

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

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AMGEN INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	CIVIL ACTION No.: 05-CV-12237WGY
F. HOFFMANN-LA ROCHE LTD,	)	
ROCHE DIAGNOSTICS GmbH,	)	
and HOFFMANN-LA ROCHE INC.	)	
	)	
	)	
Defendants.	)	

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**ROCHE’S MEMORANDUM FOR  
JULY 17, 2007 CASE MANAGEMENT CONFERENCE**

**I. INTRODUCTION**

Denying previous Amgen motions, this Court has determined that the claims in this action shall be tried to a jury. To that end the Court scheduled a conference for July 17, 2007 to discuss some of the details of that jury trial such as the number of jurors the Court will empanel; whether the jurors can keep and use notebooks during the trial; whether the parties may suggest questions for the Court to consider during voir dire; and the use of a time clock for the presentation of the parties’ evidence to the jury. Amgen’s purported “Case Management Memorandum” is a disguised motion that has little to do with the conference and in reality seeks to reargue the Court’s prior rulings on a jury trial by rehashing the very same arguments the Court has already rejected.<sup>1</sup>

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<sup>1</sup> In addition, Amgen submitted this veiled motion just a few days before the Conference to deprive Roche of the full time afforded it under the rules for responding to an actual motion.

Amgen's arguments to defeat the jury trial center on one theme - that the issues are too complex for one trial. But as this Court recently observed: "Juries, which are drawn from a representative sample of Americans, have shown time and again that they have the capacity to grapple with and pass judgment on a dizzying array of issues that face us as a society."<sup>2</sup>

Roche shares this Court's respect for a jury's abilities, as noted in *Massachusetts Eye and Ear Infirmary*:

If ever there was doubt about the capacity of juries to understand and resolve complex cases, a review of the transcript here ought settle the matter. This was exceedingly complex. It tried over three weeks. The trial transcript ran 1,847 pages. There were 330 exhibits, not the least of which included labyrinthian scientific papers and patents concerning a medical procedure that required learning a technical vocabulary to understand. Despite the daunting nature of the task that lay before it, the jury came through masterfully. *Id.*

Amgen completely ignores that the Court has already denied Amgen's earlier gambits to deny a jury trial, or to bifurcate or phase that jury trial. Amgen also mischaracterizes Roche's position; Roche contends that it has a Constitutional right to a jury not only on its antitrust and state law counterclaims, but also on its patent claims.

Amgen's disdain of a jury trial has compelled it to make numerous factual and legal misstatements in its "Case Management Memorandum." In addition, Amgen improperly tries to reargue and buttress its already submitted summary judgment motions with even more argument. What Amgen doesn't tell the Court is that just a few days ago (months after the close of fact discovery) Amgen produced new evidence that bolsters Roche's antitrust claims, puts the lie to certain arguments raised by Amgen in challenging Roche's theories, and alone warrants denial of Amgen's summary judgment motion.

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<sup>2</sup> *Massachusetts Eye and Ear Infirmary v. QLT, Inc.*, (Civ. Action No. 00-10783-WGY), (D. Mass. July 10, 2007), D.I. No. 638 at 18.

Contrary to Amgen's hyperbole about "expanding" theories, Roche has properly asserted and disclosed in discovery its arguments and theories in this case. As this Court recognized, and was resolved by agreement during the June 6, 2007 conference, Amgen has been afforded more than enough time to discover the bases for Roche's arguments -- indeed, both sides were permitted time to submit additional expert reports and further depositions of experts in this case. There is no dispute, for example, that Roche's bases and factual support for its inequitable conduct allegations were disclosed during fact discovery to Amgen.

Roche contends that the following are appropriate issues to discuss with the Court on July 17 regarding the jury trial of this action:

1. Length of trial and use of time clock in hours (are openings and closings excluded from time);
2. How many jurors the Court will empanel;
3. Number of challenges during jury selection;
4. Whether the parties may submit a short written questionnaire for the prospective jurors in advance of empanelment, or written questions for the Court to consider during voir dire;
5. Should the jury will be allowed to take notes and keep notebooks;
6. Whether the parties can give the jurors binders of admitted exhibits;
7. Whether the jurors may ask questions of the Court during the presentation of evidence;
8. Whether the parties can make changes to the demonstratives without changing substance;
9. The use of patent law experts to aid the jury's understanding of the US Patent Office;
10. If experts rely on deposition testimony from non-testifying witnesses, may that testimony be published to the jury;
11. If a party brings a witness live in their case, will that witness also be made available to the other side live in their case;
12. The order of trial including rebuttal evidence, and what constitutes rebuttal evidence;
13. The timing for submission and consideration of major *motions in limine*.

## II. SUMMARY JUDGMENT MOTIONS

Roche's positions in opposition to Amgen's summary judgment motions are set forth in its filed oppositions, and Roche will not burden the Court with recounting them here. Similarly, Roche's summary judgment motions and supporting materials contain a full and fair explanation of the issues and the Court has been provided with more than enough briefing on all the motions, so Roche respectfully encourages the Court to consider Roche's meritorious motions for summary judgment, but will not burden the Court repeating them here either. However, on two such motions important developments must be brought to the Court's attention. The Court should disregard Amgen's "summaries" of its motions as they do not fairly nor accurately recount the motions or the oppositions.

### A. **Recent Discovery of Withheld Key Documents Refuting Amgen's Motion for Summary Judgment on Roche's Antitrust and State Law Counterclaims**

Discovery has proven Roche's antitrust and tortious interference counterclaims *anything* but "wanting" (Amgen Inc.'s Memorandum at 3 ("Mem.")). The record demonstrates a blatantly anticompetitive Amgen scheme to blunt Mircera's adoption by securing long-term exclusive contracts, increasing penalties for switching to non-Amgen products, and threatening vulnerable customers with sanctions if they dare buy Roche's new product.<sup>3</sup> Contemporaneous documents candidly admit that Amgen's exclusionary conduct will keep prices *up* by impeding competition and will delay erosion of Amgen's monopoly profits. Indeed, documents *produced to Roche only late last week* confirm that Amgen's summary judgment argument that Fresenius sought a long-term exclusive contact is a cover story. Amgen told this Court that Fresenius, not Amgen, first

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<sup>3</sup> Roche's Memorandum in Opposition to Amgen's Motion for Summary Judgment on Roche's Antitrust and State Law Counterclaims (filed June 29, 2007, Docket No. 586) ("Roche Antitrust SJ Op.").

requested a five-year exclusive agreement in a May 22, 2006 letter.<sup>4</sup> Previously withheld documents from the files of Amgen's Leslie Mirani, the Amgen executive who threatened customers, shows this claim to be a fabrication. Those files contain an earlier Fresenius proposal that did *not* request exclusivity but has handwritten notations strongly suggesting that **Amgen** pushed back on Fresenius by seeking exclusivity.<sup>5</sup> The version of the proposal previously produced by Fresenius lacks the notations contained on the newly-produced version in Amgen's files.<sup>6</sup> Other newly-produced Mirani documents put the lie to Amgen's belatedly-raised argument that its long-term exclusive Fresenius agreement, which Fresenius documents and Amgen's expert admit keeps prices up, forecloses an insufficient 15% of an "all ESA market."<sup>7</sup> The withheld document identifies a "pro" of the "FMS Long-Term Contract" that "Amgen Locks up > \$1 Billion Annually in FMS Business from Competition (**Approx. 34% of US ESRD Market**)."<sup>8</sup> This newly-produced evidence thus alone warrants denial of Amgen's baseless summary judgment motion.

The evidence shows not only injury to competition and consumers, but also harm suffered by Roche. Amgen's anticompetitive conduct has *already* caused Roche substantial damages in the form of lost expected profits and – wholly ignored by Amgen – increased out-of-pocket costs, none of which turn on the date Roche begins to sell or the date Amgen terminates its unlawful conduct. The lost profit analysis is, in any event, amply supported by facts and reasonable

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<sup>4</sup> Memorandum of Law in Support of Amgen's Motion for Summary Judgment at 4 (filed June 14, 2007, Docket No. 519) & Ex. 31.

<sup>5</sup> See Supplemental Declaration of David Cousineau (filed July 16, 2007) Exs. 257 & 259.

<sup>6</sup> FMCNA 002474, Suppl. Cousineau Decl. Ex. 258.

<sup>7</sup> Reply Memorandum of Law in Support of Amgen's Motion for Summary Judgment at 1-2 (filed July 9, 2007, Docket No. 667).

<sup>8</sup> AM44 2024597, Suppl. Cousineau Decl. Ex. 260 (emphasis added).

assumptions that Amgen still cannot challenge.<sup>9</sup> Indeed, that Amgen now wants to *delay* resolution of the antitrust claims (Mem. at 11) reinforces Dr. Stiroh's lost profit assumption that Amgen's misconduct will not soon abate. Roche's antitrust and tortious interference counterclaims are meritorious, carry with them a jury trial right, and, for reasons explained herein, should be tried with the patent claims, which also must be tried to a jury.

**B. The Court's Claim Construction Decision Further Supports Roche's Non-Infringement Opposition to Amgen's Motion Relating to the Claims of the '933, '422 and '698 Patents.**

Amgen's motion for summary judgment of infringement of '422 Claim 1, '933 Claim 3, and '698 Claim 6 must fail. This Court's claim construction, issued after Roche served its opposition brief, indicated that the sequence of human erythropoietin should be interpreted in accordance with the understanding of one in skill in the art in 1983/1984. In this case, Figure 6 and Table 1 of the Lin patent were the only sources of sequence information at the time as to Lin's EPO. Those disclosures describe an amino acid sequence with 166 protein amino acid residues. Neither CERA nor epoetin beta have 166 amino acid residues of any type and neither has all of the fragment sequences from Table 1. The absence of a single amino acid residue is significant. CERA is the product of the chemical reaction between epoetin beta and an active polyethylene glycol reagent. CERA does not have these amino acid residues additionally because it contains at least a non-protein amino acid akin to, but vastly more complex than, N-acetyllysine which has been substituted for the protein amino acid lysine described in the Lin disclosure. Additionally, the Court construed a product of expression of the '933 patent to be a product "produced in a cell and recovered from the cell culture." The evidence is that CERA is the synthetic product of a chemical reaction between epoetin beta and an active polyethylene glycol reagent. As Amgen's

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<sup>9</sup> Roche's Memorandum in Opposition to Amgen's Motion to Exclude the Expert Testimony of Lauren J. Stiroh (filed July 12, 2007, Docket No. 556) ("Stiroh Exclusion Op.").

experts admit, cells cannot produce CERA and CERA cannot be recovered from a cell culture. Therefore, CERA does not infringe the '933 patent and it is not the product of the process claimed in the '698 patent. With respect to the process claims of the '698 patent, Roche's submissions in opposition demonstrate numerous genuine issues of material facts, including relating to 35 U.S.C. § 271(g), which preclude summary judgment.

### **III. A JURY MUST AND SHOULD DECIDE THE PATENT ISSUES EVEN ASIDE FROM ROCHE'S ANTITRUST AND OTHER COUNTERCLAIMS**

Roche has timely and properly demanded a trial by jury in this case under Fed. R. Civ. P. 38. This Court has also determined that the patent issues in this case will be tried to a jury. Amgen's arguments merely rehash statements rejected by the Court and do not constitute proper grounds for reconsideration. Amgen's argument that the patent holder's choice of remedy, whether damages or injunction, determines an accused infringer's constitutional right to a jury trial on its own claims of invalidity and non-infringement is incorrect, and is contrary to Federal Circuit precedent. Moreover, Amgen mischaracterizes its own position here. Amgen tries to argue that it has waived its claim for damages for Roche's alleged infringement of the patents in suit, but that is not accurate. According to Amgen, there is ongoing infringement, for which there are accruing damages. If Amgen seeks to waive damages to avoid a jury trial, it must do so for all such damages whether now or in the future. Since it will not do so (Amgen has expressly refused to do so under questioning from this Court), Roche is entitled to a jury trial on the patent claims. Amgen's purported selective, partial, temporary waiver to try to avoid a jury trial and circumvent Roche's Constitutional right to a jury has no basis in law. Lastly, the Supreme Court's recent decision in *Ebay Inc. v. Mercexchange, L.L.C.*, 126 S.Ct. 1837, 1841 (2006), which rejected the concept of automatic injunctions in patent cases and required findings on specific issues (such as the adequacy of money damages) further undermines Amgen's position.

Amgen erroneously relies on *Tegal Corp. v. Tokyo Electron America, Inc.*, 257 F.3d 1331, 1341 (Fed. Cir. 2001), but that case is inapposite. *Tegal* was the only time the Federal Circuit has ever held that an accused infringer had no jury trial right on issues of infringement and validity in a non-ANDA<sup>10</sup> patent case; there the accused infringer only pled non-infringement and invalidity as affirmative defenses to the patentee's claim of infringement and did not bring its own claims for declarations of non-infringement and invalidity. In contrast here, Roche has asserted counterclaims of invalidity, non-infringement and unenforceability. When the accused infringer brings claims for a declaration of non-infringement and invalidity, as Roche has done in the present case, the accused infringer has a clear right to a jury to determine its claims, regardless of the choice of remedies sought by the patentee.

The Federal Circuit's most complete discussion of the right to trial by jury in patent cases is *In re Lockwood*, 50 F.3d 966 (Fed. Cir. 1995), *vacated, reh'g granted, and reh'g in banc denied*, 50 F.3d 966 (Fed. Cir. 1995), *cert. granted sub nom. American Airlines, Inc. v. Lockwood*, 515 U.S. 1121, 115 S.Ct. 2274 (1995).<sup>11</sup> In *Lockwood*, the Federal Circuit held that a patentee has a right to a jury trial on the accused infringer's claims of invalidity and non-infringement even where the patentee's claim of infringement was previously dismissed from the case on summary judgment. Even with no extant claim for damages, the jury trial right was not extinguished where the party demanding the jury trial, in *Lockwood* the patentee, did everything it could to protect its

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<sup>10</sup> Abbreviated New Drug Application, see 35 U.S.C. § 271(e)(2).

<sup>11</sup> The Supreme Court granted *certiorari* in *Lockwood*, but after the grant of *cert.*, *Lockwood* withdrew his request for a jury trial. Since the issue was moot, the Supreme Court never reviewed it. The Federal Circuit "continued to rely on the 'relevant and detailed analysis' in *Lockwood*." *In re Tech Licensing Corp.*, 423 F.3d 1286, 1289 n.1 (Fed. Cir. 2005). Thus, *Lockwood* remains a key case in Federal Circuit analysis of the right to a jury trial.

Seventh Amendment right to a jury.<sup>12</sup> The Federal Circuit in *Lockwood* found that a claim for a declaration of invalidity by an accused infringer is by its nature a legal claim to which a right to a jury trial attaches, regardless of the remedy at stake for infringement. 50 F.3d at 976, 980.

In reaching its holding, the Federal Circuit in *Lockwood* first discussed the general framework for assessing Seventh Amendment claims, beginning with the language of the Seventh Amendment to the Constitution, which provides that “[i]n suits at common law . . . the right of trial by jury shall be preserved . . . .” The court noted however, that it is well settled “that the constitutional right to a jury trial extends beyond the bounds set by the common law forms of action existing at the time of the Amendment’s adoption.” 50 F.3d at 971, *quoting Curtis v. Loether*, 415 U.S. 189, 193 (1974). Thus, “any adjudication of a legal, as opposed to an equitable, right falls within the scope of the Amendment.” *Id.* at 972, *citing Tull v. United States*, 481 U.S. 412, 417 (1987). This analysis applies directly here since Roche has asserted counterclaims for invalidity, non-infringement and unenforceability. The *Lockwood* Court found in such circumstances that the accused infringer’s declaratory judgment claim of invalidity of the patents is the same as if brought as a counterclaim of invalidity in an infringement case, and parties to such a claim, such as Roche here, are entitled to a jury trial.

While *Lockwood* dealt with the right of a patentee to a jury trial on the accused infringer’s claim of invalidity, the Federal Circuit in *In re SGS-Thomson Microelectronics*, 1995 WL 258370 (Fed. Cir. 1995), *reh’g and reh’g in banc denied*, 61 F.3d 862 (Fed. Cir. 1995) faced the exact question presented in the present case, whether an accused infringer is entitled to a jury trial on its counterclaims of non-infringement and invalidity where the patentee does not seek damages as a

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<sup>12</sup> Roche has done everything to protect its right to a jury trial on its counterclaims of non-infringement and invalidity, including asserting the counterclaims of invalidity and non-infringement and timely demanding a jury trial.

remedy for its infringement claim.<sup>13</sup> Affirming the principles and reasoning of *Lockwood*, the Federal Circuit held that when, as here, in a case of infringement where plaintiff patentee seeks only injunctive relief, the accused infringer is entitled to a jury trial on its counterclaims of non-infringement and invalidity. The court made clear that the decision in *Lockwood* was based “on the legal nature of the [accused infringer’s] declaratory judgment action, not the nature of the patentee’s claim.” Accordingly, the court concluded that *SGS-Thomson* was entitled to a jury trial based on the legal nature of its invalidity and non-infringement counterclaims. *Id.* Likewise, in the present case, Roche has asserted counterclaims of non-infringement and invalidity of the patents-in-suit.<sup>14</sup> Roche has a right to a jury on the patent issues where it has brought its own claims for invalidity and non-infringement. Roche has brought claims to which a jury trial attaches, has perfected its right to a jury by timely demanding a jury pursuant to Fed. R. Civ. P. 38(b), and cannot be denied its Seventh Amendment right based on Amgen’s game-playing with the remedies it seeks.

The other case principally relied on by Amgen, *In re Technology Licensing Corp.*, 423 F.3d 1286, 1291 (Fed. Cir. 2005), also supports Roche’s position. In *Technology Licensing* the Court found persuasive the fact that the patentee had waived its claims for monetary damages after the quantum of potential damages had been reduced by the Court. The Federal Circuit found that since the patentee had waived its right to have the patent issues decided by a jury by voluntarily dismissing and waiving its claim for damages on its infringement claim it has no right to a jury. 423 F.3d at 1289-90. Here, Amgen has made no such damages waiver. If Amgen states that it is

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<sup>13</sup> The Federal Circuit’s decision in *SGS-Thomson* is unpublished, and thus not binding precedent; however, its holding flows from the *Lockwood* reasoning, is consistent with the Federal Circuit’s holdings regarding jury trial rights, and is indicative of the Federal Circuit’s likely holding if this precise question were presented to it.

<sup>14</sup> Defendants’ First Amended Answer and Counterclaims to Plaintiff’s Complaint, March 30, 2007, Docket No. 344, Count X - Declaratory Judgment of Patent Invalidity and Count XI - Declaratory Judgment of Non-Infringement.

waiving any claim to past or future damages, even should the Court determine under *Ebay* that following the Supreme Court's holding no injunction is warranted here, then perhaps Amgen might be denied a jury trial right if it asserted one. But there is no question that Amgen has refused to waive damages for infringement and is clearly planning on seeking damages on future sales should Amgen be successful on the claims in this case. These facts render the holding in *Technology Licensing* inapplicable.

Most telling in *Technology Licensing*, after the district court entered an order significantly reducing the amount of potential damages the patentee might recover were infringement found, the patentee waived its right to damages. “In this case, by contrast, the patentee has **voluntarily abandoned its claim for damages** and is proceeding only on a request for equitable relief.” *Id.* (emphasis added). There is no discussion in this case of a partial, or selective waiver of damages that Amgen strains to create here. Amgen has not abandoned its claims for damages, and cannot game the system to avoid a jury and trample on Roche's properly protected right to a jury.<sup>15</sup>

Critically, in none of these cases does a party lose a Seventh Amendment jury trial right, nor is otherwise denied the right to a jury, based on what the adverse party does. When the court has found no right to a jury, it was because the patentee demanding the jury voluntarily abandoned its damages claim, or the accused infringer did not bring its own claims of invalidity and non-

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<sup>15</sup> The other two cases cited by Amgen for their assertion that an accused infringer is not entitled to a jury trial where the patentee seeks only injunctive relief are not relevant here as they are cases involving generic drug manufacturers sued by patent holders in Abbreviated New Drug Application (ANDA) cases premised on an artificial act of infringement under 35 U.S.C. § 271(e)(2) which do not involve a right to a jury trial in any case. See *In re Apotex, Inc.*, 49 Fed. Appx. 902, 2002 U.S. App. LEXIS 23101 and *Bayer AG v. Schein Pharm. Inc.*, 2000 U.S. Dist. LEXIS 20718 (D.N.J.). In addition, *Apotex* is an unpublished, non-precedential decision that reaches its conclusions without detailed discussion, and *Bayer AG* does not even involve the issue if when a jury trial right exists, but rather goes to timing of striking a jury demand in cases which concededly do not give a jury trial right. *Apotex*, 49 Fed. Appx. at 902; *Bayer AG*, 2000 U.S. Dist. LEXIS at \*4-6.

infringement. *Technology Licensing*, 423 F.3d at 1291; *Tegal*, 257 F.3d at 1341.<sup>16</sup> Neither applies here.

Amgen has made it clear that unlike the patentee in *Technology Licensing*, Amgen is not abandoning or waiving its claims for damages from Roche.<sup>17</sup> In *Ebay*, the Supreme Court held that injunctions in patent cases are not automatic and the Court must conduct a searching inquiry that requires applying a multi-factor test. Since there is a serious question as to Amgen's so-called entitlement to equitable relief, the prospect of denying Roche its constitutionally mandated right to a jury on patent issues must be even more scrupulously protected by this Court. One of the *Ebay* factors is the adequacy of money damages. *Id.* The result Amgen seeks by gamesmanship is a result that is clearly inconsistent with the Seventh Amendment jury trial guarantee. Amgen's gambit would be an invitation to all patentees that abhor juries to circumvent the Constitution by improperly simply delaying seeking future damages and claiming an automatic injunctive right. Such a simple work-around to frustrate a fundamental constitutional right cannot be countenanced by those respectful of the power of the Seventh Amendment and the jury system. There is no harm if the case proceeds to trial by jury and the Court or Federal Circuit later assesses and on grounds disagrees with the jury's findings. Rather, wrongly denying Roche a jury would to this Court or the Federal Circuit lead inexorably to a retrial of the case. *See Zeneca Ltd. v. Pharmachemie B.V.*, 1998 WL 1013126 \*1 (D. Mass. 1998) (Collings, M.J.) (in denying motion

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<sup>16</sup> After finding that the patentee had no right to a jury trial after voluntarily abandoning its claim for damages, the Court in *In re Technology Licensing* in *dicta* incorrectly simplifies the test and holding from *Lockwood* and misapplies the *Lockwood* Court's rationale on the accused infringer's right to a jury trial on its claims of non-infringement and invalidity not depending on the patentee's choice of remedy.

<sup>17</sup> In Plaintiff's Response to First Set of Interrogatories (Nos. 1-12), January 9, 2007, Amgen stated that, "If damages accrue in this action prior to trial and decision in this actions, Amgen may or may not seek damages in this action or in a separate action. Based upon discovery of Roche's action provided to date, Amgen states that it is not seeking monetary damages for any past acts, but Amgen is not forfeiting its right to a claim for future damages based on future infringing acts of Roche and does not contend that it will never seek such a claim."

to strike accused infringer's jury demand where patentee only sought injunctive relief, court noted that "proceeding with a protracted non-jury trial runs the risk that if the right to a jury trial is sustained on appeal, the whole case would have to be retried.").

#### **IV. ROCHE'S ANTITRUST AND STATE LAW COUNTERCLAIMS REQUIRE A JURY TRIAL ON ALL ISSUES**

Even putting aside that Amgen is incorrect regarding Roche's jury trial right on Roche's counterclaims of invalidity and non-infringement, Roche's antitrust and state law counterclaims require a jury trial on the patent issues. Amgen's arguments for stripping Roche of its Seventh Amendment-guaranteed jury trial right and phasing the case to suit Amgen's preferences are groundless. This Court on March 30 ruled that Roche's jury antitrust claims "insure" a jury trial on the patent issues. Amgen's suggestion of bifurcated bench and jury trials falls with Amgen's flawed argument for ignoring the Seventh Amendment. Last, a single jury trial of both patent and antitrust issues will best promote efficiency and avoid prejudice; at a minimum, the same jury should hear both the patent and antitrust issues.

##### **A. The Seventh Amendment Mandates a Jury Trial on the Patent Issues and Roche's Antitrust and Tortious Interference Counterclaims**

This Court correctly held in its March 30, 2007 Order that Roche's "antitrust claims," "as long as they remain in the case," "*insure*" that "the patent issues (e.g., anticipation, infringement) will be tried to a jury."<sup>18</sup> In inviting the Court to revisit this ruling and hold a patent bench trial that will *bind* a later jury trial, Amgen proposes a clear violation of Roche's Seventh Amendment jury trial right. The Court got it right the first time. Because Roche's antitrust and tortious interference counterclaims ("Antitrust Counterclaims") for damages on the one hand, and the patent issues (invalidity, infringement, and enforceability) on the other, share numerous common

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<sup>18</sup> Memorandum and Order at 17 (Mar. 30, 2007, Docket No. 342) (emphasis added). Roche hereby incorporates by reference is Memorandum in Opposition to Amgen's Motion to Bifurcate (filed Dec. 18, 2006, Docket No. 184).

issues, the patent issues cannot constitutionally be tried first to the Court and the Antitrust Counterclaims later to a jury.

Amgen admits that when legal and equitable claims share “common issues” “a jury trial right” “extends to an equitable issue” (Mem. at 9). Amgen nonetheless insists there are no such common issues here. Amgen is wrong. Indeed, Amgen’s very argument (Mem. at 11, 14) that finding in its favor on the patent issues (invalidity, infringement, enforceability) would *require* termination of Roche’s Antitrust Counterclaims demonstrates common issues. If “issues” involved were *not* “common,” *how* could a resolution in Amgen’s favor on the patent issues also resolve Roche’s Antitrust Counterclaims? The common issues that require jury trials on both the patent and Antitrust Counterclaim issues are thus readily identified in Amgen’s own papers.<sup>19</sup>

Amgen thus resorts to alchemy, contending that the common issues it identifies reflect a mere “overlap” of “facts” or “issues” rather than common “legal issues” (Mem. at 9). Amgen’s premise that the ultimate “legal issues” must be common to trigger the Seventh Amendment is baseless. Common Seventh Amendment issues include not only ultimate legal issues, but also “*factual issues*.” *E.g., C.R. Bard, Inc. v. M3 Sys., Inc.*, 1994 WL 258889, at \*2 (N.D. Ill. June 9, 1994) (requiring trial to jury of inequitable conduct defense because it would resolve “factual questions that must also be determined” by jury for invalidity); *see also Cabinet Vision v. Cabinetware*, 129 F.3d 595, 600 (Fed. Cir. 1997) (explaining that “[w]e have long recognized that a *Walker Process* counterclaim and an affirmative defense of inequitable conduct share common

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<sup>19</sup> Whether Amgen engaged in inequitable conduct is common both to that patent defense and Roche’s *Walker Process* claim. Indeed, Amgen recognizes (Mem. at 13-14), if Roche demonstrates no inequitable conduct, then it cannot prevail on its *Walker Process* claim. Similarly, Amgen asserts that whether its patents are valid and infringed are issues common to Roche’s other Counterclaims, because (Amgen says) those claims presuppose that “Roche may freely import and sell its accused product in the United States” (Mem. at 2). Indeed, Amgen contends that Roche’s *antitrust* case *requires* determining if Amgen has “legitimate exclusionary power conferred by . . . *valid and enforceable patents*” (Mem. at 9) (emphasis added).

factual elements” for Seventh Amendment purposes); *Therma-Tru Corp. v. Peachtree Doors Inc.*, 44 F.3d 988, 994-95 (Fed. Cir. 1995) (citing cases from numerous circuits and recognizing that *Beacon Theatres, Inc. v. Westover*, 359 U.S. 500 (1959), applies when “equitable claims are joined with legal claims and **have factual questions in common**” (emphasis added)). Indeed, a case Amgen cites makes this very point. *See Avco Corp. v. PPG Indus., Inc.*, 867 F. Supp. 84, 98 (D. Mass. 1994) (Young, J.).

Accordingly, courts – including one Amgen cites – recognize that when, as here, patent issues can decide antitrust and related counterclaims, the Seventh Amendment is complied with **only** if juries hear **both** patent and antitrust issues. *See In re Innotron Diagnostics*, 800 F.2d 1077, 1085-86 (Fed. Cir. 1986) (Seventh Amendment satisfied because juries would hear both antitrust claims and patent claims, where “most of the facts and issues are “overwhelmingly intertwined with and overlapping with those in [the] antitrust counterclaims,” and where the antitrust claims turned on prevailing on patent defenses); *Implant Innovations, Inc. v. Nobelpharma AB*, 1996 WL 568791, at \*3 (N.D. Ill. Oct. 2, 1996) (holding that “in order to preserve [the] Seventh Amendment jury trial guarantee the Court finds that the inequitable conduct issue must be tried by a jury” because that issue “overlaps with the antitrust claim” (citing both *Innotron* and *United States Gypsum Co. v. Nat’l Gypsum Co.* 1994 WL 74989 (N.D. Ill. Mar. 10, 1994), both cited by Amgen)); *C.R. Bard*, 1994 WL 258889, at \*2 (*Beacon Theaters* required jury trial of inequitable conduct defense because that phase would resolve “factual questions that must also be determined” by jury for validity); *see also Cabinet Vision*, 129 F.3d at 599-600.

The cases Amgen advances in support of its contrary unconstitutional suggestion (Mem. at 12-15) that the Court hold a patent bench trial to narrow a later jury antitrust trial actually undermine Amgen’s argument. *Hewlett-Packard Co. v. Genrad, Inc.*, 882 F. Supp. 1141 (D.

Mass. 1995) (Bowler, M.J.), and *Innotron* did *not* bifurcate later antitrust jury trials from prior patent bench trials. Rather, those cases bifurcated patent *jury* trials from antitrust *jury* trials, a practice that can protect the Seventh Amendment right if the issues are genuinely separable. *Innotron*, 800 F.2d at 1085-86; *Ventrex Labs., Inc. v. AB Fortia*, 223 U.S.P.Q. 897, 899 (D. Me. 1983); *see also Castano v. Am. Tobacco Co.*, 84 F.3d 734, 750-51 (5th Cir. 1996). Moreover, contrary to what Amgen argues, *Beacon Theatres* and *Dairy Queen, Inc. v. Wood*, 369 U.S. 469 (1962), do not confer discretion to ignore Roche’s Seventh Amendment right because a prior patent bench trial will establish law of the case for a subsequent antitrust jury trial. It is precisely because the patent issues can decide the Antitrust Counterclaims that the Seventh Amendment requires a jury trial for both. *See Implant Innovations*, 1996 WL 568791, at \*3.

*Parklane Hoisery Co. v. Shore*, 439 U.S. 332 (1979), cited by Amgen, makes this very point and defeats Amgen’s argument. It is one thing to find collateral estoppel when a *prior* equitable “action” decides factual issues relevant to a separate, later jury action. *Id.* at 333-34. It is quite another, and as *Parklane* explains impermissible, to order the trial of legal and equitable claims joined in the *same action* – the circumstances presented here – to vitiate the jury trial right on the legal claims. *Id.*<sup>20</sup> As this Court recently stressed: “Maintenance of the jury . . . is of such importance and occupies such a place in our history and jurisprudence that any seeming curtailment of the right to a jury trial should be scrutinized with the utmost care.” *Mass. Eye & Ear Infirmary v. QLT, Inc.*, No. 00-10783-WGY, Slip Op. at 17 (D. Mass. July 10, 2007) (Young, J.). The radical curtailment of the jury trial right Amgen proposes is entirely without basis.

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<sup>20</sup> *Johns Hopkins Univ. v. Cellpro*, 1997 U.S. LEXIS 24161 (D. Del. July 24, 1997), is inapposite because the parties *consented* to a bench trial on inequitable conduct and only after an adverse decision did the antitrust plaintiff raise a Seventh Amendment challenge, *see id.* at \*10-11. *Agfa Corp. v. Creo Prods., Inc.*, 451 F.3d 1366 (Fed. Cir. 2006), also cited by Amgen, did not involve, as this case does, common issues between antitrust counterclaims and validity and infringement. Rather, *Agfa* held that on the facts before it, inequitable conduct and invalidity did not present common issues. *See id.* at 1372.

Amgen also suggests that Roche lacks a jury trial right because (i) summary judgment should terminate Roche's Antitrust Counterclaims; (ii) because Roche damages' expert should be excluded; and/or (iii) Roche, having no "present right or ability" to sell Mircera in the U.S., lacks standing to seek damages. Each is meritless for reasons Roche explains in its Oppositions.<sup>21</sup> Two points merit further emphasis. First, Amgen's effort to exclude Roche's lost profits study -- a study grounded in reasonable, well-supported facts and assumptions Amgen cannot contradict -- in no way affects Roche's jury trial right. For Roche also seeks out-of-pocket damages (increased expenses; legal fees) for Amgen's antitrust and tortious interference violations, damages Amgen itself argues require no expert testimony.<sup>22</sup> Second, as this Court recognized in its March 30 Order, present ability to sell is not required for damages standing, provided Roche meets the intent and preparedness test. *See Amtrol, Inc. v. Vent-Rite Valve Corp.*, 646 F. Supp. 1168, 1176-78 (D. Mass. 1986) (Young, J.). As this Court also held, Roche meets this test because, if FDA-approval and Mircera's entry are sufficiently imminent for Amgen's patent claims, they are sufficiently imminent for Roche's Antitrust Counterclaims. "Amgen cannot have it both ways." Mem. and Order at 9 (Mar. 30, 2007, Docket No. 342).

Accordingly, the issue of whether preserving Roche's jury trial right on its Antitrust Counterclaims requires a jury trial on the patent issues is not a close one; a jury is required. But if the issue were close, the Court should err on the side of employing a jury because "striking the jury demand and proceeding with a protracted non-jury trial runs the considerable risk that if the

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<sup>21</sup> *See Roche Antitrust SJ Op.*; *Stiroh Exclusion Op.* Roche incorporates by reference its prior submissions on standing. *See, e.g., Defendants' Sur-reply to Amgen's Reply in Support of Amgen's Motion to Dismiss* (filed Dec. 27, 2006, Docket No. 198).

<sup>22</sup> Amgen cannot contest that the Seventh Amendment applies to Roche's tortious interference claim, *see Germain v. Conn. Nat'l Bank*, 988 F.2d 1323, 1328 (2d Cir. 1993) ("claims analogous to tortious interference were historically tried in common law courts"), or that the jury could award nominal damages, *see USFL v. NFL*, 887 F.2d 408, 411-12 (2d Cir. 1989); *cf. Romano v. U-Haul Int'l*, 233 F.3d 655, 671 (1st Cir. 2000).

right to a jury trial is sustained on appeal, the whole case would have to be retried. On the other hand, if it were determined that a right to a jury trial does not exist, all that would need to be done is for the Court, on the basis of the trial record which was presented to the jury, to make findings of fact and conclusions of law. The case would not need to be retried.” *Zeneca Ltd. v. Pharmachemie B.V.*, 1998 WL 1013126, at \*1 (D. Mass. Oct. 8, 1998) (Collings, M.J.).<sup>23</sup>

**B. A Single Trial of Patent, Antitrust, and Related Issues Before the Same Jury Best Serves Rule 42(b)’s Objectives**

Accordingly, to uphold the Seventh Amendment, a jury must determine not only Roche’s antitrust and tortious interference counterclaims, but also the patent issues (invalidity, infringement, enforceability). A single trial of these issues before the same jury is most “conducive to expedition and economy.” Fed. R. Civ. P. 42(b). Courts do not, as Amgen insists, routinely order separate trial of patent issues and antitrust counterclaims. *See, e.g., Synopsys, Inc. v. Magma Design Automation*, 2006 WL 1452803, at \*4 (D. Del. May 25, 2006) (denying motion to bifurcate patent and antitrust issues); *Climax Molybdenum Co. v. Molychem, L.L.C.*, 414 F. Supp. 2d 1007, 1014 (D. Colo. 2005) (same) (*citing In re Theodor Groz & Sohne*, 972 F.2d 1352, 1992 WL 188908, at\*2 (Fed. Cir. 1992) (unpublished)); *see also ACS Commc’ns, Inc. v. Plantronics, Inc.*, 1995 WL 743726, at \*2 (N.D. Cal. Dec. 1, 1995) (same). The Court should follow these decisions and hold a single trial here. Amgen’s inequitable conduct and *Walker Process* claims are, Amgen admits, intertwined. But as courts denying bifurcation have reasoned,

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<sup>23</sup> *See also Lytle v. Household Mfg., Inc.*, 494 U.S. 545, 550-56 (1990) (where a court “erroneously dismiss[es] the legal claim” and then resolves the equitable claim, **both** claims must be retried because “issues common to both claims” must be “resolved by a jury”); *Colorado Visionary Acad. v. Medtronic, Inc.*, 397 F.3d 867, 874-76 (10th Cir. 2005) (summary judgment on legal claim reversed; new trial on equitable claim ordered); *cf. Ferrara & DiMercurio, Inc. v. St. Paul Mercury Ins. Co.*, 169 F.3d 43, 56 n.21 (1st Cir. 1999) (“in doubtful cases, allowing the case to go to the jury rather than granting a motion for judgment as a matter of law ‘is often a wise and time-sharing precaution’”).

if Roche demonstrates inequitable conduct in a separate patent phase, such a victory will not establish the more demanding *Walker Process* predicates (*i.e.*, fraud, causation), and the jury would have to hear the *same* evidence and witnesses again. *See Climax*, 414 F. Supp. 2d at 1014. “Thus, were the court to bifurcate, evidentiary presentation in one case would likely be substantially duplicative of the evidentiary presentation in the other.” *Synopsisys*, 2006 WL 1452803, at \*4; *Climax*, 414 F. Supp. 2d at 1014. Accordingly, “a single trial of the patent and antitrust issues would promote the objectives of efficiency and fairness.” 414 F. Supp. 2d at 1014.

Moreover, regardless of how the Court staggers or phases the issues to be tried, a single jury should hear all the issues. Amgen’s antitrust claims on the one hand, and validity and infringement on the other, will both require jurors to acquire background on the products, the diseases they treat, the same underlying technology, and their mechanisms of action. This militates in favor of a single jury to avoid educating different jurors “in the same relevant technology” twice. *Synopsisys*, 2006 WL 1452803, at \*4. Indeed, as another Court in this district observed: “Educating two separate juries on the complexities of [the relevant] technology would be duplicative and would prove far more taxing for the litigants and the court than conducting a single, albeit longer, jury trial.” *Abbott Labs. v. Selfcare, Inc.*, 2000 U.S. Dist. LEXIS 15263, at \*5 (D. Mass. Sept. 29, 2000). Moreover, as explained, requiring litigation of related inequitable conduct and *Walker Process* issues before separate juries is wasteful and duplicative.

Amgen can claim no prejudice from a single trial before a single jury.<sup>24</sup> Accordingly,

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<sup>24</sup> Amgen’s cases involve circumstances, absent here, where the patent claims were ready for trial first, *see Innotron*, 800 F.2d at 1085 (separate trials when patent case “will be ready for trial more than a year before the antitrust issues can be made ready”); *Ventrex Labs., Inc. v. AB Fortia*, 223 U.S.P.Q. 897, 898-99 (D. Me. 1983) (similar); *Brandt, Inc. v. Crane*, 97 F.R.D. 707, 708 (N.D. Ill. 1983) (“the parties will be prepared to try the patent issues before discovery on the antitrust issues are complete”), or the patent issues were “less complex,” *Genrad*, 882 F. Supp. at 1157. Here, the complexity of the patent issues far outdistances the incremental issues added by the Counterclaims.

“bifurcation of the antitrust claims from the infringement claims is [not] necessary to prevent jury confusion.” *Synopsys*, 2006 WL 1452803 at \*4. “[J]urors are quite adept at comprehending and adhering to the instructions they are given, even in the most complex factual and legal scenarios.” *Id.* Amgen’s protestations of prejudice simply reflect an aversion to the American jury system. By contrast, every additional day Roche remains subject to Amgen’s anticompetitive conduct harms Roche, competition, and consumers.

In its brief, Amgen also urges the Court to abandon its preferred practice of hearing validity evidence first and then infringement. As this Court has stated before, this staging of the evidence minimizes any prejudice created by the presumption of validity accorded patents and is logical and efficient because the validity of a patent is a predicate for infringement liability. Moreover the cases cited by Amgen are inapposite. E.g., *Ditto Inc. v. Minnesota Mining & Manuf. Co.*, 336 F.2d 67, 69 (8th Cir. 1964) (“The validity question is of greater public importance than the infringement issue and it is usually the better practice to first consider the validity issue.”); 26 Fed Proc., L. Ed. § 60:1131 (2006). Amgen has presented no legitimate basis for the Court to deviate from its practice here.

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Respectfully submitted,

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### **CERTIFICATE OF SERVICE**

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