

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'S MOTION IN LIMINE TO PRECLUDE ROCHE FROM ARGUING TO THE JURY THAT AMGEN COMMITTED INEQUITABLE CONDUCT THROUGH ITS CHARACTERIZATION OF THE CHUGAI ITC DECISION, THE PTO INTERFERENCE ACTIONS, AND ARTICULATION OF THE TEST FOR ODP

As part of its allegations of inequitable conduct, Roche seeks to confuse the jury with factually incorrect, legally unsupportable, and irrelevant arguments that Amgen, during the prosecution of the '868 process claims, misstated the holdings of the Chugai ITC decisions, the PTO interference decisions, and the proper application of the analysis for determining obviousness-type double patenting ("ODP"). But, as is clear from the prosecution history, Amgen correctly stated the holdings and impact of these decisions on the patentability of the process claims in responding to the ODP issue raised by the examiner and correctly stated the law of ODP when responding to the Examiner's faulty analysis. The correctness of Amgen's statements regarding prior decisions is a matter of law to be decided by the Court, not by the jury. Because Amgen's characterizations were legally correct, Roche should be precluded from arguing to the contrary.

As a second ground for precluding Roche from raising these allegations before the jury,

because the ITC decision and the PTO Interference decisions were before the examiner, Federal Circuit precedent holds that attorney argument and interpretation do not constitute affirmative misrepresentations of material fact, even when an alleged infringer claims them to be mischaracterizations.<sup>1</sup> Nor can there be a “‘failure to disclose material information’ when that information was disclosed to the PTO in time for the examiner to consider it.”<sup>2</sup> To prevent juror confusion, Roche should be precluded from pursuing these baseless inequitable conduct allegations premised on Amgen’s legal arguments and characterizations of materials that were disclosed to the examiner.

Federal Circuit precedent makes clear that neither arguments of counsel concerning the state of the law nor characterizations of materials disclosed to the examiner constitute “material misrepresentations” upon which an inequitable conduct defense may be based.<sup>3</sup> Likewise, where materials that may be relevant to patentability were disclosed such that the examiner was able to fully consider them and reach his own conclusions, there cannot be inequitable conduct based on a theory of failure to disclose.<sup>4</sup>

By way of example, Roche argues that Amgen misrepresented the court’s decision in *Amgen, Inc. v. U.S. International Trade Commission*, 902 F.2d 1532 (Fed. Cir. 1990), during the prosecution of the ‘179 application.<sup>5</sup> Roche alleges that Amgen misled the examiner by arguing that the Federal Circuit had determined the ‘008 product claims to be patentably distinct from the

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<sup>1</sup> See *Young v. Lumenis, Inc.*, 492 F.3d 1336, 1349 (Fed. Cir. 2007) (“We therefore fail to see how the statements . . . which consist of attorney argument and an interpretation of what the prior art discloses, constitute affirmative misrepresentations of material fact.”).

<sup>2</sup> *Id.*

<sup>3</sup> *Id.* See also *Akzo N.V. v. U.S. Int’l Trade Comm’n*, 808 F.2d 1471, 1481 (Fed. Cir. 1996).

<sup>4</sup> *Young v. Lumenis, Inc.*, 492 F.3d 1336, 1349 (Fed. Cir. 2007); see also *N. Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 938 (Fed. Cir. 1990).

<sup>5</sup> 3/30/07 Defendants’ First Amended Answer and Counterclaims to Plaintiff’s Complaint (Docket No. 344) at ¶ 45 [hereinafter Roche’s First Amended Answer].

process claims of the '179 application. Roche's argument fails, however, because Amgen correctly reported to the examiner that the Federal Circuit had determined that the claims of the '008 patent did not provide process protection and thus there could be no extension of rights. Amgen accurately paraphrased the Federal Circuit's decision.<sup>6</sup> Even so, characterization of a Federal Circuit decision is legal argument, and therefore cannot constitute a misrepresentation of material fact. The examiner had before him the entire decision, and was free to make his own determination regarding the scope and meaning of the decision.

Roche wages similar arguments with respect to Amgen's characterization of the PTO's determinations of patentable distinctiveness made in the context of the *Fritsch v. Lin* interference proceedings.<sup>7</sup> The Patent Office instituted separate interferences for Lin's DNA and process inventions—reflecting its conclusion that these two inventions were patentably distinct,<sup>8</sup> and explicitly stated: “While the subject matter of the three interferences is ***deemed to be patentably distinct***, the subject matter is nevertheless related.”<sup>9</sup> Amgen noted that separate interferences had been drawn, and that the PTO's position had been that the “production process subject matter claimed [therein] was patentably distinct from the DNA-related subject matter claimed in U.S. 4,703,008.”<sup>10</sup> Amgen's characterization of the PTO's position was accurate. Furthermore, information regarding these interference proceedings was before the examiner, who is presumed

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<sup>6</sup> *Amgen, Inc. v. U.S. Int'l Trade Comm'n*, 902 F.2d 1532, 1538 (Fed. Cir. 1990) (“A host cell claim does not ‘cover’ intracellular processes any more than or less than a claim to a machine ‘covers’ the process performed by that machine.”). See also 6/22/07 Amgen Inc.'s Mem. in Supp. of Its Mot. for Summ. J. of No Inequitable Conduct, Docket No. 545, at 11-12.

<sup>7</sup> *Id.* at ¶ 46-48.

<sup>8</sup> See, e.g., 37 C.F.R. 1.601(f) (1994); see also Amgen's Bench Mem. Regarding No Obviousness-Type Double Patenting, Docket No. 1310, at 45-46.

<sup>9</sup> See '178 File History, Paper No. 21, 2/9/90 Office Action, previously filed as Exh. 20 to Decl. of Craig H. Casebeer in Supp. of Amgen Inc.'s Mot. for Summ. J. of No Inequitable Conduct [Casebeer Decl.], Docket No. 547-21, at 2 (emphasis added).

<sup>10</sup> See Roche's First Amended Answer ¶ 46.

to be capable of evaluating legal arguments. Notwithstanding that Amgen correctly characterized the PTO's position, Amgen's statements to the examiner regarding these interference proceedings were legal arguments,<sup>11</sup> and thus are not material for purposes of inequitable conduct.

In each instance, not only were Amgen's characterizations of these disclosed materials accurate and proper, the PTO examiners had before them the complete references about which Amgen argued. Even though Roche now disputes the accuracy of those arguments, Roche's position is irrelevant as a matter of law.<sup>12</sup>

Roche also argues that Amgen "misstated the law" by arguing that it was inappropriate to consider prior art in conjunction with the claims of the '008 patent in assessing whether the pending claims of the '179 application were obvious.<sup>13</sup> Roche's argument is based on its mischaracterization of Amgen's statement to the PTO. Amgen responded to an Office Action that incorrectly used the prior art reference of Yokota as the starting point of ODP analysis rather than the claims of the '008 patent.<sup>14</sup> Amgen was correct in bringing to light the examiner's failure to properly apply the ODP test. Regardless, Amgen's representations regarding the application of the ODP test were legal argument; the examiner was capable of assessing the merits of Amgen's position and applying the ODP test as he saw appropriate.

Permitting Roche to pursue inequitable conduct allegations based on Amgen's prior legal arguments before the examiner would confuse the jury and result in undue prejudice to Amgen.

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<sup>11</sup> *N. Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 939 (Fed. Cir. 1990) ("It is presumed that public officials do their assigned jobs."); *see also Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (Fed. Cir.), *cert. denied*, 469 U.S. 821 (1984).

<sup>12</sup> *See Young v. Lumenis, Inc.*, 492 F. 3d 1336, 1349 (Fed. Cir. 2007).

<sup>13</sup> Roche's First Amended Answer ¶ 50.

<sup>14</sup> *See* '179 File History, Paper No. 41, 8/11/94 Office Action, previously filed as Exh. 30 to Casebeer Decl., Docket No. 547-32, at 2.

The Federal Circuit has cautioned that if “evidence of marginal probative worth necessitates lengthy rebuttal, it imparts disproportionate weight to the issue.”<sup>15</sup> In this instance, rebuttal of Roche’s arguments would entail a lengthy explanation of the ITC and PTO Board decisions. Perhaps more appropriately, the Court should instruct the jury as to these decisions, the holdings and correctness of Amgen’s characterizations. Roche’s legally baseless inequitable conduct allegations are of no probative value, and Roche’s assertions and innuendos of impropriety should be precluded.

Amgen respectfully requests that, in accordance with Fed. R. Evid. 403, Roche be precluded from pursuing inequitable conduct allegations based on Amgen’s prior legal arguments and characterizations of materials disclosed to the examiner.

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<sup>15</sup> *Magnivision Inc. v. Bonneau Co.*, 115 F.3d 956, 961 (Fed. Cir. 1997).

October 15, 2007

Respectfully Submitted,

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**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/ Michael R. Gottfried  
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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. By agreement of the parties, paper copies will not be sent to those indicated as non-registered participants.

/s/ Michael R. Gottfried  
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