IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

AMGEN, INC., IMMUNEX CORPORATION, AMGEN USA INC., AMGEN MANUFACTURING LIMITED, and IMMUNEX RHODE ISLAND CORPORATION, Plaintiffs, v. ARIAD PHARMACEUTICALS, INC., and THE WHITEHEAD INSTITUTE FOR BIOMEDICAL RESEARCH, Defendants.	C. A. No. 06-259-MPT
ARIAD PHARMACEUTICALS, INC., MASSACHUSETTS INSTITUTE OF TECHNOLOGY, THE PRESIDENT AND FELLOWS OF HARVARD COLLEGE, and THE WHITEHEAD INSTITUTE FOR BIOMEDICAL RESEARCH, Counterclaim Plaintiffs, v. AMGEN INC., IMMUNEX CORPORATION, AMGEN USA INC., AMGEN MANUFACTURING LIMITED, IMMUNEX RHODE ISLAND CORPORATION, and WYETH, Counterclaim Defendants.	

MEMORANDUM ORDER

INTRODUCTION

This is a patent case. A detailed recitation of the convoluted procedural posture

of this case is unnecessary. A brief recitation follows. On April 20, 2006, Amgen, Inc., and related entities (collectively "Amgen"), filed a Complaint for Declaratory Judgment of Patent Invalidity and Non-Infringement of U.S. Patent No. 6,410,516 ("the '516 patent"). An amended complaint was filed on April 13, 2007. On April 14, 2007, ARIAD Pharmaceuticals, Inc., and others (collectively, "ARIAD"), filed an answer to the amended complaint and a counterclaim alleging infringement of the '516 patent. On May 3, 2007, Amgen filed an a answer to ARIAD's counterclaim which included, among others, an affirmative defense of unenforceability based on purported inequitable conduct during the prosecution of the application that issued as the '516 patent and purported inequitable conduct during the reexamination of the '516 patent. On February 12, 2008, Amgen filed an amended answer to ARIAD's counterclaim adding to its unenforceability defense additional alleged inequitable conduct during the reexamination of the '516 patent.

Currently before the court is ARIAD's motion for partial dismissal for lack of subject matter jurisdiction and ARIAD's motion for partial summary judgment on inequitable conduct.

DISCUSSION

Motion for Partial Dismissal for Lack of Subject Matter Jurisdiction

Amgen's initial complaint sought a declaration that each of the 203 claims of the '516 patent is invalid. It also sought a declaration that two Amgen products (Enbrel and Kineret) do not infringe any claim of the '516 patent.

On June 14, 2006, ARIAD moved to dismiss Amgen's complaint arguing that,

because ARIAD had never threatened Amgen with a patent infringement action, this court did not have subject matter jurisdiction pursuant to the Declaratory Judgment Act. On September 11, 2006, the court denied ARIAD's motion to dismiss finding, based on "the totality of the circumstances," that there was "an objectively reasonable apprehension of suit on th[e] record to sustain jurisdiction."[1] Among the facts emphasized by the court as "highly significant" was that Enbrel and Kineret were listed in "internal presentation materials which . . . ARIAD . . . had used to educate their board, explain to their board what their planning was."[2] Were it not for the inclusion of Enbrel and Kineret as part of those internal presentation materials, the court noted "I think I would be ruling differently than I am today. In fact, I feel sure I would have."[3]

Following the court's denial of its motion to dismiss, ARIAD filed its answer to Amgen's complaint on September 25, 2006. The answer recites that:

> Prior to the filing of this action ARIAD had not conducted any investigation into whether any activities related to the Enbrel® and/or Kineret® products infringe the '516 Patent. Solely in response to this action, and the Court's denial of ARIAD's motion to dismiss, ARIAD is now seeking to determine, for the first time, whether any activities related to the Enbrel® and/or Kineret® products infringe the '516 Patent. . . . ARIAD reserves the right to amend its answer once it has determined whether any activities related to the Enbrel® and/or Kineret® products infringe the '516 Patent.[4]

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[1] D.I. 580, Ex. 3 at 75:8-12 (Motions Hearing transcript). This case was originally assigned to former District Court Judge Kent A. Jordan, who denied ARIAD's June 14, 2006 motion to dismiss. Judge Jordan was subsequently elevated to the United States Court of Appeals for the Third Circuit. Pursuant to 28 U.S.C. § 636(c) and Federal Rule of Civil Procedure 73, and Local Rule 73.1, the parties consented to the jurisdiction of United States Magistrate Judge Mary Pat Thynge to "conduct any and all proceedings in this case, except mediation, including the trial, order the entry of a final judgment, and conduct all post-judgment proceedings."

[2] D.I. 580, Ex. 3 at 79:1-4; *id.*, Ex. 3 at 80:1-4 (noting presentation slide listing Enbrel and Kineret).

[3] D.I. 580, Ex. 3 at 78:24-25.

[4] D.I. 72, ¶ 23. ARIAD maintained its contention that "[t]he Court lacks subject matter jurisdiction over this action or, in the alternative, should exercise its discretion to decline the exercise of subject matter jurisdiction over this action." D.I. 72, ¶ 24.

On April 13, 2007, ARIAD amended its answer to add a counterclaim accusing Amgen of patent infringement related to the Enbrel and Kineret products. The previous day, April 12, 2007, ARIAD served supplemental responses to two interrogatories through which Amgen requested identification of all claims of the '516 patent alleged to be infringed based on any activities related to Enbrel and/or Kineret. Those supplemental responses identified twenty-two claims of the '516 patent alleged to be infringed by those products: independent claims 1, 2, 5, 6, and 18, and dependent claims 26, 27, 29, 37, 38, 40, 59-62, 70-73, and 183-185.[5] In a subsequent supplementation of its interrogatory responses, served on December 21, 2007, ARIAD stated that "[t]o reduce the number of issues in the reexamination proceedings relating to the '516 patent, ARIAD [had] cancelled [certain claims] . . . [and that] claims 1, 2, 5, 26, 27, 29, 37, 38, 40 and 59-62" were no longer being asserted based on any activities related to Enbrel and/or Kineret,[6] leaving nine claims at issue (6, 18, 70-73, and 183-85).

By letter dated January 18, 2008, ARIAD informed Amgen that it was no longer asserting any infringement claims based on activities related to Kineret and that it was also no longer asserting infringement of claims 73 and 185–thus leaving seven claims at issue (6, 18, 70-72, 183, and 184) and only activities related to Enbrel accused of

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[5] That supplementation also noted ARIAD's express reservation of "the right to modify or supplement" its responses, "including but not limited to adding or removing particular claims from the '516 patent." The court notes that ARIAD never expanded the number of claims, rather, it subsequently reduced the number of claims at issue in this litigation.

[6] D.I. 580, Ex. 11 at 14, 26. On November 2, 2007, prior to this interrogatory response supplementation, ARIAD had informed Amgen of the cancellation of these claims in the reexamination proceedings and that those claims were no longer being asserted in this matter. The letter noted "[w]e will be providing supplemental interrogatory responses in due course, but we wanted to inform you promptly of the claim cancellation." D.I. 643, Ex. L.

infringing those claims.[7]

On February 1, 2008, the parties submitted a joint status report letter to the court. That letter noted the case had been streamlined by, among other things, ARIAD's representation that it "will not be pursuing allegations of infringement against Amgen's Kineret™ product" and that "the parties have yet to work out a stipulation or covenant that could effectively dispense with Amgen's declaratory judgment claims with respect to [Kineret]."[8]

On February 14, 2008, Amgen wrote to ARIAD:

> In light of your decision to pursue infringement allegations only with respect to 7 claims of the '516 patent, and to drop all allegations of infringement with respect to Amgen's Kineret product, we would hope that we can reach agreement on an appropriate covenant not to sue to allow us to similarly streamline our declaratory judgment claims (and thus the remainder of expert discovery, trial, etc.). To this end we would propose the attached covenant not to sue.[9]

With respect to Kineret, Amgen's proposed covenant covered all 203 claims of the '516 patent, as well as, any claim in any reissued or reexamined version of that patent. Other than claims 6, 18, 70-72, 183, and 184 (the seven remaining claims at issue), Amgen's proposal covered all the remaining claims of the '516 patent and any claim in any reissued or reexamined version of the '516 patent "that is the same as, or substantially identical to, any claim of the '516 patent as it currently reads" "with respect to all methods, processes, and products made, used, offered for sale, sold or imported by Amgen at any time, whether before or after the date of this covenant . . . includ[ing]

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[7] D.I. 580, Ex. 16.
[8] D.I. 580, Ex. 17 at 1-2.
[9] D.I. 691, Ex. 3 (02/14/2008 Sernel email).

any commercial and pipeline products, whether or not in clinical trials at the time of the covenant."

On March 18, 2008, ARIAD responded by sending Amgen a draft stipulation that included a covenant not to sue which ARIAD contends "was in all material respects identical to Amgen's proposal, except that it covered only the two products at issue in this litigation, *i.e.*, Kineret and Enbrel." Amgen rejected that stipulation. On April 25, 2008, ARIAD sent Amgen a unilateral covenant "which memorialized the commitments set forth in ARIAD's March 18, 2008 proposal."[10]

That covenant (the "April 2008 Covenant," or the "Covenant") recites:

> 1. ARIAD Pharmaceuticals, Inc., Massachusetts Institute of Technology, the President and Fellows of Harvard University and the Whitehead Institute for Biomedical Research (collectively, "ARIAD") hereby unconditionally and irrevocably covenant not to sue Amgen, Inc., Immunex Corporation, Amgen USA, Inc., Amgen Manufacturing, Ltd., and Immunex Rhone Island Corporation (collectively "Amgen") for infringement of any claim of United States Patent No. 6,410,516 (the "'516 patent") at any time (whether before or after the date of this covenant) based on any activities proscribed under 35 U.S.C. § 271 involving Kineret® or anakinra. ARIAD hereby unconditionally and irrevocably covenants not to sue anyone who manufactures, markets, imports, sells or uses Kineret® or anakinra sold or supplied by Amgen for infringement of any claim of the '516 patent at any time (whether before or after the date of this covenant) based on activities proscribed under 35 U.S.C. § 271 involving Kineret® or anakinra. The covenant set forth in this paragraph 1 extends to any claim in any reissued or reexamined version of the '516 patent.
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> 2. ARIAD further covenants not to sue Amgen or anyone who manufactures, markets, imports, sells or uses in the United States any Enbrel® or etanercept sold or supplied by Amgen for infringement of any claim of the '516 patent at any time (whether before or after the date of this covenant) based on any activities proscribed under 35 U.S.C. § 271 involving Enbrel® or etanercept, other than (i) for infringement of claims 6, 18, 70, 71, 72, 183 and 184 thereof or any claim that may emerge from

[10] D.I. 688 at 13 n.12.

> the reexamination of the '516 patent that is substantially identical to those claims; or (ii) for infringement of any claim of the '516 patent that may emerge from the reexamination of the '516 patent in a form that is not substantially identical to a claim of the '516 patent that issued on June 25, 2002. The term "substantially identical" as used herein is intended to have the same meaning as that term is used in 35 U.S.C. § 252.[11]

The issue presented by ARIAD's motion is whether the April 2008 Covenant deprives the court of jurisdiction to consider Amgen's request for declaratory judgment that all of the claims of the '516 patent are invalid and to consider Amgen's unenforceability defenses. ARIAD contends that the Covenant "divested the Court of any jurisdiction it possessed under the Declaratory Judgement Act with respect to the 196 claims of the '516 Patent that ARIAD has not asserted against any Amgen product." Consequently, through its motion, ARIAD requests that "the Court dismiss Amgen's challenges to the validity and enforceability of the claims of the '516 Patent that ARIAD has not asserted, and has promised never to assert, against Enbrel and Kineret, the only products ever at issue in this litigation."

Amgen maintains that the Covenant does not divest this court of jurisdiction and urges the court to deny ARIAD's motion. It states that the instant litigation was brought to "to seek resolution, once and for all, of ARIAD's threats of litigation under the '516 patent." It notes that the court previously determined that there is jurisdiction to hear this case and that the court should address all disputes under the '516 patent (including invalidity and unenforceability of all its claims) "that could be asserted against Amgen now and/or again in the future."

Amgen argues that the Declaratory Judgment Act permits entities to a

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[11] D.I. 580, Ex. 25 (April 25, 2008 Covenant Not to Sue).

determination of uncertain rights with respect to others' patent rights and that to permit ARIAD to avoid a determination of the invalidity and unenforceability of the '516 patent as a whole is at odds with the policy and purpose of the Act and is contrary to judicial economy, finality, and fairness to Amgen. According to Amgen, this is particularly true where, as here, litigation has been ongoing for an extended period of time and it has expended substantial time and resources to support its positions on these issues. Amgen points to the timing of the Covenant, on the day *Markman* briefs and motions for summary judgment were filed, as an eleventh-hour attempt by ARIAD to avoid the entirety of Amgen's invalidity and unenforceability arguments being considered by the court. Amgen suggests that "[t]he partial covenant is narrowly tailored to encompass most (though not even all) future suits regarding the drugs Enbrel and Kineret." It contends that this "too-little-too-late partial covenant does not remove the controversy between ARIAD and Amgen with respect to the non-asserted claims of the '516 patent." Amgen notes that it "has a robust pipeline of products that will be at risk of further litigation if these issues . . . are not resolved here and now."[12] It avers that the Federal Circuit has held that similar covenants not to sue did not divest a court of jurisdiction to consider pre-existing declaratory judgment claims for unenforceability and/or invalidity. Amgen maintains that the Covenant's application to some, but not all, of the claims of

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[12] D.I. 642 at 1. "Amgen's continuing pipeline of new drugs and indication includes 38 ongoing clinical trials and countless other drugs in other stages of development. ARIAD has indicated its belief that drugs designed to treat cancer and inflammatory diseases are allegedly enveloped by the '516 patent, and Amgen has four such drugs in Phase III trials, seven such drugs in Phase II trials, and five such drugs in Phase I trials. . . . It is reasonable to expect that ARIAD will continue to attempt to enforce the '516 patent against Amgen as new products and activities continue to roll out. . . . Because this Court has found and confirmed it has jurisdiction, Amgen has the right to resolve once and for all the invalidity and unenforceability issues for the '516 patent that have been involved in the case from the start." D.I. 642 at 5.

the '516 patent is a significant fact militating against ARIAD's motion. Finally, Amgen states that

> ARIAD's attempt to avoid a final and complete decision on these issues is an unjust attempt to keep the '516 patent hanging over Amgen's head so that ARIAD can drag Amgen (and/or others) back into court to re-litigate the same issues as here with respect to other claims of the patent. ARIAD's insufficient partial covenant does not divest this Court of jurisdiction, and ARIAD's motion for partial dismissal on the basis of this covenant must be denied.[13]

"The Declaratory Judgment Act provides that '[i]n a case of actual controversy within its jurisdiction . . . any court of the United States . . . may declare the rights and other legal relations of any interested party seeking such a declaration, whether or not further relief is or could be sought.'"[14] Jurisdiction under the Act requires

> that the dispute be "definite and concrete, touching the legal relations of parties having adverse legal interests"; and that it be "real and substantial" and "admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts."[15]

The Supreme Court summarized the distinction "between those declaratory-judgment actions that satisfy the case-or-controversy requirement and those that do not" by stating "'[b]asically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interest, of sufficient immediacy and reality to warrant the

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[13] Amgen also asks for attorneys' fees if the motion is granted, contending that due to the timing of the Covenant "ARIAD has attempted to manipulate these proceedings and divest the court of authority to determine whether the claims of the '516 patent are invalid. There are 203 claims to the '516 patent. Preparing invalidity arguments based on all of those claims, and preparing non-infringement arguments based on KINERET, and providing discovery based on KINERET as well as the assay patents, has been an exceedingly time-consuming and expensive process." D.I. 642 at 17.

[14] *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 770-71 (2007) (quoting 28 U.S.C. § 2201(a)) (alteration and omissions in original).

[15] *Id.* at 771 (quoting *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937)) (alteration in original).

issuance of a declaratory judgment.'"[16] The "actual controversy must be in existence at all stages of the litigation and cannot merely be present at the filing of the complaint."[17] "[T]he existence of a case or controversy must be evaluated on a claim-by-claim basis."[18] "When there is no actual controversy, the court has no discretion to decide the case. When there is an actual controversy and thus jurisdiction, the exercise of that jurisdiction is discretionary."[19] "Under Federal Circuit precedent, a properly executed covenant not to sue for infringement not only moots the controversy with respect to infringement, but it also eliminates subject matter jurisdiction with respect to remaining declaratory claims for patent invalidity and unenforceability."[20]

Amgen contends that the Covenant is insufficient to divest the court of jurisdiction to address the invalidity and unenforceability issues it has raised and that granting ARIAD's motion would create an unfair outcome for Amgen and an inefficient result for the court. Amgen argues that the Covenant "would . . . allow ARIAD to reinstate claims it has cancelled at the PTO, and dropped from this case, to re-assert them in a new case against Amgen." The court finds this argument unpersuasive and agrees with ARIAD that the Covenant specifically prevents ARIAD from bringing such future suits against Amgen.

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[16] *Id.* at 771(quoting *Maryland Casualty Co. v. Pacific Coal & Oik Co.*, 312 U.S. 270, 273 (1941)).

[17] *Merck & Co., Inc. v. Apotex, Inc.*, 488 F. Supp. 2d 418, 423 (D. Del. 2007). Therefore, Amgen's argument that, in denying ARIAD's earlier motion to dismiss, this court determined it has jurisdiction to hear its declaratory judgment action does not end the inquiry. "The burden is on the party claiming declaratory judgment jurisdiction to establish that such jurisdiction existed at the time the claim for declaratory relief was filed and that it has continued since." *Benitec Australia, Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1344 (Fed. Cir. 2007).

[18] *Jervis B. Webb Co. v. Southern Sys., Inc.*, 742 F.2d 1388, 1399, (Fed. Cir. 1984).

[19] *Spectronics Corp. v. H.B. Fuller Co., Inc.*, 940 F.2d 631, 634 (Fed. Cir. 1991), *abrogated on other grounds by Liquid Dynamics Corp. v. Vaughan Co., Inc.*, 355 F.3d 1361, 1370 (Fed. Cir. 2004)).

[20] *MedImmunie, Inc. v. Genentech, Inc.*, 535 F. Supp. 2d 1000, 1005 (C.D. Cal. 2008) (citing *Highway Equip. Co., Inc. v. FECO, Ltd.*, 469 F.3d 1027, 1033 n.1 (Fed. Cir. 2006)).

With regard to Kineret, the Covenant states that ARIAD "unconditionally and irrevocably covenant not to sue Amgen . . . for infringement of *any claims* of . . . [the '516 patent] *at any time* (whether before or after the date of this covenant) based on *any activities* proscribed under 35 U.S.C. § 271 involving Kineret® . . . ." The Covenant similarly covers "*anyone* who manufactures, markets, imports, sells or uses Kineret® . . . sold or supplied by Amgen" and the Covenant "extends to *any claim in any reissued or reexamined version of the '516 patent*." With regard to Enbrel, the Covenant makes corresponding representations not to sue, with the exception of the seven claims still at issue in this case (and any claim that may emerge from the reexamination of the '516 patent that is substantially identical to those claims) or any claim that may emerge from the reexamination that is *not* substantially identical to any claim of the '516 patent.

As ARIAD notes, the first exclusion for the seven remaining claims (and any substantially identical claims to emerge from the reexamination) preserves its ability to collect damages for the entire period of infringement, were such infringement ultimately to be determined. Its motion does not preclude Amgen from attempting to establish the invalidity of those seven claims. The second exclusion is for claims that may emerge from the reexamination that are *not* substantially identical to a claim of the '516 patent as issued on June 25, 2002. The form of any such claims is unknown and, at the current time, Amgen would be unable to challenge those hypothetical claims. The Federal Circuit has stated that "the future existence of a reissue patent is wholly

speculative and, therefore, cannot create a present controversy."[21]

Amgen argues that the Covenant is inadequate in that it does not cover products it is developing. It avers that it has thirty-eight new drugs in "ongoing clinical trials and countless other drugs in other stages of development." Amgen reports that "ARIAD has indicated its belief that drugs designed to treat cancer and inflammatory diseases are allegedly enveloped by the '516 patent" and that it has several such drugs in Phase I, II, or III trials. Amgen contends that it is "reasonable to expect that ARIAD will continue to attempt to enforce the '516 patent against Amgen as new products and activities continue to roll out." The court is again unpersuaded that such stated expectation on the part of Amgen regarding its pipeline drugs rises to the level of a real and substantial controversy between the parties. Amgen brought its declaratory judgment action seeking a determination that Kineret and Enbrel do not infringe the '516 patent. The inclusion of those products, and companies including Amgen, in ARIAD's internal presentation materials was "highly significant" to the court's denial of ARIAD's prior motion to dismiss for lack of subject matter jurisdiction, the absence of which the court stated "I think I would be ruling differently than I am today. In fact, I feel sure I would have." The court determines that Amgen's pipeline products do not establish real and

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[21] *Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 856 (Fed. Cir. 1999); *see also Vision Biosystems (USA) Trading, Inc. v. Ventana Medical Systems, Inc.*, No. Civ.A. 03-10391-GAO, 2004 WL 2387284, *10-*11 (D. Mass. 2004) (Vision argued the covenant not to sue was inadequate because, *inter alia*, it did "not protect Vision if any patent claims emerge from the PTO's pending reexamination of the '439 patent." Rejecting that argument, the Massachusetts court stated that "Vision's concern that some claims may emerge from the PTO's reexamination of the '439 patent is too speculative and does not provide a basis for jurisdiction at this time."). The covenant not to sue in *Amana* promised not to assert a claims based on the patent "as it presently reads." *Amana*, 172 F.2d at 856. Similarly, the covenant not to sue in *Vision Biosystems* covered "the claims as th*ey presently read* and for any claims that emerge from reexamination proceedings *without substantive change* . . . ." *Vision Biosystems*, 2004 WL 2387284, *10 (emphasis added).

substantial controversy among the parties.[22]

In *MedImmune, Inc. v. Genentech, Inc.*,[23] the district court rejected an argument similar to Amgen's concerning a covenant not to sue which did not cover a new drug even farther along than Amgen's pipeline products. Unlike the Amgen drugs in development (which Amgen states are the type ARAID "indicated" would be covered by the '516 patent), MedImmune, argued that it had a drug which was "the next generation" of, and "functionally identical" to, the drug covered by the covenant not to sue there. The clinical trials for that drug had been completed and "commercial" quantities had been produced. MedImmune expected the Food & Drug Administration ("FDA") to approve its product for sale within ten months. MedImmune argued that "[p]ermitting the Covenant to take effect despite its exclusion of [MedImmune's new drug] . . . would force it to relitigate the exact same claim construction and infringement

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[22] *See Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855 (Fed. Cir. 1999) (rejecting argument based on pipeline products stating "an actual controversy cannot be based on a fear of litigation over future products"); *see also Vision Biosystems (USA) Trading, Inc. v. Ventana Medical Systems, Inc.*, No. Civ.A. 03-10391-GAO, 2004 WL 2387284, *11 (D. Mass. Sept. 30, 2004) (covenant not to sue need not cover hypothetical, future products); *Taylor Brands, LLC v. SOG Specialty Knives, Inc.*, No. 2:06-CV-16, 2008 WL 413625 (E.D. Tenn. Feb. 13, 2008) (Report and Recommendation) ("[N]ebulous future events which may or may not occur will not defeat a Covenant Not To Sue, assuming of course that the covenant's language accomplishes its avowed purpose. And, in that regard, the only remaining question is whether the language employed by SOD in its proffer covers the products or products which are the basis of this lawsuit."). Amgen cites *BIS Advanced Software Systems, Ltd. v. Red Bend Software*, No. 04-11690, 2006 WL 753246 (D. Mass. Mar. 22, 2006) for the proposition that "[c]ourts may exercise jurisdiction to hear declaratory judgment claims that relate to future products if those claims relate to an issue that is present in the instant case." D.I. 642 at 16. In *BIS Advanced*, the court refused to dismiss declaratory judgment counterclaims. "[P]laintiff has stated that it will not bring an infringement action against defendants–but only as to 'the software products and services currently manufactured, sold, and licensed' by defendant." *Id.* at *1. The court stated two reasons for its refusal to dismiss. First, since "defendant regularly updates its products . . . it is still vulnerable to an infringement suit" and because "plaintiff has throughout the litigation shown a desire to sue defendant's customers for infringement as well." *Id.* Here, the court does not view Amgen's pipeline of new drugs to be analogous to computer software "updates." Also, unlike *BIS Advanced* where only the declaratory judgment counter-claimant was covered, ARIAD's Covenant applies to Amgen and "anyone who manufactures, markets, imports, sells or uses [Kineret or Enbrel] sold or supplied by Amgen."

[23] 535 F. Supp. 2d 1000 (C.D. Cal. 2008).

issues again in the near future."[24]

The court rejected MedImmune's arguments noting, *inter alia*, that MedImmune exclusively directed its pleadings to another drug and that, even accepting the assumption that the new drug would be approved in ten months, such approval would be after the trial scheduled there.[25] Here, Amgen sought declaratory judgment concerning Enbrel and Kineret and it was those two products upon which the court determined there was an actual controversy when it denied ARIAD's earlier motion to dismiss. ARIAD's allegations of infringement have been directed to Enbrel and Kineret, and now only Enbrel. There is no suggestion as to when Amgen's pipeline products would be on the market and, in any event, trial in this matter is scheduled for November of this year.

To the extent that Amgen's cases support the proposition that a partial covenant not to sue does not divest the court of jurisdiction where all the claims of a patent are alleged to be infringed and a covenant not to sue is later tendered which only covers a subset of a patent's claims, the court finds that those cases are distinguishable from the facts of this case.[26] In those cases, the *patent holder* initiated an infringement action

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[24] *MedImmune*, 535 F. Supp. 2d at 1008.

[25] *MedImmune*, 535 F. Supp. 2d at 1009-10.

[26] *See, e.g., Lear Auto. Dearboarn, Inc. v. Johnson Controls, Inc.*, 528 F. Supp. 2d 654 (E.D. Mich). In *Lear Auto.*, plaintiff's complaint alleged infringement of all claims of its patent. *Lear Auto.*, 528 F. Supp. 2d. at 668-69. The covenant not to sue was made *after* the parties had completed briefing on defendant's motion for summary judgment of noninfringement. It was at oral argument that "Lear . . . offered to provide a covenant not to sue . . . and it has since filed two such covenants with the Court." *Id.* at 669. In determining not to exercise its discretion to decline to consider the declaratory judgment counterclaim, it stated "it is difficult to view Lear's tactics in this case as anything other than an eleventh-hour attempt to pull the jurisdictional rug out from under a counterclaim that it could not defend against on the merits." *Id.* at 674. The court notes that the *MedImmune* court, while also distinguishing *Lear Auto.*, characterized the exception there, based on a partial covenant not to sue where all claims of the patent-in-suit had been asserted, as "questionable." *MedImmune*, 535 F. Supp. 2d at 1007 ("[T]he narrow holding of *Lear Auto.* itself was based solely on the questionable exception it fashioned from the *Super Sack* rule:

alleging infringement of all of the claims of the relevant patents, or otherwise putting all of the claims of the patent at issue. In response to declaratory judgment counterclaims, some claims were withdrawn, but the courts determined that partial covenants not to sue did not divest the court of jurisdiction to decide the declaratory judgment counterclaims.

Here, Amgen initially brought its declaratory judgment action attacking the validity of all of the claims of the '516 patent. ARIAD responded with a motion to dismiss for lack of subject matter jurisdiction, which the court denied. After that ruling, ARIAD (although still disagreeing that there was subject matter jurisdiction) answered the complaint and stated that it was "seeking to determine, for the first time," whether Enbrel and/or Kineret infringe the '516 patent. Later, ARIAD amended its answer to add a counterclaim accusing Amgen of patent infringement due to activities related to those products. The day prior to that amendment, ARIAD supplemented its responses to Amgen's interrogatories and identified twenty-two claims of the '516 patent alleged to be infringed by Enbrel and/or Kineret. Subsequent interrogatory response supplementation reduced to nine the number of claims alleged to be infringed by those products. Later communication from ARIAD informed Amgen that Kineret was no longer being accused of infringement and that two additional claims previously asserted against Enbrel were also being dropped. Finally, prior to the filing of summary judgment motions, albeit on the date for filing of those motions, ARIAD forwarded the

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the *Lear Auto.* patentee had *initially* asserted *all* its claims, rather than a subset thereof, and thus would not be permitted to limit the invalidity challenge only the claims asserted after its covenant not to sue. ").

Covenant to Amgen.[27] Under these facts, the court is unpersuaded that the cases cited by Amgen compel a denial of ARIAD's motion with regard to invalidity.[28] Therefore, the court grants ARIAD's motion for summary judgment that the court lacks subject matter jurisdiction to determine the validity of the claims of the '516 patent, other than the seven claims currently at issue.

The court reaches the opposite conclusion with regard to Amgen's declaratory judgment claim of unenforceability. The California court's *MedImmune* decision, upon which ARIAD primarily relies, notes that "a *partial* covenant not to sue may limit the scope of an invalidity counterclaim but not the scope of an unenforceability counterclaim."[29] There is no dispute that a current controversy exists concerning the infringement of the asserted claims of the '516 patent. However, a determination that inequitable conduct has occurred, upon which Amgen bases its unenforceability

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[27] The court notes that Amgen is the party that first brought up the topic of a covenant not to sue in its opposition to ARIAD's earlier motion to dismiss. Amgen stated that if ARIAD's position was that Amgen's products do not infringe the '516 patent "rather than seeking dismissal of this action, ARIAD should be willing to grant Amgen a covenant not to sue for Amgen's products." Amgen again brought up to topic in its opposition to ARIAD's motion requesting certification of an interlocutory appeal of the court's September 13, 2006 order (memorializing the denial of ARIAD's motion to dismiss) to the Federal Circuit. In that opposition, Amgen argued that "[i]f ARIAD has any real concerns about its resources to get its drug approved, then its solution is to grant Amgen a covenant not to sue. ARIAD and its counsel know very well that a properly-tailored 'covenant not to sue deprives a court of declaratory judgment jurisdiction.'" (quoting *Metabolite Labs., Inc. v. Lab. Corp. of America Holdings*, 370 F.3d 1354, 1369 (Fed. Cir. 2004)). The parties informed the court in a joint status report indicating that the parties would be attempting to work out a stipulation "that could effectively dispense with Amgen's declaratory judgment claims with respect to [Kineret]." Two weeks later, counsel for Amgen wrote to counsel for ARIAD suggesting a covenant not to sue, and attaching Amgen's proposed version of such covenant. The following month ARIAD sent Amgen its proposed covenant, which Amgen rejected. Finally, on April 25, 2008, ARIAD unilaterally sent Amgen the April 2008 Covenant. The court finds these facts are dissimilar from those that the *Lear* court characterized as "an eleventh-hour attempt to pull the jurisdictional rug out from under" Amgen's claim of invalidity.

[28] The court also declines to exercise its discretion to award Amgen attorneys' fees. The court does not find that ARIAD's actions in reducing the number of claims at issue, and providing the April 2008 Covenant (or the timing thereof) to be the "in bad faith, vexatious[], wanton[], or for oppressive reasons" nor are they "unreasonable conduct [that] has violated the rules of litigation." *Marek v. Chesny*, 473 U.S. 1, 36-37 (1985).

[29] *MedImmune*, 535 F. Supp. 2d at 1005 n.1 (emphasis in original).

defense, renders the entire patent unenforceable.[30] The court concludes that the April 2008 Covenant does not divest it of subject matter jurisdiction to hear Amgen's unenforceability defenses.[31]

Consequently, the court grants ARIAD's motion for summary judgment that the court lacks subject matter jurisdiction to consider Amgen's invalidity arguments with regard to the claims of the '516 patent other the seven claims at issue and denies that motion with respect to Amgen's unenforceability defenses.

Motion for Partial Summary Judgment on Inequitable Conduct

ARIAD moves for partial summary judgment that two of the three theories of inequitable conduct asserted by Amgen are moot in light of ARIAD's submission to the PTO of the documents that are the subject of those theories.

Summary Judgment is appropriate if the "pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and the moving party is entitled to a

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[30] *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 877 (Fed. Cir. 1998) (*en banc* in pertinent part) ("When a court has finally determined that inequitable conduct occurred in relation to one or more claims during prosecution of the patent application, the entire patent is rendered unenforceable.").

[31] *See, e.g., Biogen, Inc. v. Amgen, Inc.*, 913 F. Supp. 35 (D. Mass. 1996). In *Biogen*, the court held that "in light of [the patent holder's] latest representation that it will relinquish forever the right to sue [defendant] on any claims other than [the asserted claims], [defendant's] counterclaim will be dismissed." The court noted, however, that "[a] finding of nonjurisdiction over the counterclaim [for invalidity of non-asserted claims] does not . . . preclude [defendant] from contesting the enforceability of the '703 patent." *Id.* at 38 (citing *Scripps Clinic and Research Foundation v. Genentech Inc.*, 707 F. Supp. 1547, 1557 n.15 (N.D. Cal. 1989), rev'd on other grounds, 927 F.2d 1565 (Fed. Cir. 1991) ("[A] determination that inequitable conduct has occurred renders the 'entire patent' unenforceable. However, . . . this Court has jurisdiction only over those claims with respect to which infringement is alleged.")). The *Biogen* court noted that "[t]he reason that a conservative approach to jurisdiction is not unfair lies in the significant difference between a claim of unenforceability and a claim of invalidity. An inequitable conduct defense is directed to the former, and is not dependent on the ability to litigate the latter." *Id.* (citing *Jervis B. Webb Co. v. Southern Syss., Inc.*, 742 F.2d 1388, 1400 n.8 (Fed. Cir. 1984) (noting that "when the proof at trial establishes . . . fraud," a court declining declaratory judgment jurisdiction over nonasserted claims may nonetheless enter "a declaratory judgment that all claims are invalid.")).

judgment as a matter of law."[32] Once there has been adequate time for discovery, Rule 56(c) mandates judgment against the party that "fails to make a sufficient showing to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial."[33] When a party fails to make such a showing, "there can be no 'genuine issue as to any material fact' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial."[34] The moving party is therefore entitled to judgment as a matter of law because "the nonmoving party has failed to make a sufficient showing on an essential element of her case with respect to which she has the burden of proof.[35] A dispute of material fact exists where "the evidence is such that a reasonable jury could return a verdict for the nonmoving party."[36]

The moving party bears the initial burden of identifying portions of the record which demonstrate the absence of a genuine issue of material fact.[37] However, a party may move for summary judgment with or without supporting affidavits.[38] Therefore, "the burden on the moving party may be discharged by 'showing' – that is, pointing out to the district court – that there is an absence of evidence supporting the nonmoving party's case."[39]

If the moving party has demonstrated an absence of material fact, the

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[32] Fed. R. Civ. P. 56(c).
[33] *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986).
[34] *Id.* at 323.
[35] *Id.*
[36] *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).
[37] *Celotex*, 477 U.S. at 323.
[38] *Id.*
[39] *Id.* at 325.

nonmoving party must then "come forward with specific facts showing that there is a genuine issue for trial."[40] If the nonmoving party bears the burden of proof at trial, he "must go beyond the pleadings in order to survive a motion for summary judgment."[41] That party "may not rest upon the mere allegations or denials of his pleadings, but must set forth specific facts showing that there is a genuine issue for trial."[42] At the summary judgment stage, the court is not to "weigh the evidence and determine the truth of the matter, but to determine whether there is a genuine issue for trial."[43] Further, "there is no issue for trial unless there is sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party."[44] The threshold inquiry therefore is "determining whether there is a need for trial – whether, in other words, there are any genuine factual issues that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party."[45]

When an application for a patent is filed with the PTO, "[e]ach individual associated with the filing and prosecution of [that] patent application has a *duty of candor and good faith* in dealing with the [PTO], which includes a duty to disclose to the [PTO] all information known to that individual to be material to patentability . . . ."[46] "A breach of this duty may constitute inequitable conduct, which can arise from a failure to disclose information material to patentability, coupled with an intent to deceive the

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[40] Fed. R. Civ. P. 56(c).
[41] *Yeager's Fuel v. Pennsylvania Power & Light Co.*, 22 F.3d 1260, 1273 (3d Cir. 1994).
[42] *Anderson*, 477 U.S. at 248.
[43] *Id.* at 249.
[44] *Id.*
[45] *Id.* at 250.
[46] 37 C.F.R. § 1.56 (emphasis added).

PTO."[47]

As noted above, Amgen commenced this action seeking declarations of non-infringement and invalidity of the '516 patent. ARIAD later asserted a counterclaim of infringement. In response, Amgen filed a reply to ARIAD's counterclaim which included, among others, an affirmative defense of unenforceability based on purported inequitable conduct during the prosecution of the application that issued as the '516 patent and purported inequitable conduct during the reexamination of the '516 patent.[48] Subsequently, Amgen filed an amended answer to ARIAD's counterclaim expanding its unenforceability defense by alleging additional purported inequitable conduct during the reexamination of the '516 patent.

ARIAD's motion does not seek summary judgment with regard to Amgen's allegations of inequitable conduct during the prosecution of the '516 patent. The motion seeks summary judgment with regard to Amgen's allegations of inequitable conduct during the reexamination proceeding. The conduct Amgen specifically alleges concerns ARIAD's submissions to the PTO related to Dr. Inder Verma ("Verma") and Dr. Thomas Kadesch ("Kadesch").

Verma was retained by ARIAD as a technical expert in the reexamination proceeding. On November 9, 2006, Verma submitted a declaration to the PTO in

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[47] *M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co., Inc.*, 439 F.3d 1335, 1339-40 (Fed. Cir. 2006) (citing *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 2006)).

[48] The '516 patent is currently undergoing reexamination by the PTO. On April 4, 2005, prior to the initiation of this action, Eli Lilly and Co. ("Lilly") petitioned the PTO to reexamine the '516 patent under 35 U.S.C. § 302. At that time, Lilly was involved in separate litigation with ARIAD in another forum in which ARIAD alleged Lilly infringed certain claims of the '516 patent (the "*Lilly* litigation"). The PTO granted Lilly's petition for reexamination and commenced an *ex parte* reexamination proceeding, which is ongoing. The reexamination of the '516 patent is the Merged Proceeding of *Ex Parte* Reexamination Control Nos: 90/007,503 (Filed April 4, 2005) and 90/007,828 (filed December 2, 2005) (the "reexamination proceeding").

support of the validity of the claims of the '516 patent (the "Verma declaration"). Amgen contends the Verma declaration contains false and misleading statements and that it was a breach of ARIAD's duty of good faith and candor to the PTO that ARIAD did not also submit three articles co-authored by Verma (the "Verma articles") which purportedly contradict his declaration.

Kadesch was retained by ARIAD as an expert in the *Lilly* litigation. In that capacity, he submitted an expert report and offered deposition and trial testimony on issues of enablement, written description, and priority date. ARIAD submitted to the PTO Kadesch's report and testimony from the *Lilly* litigation. Separately, Kadesch was retained as an expert witness on behalf of defendant F. Hoffman-LaRoche, Ltd. ("Roche") in a patent case in another forum in which Amgen was the plaintiff (the "*Roche* litigation"). Kadesch was deposed by Amgen during the *Roche* litigation and purportedly recanted the testimony he gave in the *Lilly* litigation. Amgen contends that ARIAD breached its duty of candor and good faith to the PTO by failing to disclose (and by seeking to prevent the disclosure of) Kadesch's *Roche* testimony.

ARIAD contends since it subsequently submitted to the PTO the Verma articles and Kadesch's *Roche* litigation testimony at a time when the examiner in the reexamination proceeding may consider them, those defenses are moot.[49] ARIAD contends that Federal Circuit precedent establishes that allegations of inequitable conduct for failure to disclose materials are moot where, as here, those materials are

[49] ARIAD also notes that pursuant to section 609 of Manual of Patent Examining Procedure ("MPEP"), and the applicable regulations, 37 C.F.R. § 1.97, the examiner has an obligation to consider those submissions.

submitted to the PTO in sufficient time for them to be considered by the examiner.[50]

On May 17, 2007, after Amgen raised its inequitable conduct theory related to Verma, ARIAD submitted to the PTO an Information Disclosure Statement ("IDS") attaching the Verma articles Amgen alleges were wrongfully withheld.[51] On July 3, 2007, ARIAD again submitted those articles, as well as Amgen's reply to ARIAD's counterclaim, to the PTO.[52] Amgen experts Dr. Randolph Wall ("Wall") and Gerald J. Mossinghoff ("Mossinghoff") created reports, dated January 18, 2008, which include Amgen's contention that Verma's declaration is inconsistent with his prior articles. On February 20, 2008, ARIAD submitted to the PTO additional IDSs attaching the Wall and Mossinghoff reports, the Verma articles, and Amgen's reply to ARIAD's counterclaim.[53] Thus, by February of this year, ARIAD had repeatedly submitted to the PTO the Verma

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[50] D.I. 574 at 3 (citing *Young v. Lumenis, Inc.*, 492 F.3d 1336, 1348 (Fed. Cir. 2007); *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1582 (Fed. Cir. 1991).

[51] Second Supplemental Information Disclosure Statement. This IDS recites: "[i]n accordance with their duty of disclosure under 37 C.F.R. § 1.555, Patentees direct the Examiner's attention to the following disclosures . . . ." It listed (and attached) twenty-nine items, the last three (items 27, 28, and 29) being the articles co-authored by Dr. Verma. Also among the items submitted was Amgen's reply to ARIAD's counterclaim filed in this action (item 26) that includes Amgen's inequitable conduct allegations regarding Verma's declaration and the Verma articles.

[52] Third Supplemental Information Disclosure Statement. This IDS was filed "to direct the Examiner's attention to disclosure items 26-29 submitted as Exhibits 26-29 to Patentees' May 17, 2007 [IDS]." ARIAD stated that it "wish[ed] to call the Examiner's attention to these specific documents." The IDS continued: "Items 26-29 of Patentees' May 17, 2007 [IDS] are a copy of a May 3, 2007 document entitled 'Amgen['s] Reply to [ARAID's] Counterclaim' which contains certain allegations concerning the ['516 patent] and specifically the Declaration of Dr. Inder Verma submitted by Patentee and copies of publications coauthored by Dr. Verma to which the document refers. Although Patentees disagree with the allegations, Patentees request that the Examiner independently review the documents and their relevance to the claimed invention." Only Amgen's reply to ARIAD's counterclaim, the three Verma articles, and Verma's then-current *Curriculum Vitae* ("CV") were attached to this IDS. The IDS acknowledged that a previously-submitted CV for Verma had not included the Verma articles and that the CV attached to this IDS "is believed to be a complete list of Dr. Verma's publications to date."

[53] Supplemental Information Disclosure Statement. This IDS noted the attached Verma articles and Amgen's reply to ARIAD's counterclaims had been submitted twice previously, that Amgen's reply "makes certain allegations of inconsistencies between the content of the [Verma articles] and the content of Dr. Verma's two Declarations filed in the subject reexamination proceeding." It also attached Wall's report and stated that his report "makes assertions concerning alleged inconsistencies between the articles co-authored by Dr. Verma and Dr. Verma's two Declarations . . . ."

articles and Amgen's reply to ARIAD's counterclaim; and had also submitted the Wall and Mossinghoff reports which discuss Amgen's contention that ARIAD breached its duty of candor and good faith during the reexamination proceeding.

Turning to the alleged inequitable conduct with regard to Kadesch; on April 7, 2007, ARIAD submitted to the PTO an IDS that attached all of the expert reports, expert deposition testimony, and trial testimony from the *Lilly* litigation, including Kadesch's expert report and deposition and trial testimony. After Kadesch's appearances in the *Lilly* litigation, he appeared as an expert witness in the *Roche* litigation and was deposed by Amgen on June 21, 2007. In light of opinions Kadesch offered pertaining to the patent-in-suit in the *Roche* litigation that purportedly contradicted his opinions in the *Lilly* litigation, Kadesch was asked about his opinion regarding the '516 patent. According to Amgen, his answers on that subject are an unequivocal recantation of his testimony in the *Lilly* litigation.

The same law firm who represented ARIAD in the *Lilly* litigation represented Roche in its litigation with Amgen. Members of that firm were also involved with ARIAD's reexamination counsel in the preparation of ARIAD's responses during the reexamination. Kadesch's June 2007 testimony in the *Roche* litigation was not submitted to the PTO at that time, however, as Amgen contends should have happened. Moreover, Amgen contends that ARIAD took steps to conceal that testimony. At the conclusion of Kadesch's deposition, Roche's attorney designated the entire deposition transcript as "highly confidential – outside counsel's eyes only"

because "[the ARIAD] patent actually is in litigation currently with Amgen."[54] Amgen states that this designation blocked any access to that testimony by the attorneys in this case. On December 8, 2007, after numerous unsuccessful attempts, Amgen obtained Kadesch's testimony from Roche pursuant to a subpoena. On December 11, 2007, Amgen moved for leave to amend its reply to ARIAD's counterclaim to include allegations of inequitable conduct based on nondisclosure of that testimony. Two days later, on December 13, 2007, ARIAD submitted an IDS to the PTO attaching Kadesch's June 21, 2007 deposition transcript.[55]

On January 31, 2008, the court granted Amgen leave to amend its reply to ARIAD's counterclaims to include allegations related to Kadesch. The court's memorandum order noted that although "Kadesch's deposition, was eventually submitted to the PTO, it was included with a number of other materials, with no attempt to advise the PTO of potential misrepresentations."[56] After that ruling, ARIAD submitted the February 20, 2008 IDSs mentioned above, attaching, in addition to the Verma-related documents previously discussed, this court's memorandum order granting Amgen's motion to amend and resubmitting Kadesch's deposition transcript from the

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[54] Amgen contends that this designation was improper under the *Roche* litigation protective order.

[55] Ninth Supplemental Information Disclosure Statement. This IDS attached twenty-two items, including the Kadesch transcript. Other than stating "[i]n accordance with their duty of disclosure under 37 C.F.R. § 1.555, Patentees direct the Examiner's attention to the following disclosure . . .", there is nothing to particularly draw the Examiner's attention to the Kadesch deposition transcript.

[56] That order states further that "Amgen also points out that Kadesch's proffered opinion directly contradicts ARIAD's written description and priority arguments in support of patentability on re-exam. Amgen claims that Kadesch's deposition recants his testimony in the *Eli Lilly* litigation, a prior related matter in another jurisdiction dealing with the '516 patent. Amgen raises issues as to when ARIAD knew or should have known of Kadesch's recanted testimony. It reiterates the obligation to disclose by counsel or an applicant under MPEP § 2001.06, who has notice that information exists which appears material and questionable."

Roche litigation.[57]

For the purposes of its motion only, ARIAD assumes that Amgen's allegations have merit, i.e., that (1) Kadesch's allegedly inconsistent testimony in the *Roche* litigation was at one point improperly withheld from the PTO; (2) Verma's allegedly inconsistent articles were at one point improperly withheld from the PTO; and (3) the materials relating to Kadesch and Verma were "material" under the legal standards applicable to inequitable conduct analysis.[58] Nevertheless, ARIAD contends that Amgen's defenses fail and the court must grant its motion for partial summary judgment. ARIAD states that it has provided all of the allegedly withheld information to the examiner; and that its IDSs expressly advise the examiner of the existence of those materials and direct the examiner to Amgen's allegations in connection with those materials. As a result, ARIAD contends any misconduct by ARIAD during the reexamination proceedings has been cured and Amgen's inequitable conduct allegations related thereto are moot as a matter of law.

Amgen does not dispute that ARIAD submitted the materials in question as described above.[59] It does, however, contend that ARIAD has failed to do what is

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[57] This IDS noted that the court's memorandum order stated that "although Patentees submitted the June 21, 2007 Deposition Transcript of Dr. Thomas Kadesch . . . to the [PTO], Patentees did not advise the [PTO] of alleged inconsistencies between Dr. Kadesch's statements on pages 258-271 of the Deposition Transcript and the statements in the October 21, 2005 Rebuttal Report of Dr. Kadesch . . . from . . . [the Lilly litigation]." Also submitted with these IDSs are the expert report of Jeffrey Ravetch and the Wall report, both of which were said to be "relevant to the alleged inconsistencies . . . ." The Wall report (and Mossinghoff's report also submitted on the same date) recite Amgen's contention that Kadesch's testimony in the *Lilly* litigation is inconsistent with his testimony in the *Roche* litigation.

[58] ARIAD does not, however, concede the issue of intent.

[59] Amgen also does not dispute that the examiner is obligated to consider the materials submitted with the various IDSs. Amgen responds, however, that "PTO regulations do not absolve ARIAD from the burden of making the showing required under Federal law" to cure the alleged inequitable conduct.

required under the law where "cure" of inequitable conduct is attempted.[60] Amgen states that "ARIAD does not contest in its motion that it improperly withheld material information from the PTO, but instead argues that its efforts to cure have mooted the issue." To be fair, as the court noted above, ARIAD does not contest Amgen's allegations of improper withholding of material information *for the purposes of the current motion*. Amgen is correct though, that ARIAD's position is that, as a matter of law, its disclosure to the PTO of the materials at issue moots Amgen's contentions regarding purported inequitable conduct during the reexamination proceedings. That is the issue which the court must decide.

Amgen relies heavily on the Federal Circuit's decision in *Rohm & Haas Co. v. Crystal Chemical Co.* and the statement therein concerning how inequitable conduct during prosecution may be cured:

> Specifically, the narrow issue we now deal with is whether *voluntary efforts* during prosecution by or on behalf of an applicant, *knowing that misrepresentations have been made* to the examiner of his application, can ever alleviate its effect. Taking into account human frailty and all of the objectives of the patent system, we think it desirable to permit misdeeds to be overcome under certain limited circumstances. . . . [W]e also think it desirable to reserve the possibility of expiation of wrongdoing where an applicant chooses to take the necessary action *on his own initiative* and to take it openly.[61]

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[60] Amgen also contends that "ARIAD attempts to isolate the inequitable conduct it committed during the reexamination from the inequitable conduct it committed during prosecution and then argue that it 'cured' its inequitable conduct committed during the reexamination. . . . ARIAD's improper conduct and bad faith throughout prosecution and reexamination cannot be broken into separate events that can be addressed piecemeal." The court disagrees. ARIAD's motion is not addressed to Amgen's contentions of inequitable conduct committed during the prosecution of the patent application which resulted in the '516 patent. In fact, ARIAD acknowledges that Amgen is correct in the assertion that misconduct during an examination that has already closed cannot be cured. Instead, ARIAD's motion raises the discrete issue of whether the submission of the materials at issue during the reexamination proceeding moot Amgen's inequitable conduct defense as it relates to ARIAD's conduct during that proceeding.

[61] 722 F.2d 1556, 1571-72 (Fed. Cir. 1983) (emphasis added).

Amgen argues that there was nothing "voluntary" about ARIAD's disclosures to the PTO and that ARIAD made no effort to "comply" with its duty of candor until Amgen put forth its inequitable conduct contentions. The *Rohm* court set forth certain requirements in which a prior misdeed may be cured:

> The first requirement to be met by an applicant, aware of misrepresentation in the prosecution of his application and desiring to overcome it, is that he expressly advise the PTO of its existence, stating specifically wherein it resides. The second requirement is that, if the misrepresentation is of one or more facts, the PTO be advised what the actual facts are, the applicant making it clear that further examination in light thereof may be required if any PTO action has been based on the misrepresentation. Finally, on the basis of the new and factually accurate record, the applicant must establish patentability of the claimed subject matter. Considering the overall objectives of the patent system, we think it desirable that inventions meeting the statutory requirements for patentability be patented and, therefore, we also think it desirable to reserve the possibility of expiation of wrongdoing where an applicant chooses to take the necessary action on his own initiative and to take it openly. It does not suffice that one knowing of misrepresentations in an application or in its prosecution merely supplies the examiner with accurate facts without calling his attention to the untrue or misleading assertions sought to be overcome, leaving him to formulate his own conclusions.[62]

The *Rohm* court held that "where intentional material misrepresentations have been made, as here, a complete 'cure' must also be demonstrated by clear, unequivocal, and convincing evidence."[63] Amgen also maintains that ARIAD has not cured its inequitable conduct because its disclosure to the PTO do not provide the "clear, unequivocal, and convincing evidence" required by *Rohm* and, instead, merely left the examiner "to formulate his own conclusions." As such, Amgen urges the court to deny ARIAD's motion.

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[62] *Id.* at 1572.
[63] *Id.*

ARIAD contends that the Federal Circuit's opinion in *Young v. Lumenis, Inc.*,[64] rather than *Rohm & Haas*, provides the proper framework to consider its motion. In *Young*, the court considered "whether there was a 'failure to disclose' material information to the PTO sufficient to constitute inequitable conduct when that information was disclosed before the examiner's final Office Action, albeit only after the issue of disclosure was raised in a parallel district court action."[65] There, Young brought an infringement action against Lumenis. During the pendency of that litigation, Lumenis requested a reexamination of the patent-in-suit by the PTO. The PTO issued a first office action in the reexamination rejecting certain claims as unpatentable over two references submitted by Lumenis. One of those references was a chapter in a veterinary textbook, edited by Fossum (the "Fossum reference"). Approximately three weeks after that office action, Young submitted a response distinguishing the Fossum reference from the rejected claims. After further prosecution, the PTO issued a Reexamination Certificate which confirmed the patentability of all claims.[66]

During the reexamination proceeding, the trial court held a *Markman* hearing during which, Hedlund (author of the textbook containing the Fossum reference) testified concerning that reference. After Young filed its response to the first office action with the PTO, Lumenis filed a motion for summary judgement of unenforceability due to inequitable conduct during the reexamination in the district court action. Part of the basis for that motion was Young's failure to disclose the Hedlund deposition

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[64] 492 F.3d 1336 (Fed. Cir. 2007).
[65] *Id.* at 1349.
[66] *Id.* at 1341.

testimony to the PTO. Approximately three weeks later, Young submitted that testimony to the PTO. Citing *Rohm & Haas*, the district court granted Lumenis' motion for summary judgment finding, *inter alia*, that Young did not provide the information to the PTO on his "own initiative" as that information was only filed after defendant's summary judgment motion. The Federal Circuit reversed that determination. The court concluded "that there was no 'failure to disclose material information' to the PTO because the alleged material information was disclosed to the PTO at a time when it could be considered by the examiner."[67] The submission of the Hedlund deposition testimony:

> occurred after the examiner had issued its first Office Action in the reexamination, but more than five months before the examiner had issued a second Office Action. The examiner was therefore fully apprised of the Hedlund deposition testimony and was able to fully consider it and any potential effects it may have on the patentability of the claims before issuing his second Office Action. Thus, we cannot agree that there was inequitable conduct resulting from the "failure to disclose material information" when that information was disclosed to the PTO in time for the examiner to consider it.[68]

The court noted that "[t]he essence of the duty of disclosure is to get relevant information before an examiner in time for him to act on it, and that did occur here."[69] Significantly, the court also noted the district court's reliance on *Rohm & Haas* but found it distinguishable "particularly because in that case the issue related to an alleged false affidavit, where a cure hurdle may be higher than here. In this case, the issue related

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[67] *Id.* at 1348.
[68] *Id.* at 1349
[69] *Id.*

to an alleged omission, and that omission was cured by a timely submission."[70]

ARIAD argues that, like the patent holder in *Young*, it has provided to the PTO all the materials Amgen alleges were withheld. Also, those materials were provided after the examiner's first office action but "at a time when [those materials] could be considered by the examiner." ARIAD contends, therefore, that "Amgen's allegations of a 'failure to disclose material information' fail as a matter of law."[71]

The court reaches different conclusions with regard to the effect of ARIAD's submissions to the PTO of the Verma and Kadesch materials. Amgen contends that the "Verma Declaration contains materially false and misleading declaratory statements, *i.e.*, evidence, not just attorney arguments, presented to the PTO in support of patentability," thereby warranting analysis under *Rohm & Haas*. According to Amgen, affirmative representations made by ARIAD through the Verma declaration are shown to be false as they are flatly contradicted by statements made by Verma in articles he previously co-authored.

With regard to Kadesch, Amgen contends that his testimony from the *Roche* litigation involves material information, "directly recanting opinion testimony relating to arguments before the PTO, that was affirmatively withheld from the PTO with an intent to deceive." Thus, in contrast to its contentions regarding the allegedly false statements in the Verma declaration, Amgen contends that Kadesch's contradictory opinion

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[70] *Id.* at 1349-50 (citing *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1582 (Fed. Cir. 1991) ("When a reference was before the examiner, whether through the examiner's search or the applicant's disclosure, it can not be deemed to have been withheld from the examiner.")).

[71] Citing *F.D.I.C. v. Giammettei*, 34 F.3d 51, 54 (2d Cir. 1994) (explaining that partial summary judgment is appropriate for striking an affirmative defense where there is "an absence of evidence to support an essential element of the non-moving party's case").

testimony was improperly withheld from the PTO during the reexamination proceedings and, when disclosed, ARIAD did not specifically enunciate the purported contradictions.[72] The court determines, therefore, that ARIAD's conduct with regard to the Kadesch materials are not subject to analysis under *Rohm & Haas* and that under a *Young* analysis, Amgen's inequitable conduct arguments, as it relates those submissions is moot. Kadesch's *Lilly* testimony was submitted to the PTO. After Amgen received Kadesch's *Roche* testimony and sought leave to augment its inequitable conduct allegations to include ARIAD's failure to submit that testimony to the PTO, ARIAD submitted that testimony (along with the additional materials referenced above) at a time when the examiner "was fully able to consider it and any potential effects it may have on the patentability of the claims." Consequently, with regard to the Kadesch submissions, ARIAD's motion for summary judgment is granted.

With regard to Verma, the court finds there is a question of fact concerning whether the Verma declaration contains materially false statements which would subject ARIAD's attempted cure of any inequitable conduct with regard to the Verma

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[72] Amgen's expert, Mossinghoff opined that "it is my opinion that those substantively involved in the preparation and prosecution of the reexamination of the '516 patent . . . who submitted to the USPTO during the Reexamination of the '516 patent both the testimony and report of Dr. Kadesch from the . . . *Lilly* litigation and Dr. Kadesch's recantation of that testimony in the . . . *Roche* litigation – breached their duty of candor and good faith to the USPTO by submitting the testimony of Dr. Kadesch in the . . . *Roche* litigation without disclosing the inconsistencies in that testimony with the earlier testimony and report in the . . . *Lilly* litigation." Unlike the purportedly false statements contained in the declaration by Verma, Kadesch's testimony suggests a change in his opinion rather than evidence of false statements. For instance, in the *Lilly* litigation, Kadesch testified that the '516 patent contained sufficient disclosure "[a]s I understand the law." During his deposition in the *Roche* litigation, he testified that "my understanding of written description for the '516 Patent was not from the point of view of someone with legal expertise where I would interpret those claims that way I interpret the claims for the current patent, the '349 Patent. And the reason for that is that in terms of claim language, shall we say that *I've come to understand* the necessity for claim language in a way that *I didn't appreciate* with the '516 Patent. If I had been asked the same series of question around the '516 Patent, I would have said that the '516 Patent, as it's stated, cannot claim all cells." (emphasis added).

articles to an analysis under *Rohm & Haas*, rather than merely a "failure to disclose" analysis under *Young*. ARIAD argues that in Mossinghoff's expert report from January of this year, he characterized Amgen's allegations relating to Verma as a failure to disclose information. In that report, Mossinghoff stated that "it is my opinion that those substantively involved in the preparation and prosecution of the Reexamination of the '516 patent, including Dr. Verma, breached their duty of candor and good faith to the USPTO by submitting the declaration of Dr. Verma *without disclosing* the inconsistencies included in his earlier scientific articles." In his April 2008 deposition, however, Mossinghoff contended that the Verma declaration was, not merely inconsistent with the Verma articles but was "false." Mossinghoff testified that "[t]he new element is the opinion of Dr. Wall expressed during his deposition that there were false statements made, not just inconsistent or contradictory, but false statements made." During the Wall deposition referenced by Mossinghoff, Wall not only testified that the Verma declaration contains "contradictory statement[s]" but he also testified that certain statements therein were false, stating: "this can't be true"; "I do not believe it to be correct"; "[t]hat can't be true"; "[b]ased on my understanding and experience, the first statement to the [PTO] is not correct. It's misleading"; "that's not true."

The particular language of the Verma declaration (filed in response to the examiner's rejection of certain claims for anticipation and/or obviousness over prior art) referred to include Verma's disagreement with the examiner that the use of certain compounds in the prior art inherently anticipated the rejected claims. Verma's declaration states:

[T]here is considerable uncertainty relating to the potential mechanism of

> action of glucocorticoids in cells, including whether there are any potential effects on NF-κB . . .
>
> * * *
>
> The mechanisms by which glucocorticoids, including dexamethasone, mediate inflammatory responses are poorly understood . . .
>
> * * *
>
> [T]he fact that dexamethasone (or any other glucocorticoid) is administered to cells does not indicate that the administration of that glucocorticoid necessarily reduced induced NF-κB activity or NF-κB mediated-intracellular signaling.

Amgen contends that those affirmative representations are "flatly contradicted" by statements made in the Verma articles. For instance, one article states that previous studies showed that dexamethasone "leads to repression of NF-κB-activated transcription." In another article, Verma and his co-authors state that glucocorticoids "also inhibit the action of several transcription factors that are essential for immunity, such as . . . NF-κB."

Amgen also points to statements in the Verma declaration questioning inhibition of NF-κB by components of red wine which are purportedly shown to be misstatements when compared to statements in one of the Verma articles. In the Verma declaration, "red wine" is said to be "a generic term covering many different mixtures having in common the characteristic of being red in color," therefore, one would not know "what, if anything, would have induced NF-κB activity in cells, or what, if anything, would have acted to reduce NF-κB activity in cells . . . ." One of the Verma articles, however, states that "resveratrol, which is found in grapes and red wine, [has] been found to downregulate KIK and IKKα/β, resulting in inhibition of IKK activiation, decreased Iκ-Bα-

degradation, decreased p65 translocation, and a decrease in NF-κB activity." Without deciding the question, because ARIAD avers that its motion asks a purely legal question as to whether its submissions to the PTO cured any potential inequitable conduct during the reexamination proceeding, the court determines that the evidence presented at least raises a question of fact as to whether the Verma declaration is a "false affidavit, where a cure hurdle may be higher" than under *Young*.[73]

ARIAD argues that even under a *Rohm and Haas* analysis its motion should be granted. Under that analysis, ARIAD contends that it "has satisfied at least the first and third criteria identified therein." Without commenting on that contention, the court cannot find, as a matter of law, that ARIAD's submissions of the Verma articles was a "voluntary effort" taken on ARIAD's "own initiative" as the submissions were in response to Amgen's filings in this case. For that reason, at least, ARIAD's motion must be denied with respect to Amgen's inequitable conduct allegations related to the Verma submissions. Consequently, with regard to the Verma submissions, ARIAD's motion for summary judgment is denied.

CONCLUSION

For the reasons stated above:

It is ORDERED AND ADJUDGED that:

I. the Amgen's motion for partial dismissal for lack of subject matter jurisdiction

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[73] ARIAD states that "the expert reports submitted by ARIAD in this action provide an exhaustive explanation of Dr. Verma's submissions to the PTO. We do not repeat those here, since they are not germane to the present motion." The court agrees that those explanations are not germane to the issue presented here (whether the submission of the Verma articles, in and of itself, cures any inequitable conduct associated therewith). Those explanations, combined with the testimony of Amgen's experts that the Verma declaration contains false statements (as well as the text of the Verma declaration and that of the Verma articles) do raise a question of fact as to that question.

(D.I. 575) is granted in part and denied in part.

A. Amgen's motion to dismiss ARIAD's invalidity challenges to the unasserted claims of the '516 patent is **GRANTED**.

B. Amgen's motion to dismiss ARIAD's unenforceability defenses is **DENIED**.

II. Amgen's motion for partial summary judgment on inequitable conduct (D.I. 573) is granted in part and denied in part.

A. Amgen's motion for summary judgment on inequitable conduct with regard to submissions related to Kadesch is **GRANTED**.

B. Amgen's motion for summary judgment on inequitable conduct with regard to submissions related to Verma is **DENIED**.

September 19, 2008
Wilmington, Delaware

UNITED STATES MAGISTRATE JUDGE