of jury confusion is especially acute in this instance because the Jury was previously exposed to three days of testimony from Roche's ODP expert,

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<sup>10</sup> See, e.g., 10/1/07 ODP Hearing Tr. 43:9-46:24, 62:1-69:2; 10/4/07 ODP Hearing Tr. 128:23-147:25, 153:10-17; D.I. 802, 867, 898, 1037, 1122, 1310.

<sup>11</sup> See, e.g., 9/7/07 Trial Tr. 344:13-14 ("THE COURT: No, but, we're not hearing anything about who won an interference."); 9/7/07 Trial Tr. 478:15-18 ("THE COURT: Well, I've told them there's other proceedings, I told them to pay no attention to it. I'll tell them, the jury, if we need to know about it. I don't think it's necessary."); 9/7/07 Trial Tr. 505:5-12 ("THE COURT: . . . we're not going to hear anything more, we're not going to receive any evidence, further evidence before the jury on the issue of obviousness/double patenting, though we may, you may get such evidence before me."); 10/4/07 ODP Hearing Tr. 153:10-14 (admitting *Fritsch v. Lin* interference documents for purposes of the jury waived ODP proceeding only).

Dr. Lowe,<sup>12</sup> but no ODP testimony from Amgen's witnesses. To inject ODP-related testimony again in the case at this stage would likely confuse the jurors, leave them with only a one-sided view of the issue, and essentially allow Roche to argue its ODP case to the jury.

Finally, as the following summary of Roche's ODP-related inequitable conduct defense makes plain, Roche's inflammatory double-patenting rhetoric would only be amplified in the context of an inequitable conduct claim tried to the Jury:

Throughout its response to the PTO's office action rejection on double patenting, Amgen therefore intentionally misrepresented its own understanding of the claims, misrepresented the facts of prior proceedings and misstated legal standards. **This fraud on the PTO was motivated by Amgen's need to improperly extend the life of its EPO invention** by maintaining and prosecuting applications that issued into patents, which were obvious over an earlier issued and now expired patent.<sup>13</sup>

\* \* \* \*

In making such misrepresentations, **Amgen and its attorneys were motivated to "extend the life" of its patent protection and ensure that competitors like Chugai were kept out of the market upon the expiration of its '008 patent.** Because the 17 year protection promised to Amgen from 1987 to 2004 through the '008 patent proved effectively useless in litigation, **it decided to exploit all avenues to reward itself with additional patents with full patent terms** and failed to file the proper terminal disclaimers tied to the '008 patent. In doing so, **Amgen also exploited a 1995 change in law increasing the term of patent protection from 17 years to 20 years** for certain applications as evidenced by Amgen's sudden filing of multiple continuation applications in June 1995. This activity is part and parcel of Amgen's strategy in patent prosecution and is accordingly pertinent to Roche's evidence of a pattern of conduct to support an inference of intent to deceive.<sup>14</sup>

Thus, if Roche were permitted to try its ODP-related inequitable conduct defense to the Jury

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<sup>12</sup> 9/5/07 Trial Tr. at 141:23 to 9/7/07 Trial Tr. at 479:2; *see also* 10/1/07 ODP Hearing Tr. 40:11-13 ("THE COURT: . . . it might be confusing to the jury to start striking things out, we're just not going to mention that [Dr. Lowe's ODP testimony] any further.").

<sup>13</sup> Defendants' First Amended Answer (D.I. 344), at ¶ 51 (emphasis added).

<sup>14</sup> Roche's Opposition to Amgen's Motion *In Limine* No. 20 (D.I. 920), at 6-7 (emphasis added).

there would be a substantial risk that Roche's incendiary allegations would improperly influence the Jury's analysis of invalidity issues, such as obviousness under 35 U.S.C. § 103. Any such undue influence on the Jury's assessment of validity issues would unfairly prejudice Amgen.

Roche's ODP-related inequitable conduct theory necessarily involves untangling Roche's contorted allegations of inconsistencies between Amgen's positions during the *Fritsch v. Lin* interference proceedings and its positions during prosecution in response to the PTO's ODP rejection over the '008 patent claims. These are precisely the same allegations that form the heart of Roche's substantive ODP defense. Therefore, for the reasons stated herein, Amgen respectfully requests that the Court, and not the Jury, decide Roche's ODP-related inequitable conduct theory.

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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 91320-1889  
(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  
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  
McDERMOTT WILL & EMERY  
3150 Porter Drive  
Palo Alto, CA 94304  
Telephone: (650) 813-5000  
Facsimile: (650) 813-5100

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

**CERTIFICATE PURSUANT TO LOCAL RULE 7.1**

I certify that counsel for the parties have conferred in an attempt to resolve or narrow the issues presented by this motion and no agreement was reached.

/s/ Patricia R. Rich  
Patricia R. Rich

**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 October 15, 2007.

/s/ Patricia R. Rich  
Patricia R. Rich