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UNITED STATES DISTRICT COURT **DISTRICT OF MASSACHUSETTS**

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

MEMORANDUM IN SUPPORT OF AMGEN'S MOTION TO BIFURCATE ROCHE'S ANTITRUST AND UNFAIR COMPETITION COUNTERCLAIMS FROM AMGEN'S PATENT INFRINGEMENT CLAIMS FOR TRIAL AND DISCOVERY AND TO STAY **DISCOVERY ON THOSE CLAIMS**

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INTRODUCTION

In response to Amgen's Amended Complaint for Declaratory Judgment of Infringement, F. Hoffman-La Roche Ltd., Roche Diagnostics GmbH, and Hoffmann-La Roche, Inc. (collectively, "Roche") have asserted twelve separate counterclaims against Amgen, including federal antitrust violations of Sherman Act §§ 1 and 2, state antitrust violations of California's Cartwright Act and the New Jersey Antitrust Act, as well as unfair competition under Massachusetts General Law, Chapter 93A.¹ The gravamen of Roche's antitrust and unfair competition counterclaims is its allegation that Amgen's patents-in-suit are unenforceable, either because they are invalid or because they were obtained through inequitable conduct.² If, however, Roche's entry into the market will be properly foreclosed by Amgen's patents, Roche's antitrust counterclaims will be mooted for lack of standing and lack of any antitrust injury. The key causation issue for any antitrust injury to Roche will either be refuted, or narrowed, through resolution of the underlying patent case. Nevertheless, even if Roche 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. Indeed, the findings will be the law of the case in the second trial, thereby still providing a greater likelihood of achieving a just final disposition of this case. Because Roche's antitrust claims depend upon and require the prior adjudication of Amgen's

¹ As set forth in Amgen Inc.'s Motion to Dismiss Roche's Counterclaims Counts I-IX and XII ("Motion to Dismiss"), Amgen believes that all but two of Roche's counterclaims should be dismissed as a matter of law. However, pending a decision on the Motion to Dismiss, Amgen is filing this motion seeking to stay discovery on Roche's counterclaims. Moreover, Amgen files this motion to bifurcate the discovery and trial of the patent claims from the antitrust/unfair competition counterclaims now, so that if the Court should deny the Motion to Dismiss, or permit Roche to file its Amended Answer and Counterclaim, the Court can consider this motion to bifurcate at the earliest practicable time.

infringement claims and Roche's defenses to those claims, bifurcation is both warranted and appropriate, as the Federal Circuit and this Court have previously determined in directly analogous circumstances.³

Indeed, both the Federal Circuit and trial courts in this District have endorsed the "nowstandard practice of separating for trial patent issues and those raised in an antitrust counterclaim" as a sound case management practice. ⁴ Their rationale for doing so is particularly apt here:

- A. Economy will be served because adjudication of the infringement and validity of Amgen's patents and the merits of Roche's affirmative defenses may moot, severely limit, or at least, establish the law of the case for the trial of the antitrust issues;
- "Avoidance of prejudice and confusion [will be] served in trying first the patent B. issues, without injecting the different counterclaim issues which require[] different proof and different witness";⁵ and

(Continued...)

² See Roche's 11/6/06 Answer to Am. Compl. And Counterclaims at ¶65, Docket No. 140.

³ See In re Innotron Diagnostics, 800 F.2d 1077, 1084 (Fed. Cir. 1986) (affirming district court's bifurcation of patent and antitrust claims); Hewlett-Packard Co. v. GenRad, Inc., 882 F. Supp. 1141, 1157-58 (D. Mass. 1995) (staying trial and discovery of counterclaim based on inequitable conduct; "Courts often separate patent issues from antitrust counterclaim issues. . . Antitrust issues are complex and, particularly with respect to damages, raise different issues and proof."), cited with approval in Abbott Labs. v. Selfcare, Inc., 2000 U.S. Dist. LEXIS 15263, at * 5 (D. Mass. Sept. 29, 2000) ("Were it the case that there was a similar relationship linking the claims and the counterclaims, bifurcation might well be in order."); Cadam, Inc. v. Adage, Inc., 1987 U.S. Dist. LEXIS 16090, at *8-9 (D. Mass. Feb. 25, 1987) (staying discovery and trial of antitrust claims because "discovery and proof related to [antitrust claims] is no small matterqualitatively and quantitatively").

⁴ See supra note 3.

⁵ In re Innotron, 800 F.2d at 1085.

C. Expedition and convenience for the Court and the parties will be served because the patent issues involve a much narrower subset of discovery and issues than the antitrust and unfair competition counterclaims.

Recognizing, as the Federal Circuit in Innotron did, that the benefits of bifurcating the trial extend to the bifurcation of discovery as well, trial courts in this District have bifurcated both the discovery and trial of patent infringement claims from the discovery and trial of antitrust counterclaims. 6 This time-honored case-management approach is particularly well suited to this case because this is not the first time that the validity and unenforceability of four of the patents asserted herein has been litigated and confirmed by this Court and the Federal Circuit.⁷ Moreover, Roche faces a significant hurdle in attempting to establish invalidity and inequitable conduct in this case.⁸ Accordingly, as set forth more fully below, the considerations endorsed by the Federal Circuit dictate staying discovery and trial of Roche's antitrust and unfair competition claims until after such time as the Court has decided Amgen's patent claims and Roche's allegations of inequitable conduct.

ARGUMENT

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

⁶ GenRad, 882 F. Supp. at 1158; see also Cadam, 1987 U.S. Dist. LEXIS 16090, at *8-9.

⁷ See Amgen Inc. v. Hoechst Marion Roussel, Inc., 126 F. Supp. 2d 69, 137-47 (D. Mass. 2001) (rejecting allegations of material omissions and misrepresentations, and holding that "Amgen's representatives never intended to deceive that Patent Office,"), aff'd in pertinent part, 314 F.3d 1313 (Fed. Cir. 2003).

⁸ See infra notes 15 and 16. To overcome the statutory presumption of validity that automatically attaches to a patent, the defendant challenging the validity of a patent based on alleged inequitable conduct must present clear and convincing evidence. See 35 U.S.C. §282; Ulead Sys., Inc. v. Lex Computer & Mgmt. Corp., 351 F.3d 1139, 1144 (Fed. Cir. 2003); Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995).

and economy, is in furtherance of convenience, or will avoid prejudice. Although the Court has discretion in deciding to bifurcate, the factors the Court should consider weigh in favor of bifurcating this case. Indeed, following the Federal Circuit's endorsement of bifurcating patent claims from antitrust claims, it has become common practice in federal courts to stay the discovery and trial of antitrust and unfair competition counterclaims until after the discovery and trial of the patent claims. 10 The courts have held that "a stay will simplify the case, avoid confusion, and reduce the burden and costs imposed on the Court, the attorneys, and the parties by deferring the burdensome and expensive discovery that would necessarily arise from litigation of the antitrust claims, and possibly avoiding it altogether."11

See Fed. R. Civ. P. 42(b); GenRad, 882 F. Supp. at 1157; citing Data General v. Grumman Systems Support Corp., 795 F. Supp. 501, 503 (D. Mass. 1992) (decision to bifurcate "is committed to the sound discretion of the court."), aff'd 36 F.3d 1147 (1st Cir. 1994); see also Cadam, 1987 U.S. Dist. LEXIS 16090, at *8 (finding that one of the purposes of Rule 42(b) is to permit deferral of costly and possibly unnecessary discovery proceedings pending resolution of potentially dispositive preliminary issues); see also Fed. R. Civ. P. 26(c) ("The Court for good cause shown... may make any order which justice requires to protect a party... from... undue burden or expense.").

¹⁰ See GenRad, 882 F. Supp. at 1157-58 (staying counterclaim and discovery based on inequitable conduct); Cadam, 1987 U.S. Dist. LEXIS 16090, at *8-9 (same); Baxter Int'l, Inc. v. Cobe Lab., Inc., 1992 U.S. Dist. LEXIS 5660, 1992 WL 77665, at *2, 4 (N.D. Ill. April 6, 1992) (severing and staying discovery and trial of antitrust counterclaim in light of lack of common issues other than fraudulent procurement, prejudice to plaintiff in defending patent claim and Handgards claim simultaneously, burden on jury, and possibility that issues relating to antitrust counterclaim could be rendered moot); Carlisle Corp. v. Hayes, 635 F. Supp. 962, 967-68 (S.D. Cal. 1986) (severing and staying trial and discovery on antitrust counterclaims); Pharmacia, AB v. Hybritech, Inc., 1984 U.S. Dist. LEXIS 22736, at *3 (S.D. Cal. Oct. 16, 1984) (severing and staying trial and discovery on defendants antitrust and patent misuse counterclaims based on fraudulent procurement, predatory pricing, and tying); Components, Inc. v. Western Elec. Co., Inc., 318 F. Supp. 959, 966-67 (D. Me. 1970) (same).

¹¹ ASM America, Inc. v. Genus, Inc., 2002 U.S. Dist. LEXIS 1351, at *18-19 (N.D. Ca. Jan. 9, 2002) (holding "[i]t is a common practice in federal court to stay antitrust counterclaims until after the trial of the invalidity issue").

I. The Factors Courts Consider When Deciding Whether To Bifurcate A Case Weigh In Favor Of Granting Amgen's Motion.

The courts consider the following factors when deciding whether to grant a motion to bifurcate: (1) whether it would be more efficient to decide the patent issues and invalidity affirmative defenses first, thereby potentially eliminating the need to determine the antitrust and unfair competition counterclaims; (2) whether it would be more convenient and expeditious to try the patent issues first and avoid unnecessary and burdensome antitrust discovery; and (3) whether bifurcation of these issues would avoid prejudice and confusion by trying first the patent issues, without injecting the different counterclaim issues, which require different proof and different witnesses. All of these factors weigh in favor of bifurcating here the discovery and trial of the patent issues from the discovery and trial of the antitrust/unfair competition issues. ¹²

A. Bifurcation would be more efficient because it would potentially moot, severely limit, or at least be the law of the case for the trial on Roche's antitrust and unfair competition counterclaims.

Bifurcating the discovery and trial of the patent claims from the discovery and trial of the antitrust and unfair competition counterclaims will conserve judicial resources and promote efficiencies because it will avoid potentially unnecessary litigation.¹³ Here, the gravamen of Roche's antitrust and unfair competition counterclaims is based upon its assertion that Amgen's

In re Innotron, 800 F.2d at 1084-5 (separating for trial patent issues and those raised in antitrust counterclaim promotes the most efficient, convenient, expeditious, and least prejudicial resolution of the patent validity issues and likely eliminate the antitrust and unfair competition claims); see also, 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, 1417-18 (Fed. Cir. 1987) (same); U.S. v. Gypsum Co. v. National Gypsum Co., 1004 WI. 74080, et * 2 (N.D. III. Moreh 10, 1004) ("should the patents be found valid and

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").

¹³ In re Innotron Diagnostics, 800 F.2d at 1085; GenRad, 882 F. Supp. at 1157-58.

patents-in-suit are unenforceable, either because they are invalid or because they were obtained through inequitable conduct. Specifically, as most fully alleged in Roche's proposed amended Answer, it claims that Amgen misled the Examiner regarding the patentable differences between the inventions claimed in Dr. Lin's DNA, EPO glycoprotein, vertebrate cell and process claims, that Amgen misrepresented the differences between recombinant erythropoietin ("r-EPO") and urinary erythropoietin ("u-EPO"), and that Amgen is knowingly and intentionally seeking to enforce invalid and unenforceable patents to squash competition.

But the validity and enforceability of four of the patents-in-suit was previously challenged and upheld by this Court and the Federal Circuit, and alleged misrepresentations regarding differences between r-EPO and u-EPO were previously held to provide no basis for inequitable conduct.¹⁴ Therefore, as to these issues, Roche must overcome the strong precedential effect afforded to this Court's and the Federal Circuit's prior adjudication of both the validity and inequitable conduct allegations. ¹⁵ District courts give great weight to Federal

¹⁴ See Amgen Inc. v. Hoechst Marion Roussel, Inc., 126 F. Supp. 2d 69, 137-47 (D. Mass. 2001) (rejecting allegations of material omissions and misrepresentations, and holding that "Amgen's representatives never intended to deceive that Patent Office" and that "Amgen complied with its duty of candor... regarding glycosylation differences"), aff'd in pertinent part, 314 F.3d 1313 (Fed. Cir. 2003) ("The district court found that TKT has not proven inequitable conduct by clear and convincing evidence, and we have not been persuaded on appeal that a contrary result is compelled").

¹⁵ 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). The cases also establish "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. 1973), 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 (1974, (Continued...)

Circuit decisions upholding a patent and have declined to reopen the issue of validity in its entirety where the additional evidence beyond that previously examined by the Federal Circuit is de minimus. 16 Therefore, Amgen believes that Roche's claims of patent invalidity and inequitable conduct will fail, thereby mooting its Walker Process antitrust counterclaim. Nevertheless, even if Roche 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." ¹⁷ Indeed, the findings will be the "law of the case" in the second trial, thereby still providing a

Moreover, as more fully explained in Amgen's pending Motion to Dismiss, Roche currently lacks standing to assert its First, Second, Third, Fourth, and Fifth Counterclaims for violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§1 and 2 (Walker Process; "sham

greater likelihood of achieving a "just final disposition of this case." 18

(Continued...)

ND III), aff'd 547 F2d 1300 (1976, CA7 III), cert. denied, 431 US 929 (1977) (patents on plastic cups and lids twice previously held valid in same circuit were again held valid where evidence of invalidity is no better than previously considered evidence.).

¹⁶ King Instrument Corp. v. Perego, 737 F. Supp. 1227, 1230 (D. Mass. 1990) ("This Court declines to reopen the issue of validity of the . . . Patent on the ground of prior art where the Federal Circuit has acted and where additional evidence beyond that examined . . . was de minimus.").

¹⁷ In re Innotron, 800 F.2d at 1085.

¹⁸ See id. (holding that bifurcation was appropriate because defendant's affirmative defenses to the patent infringement case were identical to the antitrust counterclaims and therefore, "if [defendant] prevails at the trial on its affirmative defenses it need not again prove the same issues at the antitrust trial."); Warner Lambert Co. v. Purepac Pharm. Co., 2000 U.S. Dist. LEXIS 22559, at *31 (D. N.J., Dec. 22, 2000); Hunter Douglas, Inc. v. Comfort Corp., 44 F. Supp. 2d 145, 148 (N.D.N.Y. 1999) (holding that the interest of judicial efficiency favors separating the patent issues from those grounded on antitrust principles in part because "during the patent infringement suit, [defendant] would have an opportunity to present its defenses of patent (Continued...)

litigation;" monopolization of the End Stage Renal Disease ("ESRD") Erythropoietin Stimulating Agent market ("ESA"); attempted monopolization of the Chronic Kidney Disease ("CKD") ESA market; and unreasonable restraints of trade in the ESRD ESA and CKD ESA markets). Roche acknowledges, as it must, that it cannot legally participate in the allegedly relevant ESRD and CKD markets due to its lack of FDA approval. ¹⁹ As such, Roche currently lacks standing to seek antitrust damages because Roche has not alleged and cannot establish any past or present antitrust injury-in-fact to its business or property. Nor can it establish the requisite causal connection between any act of Amgen and any antitrust injury to Roche.²⁰ In addition, even presuming that its product is approved by the FDA, Roche will again be blocked from establishing any antitrust injury if Amgen is successful in proving Roche's infringement during the first trial. Indeed, a successful result for Amgen during the patent infringement trial would likely bar Roche from marketing its infringing product and, as a result, would strip Roche of any standing to assert antitrust injury. As such, Roche's remaining antitrust allegations would become moot, saving this Court and the litigants substantial time and effort litigating claims that, as a matter of law, Roche would have no standing to assert.

(Continued...)

invalidity and inequitable conduct. Resolution of these issues would become the law of the case and also eliminate some of the proof that would otherwise be necessary.")

¹⁹ See e.g., Roche's 11/6/06 Answer to Am. Compl. And Countercls., Counterclaims at ¶18, Docket No. 140 ("[N]o ESA may be marketed for the treatment of anemia in ESRD patients in the United States unless the FDA has approved it for use as a treatment... "); see also id. at ¶¶ 2, 22, 31, 33.

²⁰ Bristol-Myers Squibb Co. v. Copley Pharm., 144 F. Supp. 2d 21, 25 (D. Mass. 2000) (finding plaintiff lacked standing to assert antitrust injury because it did not have FDA approval to market or sell product), citing Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 489 (1977); see also Atlantic Richfield Co. v. USA Petroleum Co., 495 U.S. 328, 334 (1990) ("Establishing 'antitrust injury' is essential to standing.").

The only claim that might remain to be tried — assuming Roche establishes standing is Roche's allegation of a "sham litigation." Roche's sham allegations, however, fail to satisfy the two-part test courts apply in a "sham litigation" exception analysis. 21 Where, as here, the merits of a counterclaim are not only weak, but also depend on the prior adjudication of underlying claims on which the counterclaim depends, the court should bifurcate to avoid unnecessary discovery and conserve judicial resources.²²

Roche's "sham litigation" counterclaim will require adjudication of two "sham-specific" issues, in addition to all the other elements of an antitrust claim. ²³ First, a court must determine whether the challenged petitioning activity was objectively baseless.²⁴ A lawsuit is objectively baseless when "no reasonable litigant could realistically expect success on the merits." The Court must begin this analysis with the presumption that Amgen's patent infringement claims are being brought in good faith. 26 This presumption can be rebutted only by clear and convincing evidence of Amgen's bad faith.²⁷ "If an objective litigant could conclude that the suit is

²¹ See Professional Real Estate Investors v. Columbia Pictures Indus. (PRE), 508 U.S. 49, 60 (1992).

²² See Cadam, 1987 U.S. Dist. LEXIS 16090, at *13 (staying and bifurcating trial and discovery of antitrust claims because "this court finds that the factual predicate for the antitrust claims, based upon the current record, is insufficient.").

²³ See PRE, 508 U.S. at 60-61.

²⁴ See Cadam, 1987 U.S. Dist. LEXIS 16090, at *13.

²⁵ See id.

Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861, 876 (Fed. Cir. 1985), rev'd on other grounds, Nobelpharma AB v. Implant Innovations, 141 F.3d 1059, 1068 (Fed. Cir. 1998); Handgards, Inc. v. Ethicon, Inc., 601 F.2d 986 (9th Cir. 1979), cert. denied, 444 U.S. 1025 (1980).

²⁷ <u>Id.</u>

reasonably calculated to elicit a favorable outcome, the suit is immunized under Noerr, and an antitrust claim premised on the sham exception must fail."²⁸ Second, even if a lawsuit is objectively baseless, a court must also consider the "litigant's subjective motive" — "whether the baseless lawsuit conceals an attempt to interfere directly with the business relationships of a competitor."30

To the extent that Roche's claim for sham litigation is premised upon any allegation that Amgen knowingly asserted invalid patents, such an assertion would be meritless in light of prior adjudications by this Court and the Federal Circuit. 31 Amgen's belief that its patents are valid and infringed is not only objectively reasonable, it is completely justified. Moreover, bifurcating the sham litigation claim and first proceeding with the patent trial on the merits would result in an adjudication of the patents' validity, again streamlining the issues, if any, remaining to be tried on the sham claim.

At bottom, Roche's "sham litigation" claim devolves to a claim that Amgen's ITC petition was, at worst, premature, which Amgen submits is insufficient to state a sham claim for the reasons previously stated in its related Motion to Dismiss. Indeed, Roche's Answer and

²⁸ PRE, 508 U.S. at 60 ("Only if challenged litigation is objectively meritless may a court examine the litigants subjective motivation.").

Id.

³⁰ Id. at 60-61 (internal quotations omitted).

³¹ As noted in Amgen's Reply in Support of its Motion to Dismiss Roche's Counterclaims, to be filed with the Court on 12/18/06, Roche's Opposition concedes it is only pursuing a claim for sham litigation in the ITC and does not allege the assertion of invalid patents: "Amgen's uncognizable assertion that it believed its patents enforceable (Amgen Br. at 12-13) is irrelevant to Roche's sham litigation claim, which concerns Amgen's baseless invocation of the ITC's limited jurisdiction." See Roche's Opp. at 16 n.16.

Counterclaims allege no facts demonstrating that Amgen intentionally filed its request with the ITC for the subjective purpose of using the ITC action as an anticompetitive weapon to impose collateral injury rather than to obtain a justifiable legal remedy. Nor does Roche allege facts demonstrating that the ITC proceeding was in fact used for that purpose or had that effect.

> В. Expedition and the convenience of the Court and the parties is best served in trying the patent issues first because the antitrust and unfair competition counterclaims involve a narrower subset of evidence.

Antitrust issues are complex and, particularly with respect to antitrust damages, raise highly complex issues and proof different from those seeking declaratory and injunctive relief for patent infringement.³² It is well settled that the antitrust claims raise more complex issues and that discovery on those issues will be far more complex and wide-ranging than will discovery pertaining to the patent issues.³³ Indeed, the evidence needed for the patent issues is a narrower subset of the evidence that would be needed if the antitrust and unfair competition counterclaims were to proceed to trial, and therefore bifurcation would make the trying of this case more expeditious and convenient for the Court and the parties.³⁴

The patent claims will require proof concerning, *inter alia*, the nature of the inventions, Amgen's procurement of the patents, and the nature of Roche's accused infringing product. The antitrust claims, however, will require Roche to prove the existence of distinct economic markets in which Amgen allegedly possesses market power independent of the legitimate exclusionary

³² See GenRad, 882 F. Supp. at 1158; see also, Brant, Inc. v. Crane, 97 F.R.D. 707, 708 (N.D. Ill. 1983) ("the antitrust claims will require proof quite different in nature and scope than the proof relevant to the patent issues.").

³⁴ See Cadam, 1987 U.S. Dist. LEXIS 16090, at *5 ("Separation of issues for severed trials under Rule 42(b) is regularly used in patent cases to reduce time for discovery and trial.")

See In re Innotron, 800 F.2d at 1085.

power conferred by its valid and enforceable patents. Roche's antitrust claims will also require proof that Amgen has unlawfully used that *non-patent* economic power to exclude Roche from competing in one or more markets in which Roche, but for Amgen's allegedly unlawful acts, would have the unfettered right and present ability to compete, and that such acts of Amgen were unreasonable in light of the economic circumstances in which they were taken. Clearly, there are many significant and confusing differences between the patent and antitrust claims, such that separate trials would not only facilitate the efficient and effective discovery and preparation of each, but greatly reduce the complexity of issues for trial, and thus the likelihood of confusion and mistake at trial.

The process for defining the relevant market or markets is in and of itself a significant and complex undertaking, one that will require substantial additional discovery beyond the scope of the discovery needed for the patent issues.³⁵ Staking out the parameters and definition of the relevant product market would involve extensive discovery and "require[] acquisition and analysis of innumerable facts, albeit the stuff of economists, involving concepts and matters sounding like cross-elasticity of demand, market power, and a host of other factors."³⁶ Once that is done, disaggregating the legitimate exclusionary power attributable to Amgen's valid and enforceable patents from the alleged market power that otherwise provides a basis for the antitrust claims Roche seeks to assert entails an equally if not more daunting challenge, and convincingly demonstrates why the patent claims must necessarily be tried first.

³⁵ <u>See id.</u> (The parameters and definition of the relevant product market "has traditionally been one requiring extensive discovery--expert and lay.")

³⁶ Cadam, 1987 U.S. Dist. LEXIS 16090, at *10; see also Brant, 97 F.R.D. at 708.

Finally, the "sham litigation" claim not only increases the scope of the discovery necessary but also involves discovery that may be protected by the work product doctrine.³⁷ "Thus, counsel for plaintiff, beyond preparing for prosecution of plaintiff's claims, must be consistently vigilant to protect against incursions, directly or indirectly, into the camp and thought processes of counsel."³⁸ Those sorts of issues, arising as they no doubt will, necessarily detract from the real issues at hand. Accordingly "[s]eparation of trials will result in little, if any, duplication of proof while significantly reducing the likelihood of prejudice and confusion," and the convenience and expedition of the Court and all the parties involved weighs heavily in favor of bifurcating the discovery and trial of the patent claims from the discovery and trial of the antitrust and unfair competition counterclaims. ³⁹

C. Trying The Patent Issues First Will Avoid Prejudice And Confusion.

Bifurcation would avoid prejudice by separating the case into more manageable units. Resolution of the patent issues first will likely avoid the antitrust issues altogether. Because of the potential of causing confusion in the minds of the fact finders, in such situations, the courts have recognized that bifurcating the patent claims from the antitrust claims will avoid such confusion. 40 The issues in this case are sufficiently complex and distinct that one trial on all

³⁷ See Cadam, 1987 U.S. Dist. LEXIS 16090, at *11, citing In Re Grand Jury Subpoena (Legal Services Center), 615 F. Supp. 958 (D. Mass. 1985); In Re Sealed Case (Doe & Roe), 244 U.S. App. D.C. 11, 754 F.2d 395, 399 (D.C. Cir. 1985); U.S. Audio & Copy Corp. v. Philips Business Systems, Inc., [1983-1] Trade Cases (CCH) P 65,364 (N.D.Cal. 1983); Aegis, Inc. v. Augat, Inc., et al., Civil Action No. 85-1935-T, Memorandum and Order (Oct. 28, 1985).

³⁸ See Cadam, 1987 U.S. Dist. LEXIS 16090, at *11.

Brant, 97 F.R.D. at 708.

⁴⁰ Warner Lambert Co. v. Purepac Pha<u>rm.</u>, 2000 U.S. Dist. LEXIS 22559, at *31 (D.N.J. Dec. 22, 2000), citing In re Innotron, 800 F.2d at 1086.

issues could well cause unnecessary confusion between the patent claims and the antitrust and unfair competition claims.⁴¹

Bifurcation and stay of discovery would avoid prejudice by separating the case into more manageable units and avoiding potentially unnecessary burden on the Court and the parties both in discovery and at trial. Resolution of the patent issues first will likely avoid the antitrust issues altogether. Accordingly, the interest of avoiding prejudice and confusion by limiting the claims and evidence that a fact finder need consider favors bifurcation.⁴²

CONCLUSION

For the foregoing reasons, this Court should separate the trial on the issue of patent liability, validity, and enforceability from the trial on Roche's antitrust and unfair competition counterclaims, and should stay discovery of the antitrust and unfair competition counterclaims pending adjudication of the patent issues.

⁴¹ As discussed above, Roche's antitrust claims will require Roche to prove Amgen deprived Roche of its customers, that Amgen engaged in monopolization and exclusive dealing activities, and that Amgen had anticompetitive motives in filing suit against Roche, as well as proof of the relevant market and geographic market, market dominance, economic power and economic injury.

⁴² See In re Innotron, 800 F.2d at 1086; <u>GenRad</u>, 882 F. Supp. at 1158.

Dated: December 15, 2006 Respectfully Submitted, AMGEN INC.,

Of Counsel:

Stuart L. Watt
Wendy A. Whiteford
Monique L. Cordray
Darrell G. Dotson
MarySusan Howard
Kimberlin L. Morley
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: (617) 289-9200 Facsimile: (617) 289-9201

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

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 PURSUANT TO LOCAL RULE 7.1

I certify that counsel for the Plaintiff has attempted to confer with counsel for the Defendants, F. Hoffman-LaRoche Ltd., Hoffman LaRoche Inc. and Roche Diagnostics GmbH, in an attempt to resolve or narrow the issues presented by this motion and that no agreement could be reached.

/s/ Michael R. Gottfried
Michael R. Gottfried

CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of electronic filing and paper copies will be sent to those indicated as non-registered participants on December 15, 2006.

/s/ Michael R. Gottfried
Michael R. Gottfried