**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

| | |
|---|---|
| AMGEN INC.,<br><br>Plaintiff,<br><br>v.<br><br>F. HOFFMANN-LA ROCHE LTD, a Swiss Company, ROCHE DIAGNOSTICS GMBH, a German Company, and HOFFMANN LA ROCHE INC., a New Jersey Corporation,<br><br>Defendants. | Civil Action No.: 1:05-cv-12237 WGY |

**AMGEN INC'S MEMORANDUM FOR**
**JULY 17, 2007 CASE MANAGEMENT CONFERENCE**

## I. INTRODUCTION

Amgen, Inc. ("Amgen") respectfully submits that there are three important objectives for the July 17, 2007 Case Management Conference:

(i) To define and limit the issues requiring trial;

(ii) To decide, in light of the issues requiring trial, the proper roles of the Court and jury, and

(iii) To determine the most efficient, judicious manner in which to stage the trial of this dispute.

As discussed at the previous Case Management Conference on June 6, 2007, Roche has raised numerous arguments and defenses, most with very little legal or factual bases for presenting them at trial. And the list of Roche's arguments keeps growing. In the past week, for example, Roche has attempted to expand once again its inequitable conduct allegations to add new arguments not previously pleaded and to present new theories and expert opinions on double patenting. Amgen urges the court to reject Roche's attempts to continually expand the issues in

this case beyond those for which Roche timely met its pleading and disclosure obligations.

Amgen has filed Summary Judgment Motions on five issues that are ripe for this Court to decide in advance of trial: antitrust, inequitable conduct, double patenting, infringement of certain claims, and indefiniteness. Resolving these issues on motions would greatly aid the parties and the Court in focusing the trial on the factual points truly in dispute.

As to the trial itself, Amgen submits that in order to efficiently and fairly differentiate the respective burdens of the parties and order the presentation of evidence on the various issues for trial, the trial should be conducted in stages, with the patent case proceeding first followed by the antitrust case, if any. To the extent that Roche's antitrust claims survive summary judgment, they are predicated on the assumption that Roche will successfully defend Amgen's patent infringement claims, and that Roche may freely import and sell its accused product in the United States. Whether Roche infringes Amgen's patents should therefore be decided ***before*** Roche's antitrust counterclaims are presented. Not only would it be terribly inefficient for the parties to present an antitrust case without a decision first on the patent case, but it could be prejudicial to Amgen's patent case for a fact-finder to hear Roche's inflammatory and unsubstantiated antitrust claims when the premise on which those claims are based –unenforceable patents – has not been first established. For these reasons, Amgen submits that the trials of the patent and antitrust cases should be bifurcated, and that the trial of the patent case should precede the trial, if any, of the antitrust case.

The question of what role, if any, a jury should play in this case remains to be determined. The relief Amgen seeks on its claims of patent infringement is entirely equitable in nature. Consequently, the Court – not a jury – must ultimately decide Amgen's claims of infringement and Roche's defenses of patent invalidity and unenforceability. *Tegal Corp. v.*

*Tokyo Election America*, 257 F.3d 1331 (Fed. Cir. 2001). In light of the number and complexity of defenses raised by Roche in response to Amgen's infringement claims, Amgen submits that – irrespective of the Court's decision of Amgen's pending motion for summary judgment on Roche's antitrust counterclaims – it would be overly confusing and exceedingly inefficient to empanel an advisory jury to hear the patent issues.

Finally, in the trial of the patent case, the Court indicated that it might consider re-ordering the presentation of proof to allow defendants to present their defenses of invalidity of Amgen's patents before Amgen presents its claims of infringement. With the utmost respect, Amgen submits that such a procedure should be available only in the context of a non-jury trial, where the Court can be trusted to maintain the correct identity and respective burdens of the litigants at the forefront of its decision-making. In the context of a jury trial, a trial which begins with a defendant's presentation of its defenses to liability runs a very grave risk of juror confusion and prejudice over the respective identities and evidentiary burdens of the parties, and would effectively result in an unwarranted reversal of the roles of plaintiff and defendant and the statutory presumptions and burdens that attach to those roles. At a minimum, if the Court intends to allow the defendant to present its validity challenges prior to infringement, the patent owner and plaintiff should be allowed to open the case by first presenting a description of its patents, the inventions they claim, the relevant technology and the claimed advances of the patent over the prior art.

## II. SUMMARY JUDGMENT MOTIONS

### A. AMGEN'S MOTION FOR SUMMARY JUDGMENT DISMISSING ROCHE'S ANTITRUST COUNTERCLAIMS (D.I. 519)

While Roche's antitrust counterclaims survived a motion to dismiss, the Court indicated at the time that Roche's claims "appear somewhat wanting." With the failure of the FDA to

approve Roche's product for sale in the U.S. in May, coupled with discovery of Roche's allegations, the undisputed facts show that Roche's antitrust claims are, indeed, completely wanting and lacking any merit. Accordingly, Amgen has moved for summary judgment to dismiss Roche's antitrust counterclaims. In addition, Amgen has filed a Motion to Exclude the Testimony of Roche's Damages Expert Lauren Stiroh. Although Roche cannot sell its product in the United States and does not expect to begin doing so until months after the trial, Stiroh predicts that Roche will suffer $300 million in "damages" ***after*** Roche enters the market, based on two assumptions provided by Roche's lawyers: (1) that Amgen would continue to violate the antitrust laws (even after a jury has presumably found against it) and (2) that the Court would not promptly enjoin such unlawful activity.

Such unsubstantiated claims for damages should not survive summary judgment. If the Court grants Amgen's motion and dismisses Roche's antitrust counterclaims, the trial will be limited to Amgen's infringement claims and Roche's defenses.

**B. AMGEN'S MOTION FOR SUMMARY JUDGMENT OF NO INEQUITABLE CONDUCT (D.I. 545)**

Roche's First Amended Answer and Counterclaims allege three instances of inequitable conduct. Amgen has moved for summary judgment that Roche cannot establish any wrongful conduct in its actions before the PTO. This Court has heard the best of the inequitable conduct allegations before and rejected them. The "new" allegations are based solely on Roche's contortions of the record and are plainly rebutted by a clear reading of the prosecution history. In addition to failing to show the lack of disclosure or the misstatement of any material information, Roche utterly fails to come forward with any evidence of intent to mislead the PTO. This failure is dispositive, not only of the inequitable conduct claim but also Roche's *Walker Process* claim which requires an even higher standard – that of fraud on the PTO.

### C. AMGEN'S MOTION FOR SUMMARY JUDGMENT OF NO OBVIOUSNESS-TYPE DOUBLE PATENTING (D.I. 499)

Because obviousness type double patenting ("ODP") is a question of law for resolution by the Court, Amgen has moved for summary judgment on Roche's defense. The Court can and should delimit the issues for trial by deciding, as a matter of law, that the safe harbor provision of 35 U.S.C. § 121 immunizes the asserted claims of the '933, '349, and '422 patents from ODP over the claims of the '008 patent. Similarly, the Court should decide the appropriate legal test – the "one-way" or "two-way" test - and that under either test, the claims of the patents-in-suit are patentably distinct over Claim 10 of the Lai/Strickland '016 patent.

### D. AMGEN'S MOTION FOR SUMMARY JUDGMENT OF INFRINGEMENT OF '422 CLAIM 1, '933 CLAIM 3, AND '698 CLAIM 6 (D.I. 510)

Amgen seeks summary judgment that Roche's importation, use or sale of peg-EPO in the U.S. will literally infringe claim 1 of the '422 patent, claim 3 of the '933 patent, and claim 6 of the '698 patent. The relevant inquiry is whether each of the claim limitations is present in Roche's accused product. There is and can be no genuine issue of material fact regarding the composition and identity of Roche's accused product or the process by which peg-EPO is produced in Germany. The only dispute is purely a legal dispute over the Court's construction of the relevant claim terms and the statutory test for infringement under 35 U.S.C. § 271(g) for imported products made by a process patented in the United States.

### E. AMGEN'S MOTION FOR SUMMARY JUDGMENT THAT LIN'S '933 AND '349 CLAIMS ARE DEFINITE (D.I. 532)

Amgen and Roche both agree that there are no genuine issues of material fact regarding Amgen's motion for summary judgment that Lin's asserted 933, '422 and '349 claims are definite, and that the issue of definiteness under 35 U.S.C. § 112 presents a question of law for the Court's decision.

## III. THE COURT, AND NOT A JURY, MUST DECIDE THE PATENT CASE

### A. THERE IS NO RIGHT TO A TRIAL BY JURY ON THE PATENT CASE

#### 1. The Right To A Trial By Jury Is Limited To Issues "Triable of Right"

Federal Rule of Civil Procedure 38(b) limits the right to a trial by jury to issues that are *triable of right*:

> Any party may demand a trial by jury of any ***issue triable of right*** by a jury by (1) serving upon the other parties a demand therefor in writing at any time after the commencement of the action and not later than 10 days after the service of the last pleading directed to the issue, and (2) filing the demand as required by Rule 5(d). Such demand may be indorsed upon a pleading of the party. Fed. R. Civ. P. 38(b). Fed. R. Civ. P. 38(b) (emphasis added)

Rule 39(a)(2) further prescribes that where the Constitution or statutes of the United States do not grant a right to a jury trial, this Court must so find and enforce that limitation:

> When trial by jury has been demanded as provided in Rule 38, the action shall be designated upon the docket as a jury action. ***The trial of all issues so demanded shall be by jury, unless*** (1) the parties or their attorneys of record, by written stipulation filed with the court or by an oral stipulation made in open court and entered in the record, consent to trial by the court sitting without a jury or (2) ***the court upon motion or of its own initiative finds that a right of trial by jury of some or all of those issues does not exist under the Constitution or statutes of the United States.*** Fed. R. Civ. P. 39(a) (emphasis added).

Under Rule 39(c), when issues are not triable to a jury by right, the Court can order a binding jury trial on such issues only with the consent of both parties:

> ***In all actions not triable of right by a jury*** the court upon motion or of its own initiative may try any issue with an advisory jury or, except in actions against the United States when a statute of the United States provides for trial without a jury, the court, ***with the consent of both parties, may order a trial with a jury*** whose verdict has the same effect as if trial by jury had been a matter of right. Fed. R. Civ. P. 39(c)

Amgen has not consented to try the patent issues to a jury.

#### 2. Because Amgen's Patent Claims Seek Equitable Relief, There is No Right to a Trial by Jury of the Patent Case

It is well settled that the Seventh Amendment right to a jury trial is restricted to suits "at

common law" and does not extend to suits in equity. *Chauffeurs, Teamsters and Helpers, Local No. 391 v. Terry*, 494 U.S. 558, 564-65 (1990). Thus, here, where Amgen has brought claims seeking to enjoin future infringement of its patents, Roche is not entitled to a jury trial on these claims. *See e.g., Tegal Corp. v. Tokyo Election America*, 257 F. 3d 1331 (Fed. Cir. 2001) (affirming denial of a jury trial in context of a claim for infringement seeking an injunction and no damages); *In re Tech Licensing Corp.*, 423 F.3d 1286, 1287 (Fed. Cir. 2005) (denying writ of mandamus and holding no right to a jury trial as to either infringement or validity claims where plaintiff only sought an equitable remedy)*; Bayer A.G. v. Schein Pharm. Inc.*, 2000 U.S. Dist. LEXIS 20718 (D.N.J. Feb. 28, 2000) (no right to a jury trial in cases seeking to enjoin future infringement); *In re Apotex, Inc.*, 2002 U.S. App. Lexis 23101 (Fed. Cir. 2002) (unpublished) (where only future infringement was at issue, no right to a jury trial, because the only relief before the district court was equitable in nature).

In *Tegal*, a patentee sued for infringement seeking damages and an injunction, and demanded a jury trial. The defendant asserted affirmative defenses, but did not file a counterclaim. The patentee then dropped its demand for damages and the judge ordered a bench trial, denying the defendant's motion for trial by jury. The Federal Circuit affirmed the denial of the jury trial because the nature of the remedy sought is more important than the nature of the action, and in *Tegal*, the patentee was only seeking an injunction, not damages.

*In re Tech Licensing Corp.*, a patentee brought suit for patent infringement and requested a jury trial. The defendant filed a declaratory judgment action against plaintiff, seeking a declaration that plaintiff's asserted patents were invalid, unenforceable, and not infringed, and requested a jury trial. After plaintiff withdrew its claim for damages, limiting its requested relief to an injunction, the defendant withdrew its request for a jury trial. The patentee contended that

it was still entitled to a jury trial. The district court disagreed that a jury trial was appropriate, and the Federal Circuit affirmed holding that "if ***the patentee seeks only equitable relief, the accused infringer has no right to a jury trial,*** regardless of whether the accused infringer asserts invalidity as a defense (as in the *Tegal* case) or as a separate claim (as in this case)." *Id.* at 1290 (*citing Tegal Corp.*, 257 F.3d at 1341.) Indeed, "[b]y choosing the equity route for its infringement action," "neither claim [infringement and validity] would be triable to a jury." *Id.* at 1291.

Nor does Roche's affirmative defense of "inequitable conduct" entitle it to a jury trial. *See Paragon Podiatry Lab., Inc. v. KLM Lab, Inc.*, 984 F. 2d 1182, 1190 (Fed. Cir. 1993) (per curiam) *citing Ross v. Bernhard*, 396 U.S. 531, 538 (1970) ("The defense of inequitable conduct in a patent suit, being entirely equitable in nature, is not an issue for a jury to decide.")

### B. ROCHE'S ANTITRUST COUNTERCLAIMS CANNOT TRANSFORM THE PATENT CASE INTO A JURY-TRIABLE CASE BECAUSE THERE ARE NO "COMMON ISSUES" BETWEEN THE PATENT AND ANTITRUST COUNTERCLAIMS

As described above, Amgen has moved for summary judgment on Roche's antitrust and state law counterclaims. If Amgen's motion for summary judgment is granted, the only issues remaining in this case will be the equitable patent issues (i.e., infringement, validity, and enforceability) as to which there is no right to a jury trial. Even if Roche's antitrust claims survive summary judgment, Roche's claims are entirely equitable in nature, since Roche does not have a present right or ability to sell peg-EPO in the United States, and therefore lacks standing to seek antitrust damages under Clayton Act § 4. Likewise, if the court grants Amgen's motion to exclude antitrust damages testimony, no antitrust issues will remain for which a jury trial is appropriate.

Even if Roche's antitrust counterclaims survive to trial however, Roche's counterclaims will not transform Amgen's equitable patent suit into a jury-triable case. *See In re Impax Lab,*

*Inc.*, 06-815, 2006 U.S. App. LEXIS 6931 at * 840 (Fed. Cir., Mar. 2, 2006) (a defendant alleging antitrust violations was not entitled to a jury trial on patent issues where the patentee only requested equitable relief).[1] Instead, Roche is only entitled to a jury trial on the equitable claims if they share ***common issues*** with its legal claims. *See Beacon Theatres, Inc. v. Westover*, 359 U.S. 500 (1959). It is well established that mere overlap of issues or facts is not enough; instead, the ***issues must be common*** in order for the right to a jury trial to extend to an equitable issue. *See Afga Corp. v. Creo Prods. Inc.*, 451 F.3d 1366 (Fed. Cir. 2006) (affirming district court's decision to sever inequitable conduct issue from the rest of the case and conduct a bench trial on that issue, because while the issues of inequitable conduct and invalidity overlapped to some degree they were not common issues).

There is simply no basis for finding that the patent and antitrust claims in this case share "common" legal issues. Analysis of patent infringement claims ordinarily require a two-step analysis: (1) construing the disputed claims of the patent – a matter of law – and (2) comparing the accused device to the patent claims--a matter of fact." *Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1358 (Fed. Cir. 2006.) Applied here, this analysis would require (i) an evaluation of peg-EPO and its manufacturing processes to determine whether peg-EPO unlawfully infringes on Amgen's patents, and (ii) an analysis of whether Roche's peg-EPO is "materially changed."

In sharp contrast to the patent claims, to prove its antitrust claims, Roche must establish (1) the existence of distinct economic markets in which Amgen allegedly possesses market power independent of the legitimate exclusionary power conferred by its valid and enforceable patents; (2) that Amgen has unlawfully used that non-patent economic power to exclude Roche

[1] Amgen recognizes that this unpublished opinion is not precedent on this Court.

from competing in one or more markets in which Roche (and but for Amgen's unlawful acts it, would have had the unfettered right and present ability to compete); (3) that such acts of Amgen were unreasonable in light of the economic circumstances in which they were taken; and (4) that such activities injure competition. Thus, because the antitrust claims do not require any technical evaluation of the relevant products, and instead relate entirely to pricing issues, market issues, and allegations regarding Amgen's marketplace behavior and Roche's damages, there are no "common" legal issues, and Roche is not entitled to a jury trial on the patent claims.

Moreover, because this Court, and not a jury, must decide the infringement and invalidity issues – irrespective of whether the antitrust counterclaims survive summary judgment – it would be exceedingly inefficient to use an advisory jury to help the Court resolve the patent issues. Because this Court will be required to decide all disputed matters and issue findings of fact and conclusions of law on Amgen's patent claims and Roche's patent defenses, employing an "advisory" jury under Fed. R. Civ. P. 39(c) in the patent case would ultimately complicate the trial, impose on the jurors to hear issues they cannot decide, and very likely confuse the issues a jury can decide. [2] *Merex A.G. v. Fairchild Weston Sys., Inc.*, 29 F.3d 821, 826 (2d. Cir. 1994) ("absent the consent of the parties it would be highly questionable for a court to submit an equitable issue to an advisory jury for a binding verdict").

## IV. THIS COURT SHOULD BIFURCATE THE ANTITRUST ISSUES FROM THE PATENT ISSUES

To the extent that Roche's antitrust damages claims survive to trial, Amgen respectfully

[2] Indeed, "the responsibility for the decision rendering process remains with the judge even though an advisory jury is used." *Indiana Lumbermens*, 195 F.3d at 376. It is wholly within the judge's discretion whether to accept or reject, in whole or part, the jury's verdict. *Id.* The judge has "complete freedom" to use or disregard the jury's findings. *Id.*; *See Gragg v. City of Omaha*, 20 F.3d 357, 358-359 (8th Cir. 1994) (court is free to accept or reject advisory jury's verdict when making its findings); *Harris v. Secretary, U.S. Dept. of the Army*, 119 F.3d 1313, 1320 (9th Cir. 1197) ("when a district court submits a claim to an advisory jury, the court is free to accept or reject the jury's advisory verdict in making its own findings").

submits that the Court should structure the trial into separate bench and jury trials.[3] First, it should conduct a bench trial on the patent claims (*i.e.*, infringement, validity and the affirmative defense of inequitable conduct if not already decided on summary judgment). If Amgen is successful on its patent claims, the Court then should decide the injunction question. While Amgen believes that any antitrust claims that survive summary judgment would be completely undone by a finding in Amgen's favor on the patent issues, at the very least, the outcome of the patent case would define the boundary of Amgen's legitimate exclusionary right laying the foundation for a determination of the proper scope and efficient conduct of an antitrust trial (e.g., whether a distinct economic market exists for which Amgen has market power and for which Roche has antitrust standing.)

If Roche defeats all of Amgen's claims of patent infringement, the Court could then proceed with a jury trial on any remaining antitrust claims. If the only surviving antitrust counts are for injunctive relief, this Court should try them to the bench.

This bifurcation will avoid needless waste of jurors' time and this Court's resources by eliminating the introduction of irrelevant evidence regarding issues not before the jury. It will also preserve Amgen's right to choose to proceed in equity and have its patent claims resolved by this Court, as well as Roche's right to a jury trial on its non-equitable counterclaims, to the extent such claims survive.

Amgen recognizes that there is some precedent for trying the inequitable conduct defense (a non-jury claim) with the *Walker Process* counterclaims. *Avco Corp. v. PPG Indus.*, 867 F. Supp. 84, 98 (D. Mass. 1994). Even though there may be common *factual issues* between Roche's inequitable conduct affirmative defense and its *Walker Process* counterclaims alleging

[3] Amgen addresses the bifurcation issue here in light of the Court's statement at the Motion to Dismiss hearing that it would revisit the bifurcation issue at the final pre-trial conference. *12/20/2006 Trans. at 20:11-19*

similar activity before the Patent Office, there is simply no basis for allowing Roche to bootstrap a jury trial onto Amgen's equitable patent claims. It would be a tremendous waste of resources for a jury to sit through, as Roche suggests, weeks of technical evidence regarding Amgen's patent case and Roche's multitude of invalidity and unenforceability defenses, where such evidence is irrelevant to Roche's *Walker Process* counterclaim - the only claim the jury would be deciding.

In light of the size and complexity of this case, bifurcation is necessary to achieve streamlined case management. Amgen submits that in the interests of efficiency and avoiding undue prejudice, this Court should exercise its discretion and first try Amgen's patent case, including Roche's affirmative defense of invalidity and inequitable conduct, and to the extent they survive to trial, the *Walker Process* claims should be tried separately. Pursuant to Federal Rule of Civil Procedure 42(b), this Court has wide discretion to decide whether to order a separate trial of any claims or issues when it is conducive to expedition and economy, is in furtherance of convenience, or will avoid prejudice. *See Fed. R. Civ. P. 42* (b); *Hewlett-Packard Co. v. Genrad, Inc*. 882 F.Supp. 1141, 1157 (D. Mass. 1995) (decision to bifurcate "is committed to the sound discretion of the court.") "It is important that [separation of issues for trial] be encouraged where experience has demonstrated its worth." *Fed. R. Civ. P. 42(b) (Advisory Committee's Note).*

Courts have routinely exercised their discretion and separated for trial, patent issues and those raised in antitrust counterclaims. *Hewlett-Packard Co. v. GenRad, Inc*., 882 F.Supp. at 1157 *citing, In re Innotron Diagnostics*, 800 F.2d 1077, 1084 (Fed. Cir. 1986) (noting that lower court cited cases which reflect "the now-standard practice of separating for trial patent issues and those raised in an antitrust counterclaim"); *Brandt, Inc. v. Crane*, 97 F.R.D. 707. 708 (N.D. Ill.

1983) (separate trials of patent and antitrust issues furthers convenience, expedience and economy as "a general rule"). Commentators have also expressly acknowledged the utility of bifurcating patent claims and antitrust counterclaims under Rule 42(b):

> . . . Equitable defenses [to patent infringement claims] are potential candidates for bifurcation, and separating antitrust counterclaims also is common. Deferral of claims asserting unfair competition or antitrust until resolution of the patent issues frequently results in the claims' voluntary dismissal or settlement. *Manual for Complex Litigation (4th)* § 33.23 (2005) (internal footnotes omitted).

Bifurcating the equitable issues from jury-triable factual issues (to the extent any remain) would result in the most economical use of the Court's and the jury's time. As an initial matter, the lynchpin of Roche's antitrust counterclaims rests on the contention that Amgen's patents-in-suit are unenforceable because they were allegedly obtained through fraud on the Patent Office. Where the validity and enforceability of four of these patents was previously challenged and upheld by this Court and the Federal Circuit, at trial, Roche must not only overcome the strong evidentiary weight that should be accorded the prior adjudication of the patents' validity and the rejection of virtually identical allegations of inequitable conduct. *See Ralston Purina Co. v. Griffith Laboratories Inc.*, 1988 U.S. Dist. LEXIS 12562, at *10 (N.D. Ill. Nov. 9, 1988) (holding that one court's prior determination of no inequitable conduct is an issue entitled to evidentiary weight.)[4]

Thus bifurcation would eliminate inefficiencies because if Roche's claims of patent invalidity and inequitable conduct fail, its *Walker Process* antitrust counterclaim will be moot.

[4] There is also a "high presumption of validity" created by a prior adjudication favorable to the patentee. *See, e.g., General Tire & Rubber Co. v. Firestone Tire & Rubber Co., 489 F. 2d 1105, 1116 (6th Cir. `973), cert. denied, 417 U.S. 932 (1974); Columbia Broadcasting System, Inc. v. Zenith Radio Corp., 391 F. Supp. 780, 785 (N.D. Ill. 1975), aff'd 537 F. 2d. 896 (7th Cir. 1976) ("great weight"); Barr Rubber Products Co. v. Sun Rubber Co., 425 F. 2d 1114, 1120 (2d. Cir. 1970), cert. denied, 400 U.S. 878 (1970) ("respectful consideration"); Illinois Tool Works, Inc. v. Foster Grant Co. , 395 F. Supp. 234 (N.D. Ill. 1974) (patents on plastic cups and lids previously held valid in same circuit were again held valid where evidence of invalidity is no better than previously considered evidence.)*

*GenRad*, 882 F. Supp. at 1157 (failure to prove inequitable conduct eliminated defendant's antitrust and unfair competition counterclaim); *FMC Corp. v. Manitowoc Co., Inc*., 835 F. 2d 1411, 1417-1418 (Fed. Cir. 1987) (same); *United States v. Gypsum Co. v. National Gypsum Co*., 1994 WL 74989, at *2 (N.D.Ill. March 10, 1994) ("should the patents be found valid and enforceable in the patent trial, a motion for a directed verdict on the defendant's *Walker Process* counterclaims may be in order"). Indeed, even if Roche's patent claims were to succeed, it would still be more efficient to have bifurcated the case, because Roche will "need not again prove the same issues at the antitrust trial." *See In re Innotron*, 800 F. 2d at 1085.

Roche – well aware of the frailty of its counterclaims and defense of inequitable conduct – has previously opposed Amgen's request to have the "inequitable conduct" (non-jury) defense first tried to the bench. Indeed, Roche argued in its Opposition to Amgen's Motion for Bifurcation that under *Beacon Theatres* and *Dairy Queen*,[5] holding a bench trial first on the inequitable conduct claim would violate its Seventh Amendment right to a jury trial. Roche's argument is without merit.

As the Supreme Court has instructed, *Beacon Theatres* "enunciated no more than a general prudential rule," and, therefore does not have the all-encompassing reach that Roche asserts. *Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 336 (1979). Moreover, "[b]oth *Beacon Theatres* and *Dairy Queen* recognize that there might be situations in which the Court could proceed to resolve the equitable claim first even though the results might be dispositive of the issues involved in the legal claim." *Id.* at 335 *citing Katchen v. Landy*, 382 U.S. 323, 339 (1965) (an equitable determination can have collateral-estoppel effect in a subsequent legal action and that this estoppel does not violate the Seventh Amendment). Roche also overlooks

[5] Beacon Theatres v. Westover, 359 U.S. 500 (1959); 369 U.S. 469 (1962)

caselaw explicitly holding that a decision to bifurcate and try patent issues first to the bench does not violate the Seventh Amendment. *John Hopkins University v. CellPro*, 1997 U.S. Dist. LEXIS 24161, at *18-19 (D.Del. July 24, 1997) (McKelvie D.J.) (Trial of the inequitable conduct claims to the bench before antitrust claims did not violate the Seventh Amendment.).[6]

While Amgen notes that a rejection of Roche's inequitable conduct defense would effectively terminate Roche's *Walker Process* counterclaim, this does not violate Roche's Seventh Amendment right to a jury trial any more than would a summary judgment disposition or directed verdict. It is well established that such mechanisms, when properly utilized, are constitutional. *Macneill Eng'g Co. v. Trisport, Ltd.*, 126 F. Supp. 2d 51, 68-69 (D. Mass. 2001) (a district court may properly take theories and claims away from the jury even after the parties have presented evidence in reliance on those theories being alive during the case); *see e.g.,* Fed. R. Civ. P. 50 (governing judgment as matter of law). *see e.g.*, *Galloway v. United States*, 319 U.S. 372, 388-94 (1943) (holding that directed verdict does not violate Seventh Amendment).

Thus, if Roche cannot persuade this Court of its inequitable conduct claim – a claim which requires a lesser showing than Roche's *Walker Process* claim – its *Walker Process* claim should be dismissed as a matter of law. Rule 42(b) explicitly provides this Court with the authority to manage this case in its discretion, and avoid this tremendous waste of judicial resources.

Bifurcating the trial would also avoid the unfair prejudice and confusion that Roche's counterclaims and equitable defense would create. It is well recognized that antitrust issues are complex – particularly with respect to damages – and raise different issues and proof. *See, e.g., Hewlett-Packard,* 882 F. Supp. at 1158 (observing that "antitrust issues are complex and . . .

[6] Roche further ignores the fact that if it were to succeed on its inequitable conduct claim in front of this Court, this would not in any way affect its claimed right to a jury trial on its *Walker Process* claim

raise different issues and proof" than patent claims). *See Brandt*, 97 F.R.D. at 708 (antitrust counterclaims required proof different in nature and scope than proof relevant to patent issues); *Innotron*, 800 F.2d at 1086 (stating that separate jury trials are appropriate where issues to be tried in each are, as in patent/antitrust cases, "distinct and separable"). Assuming Roche's antitrust counterclaims survive summary judgment, unless this trial is bifurcated, the jury - in addition to listening to the evidence on the antitrust issues - would be faced with evaluating evidence of infringement, the scope and content of the prior art, the level of skill in the art, the objective evidence of non-obviousness, enablement, written description, and inequitable conduct for five patents. In contrast, bifurcating the equitable issues from jury-triable factual issues (to the extent any remain) would simplify and shorten the jury trial by eliminating evidence, testimony of fact and expert witnesses, and jury instructions that relate to infringement and validity and inequitable conduct. *Real v. Bunn-O-Matic Corp.*, 195 F.R.D. 618, 620-622 (N.D. Ill. 2000) (extenuating circumstances that usually warrant bifurcation include infringement issues or multiple patents, infringing products, claims, counterclaims, or parties).

Bifurcation will therefore eliminate the risk of prejudice to Amgen arising from jury confusion regarding patent issues (infringement and validity) which the jury is not deciding. Under similar circumstances, Judge Gignoux in *Ventrex* concluded that "it's almost inconceivable that a jury could arrive at an intelligent verdict." 223 USPQ at 899. *See also, Innotron*, 800 F.2d at 1085 ("avoidance of prejudice and confusion is served in trying first the patent issues, without injecting the different [and highly complex antitrust] counterclaim issues which required different proof and different witnesses."); *Brandt*, 97 F.R.D. at 708 (concluding that separation of trials will not only result in little, if any, duplication of proof, it will "significantly reduce the likelihood of prejudice and confusion").

## V. IF BOTH THE PATENT AND ANTITRUST ISSUES ARE TRIED BEFORE THE JURY, AMGEN SHOULD BE ABLE TO PRESENT INFRINGEMENT EVIDENCE FIRST TO AVOID UNFAIR PREJUDICE

To the extent this Court uses an advisory jury, Amgen requests that it conduct the jury trial according to the normal order of proof in patent infringement trials, *i.e*. infringement evidence presented before validity evidence. *Plumtree Software Inc. v. Datamize LLC*, 2003 U.S. Dist. LEXIS 26948 (N.D. Ca. Oct 6, 2003) ("It is simply more logical to present the affirmative case for infringement first, rather than presenting the case for noninfringement first.")

Amgen understands that in the past this Court has deviated from this order, such that the defense has presented evidence of invalidity before the plaintiff presented its infringement evidence. In the interests of efficiency and avoiding confusion, however, Amgen respectfully requests that it be allowed to present its case of infringement before Roche presents its affirmative case concerning validity.

In declaratory judgment cases such as this one, where both plaintiff and defendant bear burdens of proof, courts ordinarily allow the plaintiff to proceed first. *See Anheuser-Busch, Inc. v. John Labatt*, 89 F.3d 1339, 1344 (8th Cir. 1996) (allowing the actual plaintiff who filed the lawsuit to proceed first, where both parties bore the burden of proof on distinct counts of their causes of action); *see also L-3 Communs. Corp. v. OSI Sys.*, 418 F.Supp.2d 380, 383 (S.D.N.Y. 2005) ("Where both parties bear the burden of proof on distinct counts of their causes of action, as is the case here, the court has good grounds for allowing 'the actual plaintiff, the party that filed the lawsuit to proceed first.'") *See also, Fresenius Medical Care Holdings, Inc. v. Baxter Int'l Inc*., 2006 U.S. Dist. LEXIS 42159, *17, *24 (N.D. Ca. June 12, 2006) ("As the party that filed the action, Fresenius is the plaintiff and is entitled to proceed first in all phases of the case (voir dire, opening statements, presentation of proof, and closing arguments).")

As the lawful patentee, Amgen would be severely prejudiced in this case if Roche were

allowed to attack the validity of the patents-in-suit before Amgen were allowed to introduce any evidence regarding the nature of the subject inventions. Specifically, Amgen will be placed in the untenable position of having to first correct whatever misimpressions may be created regarding the nature and scope of its claimed inventions, and then to defend their validity – patents which are not only entitled to a presumption of validity, but have previously been upheld and enforced through trial and appeal. And then, only after the validity of Amgen's patents has been challenged and defended, would the jury hear the evidence of Roche's infringement. Amgen respectfully submits that such re-ordering of proof will lead to increased juror confusion and likely prejudice over the respective roles and burdens of Amgen and Roche.

Moreover, the jury could not fairly evaluate the validity arguments without first understanding the technology and the nature of the inventions claimed in the patents-in-suit. It would be highly prejudicial and unfair to allow defendants instead of the patent owner to explain the patent, the technology and the nature of the inventions to the jury. If the Court determines to proceed first on validity issues, at least, Amgen should be allowed to open the case to the jury and explain the technology, the patents and the claimed inventions.

## VI. CONCLUSION

Amgen submits that the following summary judgment motions have the greatest potential to simplify the trial and deserve the court's earliest attention:

(i) Amgen's Motion for Summary Judgment to Dismiss Roche's Antitrust Counterclaims including its Motion to Exclude the Testimony of Roche's Damages Expert Lauren Stiroh;

(ii) Amgen's Motion for Summary Judgment of No Inequitable Conduct;

(iii) Amgen's Motion for Summary Judgment of No Obvious-Type Double Patenting;

(iv) Amgen Motion for Summary Judgment of Infringement of '422 Claim 1, '933

Claim 3, and ‘698 Claim 6; and

(v) Amgen’s Motion for Summary Judgment that Lin’s Asserted ‘933 and ‘349 Claims Are Definite, Adequately Described and Enabled (D.I. 532)

Because this Court, and not a jury, must decide the infringement and invalidity and at least a portion of the inequitable conduct issues - irrespective of whether the antitrust counterclaims survive summary judgment – it would be exceedingly inefficient to use an advisory jury to decide the patent issues. To the extent any antitrust issues survive to trial, this Court should bifurcate the trials of the patent and antitrust cases, and this Court should try the infringement, validity and inequitable conduct claims first.

Dated: July 11, 2007

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 91320-1789
(805) 447-5000

*/s/ Michael R. Gottfried*
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. (*pro hac vice*)
DAY CASEBEER, MADRID &
BATCHELDER LLP
20300 Stevens Creek Boulevard, Suite 400
Cupertino, CA 95014
Telephone: (408) 873-0110
Facsimile: (408) 873-0220

William G. Gaede, III (*pro hac vice*)
McDERMOTT WILL & EMERY
3150 Porter Drive
Palo Alto, CA 94304
Telephone: (650) 813-5000
Facsimile: (650) 813-5100

Kevin M. Flowers (*pro hac vice*)
MARSHALL, GERSTEIN & BORUN LLP
233 South Wacker Drive
6300 Sears Tower
Chicago, IL 60606
Telephone: (312) 474-6300
Facsimile: (312) 474-0448

**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.

*/s/ Michael R. Gottfried*
Michael R. Gottfried

BST99 1546150-8.041925.0056