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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

ROCHE PALO ALTO LLC, formerly known as SYNTEX (U.S.A.) LLC, a Delaware corporation, and ALLERGAN, INC., a Delaware corporation, Plaintiffs, v. APOTEX, INC., a Canada corporation, and APOTEX CORP., a Delaware corporation, Defendants.	Case No. 3:05-cv-02116-MJJ **PLAINTIFFS' NOTICE OF MOTION and MOTION FOR SUMMARY JUDGMENT; MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT THEREOF** Judge: Hon. Martin J. Jenkins Date: August 31, 2007 Time: 9:30 a.m. Dept.: Courtroom 11

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NOTICE OF MOTION AND MOTION

TO ALL DEFENDANTS AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that, pursuant to the Federal Rule of Civil Procedure 56, Plaintiffs Roche Palo Alto LLC, and Allergan, Inc. (collectively, "Plaintiffs") will and hereby do move this Court to grant summary judgment that (a) Apotex, Inc. and Apotex Corporation (collectively, "Defendants") infringe claims 1-5, 15 and 16 of U.S. Patent No. 5,110,493 ("the '493 patent") by virtue of Defendants' filing of Abbreviated New Drug Application ("ANDA") 77-308, and (b) the '493 patent is enforceable and not invalid; and to grant an order pursuant to 35 U.S.C. § 271(e)(2)(A) and 21 U.S.C. 355a(a)(2)(B) that the effective date of any approval of ANDA 77-308 be a date not earlier than six months after the date of the expiration of the '493 patent. In the alternative, Plaintiffs move for an order pursuant to Federal Rule of Civil Procedure 56(d) establishing at least the fact that Defendants have already litigated numerous invalidity and enforceability arguments in a previous case between the parties and are precluded from relitigating them in this case.

With respect to Defendants' infringement of the '493 patent, this motion is made on the ground that the submission of ANDA 77-308 infringed the '493 patent. With respect to the validity and enforceability of the '493 patent, this motion is made on the grounds of claim preclusion and issue preclusion. In a prior lawsuit between Plaintiffs and Defendants for infringement of the '493 patent, *Syntex v. Apotex*, Case No. 3:01-cv-02214-MJJ (N.D. Cal.) ("*Syntex*"), the issues of the '493 patent's validity and enforceability were fully litigated and decided in Plaintiffs' favor. Therefore, in this second action for Defendants' infringement of the '493 patent, Defendants are barred by claim and issue preclusion from relitigating validity and unenforceability.

This motion is based on this Notice of Motion and Motion, the accompanying Memorandum of Points and Authorities, the Request for Judicial Notice and Declaration of Nathan E. Shafroth in Support of Plaintiffs' Motion for Summary Judgment, filed herewith, the files and records in this case and in *Syntex*, and such argument and further filings and evidence as this Court may receive on this motion.

MEMORANDUM OF POINTS AND AUTHORITIES

INTRODUCTION

Plaintiffs move for a judgment that Defendants infringe the '493 patent, and that that patent is enforceable and not invalid. None of these three issues is subject to debate. With respect to infringement, Defendants have admitted that their proposed generic drug literally reads on the patent's claims at issue. With respect to validity and enforceability, this Court has already decided, and the Federal Circuit has affirmed, that the '493 patent is valid and enforceable. Defendants' invalidity and unenforceability defenses and counterclaim are thus wholly barred by two doctrines: claim preclusion and issue preclusion.

Claim preclusion applies to this case because it involves the same claim, or cause of action, as *Syntex*—the claim that a ketorolac tromethamine-based ophthalmic solution with identical ingredients to that involved in *Syntex* infringes the '493 patent. Under the doctrine of claim preclusion parties are precluded from relitigating all issues and defenses that were *or could have been* raised in the parties' previous litigation. Thus, Defendants are precluded from litigating any defense or counterclaim relating to the invalidity or enforceability of the '493 patent. All such defenses could have been raised by Defendants in *Syntex*. Claim preclusion is thus a total bar to Defendants' invalidity and unenforceability defenses

Even if this case did not involve the same claim as that involved in *Syntex*, however, Defendants would still be barred from relitigating their invalidity and unenforceability defenses by the separate doctrine of issue preclusion. Issue preclusion applies to this case because the issues of the validity and enforceability of the '493 patent were litigated and decided in Plaintiffs' favor in *Syntex*. It is irrelevant that Apotex may seek to raise new grounds or new arguments for its contention that the '493 patent is invalid or unenforceable, since issue preclusion bars relitigation of the issues of validity and unenforceability regardless of the way in which they may be argued.

Each preclusion doctrine is independently sufficient to bar *all* of Defendants' invalidity and unenforceability defenses and counterclaim, and to prevent Defendants from raising any new defenses relating to those issues. No exception to either doctrine applies. Therefore, Plaintiffs motion for summary judgment must be granted, and an order must issue setting the effective date of

Defendants' ANDA 77-308 to be a date not earlier than six months after the date on which Plaintiffs' patent expires.

STATEMENT OF FACTS AND PROCEDURAL BACKGROUND

I. THE PARTIES, PATENT, AND PRODUCTS

This case involves the same parties, and concerns the same subject matter, as another case previously litigated to Judgment before this Court, *Syntex v. Apotex*, Case No. 3:01-cv-02214-MJJ (N.D. Cal.) ("*Syntex*"). Like *Syntex*, this case concerns Defendants' proposal to make and sell a ketorolac tromethamine ("KT") ophthalmic solution which would infringe U.S. Patent 5,110,493 ("the '493 patent") under 35 U.S.C. section 271(e)(2).

The '493 patent is entitled "Ophthalmic NSAID Formulations Containing a Quaternary Ammonium Preservative and a Non-Ionic Surfactant." Declaration of Nathan E. Shafroth in Support of Plaintiffs' Motion for Summary Judgment ("Shafroth Decl."), Ex.1. Pertinent to this motion, the '493 patent claims (1) formulations for sterile, preserved eye drops comprising particular ingredients in particular concentrations, and (2) the preservative system contained in such formulations. Plaintiff Roche Palo Alto LLC ("Roche") is the owner of the '493 patent. Plaintiff Allergan, Inc. ("Allergan") is the exclusive U.S. manufacturer and distributor of the ophthalmic formulations of the '493 patent.

Allergan is the holder of a New Drug Application ("NDA") approved by the Food and Drug Administration ("FDA") by which Allergan received permission to sell an 0.4% KT ophthalmic solution known as ACULAR LS®. ACULAR LS® has received "pediatric exclusivity" from the FDA pursuant to 21 U.S.C. section 355a(a). Shafroth Decl., Ex. 7. Allergan also holds an NDA for a 0.5% KT ophthalmic solution known as ACULAR®. ACULAR® and ACULAR LS® are both covered by the '493 patent.

Defendants Apotex, Inc. and Apotex Corp. are in the business of making and selling generic pharmaceutical products.[1] Generic companies like Defendants who wish to obtain FDA-approval

[1] Apotex, Inc. is a Canadian Corporation, and Apotex Corp. is a Delaware corporation, wholly owned by Apotex, Inc.

to make and sell a generic version of a drug previously approved by the FDA ("the listed drug") without spending the time and money to prosecute a full NDA may file an Abbreviated New Drug Application ("ANDA"). 21 U.S.C. § 355(j). An ANDA for a generic ophthalmic drug must indicate that the proposed generic drug has the same ingredients in the same concentration as the listed drug. 21 C.F.R. 314.94(a)(9)(iv); 21 U.S.C. § 355(j). It must also include a certification by the ANDA applicant concerning any patent claiming the listed drug, including at its option, a certification that the patent is invalid or will not be infringed by the drug for which the ANDA is submitted ("a Paragraph IV certification"). 21 U.S.C. § 355(j)(2)(A)(vii)(IV). At issue in this case is Defendants' filing of an ANDA seeking approval to make and sell a generic copy of ACULAR LS, and containing a Paragraph IV certification that the '493 patent is invalid, unenforceable, and not infringed.

II. PRIOR LITIGATION: *SYNTEX V. APOTEX*

On June 6, 2001, Roche's predecessor, Syntex (U.S.A.) LLC ("Syntex") and Allergan filed a complaint against Defendants and Novex Pharma (formerly an affiliate of Apotex, Inc., and now no longer in existence) in this Court, alleging that Defendants' ANDA 76-109 infringed the '493 patent. Request for Judicial Notice ("RJN"), Ex. A. The drug for which Defendants sought approval pursuant to ANDA 76-109 was a 0.5% KT ophthalmic solution identical to ACULAR®. RJN, Ex. B at ¶ 10

Defendants denied infringement, based on the contention that the Octoxynol 40 in the ANDA 76-109 formulation was not a "stabilizing" amount because it was not "performing any stabilizing function" in the formulation. RJN, Ex. C; Shafroth Decl., Ex. 2. Defendants also raised the affirmative defenses that the '493 patent was invalid (on the grounds that it allegedly lacked utility, lacked enablement, failed to disclose the best mode, was indefinite, and was obvious) and unenforceable (because Syntex allegedly committed inequitable conduct in prosecuting the patent). RJN, Ex. C.

On November 19, 2002, this Court filed an Order Regarding Claim Construction, in which it held that "stabilizing" and "antimicrobially effective" are not limitations of the claims of the '493 patent. RJN, Ex. D. Based on this determination, the Court granted summary judgment of patent

infringement in favor of Plaintiffs on March 19, 2003. RJN, Ex. E.

From June 2-20, 2003, a bench trial was conducted before this Court on the issues of the validity and enforceability of the '493 patent. RJN, Ex. B at 3. On December 29, 2003, this Court decided the validity and enforceability issues in favor of Plaintiffs and on January 5, 2004, the Court issued Findings of Facts and Conclusions of Law in support of its decision. *Id*.

On May 18, 2005, the United States Court of Appeals for the Federal Circuit (the "Federal Circuit") affirmed this Court's claim construction and this Court's determination that there was no inequitable conduct in the prosecution of the '493 patent, but remanded the case to this Court for further consideration of obviousness. *Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d 1371 (Fed. Cir. 2005). The parties submitted two full rounds of briefing on remand, and this Court held a hearing on obviousness on February 23, 2006. RJN, Ex. H. On June 2, 2006, this Court filed Findings of Fact and Conclusions of Law in which it found, once again, that the '493 patent was not invalid based on obviousness. *Id*.

On April 9, 2007, the Federal Circuit affirmed this Court's determination that the '493 patent is not invalid and is nonobvious. RJN, Ex. J. On May 3, 2007, Defendants filed a motion with the Federal Circuit requesting that the Federal Circuit recall and stay its mandate in *Syntex*, and accept a petition for rehearing by panel or *en banc*. RJN, Ex. K. The purported ground for Defendants motion was that the Supreme Court's recent decision in *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007), constituted a "sweeping change in the law of obviousness" under which this Court's judgment in *Syntex* that the '493 patent was not invalid (and the Federal Circuit's affirmance thereof) could not stand. *Id.* at 2. The Federal Circuit was not persuaded, and summarily denied Defendants' motion on June 5, 2007. RJN, Ex. L.[2]

III. THE INSTANT LITIGATION

On April 11, 2005, Apotex, Inc. sent Plaintiffs a letter which stated that Apotex, Inc. had submitted a second ANDA—ANDA 77-308—to the FDA, this time for an 0.4% KT ophthalmic

[2] On July 9, 2007 Defendants filed a petition for a writ of certiorari with the U.S. Supreme Court, seeking to have the Federal Circuit's April 9, 2007 decision summarily vacated and remanded. That petition is pending.

solution, which would be a generic copy of ACULAR LS®. Shafroth Decl., Ex. 3. Specifically, Defendants have admitted, and the ANDA specification shows, that the formulation defined by ANDA 76-109 contains the following ingredients: (1) 0.4% wt/vol ketorolac tromethamine (KT), an ophthalmologically acceptable anti-inflammatory carboxyl group-containing drug; (2) 0.0126% wt/vol benzalkonium chloride (BAC), a quaternary ammonium preservative, in the form of a 50% aqueous solution; (3) 0.004% wt/vol of Igepal CA-897, a 70% aqueous solution of Octoxynol 40; (4) 0.015% wt/vol edetate disodium (EDTA), a chelating agent; (5) 0.8% wt/vol of sodium chloride, a tonicifier; (6) an amount of 1N NaOH or 1N HCl sufficient to adjust pH to 7.4±0.4, and (7) an aqueous vehicle q.s. to 100%.[3] Shafroth Decl., Ex. 4, Responses 2, 3, 5, 6, 9, 10, 12, 14, 15, 17, 18 19, 20. Apotex Inc.'s ANDA notice letter also reasserted that the '493 patent was "invalid, unenforceable and not infringed." Shafroth Decl., Ex. 3 at 2.

On May 24, 2005, Roche and Allergan filed another complaint against Defendants in this Court, alleging that ANDA 77-308 infringed the '493 patent (Doc. #1). On August 24, 2005, Defendants filed an amended answer to the new Complaint, alleging that ANDA 77-308 does not infringe the '493 patent, and that the '493 patent is invalid (on the grounds that it allegedly lacks utility, lacks enablement, fails to disclose the best mode, is indefinite, is obvious, and constitutes obviousness-type double patenting) and unenforceable (because Syntex allegedly committed inequitable conduct in prosecuting the patent) (Doc. #23).

ARGUMENT

I. SUMMARY JUDGMENT STANDARD

Summary judgment should be granted in favor of the moving party if the record shows that "there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); *Miller v. Glenn Miller Productions, Inc.*, 454 F.3d 975, 987 (9th Cir. 2006). In the Hatch-Waxman context there will "almost never be a genuine dispute of material fact" that a patent claim is infringed with respect to a limitation if an ANDA specification

[3] The term "q.s." means adding a quantity sufficient to achieve a stated function, e.g., to bring a solution to the desired volume (i.e., 100%).

defines the product in such a way that it must infringe that limitation. *Abbott Laboratories v. TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002). Summary judgment is also appropriate with respect to the issues of validity and enforceability: because applications of claim and issue preclusion are questions of law, there can be no genuine issue as to any material fact. *See In re Schimmels*, 127 F.3d 875, 880 (9th Cir. 1997) ("The applicability of the doctrine of *res judicata* is a question of law subject to *de novo* review."); *Resolution Trust Corp. v. Keating*, 186 F.3d 1110, 1114 (9th Cir. 1999) ("Whether collateral estoppel, which is more accurately designated 'issue preclusion,' is available to a litigant is a question of law that we review *de novo*.").[4] Because Plaintiffs are entitled to judgment and there are no genuine issue of material fact in this case, summary judgment should issue.

II. PLAINTIFFS ARE ENTITLED TO SUMMARY JUDGMENT OF INFRINGEMENT

A. Standard for Infringement in ANDA Cases

Submission of an ANDA is an act of patent infringement if the ANDA seeks approval for a drug that is claimed in a patent or the use of which is claimed in a patent. 28 U.S.C. § 271(e) states:

> (2) It shall be an act of infringement to submit –
>
> (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent….
>
> If the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

28 U.S.C. §271(e). An ANDA is an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 355(j).

Determination of patent infringement is a two-step analysis. *Karlin*, 177 F.3d at 971 (citing

[4] Because this motion turns on general principles of claim and issue preclusion, Ninth Circuit law—rather than Federal Circuit law—applies. *See, e.g., Media Technologies Licensing, LLC. v. Upper Deck Co.*, 334 F.3d 1366, 1369 (Fed. Cir. 2003) (applying 9th Circuit claim preclusion law in patent infringement case); *Dana v. E.S. Originals, Inc.*, 342 F.3d 1320, 1323 (Fed. Cir. 2003) (applying regional circuit issue preclusion law in patent infringement case). Circuit law is largely uniform on these issues, however, so Plaintiffs also cite cases from the Federal Circuit and other circuits where particularly apt. *Cf. Foster v. Hallco Manufacturing Co.*, 947 F.2d 469, 477 n.7 (Fed. Cir. 1991) (noting that there is "no significant difference between the Ninth Circuit and Federal Circuit in the understanding of these principles or their application").

Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995)); *Gart v. Logitech, Inc.*, 254 F.3d 1334, 1339 (Fed. Cir. 2001). The first step is to construe, or interpret, a claim of the patent. *Id*. The second step is to compare the accused device—in this case, the drug formulation described in ANDA 77-308—to the properly construed claim. *Id*. The accused device literally infringes the claim if every limitation of the properly construed claim is found in the accused device. *Karlin*, 177 F.3d at 974. Summary judgment of infringement is proper if no reasonable jury could find that any limitation recited in the properly construed claim is not found in the accused device either literally or under the doctrine of equivalents. *Gart*, 254 F.3d at 1339.

B. Defendants' ANDA 77-308 Infringes Claims 1-5, 15 & 16 of the '493 Patent

The claims of the '493 patent were construed in *Syntex*." Therefore, Defendants are precluded from challenging this Court's determinations in *Syntex* that "stabilizing" and "antimicrobially effective" are not limitations of the claims of the '493 patent. *Del Mar Avionics, Inc. v. Quinton Instrument Co.*, 836 F.2d 1320, 1323 (Fed. Cir. 1987) ("The prior determination of certain issues, including the issues of claim construction . . . bars judicial redetermination of those issues as between the parties to the prior actions."). For this reason, Defendants may not escape literal infringement by contending—as they unsuccessfully contended in *Syntex*—that the Octoxynol 40 in the ANDA 77-308 formulation is not a "stabilizing" amount because it does not "perform[] any stabilizing function" in the formulation.[5] *See* Shafroth Decl., Ex. 2.

With respect to the limitations that *are* contained in claims 1-5, 15 and 16 of the '493 patent, Defendants admit that the ANDA 77-308 formulation literally reads on every one of them. Claims 1-5 cover an ophthalmologically acceptable non-steroidal anti-inflammatory drug formulation comprising particular ingredients in particular concentrations. As shown in detail in Appendix A, Defendants have admitted that the formulation defined by ANDA 77-308 contains each limitation of claims 1-5 of the '493 patent. Claims 15 and 16 claim an antimicrobially effective preservative

[5] Nor does the so-called "reverse doctrine of equivalents" provide Defendants an escape. The continued vitality of this defense, applicable only after a finding of literal infringement, is dubious at best. The Federal Circuit has *never* affirmed a finding of non-infringement based on this "anachronistic exception." *Tate Access Floors Inc. v. Interface Arch. Res. Inc.*, 279 F.3d 1357, 1368 (Fed. Cir. 2002).

system for an ophthalmologically acceptable non-steroidal anti-inflammatory carboxyl group-containing drug formulation, comprising particular ingredients in particular concentrations. As shown in detail in Appendix A, Defendants have admitted that the preservative system used for the ANDA 77-308 formulation, which is an ophthalmologically acceptable non-steroidal anti-inflammatory carboxyl group-containing drug formulation, contains each limitation of claims 15 and 16 of the '493 patent. Thus, the submission of ANDA 77-308 literally infringed claims 1-5, 15 and 16 of the '493 patent, and Plaintiffs are entitled to summary judgment of infringement of these claims.

III. PLAINTIFFS ARE ENTITLED TO SUMMARY JUDGMENT REGARDING THE VALIDITY AND ENFORCEABILITY OF THE '493 PATENT

Plaintiffs move to prevent Defendants from relitigating the same issues and defenses that they already litigated and lost in a case that was affirmed by the Federal Circuit just months ago. This case—like the case that was just affirmed—concerns Defendants' attempt to sell a ketorolac tromethamine-based ophthalmic solution that infringes the '493 patent. In this case—just as in the previous case—Defendants contend that the '493 patent is invalid and unenforceable. Because this Court and the Federal Circuit have already both determined that these very contentions have no merit, Defendants are barred from making them again.

A. Apotex's Validity and Unenforceability Defenses are Barred by Claim Preclusion

"Under the doctrine of claim preclusion, '[a] final judgment on the merits of an action precludes the parties or their privies from relitigating issues that were or could have been raised in that action.'" *Shaw v. Hahn*, 56 F.3d 1128, 1132 (9th Cir. 1995) (quoting *Federated Dep't Stores, Inc. v. Moitie*, 452 U.S. 394, 398 (1981)).[6] Accordingly, in this case, claim preclusion bars Defendants from litigating any defense or counterclaim relating to the validity or unenforceability

[6] In earlier cases, "claim preclusion" was referred to as "res judicata," and "issue preclusion" was referred to as "collateral estoppel." As the Ninth Circuit has observed, however, due to potential confusion caused by the use of the old terms, "the Supreme Court has in recent years generally used the terms 'claim preclusion' and 'issue preclusion.'" *Syverson v. International Business Machines Corp.*, 472 F.3d 1072, 1078 (9th Cir. 2007) (quotation and alteration omitted), a practice the Ninth Circuit has followed. *See id.*; *Littlejohn v. U.S.*, 321 F.3d 915, 920 (Ninth Cir. 2003) ("We use the term 'claim preclusion' rather than 'res judicata' for purposes of clarity.").

of the '493 patent, all of which were raised or could have been raised when Plaintiffs sued Defendants for infringement of the same patent in *Syntex*.

1. Claim Preclusion Applies in this Case.

Claim preclusion applies when "the earlier suit (1) involved the same 'claim' or cause of action as the later suit, (2) reached a final judgment on the merits, and (3) involved identical parties or privies." *Mpoyo v. Litton Electro-Optical Systems*, 430 F.3d 985, 987 (9th Cir. 2005) (quotations and alterations omitted). All of these elements are easily met in this case.

First, for purposes of claim preclusion, this lawsuit involves the same claim or cause of action as did *Syntex*. Specifically, both lawsuits involve Plaintiffs' claims that Defendants' KT ophthalmic solution would infringe the '493 patent. The ophthalmic solution in *Syntex* and the ophthalmic solution in this case *contain identical ingredients*. It is not important that the two solutions contain slightly different concentrations of the same ingredients because all of those concentrations are well within the ranges claimed in the '493 patent. "Colorable changes in an infringing device or changes unrelated to the limitations in the claim of the patent [do] not present a new cause of action" for purposes of claim preclusion. *Foster v. Hallco Manufacturing Co.*, 947 F.2d 469, 480 (Fed. Cir. 1991) (applying Ninth Circuit law).

The minor differences between Defendants' two proposed infringing ophthalmic solutions are as follows:

Solution	**KT**	**BAC**	**Octoxynol 40**	**edetate disodium**	**sodium chloride**	**1 N NaOH and 1N HCl**
ANDA 76-109 (*Syntex*)	.5%	.02%	.007%	.1%	0.8%	sufficient to adjust pH to 7.4.+-.0.4
ANDA 77-308 (this suit)	.4%	.0063%	.0028%	.015%	0.8%	sufficient to adjust pH to 7.4.+-.0.4

As far as the '493 patent's asserted claims are concerned, however, these are no differences at all. Claims 1-5 claim KT, but claim it (or a class of anti-inflammatories including KT) in the full range of concentrations from 0.001% to 10.0%. Shafroth Decl., Ex. 1. Claims 1-5, 15 and 16 claim BAC (or a class of preservatives including BAC) and Octoxynol 40, but claim them each in the full range of concentrations from 0.001% to 1.0%. *Id.* Claim 5 claims edetate disodium, but claims it in the full range of concentrations from 0.01% to 1.0%. *Id.* Since the concentrations of the ingredients in the ANDA 76-109 and ANDA 77-308 formulations all fall *well within* the ranges claimed by the

'493 patent, the differences between the two formulations are unrelated to the claims' scopes or limitations. Thus, Plaintiffs' claim of infringement in this lawsuit is the "same claim" as the infringement claim on which Plaintiffs previously succeeded in *Syntex*. *Foster*, 947 F.2d at 480.

Second, *Syntex* plainly reached a final judgment on the merits. This is evident from this Court's two lengthy and comprehensive Findings of Fact and Conclusions of Law, entered after a full bench trial and remand proceedings, and the entries of Judgment that followed. *See* RJN, Exs. B and H. If that were not enough, this Court's Judgments were also affirmed by the Federal Circuit after full briefing and argument on appeal. *See Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d 1371 (Fed. Cir. 2005); RJN, Ex. J.

Third, this suit involves the "identical parties or privies" that were involved in *Syntex*. That Roche has changed its name in the meantime, and that Novex Pharma has ceased to exist, is irrelevant. What is important is that all of the parties to the instant suit were parties to *Syntex*, and therefore had every opportunity and incentive to litigate the validity and enforceability of the '493 patent already in that case. *See* Charles A. Wright, Arthur R. Miller, Edward H. Cooper, *Federal Practice and Procedure* § 4449 (2002) ("The bare fact that other parties were involved in the prior action and are not involved in the later action does not oust preclusion as to parties participating in both actions.") (citing cases).

Because the requirements of claim preclusion are all met in this case, Defendants are barred from pursuing any defense or counterclaim here that they raised or could have raised in *Syntex*. *Shaw*, 56 F.3d at 1132. Specifically, this means that Defendants may not maintain their second (invalidity under 35 U.S.C. § 101 *et seq*), third (invalidity due to obviousness), fourth (invalidity due to obviousness-type double patenting), fifth (invalidity under 35 U.S.C. § 112), sixth (unenforceability due to inequitable conduct), or ninth (invalidity due to obviousness affirmative defenses, and may not raise any additional invalidity or unenforceability defenses; and that Defendants' Counterclaim (for a judgment of invalidity and unenforceability) must fail.[7]

[7] Defendants' first affirmative defense (non-infringement) and seventh affirmative defense (failure to state a claim) fail for the reasons stated in ARGUMENT Section II, *supra*. Defendants' eighth purported affirmative defense alleges that plaintiffs are not entitled to attorneys fees and is thus not an affirmative defense at all.

Defendants raised nearly all of these arguments in *Syntex*—and lost them. Defendants certainly *could have* raised all of its arguments about the '493 patent's validity and unenforceability in *Syntex*. *See Foster*, 947 F.2d at 478 ("The general concept of claim preclusion is that when a judgment is rendered in favor of a party to litigation, . . . defenses that were raised or *could have been* raised by the defendant in that action are extinguished.") (citation omitted; emphasis in original). Accordingly, all of Defendants' affirmative defenses asserting invalidity and unenforceability (2nd through 6th), and Defendants counterclaim, are barred by claim preclusion.

2. There Is No Exception to Claim Preclusion Applicable to the Circumstances of this Case.

Nor is there any exception to claim preclusion doctrine that could prevent granting Plaintiffs' motion for summary judgment. Specifically, there is no general "change in law" exception to the application of claim preclusion.

a. There is no general "change in law" exception to the application of claim preclusion.

In their motion to recall the Federal Circuit's mandate, Defendants argued that the Supreme Court's recent decision in *KSR International Co. v. Teleflex Inc.* constitutes a "sweeping change in the law of obviousness" under which this Court's judgment in *Syntex* (and the Federal Circuit's affirmance thereof) could not stand. RJN, Ex. K at 2. The Federal Circuit was not persuaded, and summarily denied Defendants' motion. RJN, Ex. L. Nonetheless, Plaintiffs expect Defendants to repeat this argument in opposition to this motion. But the *KSR* case has *no bearing* on the applicability of claim preclusion in this case because there is no general "change of law" exception to the application of claim preclusion.

Rather, the rule is that "the res judicata consequences of a final, unappealed[8] judgment on

[8]The word "unappealed" is not a limitation on the rule, *see, e.g., Wilson v. Lynaugh*, 878 F.2d 846, 850 (5th Cir. 1989) ("As a general rule, changes in law do not prevent the application of res judicata"), and it would make no doctrinal sense to treat it as such: a judgment does not become any more or less final depending on whether it is appealed. *See, e.g., Robi v. Five Platters, Inc.*, 838 F.2d 318, 327 (9th Cir. 1988) ("in federal courts the preclusive effects of a lower court judgment cannot be suspended simply by taking an appeal that remains undecided") (quoting 18 Wright, Miller & Cooper § 4433) (alteration omitted). The Supreme Court included the word "unappealed" in its statement of the general rule simply based on the facts of the case before it, in which a defendant sought to escape the preclusive effects of a judgment against him based on a successful appeal by his co-defendants that he did not join.

the merits [are not] altered by the fact that the judgment may have been wrong or rested on a legal principle subsequently overruled in another case." *Federated Dept Stores, Inc. v. Moitie*, 452 U.S. 394, 398-99 (1981). This is the rule in this circuit, *see Clifton v. Atty. Gen. of State of Cal.*, 997 F.2d. 660 (9th Cir. 1993) ("For us to conclude . . . that the district court's order has become an 'instrument of wrong' merely because it rests on a since repudiated rationale would be to nullify the doctrine of res judicata."), and throughout the nation. *Precision Air Parts, Inc. v. Avco Corp.*, 736 F.2d 1499, 1503 (5th Cir. 1984) ("The general rule . . . throughout the nation, is that changes in the law after a final judgment do not prevent the application of res judicata and collateral estoppel, even though the grounds on which the decision was based are subsequently overruled.") (citing cases).[9]

Nor does the ordinary rule change just because the purportedly law-changing intervening decision comes from the Supreme Court. *See, e.g., U.S. v. Tippett*, 975 F.2d 713, 719 (10th Cir. 1992); *Erspan v. Badgett*, 659 F.2d 26 (5th Cir. 1981); *Harrington v. Vandalia-Butler Bd. of Educ.*, 649 F.2d 434, 437 (6th Cir. 1981). Thus, even if *KSR* did constitute the "sweeping change in the law of obviousness" that Defendants contend it does, claim preclusion would still prevent Defendants from raising any defense that the '493 patent is invalid or unenforceable in this case.

b. The narrow exceptions to the ordinary "change in law" rule do not apply in this case.

Courts have created only two narrow exceptions to the normal rule that an intervening change in law will not strip a final judgment of its claim preclusive effects—neither of which applies in this case.

First, some courts have held that the normal rule does not apply when the judgment at issue (and the intervening legal change) adjudicated important *fundamental constitutional* rights. *See, e.g., Christian v. Jemison*, 303 F.2d 52, 54 (5th Cir. 1962) (denying claim preclusive effect of Louisiana state court judgment upholding racial segregation where *Brown v. Board of Education*

[9] *See also Hardison v. Alexander*, 655 F.2d 1281 (D.C. Cir. 1981) ("civil judgments, unlike criminal convictions, cannot be collaterally attacked on the basis of subsequent judicial pronouncements"); *In re Tennessee Cent. Ry. Co.*, 498 F.2d 904, 906 (6th Cir. 1974) ("The principles of res judicata would govern disposition of this case, even if there had been . . . a change in controlling case law.").

issued three months later). This is an extremely narrow exception, and courts have refused to apply it outside the constitutional rights context. *See Precision Air Parts*, 736 F.2d at 1503-04 (rejecting "proposition that where new court decisions change the law, the res judicata effect of the first litigation is removed" and limiting exception to cases "involv[ing] momentous changes in important, fundamental constitutional rights"); *Badgett*, 659 F. 2d at 28 n.2 (distinguishing cases providing "change in law" exception to claim preclusion as "adjudicating constitutional rights"); *cf.* This case, of course, does not concern anyone's constitutional rights; and application of claim preclusion—while not what Defendants would prefer—does not risk violating the fundamental democratic principle on which the narrow constitutional exception is based: that "the constitution would be applied differently in different locations." *Jackson v. DeSoto Parish School Board*, 585 F. 2d 726, 729 (5th Cir. 1978) (quotation omitted). The fundamental constitutional rights exception to claim preclusion does not apply in this case.

Second, a line of cases descending from *Commissioner v. Sunnen*, 333 U.S. 591 (1948), has established an exception applicable only in *taxation cases*. Under this exception, a judgment imposing a certain tax treatment for a given tax year will not preclude a later suit challenging this tax treatment as applied to a later tax year if there has been an intervening change in taxation law. *See, e.g., Burlington Northern Santa Fe R. Co. v. Assiniboine and Sioux Tribes of Fort Peck Reservation*, 323 F. 3d 767, 770 (9th Cir. 2003). The *Sunnen* exception has never been extended beyond the narrow context of taxation law, however, and for good reason: its rationale is wholly inapplicable outside that context. This rationale—that because tax rights and liabilities are renewed with each tax year, a past decision may not "endow[] taxpayers with perpetual, vested rights in a certain tax treatment," *Carter v. United States*, 973 F.2d 1479, 1483 n.1 (9th Cir.1992), or "establish[] [a taxpayer]'s tax liability forever," *Burlington Northern*, 323 F. 3d at 771—is *particularly* inapt to the patent infringement context, where patents' limited 20-year lives already preclude the possibility of "perpetual" entitlements that last "forever." The taxation law exception to claim preclusion does not apply in this case.

Thus, the *KSR* decision did not create an exception to the claim preclusive effects of the *Syntex* case because neither *KSR* nor this case involves constitutional rights or taxation. Because

claim preclusion applies to this case, and there is no applicable exception, Plaintiffs' motion for summary judgment regarding the validity and enforceability of the '493 patent must be granted.

B. Apotex's Validity and Unenforceability Defenses are Barred by Issue Preclusion

As set forth above, the doctrine of claim preclusion bars Defendants from relitigating the validity or enforceability of the '493 patent because this case concerns the same claim, or cause of action, as *Syntex*. Even if the Court is not persuaded that the two cases concern the same claim, however, Defendants are nonetheless barred from relitigating the validity and enforceability of the '493 patent by the separate doctrine of *issue* preclusion, which does not require an identity of claims.

1. Issue Preclusion Bars Re-litigation of the Issues of Unenforceability and Validity of the '493 patent.

Issue preclusion bars relitigation of issues adjudicated in an earlier proceeding if three requirements are met: (1) the issue necessarily decided at the previous proceeding is identical to the one which is sought to be relitigated; (2) the first proceeding ended with a final judgment on the merits; and (3) the party against whom collateral estoppel is asserted was a party or in privity with a party at the first proceeding. *Reyn's Pasta Bella, LLC v. Visa USA, Inc.*, 442 F.3d 741, 746 (9th Cir. 2006). As discussed above, it is beyond argument that the second and third requirements of this test are met. *See* ARGUMENT Section III.A.1., *supra*.

The first requirement of the issue preclusion test is easily met as well. This Court decided in *Syntex* that the '493 patent is enforceable and not invalid. RJN, Ex. B at 60; *id.*, Ex. H (6/2 FF/CL) at 37-38; *id.*, Ex. F; *id.*, Ex. I. Moreover, Defendants appealed both of those decisions to the Federal Circuit, and the Federal Circuit affirmed. *See Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d 1371 (Fed. Cir. 2005); RJN, Ex. J. These issues of validity and enforceability were "necessarily decided" by this Court because, Defendants having raised them as defenses, they were prerequisite to the Court's granting of relief to Plaintiffs for Defendants' infringement. *See* 35 U.S.C. § 282 (invalidity and unenforceability are affirmative defenses to "any action involving the . . . infringement of a patent").

Furthermore, the issues at stake in this case are identical to those in *Syntex*: (1) whether the

'493 patent is unenforceable for inequitable conduct and (2) whether the '493 patent is invalid. It is undisputed that Defendants raised the exact inequitable conduct defense in *Syntex* as they have raised in this case. *Compare* RJN, Ex. C at ¶ 30 *with* Amended Answer (Doc. #23), ¶ 32 (Sixth Affirmative Defense) and Counterclaim, ¶¶ 13-37. Defendants are therefore barred by issue preclusion from relitigating the enforceability of the '493 patent.

It is also undisputed that in *Syntex*, just as in this case, Defendants raised arguments, styled as affirmative defenses, to the effect that the '493 patent is invalid. *Compare* RJN, Ex. C at ¶ 30 *with* Amended Answer (Doc. #23). It is irrelevant to issue preclusion doctrine that in both *Syntex* and in this case, Defendants split their invalidity defense into numerous sub-defenses (e.g., lack of utility, obviousness, etc.). It is equally irrelevant that Defendants did not make every possible iteration of invalidity argument in *Syntex*. The *issue* that was decided in *Syntex* was whether the '493 patent was invalid. *See Dana v. E.S. Originals*, 342 F.3d 1320, 1324 (Fed. Cir. 2003) (characterizing both validity and infringement as single issues in the context of an issue preclusion inquiry). It is *this issue*, and not just particular *arguments* relating to this issue, that Defendants are now precluded from re-litigating. Therefore, under principles of issue preclusion, Defendants may no more argue in this case that the '493 patent is invalid for, e.g., obviousness-type double patenting than they may re-argue that the patent is invalid for obviousness. Both routes to the validity issue are closed.

Under Ninth Circuit law, as well as under the Restatement (Second) of Judgments, *validity* is the "issue" relevant to issue preclusion doctrine. *Applied Medical Resources Corp. v. U.S. Surgical Corp.*, 352 F. Supp. 2d 1119, 1124-26 (C.D. Cal. 2005) ("*Applied II*"). In *Applied II*, Applied had sued U.S. Surgical in an earlier case for infringement of, *inter alia*, claim 18 of its '553 patent. *Id.* at 1121 (citing *Applied Medical Resources Corp. v. United States Surgical Corp.*, 967 F. Supp. 861 (E.D. Va. 1997) ("*Applied I*")). At trial in *Applied I*, U.S. Surgical had contended that the asserted claims of the '553 patent were invalid on grounds of failure to disclose the best mode, and anticipation by prior sale, prior publication, and public use. *Id.* at 1121-22. U.S. Surgical was unsuccessful on these grounds, and the District Court in *Applied I* entered judgment that the asserted claims of the '553 patent were not invalid and were infringed. *Id.* at 1122. U.S. Surgical

appealed the *Applied I* judgment, but the Federal Circuit affirmed. *Applied Medical Resources Corp. v. United States Surgical Corp.*, 174 F.3d 1374 (Fed. Cir. 1998).

A year later, Applied brought a second lawsuit against U.S. Surgical, alleging that a new U.S. Surgical product also infringed, *inter alia*, claim 18 of the '553 patent. *Applied II*, 352 F. Supp. 2d at 1122. In its Answer to the new complaint, U.S. Surgical again challenged the validity of the '553 patent. *Id.* Applied then brought a motion for partial summary judgment that U.S. Surgical was "collaterally estopped from relitigating the validity of Claim 18." *Id.* at 1121. U.S. Surgical opposed the motion by arguing that "the verdict in *Applied I* dealt with only four issues: anticipation by prior sale, best mode, public use, and prior publication," and therefore could not preclude U.S. Surgical from arguing in *Applied II* that claim 18 was invalid based on, *inter alia*, prior art anticipation and obviousness. *Id.* at 1124.

The *Applied II* court rejected U.S. Surgical's argument. Relying on the Restatement (Second) of Judgments and on the Ninth Circuit's decision in *Kamilche Co. v. United States*, 53 F.3d 1059 (9th Cir. 1995), the court held that the "issue" that U.S. Surgical was precluded from relitigating was *the validity* of claim 18 of the '553 patent. *Applied II*, 352 F. Supp. 2d at 1124-26.[10] The court held that what U.S. Surgical argued were the "issues"—anticipation by prior sale, best mode, public use, and prior publication—were "just the particular arguments raised in support of [invalidity] in the first case." *Id.* at 1125 (quoting *Kamilche*, 53 F.3d at 1063). As a result, U.S. Surgical was barred not only from re-raising any grounds on which it had argued invalidity in *Applied I*, but also any new invalidity grounds, such as prior art anticipation and obviousness. *Id.* at 1127-28; *cf. Kamilche*, 53 F.3d at 1063.

[10] In *Kamilche*, the Ninth Circuit held that the United States was issue-precluded from arguing ownership of a piece of property based on adverse possession where in a previous case it had unsuccessfully argued ownership of a portion of that property based on a land survey. *Kamilche*, 53 F.3d at 1060-62. The Ninth Circuit reasoned that *ownership* was the issue, and that it was therefore irrelevant that the United States had never raised its adverse possession argument in the prior case, since "any contention that is necessarily inconsistent with a prior adjudication of a material and litigated issue is subsumed in that issue and precluded by the effect of the prior judgment as collateral estoppel." *Id.* at 1063 (internal quotation omitted). Similarly, section 27 of the Restatement (Second) of Judgments states that "if the party against whom preclusion is sought did in fact litigate an issue ... and suffered an adverse determination, ... new arguments may not be presented to obtain a different determination of that issue.")

There is nothing extraordinary about the result reached in *Applied II*. Indeed, "*the overwhelming weight of authority* suggests that the 'issue' that is to be given issue-preclusive effect to a judgment in the patent context is the ultimate determination on patent validity itself, not the sub-issues or the individual pieces of evidence and arguments that may have been necessary to support the validity determination." *Crossroads Systems (Texas), Inc. v. Dot Hill Systems Corp.*, 2006 WL 1544621, *5 (W.D. Tex. May 31, 2006) (emphasis added) (barring previously unasserted § 112 invalidity defense and introduction of new prior art).[11]

This case is the same. Defendants litigated the issue of the validity of the '493 patent in *Syntex* and lost. They are now barred from re-litigating that issue, whether on old grounds or new. Because Defendants are also barred from relitigating the issue of the unenforceability of the '493 patent, Plaintiffs' motion regarding the validity and enforceability of the '493 patent should be granted in full based on issue preclusion.

2. There Is No Exception to Issue Preclusion Applicable Here.

a. For a change in law to prevent application of issue preclusion, the change must be major and direct.

Issue preclusion will apply to prevent relitigation of previously determined issues "unless there have been *major* changes in the law." *Montana v. United States*, 440 U.S. 147, 161 (1979) (emphasis added). Legal conclusions may be reexamined only if there has been "a *significant* change in the legal climate." *Kamilche*, 53 F.3d at 1063 n.3 (emphasis added).

[11] *See also Advanced Display Sys. v. Kent State Univ.*, 2002 WL 1489555, *10 (N.D. Tex. July 10, 2002) ("To the extent that any [previously unasserted validity] defenses exist, ADS is precluded from litigating them under the doctrine of collateral estoppel."); *Pall Corp. v. Fisher Scientific Co.*, 962 F. Supp. 210, 213 (D. Mass. 1997) ("Even assuming that Fisher now seeks to invalidate the patent on different grounds than those asserted by MSI in the 1986 action, the issue remains the same."); *Zip Dee, Inc. v. Dometic Corp.*, 905 F. Supp. 535, 537 (N.D. Ill. 1995) ("Where Dometic runs afoul of both law and logic is in its failure to recognize the distinction between an *issue*, in the sense employed by the Restatement [of Judgments] and by preclusion doctrine generally, and the *arguments* that a party may advance in its effort to prevail on such an issue.") (barring previously unasserted on-sale and public-use defenses); *see also Boston Sci. Corp. v. Schneider*, 938 F. Supp. 245, 256-57 (D. Mass. 1997) ("[T]he . . . criteria for collateral estoppel exist, and I therefore hold that SciMed may not relitigate the issues of validity, enforceability, or inequitable conduct."); *Unique Coupons v. Northfield*, 2000 WL 631324, *1 (N.D. Ill. May 16, 2000) ("Insofar as Count I seeks a declaration of invalidity and unenforceability of the '901 and '280 patents, that claim is dismissed because the exact issue was previously litigated and resolved in favor of Unique in a prior litigation between the same parties.").

A relatively recent Ninth Circuit case, *Steen v. John Hancock Life Insurance Co.*, 106 F.3d 904 (9th Cir. 1997), illustrates the narrowness of the "major change in the law" exception to issue preclusion. In that case, the issue was whether the plaintiff trusts were barred from relitigating the issue of whether reserve funds managed by defendants were governed by ERISA. In a prior between the parties, *American Institute of Architects Benefit Insurance Trust v. John Hancock Mutual Life Insurance Co.*, 1988 WL 91140 (9th Cir. Aug. 29, 1988) (*AIA-BIT*), the district court had held, and the Ninth Circuit had affirmed, that the reserve funds were not ERISA funds. *Steen*, 106 F.3d at 909 (quoting *AIA-BIT*, 1988 WL 91140 at *3-4).

Following the *AIA-BIT* decision, however, the Supreme Court held in *John Hancock Mutual Life Insurance Co. v. Harris Trust & Savings Bank*, 510 U.S. 86 (1993), that funds of this type were governed by ERISA. *Steen*, 106 F.3d at 909 (citing *Harris Trust*, 510 U.S. at 101-07). Thus, when the trusts brought the *Steen* lawsuit to recover other reserve funds allegedly due, they argued that *Harris Trust* constituted a major intervening change in law sufficient to prevent the otherwise preclusive effects of the decision in *AIA-BIT* that the reserve funds were not ERISA funds.

The Ninth Circuit disagreed. First, the court reasoned that if the issues decided in *AIA-BIT* were factual in nature, then there was no "change in law" exception to issue preclusion at all. *See Steen*, 106 F.3d at 914 ("a change in law does not justify denying collateral estoppel effect to our factual conclusions in *AIA-BIT*"). In this case, of course, this Court made many factual findings underlying its validity determination—findings on such matters as the scope and content of the prior art and the differences between the prior art and the patented inventions—and the Federal Circuit affirmed those factual findings. *See* RJN, Exs. B and H. No change in law could disturb the preclusive effect of these factual findings.

Second, the Ninth Circuit reasoned that if the issues decided in *AIA-BIT* were legal in nature, "those legal conclusions could only be reexamined if there had been a *significant* change in the legal climate." *Steen*, 106 F.3d at 914 (emphasis added). The court then indicated just how "significant" a legal change would have to be in order to invoke the exception, stating that even "[a]ssuming arguendo that *Harris Trust* indicates that we erroneously applied the law in *AIA-BIT*, that alone would not provide a ground for relief from collateral estoppel." *Id.*; *see also United*

States v. Moser, 266 U.S. 236, 242 (1924) ("a fact, question or right distinctly adjudged in the original action cannot be disputed in a subsequent action, even though the determination was reached upon an erroneous view or by an erroneous application of the law"). In order to prevent the issue preclusive effects of *AIA-BIT*, the *Steen* plaintiffs would have had to show not only that *Harris Trust* rendered *AIA-BIT* incorrect, but also that *Harris Trust* "discount[ed] . . . prior case law." *Steen*, 106 F.3d at 914.

b. The Federal Circuit already rejected the argument that *KSR* constitutes a change in law necessitating reconsideration of the validity of the '493 patent.

There has been no "major change in the law" of obviousness since the Federal Circuit affirmed this Court's decision in *Syntex*. The *KSR* case was not, as Defendants apparently contend, such a change. Indeed, the Federal Circuit already rejected this exact argument from Defendants. In their Motion to Recall the Mandate, Defendants argued that *KSR* constituted a "sweeping change in the law of obviousness," under which this Court's judgment in *Syntex* (and the Federal Circuit's affirmance thereof) could not stand. RJN, Ex. K at 5. But the Federal Circuit denied Apotex's motion, allowing *Syntex* to stand despite *KSR*. RJN, Ex. L.

This Court should follow the Federal Circuit's lead by rejecting Defendants' "sweeping change in the law" argument regarding *KSR* in this case. In *KSR*, the Supreme Court held that the Federal Circuit had applied the "TSM" test for obviousness in an excessively narrow manner in *Teleflex, Inc. v. KSR Intern. Co.*, 119 Fed. Appx. 282 (Fed. Cir. 2005). The Supreme Court made abundantly clear, however, that its decision (a) was based on legal principles that had remained constant for at least half a century, and (b) was a narrow decision, reversing only the Federal Circuit's decision that was before it. Thus, the Supreme Court began its legal discussion in *KSR* by noting that "*[t]hroughout* this Court's engagement with the question of obviousness, our cases *have set forth* an expansive and flexible approach inconsistent with the way the Court of Appeals applied its TSM test *here*." *KSR*, 127 S. Ct. at 1739 (emphases added). The Court emphasized that not even the enactment of section 103 of the patent code or the Supreme Court's watershed 1966 decision in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), had fundamentally changed the legal principles underlying the obviousness inquiry. *Id*. at 1739 (citing *Great Atlantic*

& Pacific Tea Co. v. Supermarket Equipment Corp., 340 U.S. 147 (1950)). Finally, the Court made clear that its holding in *KSR* necessarily resulted from application of these longstanding legal principles. *Id.* at 1743 ("What we hold is that the fundamental misunderstandings identified above led the Court of Appeals in this case to apply a test inconsistent with our patent law decisions.").

Thus, *KSR* did not "change" the law of obviousness at all. Rather, it held that the Federal Circuit decision it was reviewing was inconsistent with longstanding obviousness law. *KSR* is thus precisely the type of decision that the Ninth Circuit has held does *not* give rise to an exception to issue preclusion. "[I]t is only an intervening *change* in the law that defeats collateral estoppel—the correctness of a prior ruling, even if based upon erroneous application of the law, is irrelevant." *Richey v. I.R.S.*, 9 F.3d 1407, 1412 (9th Cir. 1993) (emphasis in original) (intervening Supreme Court decision did not constitute a change in the law where it relied on settled principles).[12]

In addition to plainly not constituting a "change" in controlling Supreme Court obviousness jurisprudence, *KSR* did not purport to overrule or discount *a single* Federal Circuit decision other than the one before it on direct review. To the contrary, the Supreme Court explicitly noted that "in the years since the Court of Customs and Patent Appeals set forth the essence of the TSM test, the Court of Appeals *no doubt* has applied the test in accord with [the principles laid out in *KSR*] in *many* cases." *KSR*, 127 S. Ct. at 1741 (emphases added). Thus, pursuant to binding Ninth Circuit precedent, *KSR*—which neither purports to change controlling law nor overrules or discounts any prior appellate decisions—*cannot* function to bar application of issue preclusion. *Steen*, 106 F.3d at

[12] For recent cases such as *Syntex*, which was heard months after the Supreme Court granted certiorari and heard arguments in *KSR*, it is even more apparent that *KSR* brought no major change to the law of obviousness. The Supreme Court went out of its way to "note that the Court of Appeals ha[d] since elaborated a broader conception of the TSM test than was applied in the instant matter," and expressly declined to criticize or discount the cases applying the "broader" TSM. *KSR*, 127 S. Ct. at 1743 (citing *DyStar Textilfarben GmbH & Co. Deutschland KG . C.H. Patrick Co.*, 464 F.3d 1356 (Fed. Cir. 2006) and *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286 (Fed. Cir. 2006)). The Federal Circuit was operating under this "broader conception" in this case—the *Alza* case cited by the Supreme Court was also cited extensively by both parties in *Syntex*. Shafroth Decl., Ex. 5 at 5; *id.*, Ex. 6 at 9. *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348 (Fed. Cir. 2007), cited by Defendants in the June 4, 2007 Joint Status Conference Statement as the herald of *KSR*'s "change" in Federal Circuit obviousness law (Doc. # 37 at 4) was also issued weeks before the Federal Circuit heard oral argument in *Syntex*, and was actually cited by Defendant's counsel at that argument. Shafroth Decl., ¶ 9.

914 (applying issue preclusion because "[t]he Supreme Court's decision in *Harris Trust* . . . did not discount any prior caselaw"); *Richey*, 9 F.3d at 1412 ("only an intervening *change* in the law that defeats collateral estoppel"); *Kamilche*, 53 F.3d at 1063 n.2 (legal conclusions may only be reexamined if there has been a "significant change in the legal climate").

Moreover, the Federal Circuit recently rejected this same "change in law" argument again in another post-*KSR* obviousness case, *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, No. 06-1329 (Fed. Cir. June 28, 2007). In that case, Alphapharm challenged a finding of nonobviousness based on the contention that the district court's pre-*KSR* opinion had "misappl[ied] the law relating to obviousness of chemical compounds" in light of the Supreme Court's decision in *KSR*. *Id.*, slip op. at 8. The Federal Circuit disagreed, instead reaffirming the principles announced in *In re Grabiak*, 769 F.2d 729 (Fed. Cir. 1985), *In re Dillon*, 919 F.2d 688 (Fed. Cir. 1990), and *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995), that "in addition to structural similarity between the compounds, a prima facie case of obviousness also requires . . . showing[s] of adequate support in the prior art for the change in structure . . . [and] that the prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention." *Takeda*, slip op. at 9 (internal quotations omitted). The Federal Circuit rejected Alphapharm's argument that these requirements could not stand in the face of *KSR*, pointing out that the Supreme Court in *KSR* "acknowledged the importance of identifying 'a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does' in an obviousness determination." *Id.* (quoting *KSR*, 127 S. Ct. at 1731).

Because there has been no "major change in the law" of obviousness, Defendants are precluded from relitigating their obviousness arguments in this case.[13]

C. In the Alternative, the Court Should Issue an Order Specifying the Material Facts not Subject to Reconsideration at Trial

Claim and issue preclusion each independently bar Defendants from contesting the validity

[13] Nor has there been any "major change in the law" of inequitable conduct since the Federal Circuit affirmed this Court's inequitable conduct decision in *Syntex*. Defendants are therefore precluded from relitigating the issue that the '493 patent is unenforceable due to inequitable conduct.

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or enforceability of the '493 patent. If the Court for any reason disagrees, however, and declines to issue judgment precluding all of Defendants' defenses and counterclaim, Plaintiffs request in the alternative that the Court issue an order pursuant to Federal Rule of Civil Procedure 56(d) precluding the relitigation of any defenses under 35 U.S.C. sections 101, 103, 112, and the defense of inequitable conduct.

IV. THE COURT MUST ISSUE AN ORDER PURSUANT TO 35 U.S.C. § 271(e)(4)(A)

Defendants' submission of ANDA 77-308 literally infringed the valid and enforceable '493 patent under 35 U.S.C. § 271(e)(2). Therefore, this Court "shall" issue an order preventing Defendants' ANDA from being approved at any time prior to six months after the expiration of the '493 patent. Section 271(e)(4) provides, in relevant part:

> For an act of infringement described in [35 U.S.C. § 271(e)(2)]:
>
> (A) the court shall order the effective date of any approval of the drug [] involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed.

21 U.S.C. 355a(a)(2)(B) additionally provides that where the FDA has granted pediatric exclusivity to the listed drug, as the FDA did for ACULAR® LS, "the period during which an [ANDA] may not be approved . . . shall be extended by a period of six months after the date the patent expires."

Because Defendants literally infringe the '493 patent, an order pursuant to section 271(e)(4)(A) must issue.

CONCLUSION

Defendants have admitted that their proposed ANDA 77-308 formulation literally reads on every limitation of claims 1-5, 15 and 16 of the '493 patent. Defendants are barred by the doctrines of claim preclusion and issue preclusion from raising any argument or defense related to the issues of the validity and unenforceability of the '493 patent. Thus, for the foregoing reasons, Plaintiffs respectfully request that summary judgment be granted, that this Court order that the '493 patent is enforceable and not invalid, and that the court order that the effective date of any approval of ANDA 77-308 be not earlier than the date six months after the expiration of the '493 patent.

DATED: July 30, 2007

HELLER EHRMAN LLP

By /s/ Keith R. Weed
KEITH R. WEED

Attorneys for Plaintiffs
SYNTEX (U.S.A.) LLC and ALLERGAN, INC.

APPENDIX A

Claim Language	Admissions
1. An ophthalmologically acceptable non-steroidal anti-inflammatory drug formulation, comprising:	Admitted Request For Admission No. 3: Apotex's Ketorolac Tromethamine Ophthalmic Solution 0.4%[14] contains ketorolac tromethamine in the amount of 0.40% wt/vol. Admitted Request For Admission No. 2: Ketorolac tromethamine is an ophthalmologically acceptable non-steroidal anti-inflammatory carboxyl group-containing drug.
an ophthalmologically acceptable non-steroidal anti-inflammatory carboxyl group-containing drug in an effective amount for ophthalmic treatment between 0.001% and 10.0% wt/vol;	Admitted Request For Admission No. 3: Apotex's Ketorolac Tromethamine Ophthalmic Solution 0.4% contains ketorolac tromethamine in the amount of 0.40% wt/vol. Admitted Request For Admission No. 2: Ketorolac tromethamine is an ophthalmologically acceptable non-steroidal anti-inflammatory carboxyl group-containing drug. Admitted Request For Admission No. 1: Apotex's Ketorolac Tromethamine Ophthalmic Solution 0.4% contains ketorolac tromethamine in an effective amount for ophthalmic treatment.
a quaternary ammonium preservative in an antimicrobially effective[15] amount for between 0.001% and 1.0% wt/vol;	Admitted Request For Admission No. 4: Apotex's Ketorolac Tromethamine Ophthalmic Solution 0.4% contains benzalkonium chloride between 0.001% and 1.0% wt/vol. Admitted Request For Admission No. 5: Benzalkonium chloride is a quaternary ammonium preservative.
an ethoxylated alkyl phenol that conforms generally to the formula: $C_8H_{17}C_6H_4(OCH_2CH_2)_nOH$ where n has an average value of 40 in a stabilizing[16] amount between 0.001% and 1.0% wt/vol; and	Admitted Request For Admission No. 7: Apotex's Ketorolac Tromethamine Ophthalmic Solution 0.4% contains an ethoxylated alkyl phenol that conforms generally to the formula $C_8H_7C_6H_4(OCH_2CH_2)_nOH$ where n has an average value of 40 in an amount between 0.001% and 1.0% wt/vol.

[14] "Apotex's Ketorolac Tromethamine Ophthalmic Solution 0.4%" is defined as "the product that is the subject of Apotex's Abbreviated New Drug Application ("ANDA") No. 77-308 submitted to the United States Food and Drug Administration" in the Plaintiffs' First Set of Requests For Admissions.

[15] This Court has ruled that "antimicrobially effective" is not a limitation. Plaintiffs therefore do not address this term further in this motion.

[16] This Court has ruled that "stabilizing" is not a limitation. Plaintiffs therefore do not address this term further in this motion.

Claim Language	Admissions
an aqueous vehicle q.s. to 100%	Admitted Request For Admission No. 12: Apotex's Ketorolac Tromethamine Ophthalmic Solution 0.4% contains an aqueous vehicle q.s. to 100%.
2. The ophthalmologically acceptable non-steroidal anti-inflammatory drug formulation of claim 1 wherein said quaternary ammonium preservative is benzalkonium chloride.	Admitted Request For Admission No. 4: Apotex's Ketorolac Tromethamine Ophthalmic Solution 0.4% contains benzalkonium chloride between 0.001% and 1.0% wt/vol.
3. The ophthalmologically acceptable non-steroidal anti-inflammatory drug formulation of claim 2 wherein said ophthalmologically acceptable non-steroidal anti-inflammatory carboxyl group-containing drug is selected from the group selected from ketorolac, indomethacin, flurbiprofen, and suprofen.	Admitted Request For Admission No. 3: Apotex's Ketorolac Tromethamine Ophthalmic Solution 0.4% contains ketorolac tromethamine in the amount of 0.40% wt/vol.
4. The ophthalmologically acceptable non-steroidal anti-inflammatory drug formulation of claim 3 wherein said ophthalmologically acceptable non-steroidal anti-inflammatory carboxyl group-containing drug is ketorolac tromethamine.	Admitted Request For Admission No. 3: Apotex's Ketorolac Tromethamine Ophthalmic Solution 0.4% contains ketorolac tromethamine in the amount of 0.40% wt/vol.
5. The ophthalmologically acceptable non-steroidal anti-inflammatory drug formulation of claim 1, further comprising:	
a chelating agent in an amount between 0.01% and 1.0% wt/vol;	Admitted Request For Admission No. 13: Apotex's Ketorolac Tromethamine Ophthalmic Solution 0.4% contains edetate disodium dihydrate in an amount between 0.01% and 1.0% wt./vol. Admitted Request For Admission No. 14: Edetate disodium dihydrate is a chelating agent.
a tonicifier q.s. to achieve isotonicity with lacrimal fluid; and	Admitted Request For Admission No. 16: Apotex's Ketorolac Tromethamine Ophthalmic Solution 0.4% contains sodium chloride q.s. to achieve isotonicity with lacrimal fluid. Admitted Request For Admission No. 17: Sodium chloride is a tonicifier.

Claim Language	Admissions
1N NaOH or 1N HCl q.s. to adjust pH to 7.4±0.4.	Admitted Request For Admission No. 19: Apotex's Ketorolac Tromethamine Ophthalmic Solution 0.4% contains an amount of I N NaOH in the amount of 0.0065% wt/vol plus any additional amount necessary to adjust the pH of the solution to 7.4± 0.4. Admitted Request For Admission No. 20: Apotex's Ketorolac Tromethamine Ophthalmic Solution 0.4% contains an amount of IN HCI sufficient to adjust pH to 7.4± 0.4.
15. An antimicrobially effective preservative system for an ophthalmologically acceptable non-steroidal anti-inflammatory carboxyl group-containing drug formulation, comprising:	Admitted Request For Admission No. 22: Apotex's Ketorolac Tromethamine Ophthalmic Solution 0.4% remains clear and antimicrobially effective for its anticipated shelf life. Admitted Request For Admission No. 3: Apotex's Ketorolac Tromethamine Ophthalmic Solution 0.4% contains ketorolac tromethamine in the amount of 0.40% wt/vol. Admitted Request For Admission No. 2: Ketorolac tromethamine is an ophthalmologically acceptable non-steroidal anti-inflammatory carboxyl group-containing drug.
a quaternary ammonium preservative in an antimicrobially effective amount between 0.001% and 1.0% wt/vol of the formulation; and	Admitted Request For Admission No. 4: Apotex's Ketorolac Tromethamine Ophthalmic Solution 0.4% contains benzalkonium chloride between 0.001% and 1.0% wt/vol. Admitted Request For Admission No. 5: Benzalkonium chloride is a quaternary ammonium preservative.
an ethoxylated alkyl phenol that conforms generally to the formula: $C_8H_{17}C_6H_4(OCH_2CH_2)_nOH$ where n has an average value of 40 in a stabilizing amount between 0.001% and 1.0% wt/vol of the formulation.	Admitted Request For Admission No. 7: Apotex's Ketorolac Tromethamine Ophthalmic Solution 0.4% contains an ethoxylated alkyl phenol that conforms generally to the formula $C_8H_7C_6H_4(OCH_2CH_2)_nOH$ where n has an average value of 40 in an amount between 0.001% and 1.0% wt/vol.
16. The preservative system of claim 15 wherein said preservative is benzalkonium chloride.	Admitted Request For Admission No. 4: Apotex's Ketorolac Tromethamine Ophthalmic Solution 0.4% contains benzalkonium chloride between 0.001% and 1.0% wt/vol.

Heller Ehrman LLP

CERTIFICATE OF SERVICE

I hereby certify that all counsel of record, who are deemed to have consented to electronic service are being served this 30th day of July 2007, with a copy of this document via the Court's CM/ECF system.

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

ROCHE PALO ALTO LLC, formerly known as Syntex (U.S.A.) LLC, a Delaware corporation, and ALLERGAN, INC., a Delaware corporation,

Plaintiffs,

v.

APOTEX, INC., a Canadian corporation. and APOTEX CORP., a Delaware corporation,

Defendants.

Case No. C05-02116 MJJ

Related Case:
Case No. C01-02214 MJJ

DEFENDANTS' MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Honorable Martin J. Jenkins
Date: August 31, 2007
Time: 9:30 a.m.
Courtroom: 11, 19th Floor

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I. INTRODUCTION

Plaintiffs' Motion seeks summary judgment (1) of infringement of U.S. Patent No. 5,110,493 ("the '493 patent) and (2) that the '493 patent is not invalid and enforceable because Apotex is precluded from challenging the validity and enforceability of the '493 patent under the doctrines of claim preclusion and issue preclusion. Plaintiffs' Motion should be denied because there are genuine issues of material fact as to whether (1) the accused Apotex ANDA formulation infringes the asserted claims of the '493 patent; and (2) Apotex' defenses of invalidity and unenforceability of the '493 patent are barred by either the doctrines of claim preclusion or issue preclusion.

Apotex' Opposition is based on this Memorandum, the Declarations of Mona Gupta and Dr. Ashim Mitra and Apotex' Objections and Response to Plaintiffs' Request for Judicial Notice, the record in *Syntex I* and any counsel arguments or further evidence that this Court may receive.

The Court found in *Syntex I* [1] that in the '493 patent formulation, Octoxynol 40 ("O_{40}") provides "'robust' stability because O_{40} forms micelles in the solution. ... [and] [t]he formation of these micelles can prevent the interaction between the NSAID and BAC." (RJN,[2] Exhibit B - December 28, 2003 Findings of Fact and Conclusions of Law ("Findings/Conclusions") at ¶ 47). Under the reverse doctrine of equivalents, there is no infringement if the product is so far changed in principle from a patented article that it performs the same or a similar function in a substantially different way. The tests of Apotex' expert, Dr. Mitra, show that the 0.004% O_{40} that is used in the accused Apotex ANDA formulation does not form micelles and as a result O_{40} does not prevent the NSAID/BAC interaction and does not provide "robust" stability to the formulation, which the Court found was the function and purpose of O_{40} in the '493 patent formulations. (Mitra Decl.[3] at ¶¶ 37,

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[1] "*Syntex I*" refers to the earlier lawsuit between the same parties (or their predecessor) involving the '493 patent before this Court, *Syntex v. Apotex,* Case No. 3:01-cv-02214-MJJ (N.D. Cal.).

[2] "RJN" refers to Plaintiffs' Request for Judicial Notice that accompanied Plaintiffs' Motion for Summary Judgment.

[3] "Mitra Decl." refers to the Declaration of Dr. Ashim K. Mitra in support of Defendants' Opposition to Plaintiffs' Motion for Summary Judgment.

45, 49). Rather, the NaCl in the accused Apotex ANDA formulation prevents the NSAID/BAC interaction by a mechanism that is completely different from the O_{40} micelle formation process. (*Id.* at ¶¶ 39, 41, 46). Accordingly, there is no infringement under the reverse doctrine of equivalents because the function/purpose, or lack thereof, of O_{40} in the accused ANDA formulation is so far changed in principle from what the Court required in the '493 patent formulations. (*Id.* at ¶¶ 49, 53). Although Apotex is not required to prove its case at the summary judgment level, it has raised a material fact in dispute regarding infringement and therefore Plaintiffs' Motion seeking summary judgment of infringement should be denied.

Apotex' defenses of patent invalidity and unenforceability are not barred by the doctrines of claim preclusion or issue preclusion because all of the requirements for those doctrines are not met. Specifically, the current accused ANDA formulation is materially different from the one at issue in *Syntex I*, the issues decided in *Syntex I* are not identical to the issues here and the decision in *Syntex I* is not a final judgment on the merits because Apotex' Petition for Certiorari in *Syntex I* is pending. Further, even if the requirements of the doctrine are satisfied, equitable principles and fairness dictate that these doctrine should not be applied here because of the change in the law of obviousness under the Supreme Court's decision in *KSR v. Teleflex.* Such facts are material and to the extent that Plaintiffs dispute them, Plaintiffs' Motion for Summary Judgment seeking validity and enforceability of the '493 patent should be denied.

Plaintiffs' request for a Fed.R.Civ.P. 56(d) Order should be denied because it is improper and essentially asks the Court grant it the same type of relief as if their Motion for Summary Judgment was granted.

Finally, Plaintiffs' request for an Order setting the effective date of Apotex' ANDA at issue to be a date not earlier than six months after the date on which the '493 patent expires should be denied because the Court does not have jurisdiction over the U.S. Food and Drug Administration ("FDA") and therefore cannot order the FDA to reset the effective date of Apotex' ANDA.

II. RELEVANT FACTS

The '493 patent claims ophthalmic formulations (eye drops) for treating eye inflammation and conjunctivitis. Specifically, the '493 patent teaches combining a nonsteroidal anti-inflammatory drug ("NSAID"), such as ketorolac tromethamine ("KT"), and a preservative, such as benzalkonium chloride ("BAC"), with the nonionic surfactant O_{40} "in a stabilizing amount." (Mitra Decl. at ¶ 18). A "surfactant" is a "surface active agent" often used to make otherwise insoluble chemicals soluble in water. (*Id.* at ¶ 19). Surfactants can be used to stabilize pharmaceutical formulations. (*Id.*). The '493 patent alleges that "a complex was found to form between the NSAID and BAC," making the formulation unstable (*e.g.*, appear cloudy). (*Id.* at ¶ 20). The '493 inventors allegedly found that this complexation could be eliminated by adding O_{40} to clear and thus ***stabilize*** the formulation. (*Id.*). In other words, the '493 patent contends that the NSAID and BAC require the surfactant O_{40} to help prevent a chemical interaction between them. (*Id.*).

Plaintiffs sell ophthalmic formulations under the brand names Acular® (the subject matter in *Syntex I*) and Acular LS® (the subject matter in this case) and they contend that both Acular® and Acular LS® are covered by the '493 patent. (Mem. at 3:18-23).[4] Acular® contains 0.5% of the active ingredient KT; whereas Acular LS® contains 0.4% KT.

Apotex is in the business of developing and providing generic pharmaceutical products at more affordable prices for consumers. Pursuant to 21 U.S.C. 355(j), Apotex filed Abbreviated New Drug Applications ("ANDAs") with the FDA to market generic versions of Acular® (in *Syntex I*) and Acular LS® (in this case).

The relevant ingredients and their concentrations in Plaintiffs' New Drug Application ("NDA") No. 21-528 for Acular LS® ("0.4% KT NDA formulation"), Apotex' ANDA No. 77-308 for a generic form of Acular LS® ("0.4% KT ANDA formulation") and Apotex' ANDA No. 76-109

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[4] "Mem." refers to Plaintiffs' Notice of Motion and Motion for Summary Judgment; Memorandum of Points and Authorities in support thereof and reference to page and line numbers is by "page no. : line nos."

for a generic form of Acular® ("0.5% KT ANDA formulation") (re *Syntex I*) are as follows:

Ingredient	0.4% KT NDA	0.4% KT ANDA	0.5% KT ANDA
KT (wt/vol)	0.4%	0.4%	0.5%
BAC (wt/vol)	0.006%	0.0063%	0.01%
O_{40} (wt/vol)	0.003%	0.004%	0.01%
Sodiuim Chloride (NaCl) (wt/vol)	0.79%	0.8%	0.8%

(Mitra Decl. at ¶¶ 28, 29, 30). Plaintiffs assert that the Apotex 0.4% KT ANDA formulation infringes claims 1-5, 15 and 16 of the '493 patent.

As explained below, because the concentrations of the ingredients in the Apotex 0.4% ANDA formulation are different from that of the 0.5% ANDA formulation, especially the amount of O_{40}, the ingredients interact and function differently making the two formulations materially different from each other. (*Id.* at ¶ 31).

Plaintiffs incorrectly state that an ANDA "must indicate that the proposed generic drug has the same ingredients in the same concentration as the listed drug." Rather, an ANDA can be filed if the generic drug manufacturers' active ingredient is the "bioequivalent" of the listed drug. *See* 21 U.S.C. § 355(j)(2)(A)(iv).

In the Court's December 29, 2003 Findings/Conclusions, the Court described the function and purpose of O_{40} in the '493 patent formulations as follows:

> (¶ 47) The addition of Octoxynol 40 to a solution of a carboxyl group-containing NSAID and BAC results in a solution that has 'robust' stability because Octoxynol 40 forms micelles in the solution. These micelles include a 'water-liking' outer sphere and a 'water-repelling,' or hydrophobic, inner portion. The formation of these micelles can prevent the interaction between the NSAID and BAC in two ways: either the NSAID and BAC are incorporated into the micelle itself, preventing the formation of a complex, or the insoluble complex is incorporated into, and solubilized in, the inner hydrophobic core of the micelle. R.T. 1686:13-1689:21, 1016:1-1017:25.
>
> (¶ 75) … the Court finds that the record here establishes that Octoxynol 40 serves a useful stabilizing function in the patented formulations, preservative systems, and methods of using those formulations.

(RJN, Exhibit B at ¶¶ 47 and 75).

III. SUMMARY JUDGMENT STANDARD

Summary Judgment is appropriate only when no genuine issue exists as to any material fact. Fed.R.Civ.P. 56. To prevail, the nonmovant, Apotex, "is required merely to point to an evidentiary conflict created on the record." *Armco, Inc. v. Cyclops Corp.*, 791 F.2d 147, 149 (Fed. Cir. 1986). At the summary judgment stage the court's function is not to weigh the evidence and determine the truth of the matter, but rather to determine whether there is a genuine issue for trial. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). "The evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor," Apotex in this case. *Id.* at 255. "Infringement, whether literal or under the doctrine of equivalents, is a question of fact." *Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Inc.*, 476 F.3d 1321, 1326 (Fed. Cir. 2007).

Plaintiffs' cite *Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002) to show that in "the Hatch-Waxman context there will 'almost never be a genuine dispute of material fact'" as to infringement. (Mem. at 6:24-7:2). However, just as in other patent cases, motions for summary judgment of infringement have been denied in the Hatch-Waxman ANDA cases. *See, e.g., Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, 418 F.3d 1326, 1348 (Fed. Cir. 2005) (reversing district court's grant of summary judgment, finding there were material issues of fact as to infringement and enablement). Further, in the ANDA context, the Federal Circuit has affirmed a motion for summary judgment of *non*-infringement. *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1254 (Fed. Cir. 2000).

IV. ARGUMENT

A. Plaintiffs' Motion seeking summary judgment of infringement should be denied because the Apotex 0.4% KT ANDA formulation does not infringe the asserted claims of the '493 patent under the reverse doctrine of equivalents, raising a material fact in dispute as to infringement.

1. Infringement standard and the reverse doctrine of equivalents.

Apotex agrees with Plaintiffs that determination of patent infringement is a two-step process that requires the claims to be construed and then compare the accused device to the properly construed claims. (*See* Mem at 7:22-8:4) (case citations omitted). However, Apotex disagrees with

Plaintiffs that "[t]he accused device literally infringes the claim if every limitation of the properly construed claim is found in the accused device" (Mem. at 8:4-6) because Plaintiffs failed to consider the reverse doctrine of equivalents which, when applicable, avoids infringement. *Precision Metal Fabricators, Inc., v Jetstream Sys. Co., Div. of Oerlikon Motor Corp.*, 693 F. Supp. 814, 819 (N.D. Cal. 1988) ("[I]t is not legally improper for the court to consider the reverse doctrine of equivalents prior to resolving the literal infringement issue.").

Under the reverse doctrine of equivalents, "'where a device is so far changed in principle from a patented article that it performs the same or a similar function in a substantially different manner, but nevertheless falls within the literal words of the patent,' no infringement will be found." *Precision Metal,* 693 F. Supp. at 819 citing *Graver Tank & Mfg. Co. v. Linde Air Prod. Co.,* 339 U.S. 605, 608-09 (1950) (citations omitted); *see also* Donald S. Chisum, 5A Chisum on Patents § 18.04 (2007).

Plaintiffs purport to discount the reverse doctrine of equivalents on the basis that the Federal Circuit has never affirmed a finding of non-infringement based on this doctrine. (Mem. at 8:25-28). That is not true. The Federal Circuit's predecessor court, the Court of Claims,[5] has affirmed non-infringement based on the reverse doctrine of equivalents. *See Leesona Corp. v. United States,* 530 F.2d 896, 906 (Ct. Claims 1996). In *Precision Metal*, this Court cited *Leesona* with approval and explained that:

> In *Leesona,* plaintiff's patent required a porous metal layer with uniform porosity. Defendant's alleged infringement fit the description of plaintiff's patented device, but it did not perform the same function. As the court stated, '[w]hile [defendant's alleged infringement] is porous and ... in a very loose sense, could be said to have a uniform and controlled porosity, it is clear that it is neither intended to perform the [same function as plaintiff's patented equipment], nor in fact does so.' *Id.* at 906. The court held that such 'incidental and entirely insignificant' infringement does not create liability for patent

[5] *See Casio, Inc. v. U.S.*, 73 F.3d 1095, 1099 (Fed. Cir 1996) ("This court has adopted as precedent the holdings of its predecessor courts, the United States Court of Claims and the United States Court of Customs and Patent Appeals,... .").

infringement. *Id.*

Precision Metal, 693 F. Supp. at 819 (N.D. Cal. 1988). For similar reasons, in *Precision Metal* this Court found no infringement under the reverse doctrine of equivalents stating:

> Defendant Jetstream's machines do not operate on the same principle as plaintiff's patent inventions. Whatever similarities exist are incidental and do not enhance the operation of defendant's machines." ... This appears to be a case where defendants are not gaining the benefit of plaintiff's patents, but their equipment could fall within the literal language of the patents ... In this case, plaintiff has failed to go beyond the literal language of its patents to show that defendant's equipment performs the same function in a substantially similar way.
>
> Thus, based on the reverse doctrine of equivalents, defendants are entitled to summary judgment [of non-infringement] as to all three patents.

Id. Other courts have also found non-infringement based on the reverse doctrine of equivalents. *See, e.g., Brenner v. Recognition Equip. Inc.*, 593 F. Supp. 1275, 1278 (S.D.N.Y. 1984) (invoking the reverse doctrine of equivalents to find for non-infringement); *Technicon Instruments Corp. v. Alpkem Corp.*, 664 F. Supp. 1558, 1575 (D. Or. 1986) (same), *rev'd-in-part on other than ground* 837 F.2d 1097 (Fed. Cir. 1987).

2. Apotex' 0.4% KT ANDA formulation does not infringe the claims of the '493 patent under the reverse doctrine of equivalents because the function or purpose of O_{40} in the ANDA formulation is so far changed in principle from what the Court required in the '493 patent formulations.

Plaintiffs' infringement analysis ignores key findings that the Court made in *Syntex I* regarding the function and purpose of O_{40} in the '493 patent formulations and does not take into account the reverse doctrine of equivalents; therefore, Plaintiffs' infringement analysis is incomplete and incorrect.[6]

Dr. Mitra explains in his Declaration that a person of ordinary skill in the art reading the

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[6] Plaintiffs incorrectly state that Apotex admits that the 0.4% KT ANDA formulation literally infringes the asserted claims (Mem. at 8:19-20) because Plaintiffs' infringement analysis is incomplete and incorrect.

Court's December 29, 2003 Findings/Conclusions, and in particular the portions mentioned in paragraph 21 of his Declaration, would interpret them to mean that the function and purpose of O_{40} is to provide "robust" stability to the '493 patent formulations by forming micelles to prevent the KT/BAC interaction. (Mitra Decl. at ¶¶ 25, 48; *see also* RJN, Ex. B at ¶¶ 47, 75, 83).

Plaintiffs ignore this function and purpose of O_{40} in the '493 patent formulations purportedly on the grounds that the Court found in the Claim Construction Order (RJN, Ex. D at 9) that the term "stabilizing"[7] in the '493 patent claims is not a claim limitation. (*See* Mem. at 8:10-18). However, the Court's findings subsequent to the Claim Construction Order cannot be ignored. Further, to the extent there is any tension between the Court's December 29, 2003 Findings/Conclusions and its earlier Claim Construction Order, the Findings/Conclusions control. *Regents of University of California v. Micro Therapeutics, Inc.*, 2007 WL 734998 at *3 (N.D. Cal. Mar. 2, 2007) ("To the extent a construction given in this Order to a particular word or phrase as it is used in a particular claim conflicts with the construction given in the [earlier] August 2005 Markman Order, the construction in this Order controls as to that claim."); *ISCO Intern., Inc. v. Conductus, Inc.*, 2003 WL 276250 at *5, n.5 (D. Del. Feb. 10, 2003)("Of course, to the extent this conclusion is inconsistent with the [earlier] claim construction order of October 30, 2002, the present order controls.").

The Court's finding — that O_{40} provides robust stability to the '493 formulations by forming micelles to prevent the KT/BAC interaction — can be accomplished by (1) entrapping the KT ions, the BAC ions, or both, into the micelles[8], thereby preventing the two charged species (KT/BAC) from interacting and forming a complex or (2) entrapping the KT/BAC complex in the water-repelling interior of the micelle, thereby solubilizing the complex. (Mitra Decl. at ¶ 26). Both

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[7] In the '493 patent claims, "stabilizing" appears as "[O_{40}] in a stabilizing amount… ."

[8] A person of ordinary skill in the art would know that a micelle is a molecular spherical cage having a hydrophilic ("water-liking") exterior and a hydrophobic ("water-repelling") interior. A hydrophobic drug (water-repelling) can be captured within the micelle and solubilized by the water-liking exterior of the micelle. (Mitra Decl. at ¶ 22).

methods require that O_{40} form micelles in the solution and this can be accomplished when the concentration of O_{40} is above its "Critical Micellar Concentration" level of 0.04%. (*Id.*). A person of ordinary skill in the art would know that O_{40} can form micelles when the concentration of O_{40} is above a particular concentration known as the Critical Micellar Concentration ("CMC") and O_{40}'s CMC is 0.04%. (*Id.* at ¶¶ 23, 24).

Dr. Mitra's tests show that the 0.004% O_{40} in the Apotex 0.4% KT ANDA formulation is far below O_{40}'s CMC of 0.04% and therefore O_{40} does not produce micelles in the ANDA formulation and does not solubilize the KT/BAC complex to clear-up the formulation.[9] (*Id.* at ¶¶ 33, 35, 36, 37).

Instead, Dr. Mitra found that it was the NaCl in the 0.4% KT ANDA formulation that cleared-up the formulation. (*Id.* at ¶¶ 39, 40). That is, the NaCl in the Apotex 0.4% KT ANDA formulation is serving the function of a stabilizer by ionically shielding the KT and BAC ions thereby preventing them from interacting and forming a water insoluble complex. (*Id.* at ¶ 41). This ionic shielding of the KT and BAC ions is distinctly different from a micellar solubilization and stabilization effect that is produced by nonionic surfactants, such as O_{40}. (*Id.*). Therefore Apotex' 0.4% KT ANDA formulation is being stabilized by a completely different agent and by a completely different mechanism compared to the Court's findings, which was for O_{40} to form micelles to stabilize the formulation. (*See* RJN, Ex. B at ¶¶ 47, 75, *see also id.* at ¶¶ 48, 50, 59, 60 and 83); (Mitra Decl. at ¶¶ 41, 46).

Further, the Court found that NaCl could not perform the *same* stabilizing function as O_{40}. The importance of O_{40} forming micelles in the '493 patent formulations is shown by the Court distinguishing and discounting the effect that NaCl has on the '493 patent formulations in terms of its ability to form micelles, as follows:

> (¶ 49) Sodium chloride [NaCl] does not affect a solution of a carboxyl group-containing NSAID [KT] and BAC in the same manner as does

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[9] Dr. Mitra also tested concentrations of O_{40} at 0.003% and 0.004% without combining it with other ingredients and found that at such concentrations do not produce micelles. (Mitra Decl. at ¶ 34).

> Octoxynol 40. Although sodium chloride has some effect on micelle formation, it does not have the same effect as Octoxynol 40 in that it does not significantly limit the concentration ranges of NSAID and BAC at which a complex will form. The addition of sodium chloride to a solution of a carboxyl group-containing NSAID and BAC will not, therefore, lead to a robust formulation. R.T. 1662:9-1664:11.

(RJN, Ex. B at ¶ 49).

To one skilled in the art, Apotex' 0.4% KT ANDA formulation does not infringe the asserted claims of the '493 patent under the reverse doctrine of equivalents[10] because the concentration of O_{40} that is used in the Apotex 0.4% KT ANDA formulation does not form micelles to solubilize and/or stabilize the KT/BAC complex. (Mitra Decl. at ¶ 45). Specifically, the 0.004% O_{40} in the Apotex 0.4% KT ANDA formulation is far below O_{40}'s CMC level of 0.04% and therefore O_{40} is incapable of forming micelles in the Apotex formulation, is not serving any function or purpose in the formulation and certainly is not providing "robust" stability to the formulation. (*Id.*).

The fact that the Court found that Apotex' 0.5% KT ANDA formulation infringes the claims of the '493 in *Syntex I* has no bearing on this case because the 0.4% KT ANDA formulation at issue here is materially different from the 0.5% KT ANDA formulation because of the different amount of O_{40} concentrations used. In the Apotex 0.5% KT ANDA formulation, 0.01% O_{40} was used, which is at a much higher concentration than the 0.004% O_{40} used in the 0.4% KT ANDA formulation. (*Id.* at ¶ 51). Although the 0.01% O_{40} in the Apotex 0.5% KT formulation is below O_{40}'s CMC of 0.04%, it is not as far below the CMC as the 0.004% O_{40} in the 0.4% KT ANDA formulation. (*Id.* at ¶¶ 42, 51). As such, O_{40} is able to form micelles in the 0.5% KT ANDA formulation but not in the 0.4% KT ANDA formulation. (*Id.*).

Apotex' 0.4% KT and 0.5% KT ANDA formulations are not the same formulation because O_{40} functions differently in both ANDA formulations causing the ingredients to interact differently in

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[10] By arguing non-infringement under the reverse doctrine of equivalents, Apotex is not conceding that its 0.4% ANDA formulation literally infringes the asserted claims of the '493 patent, nor is it required to. *See Precision Metal,* 693 F. Supp at 820, n.5 citing *SRI Int'l v. Matsushita Elec. Crop. of America,* 775 F.2d 1107, 1118 (9th Cir. 1985) .

the formulations. (*Id.* at ¶ 52). Therefore, the 0.4% KT ANDA formulation is materially different from the 0.5% KT ANDA formulation and the 0.4% KT ANDA formulation requires NaCl to keep it clear. (*Id.*).

Because the concentration of O_{40} in the Apotex 0.4% KT ANDA formulation is far below its CMC, O_{40} does not form micelles in the Apotex formulation and therefore does not provide "robust" stability as required by the Court's earlier findings. (*Id.* at ¶ 49). Because O_{40} is not forming micelles in the Apotex 0.4% KT ANDA formulation, O_{40} is not serving any function or purpose in the formulation and certainly is not providing "robust" stability by forming micelles that is required by the Court's earlier findings. (*Id.*). The function/purpose, or lack thereof, of O_{40} in the Apotex 0.4% KT ANDA formulation is so far changed in principle from what the Court required of O_{40} in the '493 patent formulations, that the resulting stabilization of the ANDA formulation is accomplished by a substantially different way. (*Id.*). That is, the NaCl stabilizes the Apotex 0.4% KT ANDA formulation by a different mechanism than called for by the Court; *i.e.,* through ionic shielding rather than O_{40} micellar formation. (*Id.* at ¶ 47). Therefore, the Apotex 0.4% KT ANDA formulation does not infringe any of the claims of the '493 patent under the reverse doctrine of equivalents. (*Id.* at ¶¶ 49, 53).

This reverse doctrine of equivalents is equitably applied based upon underlying questions of fact, *see Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1581 (Fed. Cir. 1991), when the accused infringer proves that, despite the asserted claims literally reading on the accused device, "it has been so changed that it is no longer the same invention." *Del Mar Avionics, Inc. v. Quinton Instr. Co.,* 836 F.2d 1320, 1325 (Fed. Cir. 1987) (citing *Graver Tank*, 339 U.S. at 608-09). This is precisely such a case where equity commands a determination of non-infringement.

Although Dr. Mitra's Declaration clearly shows that the Apotex 0.4% KT ANDA formulation does not infringe the '493 patent claims under the reverse doctrine of equivalents, Apotex does not need to show non-infringement to defeat summary judgment, rather only that there is a genuine issue of material fact as to infringement. *See Gil v. Reed*, 381 F.3d 649, 659 (7th Cir. 2004) ("To survive summary judgment, Gil need not prove his claim; he need only show that there is a genuine issue of

material fact as to each of these elements").

The fact that Plaintiffs did not even attempt to apply the reverse doctrine of equivalents or apply the Court's findings about O_{40} micellar formation raises a genuine issue of material fact as to whether the Apotex 0.4% KT ANDA formulation infringes the '493 patent. "Because the determination of infringement is a question of fact, summary judgment of infringement is improper if a reasonable jury could find that not every limitation of the claim in question would be met by the allegedly infringing product." *Abbott*, 300 F.3d at 1373; *Warner-Lambert,* 418 F.3d at 1342 (reversing summary judgment of infringement because genuine issue of material fact existed as to whether magnesium carbonate in the accused ANDA formulation inhibited oxidative discoloration of quinapril). Accordingly, Plaintiffs' Motion seeking summary judgment of infringement should be denied.

B. Plaintiffs' Motion seeking summary judgment of validity and enforceability of the '493 patent should be denied because Apotex' defenses of patent invalidity and unenforceability are not barred by the doctrines of either claim preclusion or issue preclusion.

1. The doctrine of claim preclusion does not apply because all of the requirements of the doctrine are not met.

Although Plaintiffs correctly recite the requirements for the claim preclusion doctrine —"the earlier suit (1) involved the same 'claim' or cause of action as the later suit, (2) reached a final judgment on the merits, and (3) involved identical parties or privies" (Mem. at 10:4-6) (case citations omitted) — they misapplied the doctrine because the first two requirements are not met.

a. Claim preclusion does not apply because the 0.4% KT ANDA formulation at issue is materially different from the formulation at issue in *Syntex I*.

Plaintiffs, the party asserting claim preclusion, have the burden to show that Apotex' 0.4% ANDA formulation at issue in this litigation is essentially the same as the 0.5% KT ANDA formulation at issue in *Syntex I*. *Foster v. Hallco Mfg. Co.*, Inc., 947 F.2d 469, 480 (Fed. Cir. 1991). Plaintiffs have failed to meet their burden.

Plaintiffs summarily conclude that the 0.4% KT ANDA formulation is the same as the 0.5%

KT ANDA formulation in *Syntex I* despite the differences in the concentrations of KT, BAC, O_{40} and other ingredients that are used in the 0.4% KT and 0.5% KT ANDA formulations. Plaintiffs have not provided any scientific evidence that would show that the formulation in *Syntex I* and here are essentially the same. Merely listing the different concentrations of the ingredients in both the 0.4% and 0.5% KT ANDA formulations and stating that the concentrations fall within the range of concentrations claimed in the '493 patent (Mem at 10:19 – 11:2), is not sufficient to show that the two chemical compositions are essentially the same.

In contrast, as explained in section (IV)(A)(2), *supra,* Apotex has presented scientific evidence showing that Apotex' 0.4% KT ANDA formulation is materially different from the 0.5% KT ANDA formulation in *Syntex I* due to the difference in the amount of O_{40} used in each formulation. Specifically, in the Apotex 0.5% KT ANDA formulation, 0.01% O_{40} was used, which is a much higher concentration than the 0.004% O_{40} used in the 0.4% KT ANDA formulation. (Mitra Decl. at ¶ 51). Although the 0.01% O_{40} in the Apotex 0.5% KT formulation is below O_{40}'s CMC of 0.04%, it is not as far below the CMC as the 0.004% O_{40} in the 0.4% KT ANDA formulation. (*Id.* at ¶¶ 42, 51). As such, O_{40} is able to form micelles in the 0.5% KT ANDA formulation but not in the 0.4% KT ANDA formulation. (*Id.*).

Apotex' 0.4% KT and 0.5% KT ANDA formulations are not the same formulation because O_{40} functions differently in both ANDA formulations causing the ingredients to interact differently in the formulations. (*Id.* at ¶ 52). Therefore, the 0.4% KT ANDA formulation is materially different from the 0.5% KT ANDA formulation and the 0.4% KT ANDA formulation requires NaCl to keep it clear. (*Id.*).

"The Supreme Court has cautioned that the offensive use of *res judicata* should be examined carefully to determine whether it would be unfair to the defendant." *Sharp Kabushiki Kaisha v. ThinkSharp, Inc.* 448 F.3d 1368, 1371 (Fed. Cir. 2006) (citing *Parklane Hosiery Co., Inc. v. Shore*, 439 U.S. 322 (1979).). "[R]es judicata is not applicable where 'it is apparent that all the questions of fact and law involved ... [in the second proceeding] were not determined in the previous proceeding.'" *In re Bose Corp.*, 476 F.3d 1331, 1335 (Fed. Cir. 2007) (internal citation omitted).

Res judicata "blockades unexplored paths that may lead to truth. For the sake of repose, res judicata shields the fraud and the cheat as well as the honest person. It is therefore invoked only after careful inquiry." *Kearns v. General Motors Corp.*, 94 F.3d 1553, 1556 (Fed. Cir. 1996).

The present suit requires careful inquiry, indeed. This inquiry is necessary in order to reveal the significant differences between the formulations at issue in *Syntex I* and the present suit, which give rise to wholly distinguishable claims.

Apotex has presented a genuine issue of material fact as to whether the same "claim" is at issue here as in *Syntex I.* Accordingly, Plaintiffs' Motion should be denied.

b. Claim preclusion does not apply because *Syntex I* did not reach a final judgment on the merits.

"It is not every case in which a litigant has had 'one bite at the cherry' that the law forbids another. In other words, it is not every such case in which the policy of stopping litigation outweighs that of showing the truth." *Kearns*, 94 F.3d at 1557. Such is the circumstance here, as not only has *KSR* presented a substantive change in the law at issue, but it also presents a material question of the finality of *Syntex I.* Plaintiffs fail to mention that Apotex, based upon the recent change in law resulting from the *KSR* decision, currently has pending before the Supreme Court a petition for certiorari in *Syntex I*, which is likely to be granted. Therefore, there is a material fact in dispute as to whether *Syntex I* ended with a final judgment. Accordingly, Plaintiffs' motion should be denied and Apotex should not be precluded from challenging the validity and enforceability of the '493 patent.

c. Principles of fairness dictate that claim preclusion should not apply when there is a change in the law.

Plaintiffs, in conclusory fashion, make the erroneous statement that "if *KSR* did constitute [a] 'sweeping change in the law of obviousness'…claim preclusion would still prevent Defendants from raising any defense that the '493 patent is invalid or unenforceable in this case." For this mistaken proposition, Plaintiffs cite *U.S. v. Tippett*, 975 F.2d 713, 719 (10th Cir.1992); *Erspan v. Badgett*, 659 F.2d 26 (5th Cir. 1981); *Harrington v. Vandalia-Butler Bd. Of Educ.*,649 F.2d 434, 437 (6th Cir. 1981). (Mem. at 13:11-15.) None of these cases clearly stands for the proposition for which Plaintiffs cite them.

Tippet considers the situation of "an adverse judgment from which no appeal has been taken." 975 F.2d at 719. In that case, the party against whom res judicata was applied had failed to join as a party to a petition for writ for certiorari. That is contrary to the circumstances in this matter as Apotex has filed a petition for writ of certiorari in *Syntex I*.

In *Badgett,* a case involving the divisibility of railroad retirement benefits as marital property, the Supreme Court decided a case with a related question of law overturning the existing precedent. Based on that change in law, the former husband then petitioned for rehearing of the parties' earlier case, seeking reversal of the resultant divorce decree. This petition was denied. The court summarized the situation:

> Unlike both *McCarty* and *Hisquierdo*, however, which were direct appeals from state court divorce decrees, the case sub judice is not: there is no divorce decree before this Court. Moreover, notwithstanding defendant's invitation for this Court to "reverse" the February 21, 1963 judgment of the 65th Judicial District Court of El Paso County, Texas, we have no such jurisdiction.

Badgett, 659 F.2d 26, 27-8 (5th Cir. 1981).

In *Badgett*, a Fifth Circuit case which has no precedential value in this circuit, in addition to the fact that the court makes no broad proclamations of law, the legal, factual and procedural trappings of the case bear no similarity to the instant case. Moreover, Westlaw shows that *Badgett*, which has stood for 26 years, has never been cited in a judicial opinion for the proposition that Plaintiffs assert or for any other. Its citation by Plaintiffs is of no weight in the present matter.

Similarly, Plaintiffs cite to *Precision Air Parts, Inc. v. Avco Corp.,* 736 F.2d 1499 (11th Cir. 1984) in hopes of establishing that denial of res judicata or collateral estoppel is an extraordinary occurrence. However, the court in that matter made clear that such denial may serve the interests of justice:

> "This court is well aware of the value that the bar and estoppel doctrines serve in achieving a finality to litigation and in preventing harassment of a party and a waste of the court's resources through multiplicitous law suits. We are unwilling to hold, however, that they constitute an absolute from which we must never stray, even when a mechanical application would result

> in manifest injustice. Rather, we believe that the occasional adoption of an exception to the finality rule when public policy so demands does not undermine its general effectiveness." 736 F.2d at 1504.

Finally, *Harrington v. Vandalia-Butler Bd. Of Educ.* is a Sixth Circuit case that cannot be said to clearly stand for any general principle. While the court in that matter did apply the *res judicata* doctrine, one of only two cases citing *Harrington* in its 26 year history has gone the other direction, holding that "preclusion would not apply in th[e] [present] case because the controlling legal principles have changed significantly." *Ervin v. Medtronic*, 22 Fed. Appx. 462, 463 (6th Cir. 2001). *Harrington* and the other cases cited by Plaintiffs hardly constitute a general rule regarding the effect of an intervening change in law on the operation of *res judicata* principles.

d. Application or denial of claim preclusion is independent of the factual context of the case

Plaintiffs assert that "exceptions" to the claim preclusion doctrine may only be had within certain specific factual contexts, citing for this proposition the case of *Commissioner v. Sunnen,* 333 U.S. 591 (1948). (Mem. at 14:13.) This assertion is without merit and no such limitation may be found in any judicial opinion. Claim preclusion may be denied in appropriate circumstances, regardless of the facts giving rise to the suit.

As cited in the previous section, the Eleventh Circuit in *Precision Air Parts*, a patent infringement suit, stated clearly that the application of claim preclusion is not an absolute. Similarly, the Federal Circuit in *Kearns*, also cited above, states that "[i]t is not every case in which a litigant has had 'one bite at the cherry'" that claim preclusion applies. *Kearns*, 94 F.3d at 1557. Plaintiffs pronouncement that the application or denial of claim preclusion is found only in exceedingly narrow circumstances is simply unsupported. Claim preclusion may be applied or denied in any factual context, based upon the presence or absence of the three elements of the doctrine, set forth in §B(1), above.

2. The doctrine of issue preclusion does not apply because all of the requirements of the doctrine are not met.

Although Plaintiffs correctly recite the requirements for the issue preclusion doctrine — "(1)

the issue necessarily decided at the previous proceeding is identical to the one which is sought to be relitigated; (2) the first proceeding ended with a final judgment on the merits and (3) the party against whom collateral estoppel is asserted was a party or in privity with a party at the first proceeding" — (Mem. at 15:11-16) (case citations omitted), they misapplied the doctrine because the first two requirements are not met.

The second requirement,that the first proceeding end with a final judgment on the merits,was already discussed in connection with claim preclusion at Section (IV)(B)(1)(b). For those reasons, *Syntex I* did not end with a final judgment on the merits and therefore the second requirement for issue preclusion is not met.[11]

a. Issue preclusion does not apply because the issues decided in *Syntex I* are not identical to ones at issue in this litigation.

As for the first requirement, that the issue decided in *Syntex I* is identical to the issue here, Plaintiffs bear the burden of showing, with clarity and certainty, what was determined by the prior judgment. *Applied Medical Resources Corp. v. U.S. Surgical Corp.*, 352 F. Supp.2d 1119, 1124 (C.D. Cal. 2005) ("*Applied II*") citing *Clark v. Bear Stearns & Co.,* 966 F.2d 1318, 1320 (9th Cir. 1992). Plaintiffs cite *Dana v. E.S. Originals, Inc.,* 342 F.3d 1320, 1324 (Fed. Cir. 2003) to support their contention that both patent validity and infringement are single issues in the context of an issue preclusion inquiry. (Mem. at 16:12-14). However, *Dana* is not on point because regional circuit law applies to issue preclusion, and the Federal Circuit in *Dana* applied Eleventh Circuit law. *Dana*, 342 F.3d at 1323. In addition, *Dana* involved *offensive* collateral estoppel, *i.e.,* the use of collateral estoppel by a plaintiff who was not a party to the prior action against a defendant who was, which is not the case here. *Id.* at 1322.

Plaintiffs cite *Applied II* to show that patent validity (invalidity), and not the particular

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[11] Plaintiffs incorrectly state the Federal Circuit in the first appeal (*Syntex(U.S.A.) LLC v. Apotex*, Inc., 407 F.3d 1371 (Fed. Cir. 2005)) affirmed that the '493 patent is enforceable and not invalid. (Mem. at 15:18-22). To the contrary, the Federal Circuit reversed and remanded the Court's finding of obviousness. *Syntex*, 407 F.3d at 1385.

arguments raised to show patent invalidity, is the "issue" relevant to the issue preclusion doctrine and that such a definition encompasses not only the patent invalidity defenses that were actually raised and litigated in the prior proceeding but also any new invalidity grounds. (Mem. at 16-18).[12] *Applied II*, citing *Kamilche Co. v. United States,* 53 F.3d 1059, 1063 (9th Cir. 1995). Thus, Plaintiffs allege that because Apotex has already argued the invalidity of the '493 patent in *Syntex I*, Apotex is barred from re-litigating this issue whether based on old grounds or new ones. Apotex disagrees because there were at least two defenses (obviousness type double patenting and best mode) that Apotex was prepared to litigate in *Syntex I* but the Court dismissed those defenses during pre-trial due to a technical defect. Thus, this is not a situation where Apotex "forgot" to raise a defense in the earlier proceeding, rather a technical defect precluded Apotex from arguing the defenses at trial and therefore those defenses were not "necessarily decided at the previous proceeding." "[F]or collateral estoppel to apply, the parties must have had a full and fair opportunity to litigate the claims at issue." *Applied II*, 353 F. Supp. 2d at 1127, citing *Durkin v. Shea & Gould,* 92 F.3d 1510, 1515 (9th Cir. 1996).

Thus, Apotex has raised a material fact at issue as to whether the issues decided in *Syntex I* are identical to the ones raised here and whether the decision in *Syntex I* is final. Accordingly, Plaintiffs' Motion seeking summary judgment that the '493 patent is valid and enforceable should be denied.

Also, as explained below, the legal framework surrounding the obviousness inquiry changed dramatically between *Syntex I* and the current proceeding. Thus principles of fairness (discussed more extensively below) dictate that the issue preclusion doctrine should not apply in this case. "If there is any doubt as to its appropriateness, collateral estoppel should **not** be applied." *Applied II*, 352 F. Supp. 2d at 1124 (emphasis added), citing *Harris v. Jacobs*, 621 F.2d 341, 343 (9th Cir. 1980).

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[12] Plaintiffs incorrectly state that in *Crossroads Sys. (Texas), Inc. v. Dot Hill Sys. Corp.,* 2006 WL 1544621, at *5 (W.D. Tex. May 31, 2006) the previously unasserted invalidity defenses were barred (Mem. at 18:5-7), however, in that case the court the declined to apply collateral estoppel. *Id.* at *7-*8.

b. Principles of fairness dictate that issue preclusion should not apply because there has been a significant change in the law since the decision in *Syntex I*.

While there is some overlap between Apotex' patent invalidity/unenforceability defenses asserted in *Syntex I* and here, the issue preclusion inquiry is not that rigid and takes into account principles of fairness and judicial discretion before its application. That is,"[e]ven if the elements of collateral estoppel are satisfied, special circumstances, such as doubt as to the quality, extensiveness or fairness of procedures followed in the first litigation may warrant an exception to the normal rules of preclusion." *Applied II*, 353 F. Supp. 2d at 1127, citing *Durkin,* 92 F.3d at 1515. It would be unfair to consider Apotex' invalidity and unenforceability defenses in a vacuum without taking into consideration the legal framework behind them, such as the state of the law on obviousness between the time of *Syntex I* and now.

When "an identical issue had not been actually litigated in a prior trial…it is clear beyond peradventure that collateral estoppel does not apply." *Suntiger, Inc. v. Scientific Research Funding Group*, 189 F.3d 1327, 1333 (Fed. Cir. 1999). "Where the situation is vitally altered between the time of the first judgment and the second, the prior determination is not conclusive. A judicial declaration intervening between the two proceedings may so change the legal atmosphere as to render the rule of collateral estoppel inapplicable." *Texaco Inc. v. United States*, 579 F.2d 614, 616 (Ct. Cl. 1978). Because the Supreme Court's decision in *KSR Int'l Co. v. Teleflex, Inc.,* 127 S.Ct. 1727 (2007) significantly changed the law of obviousness between the time of the decision in *Syntex I* and the present proceeding, the issue of obviousness of the '493 patent in view of *KSR* is not the same issue that was decided by the Court in *Syntex I*. Moreover, the earlier decision in *Syntex I* remains at issue because Apotex' Petition for Certiorari is pending, and therefore the *Syntex I* decision is not a final decision.

Where, as here, within the interim of the first and second proceedings, the relevant legal precedent changes such that its application may lead to an entirely different outcome in the second proceeding, the entire purpose of the doctrine of collateral estoppel is frustrated. The Supreme Court

held in such circumstances that "[t]he supervening decision of the . . . court interpreting that law in direct relation to this [dispute] cannot justly be ignored in the present proceeding." *Blair v. Comm'r of Internal Revenue*, 300 U.S. 5, 9 (1937).

Plaintiffs acknowledge that "[i]ssue preclusion will apply to prevent relitigation of previously determined issues 'unless there have been *major* changes in the law,'" (Mem. at 18:15-17) (case citation omitted); however, they inappropriately carve out a narrow exception to the rule rather than stating that principles of fairness and judicial discretion need to be considered in the application of issue preclusion. *See Applied II*, 353 F. Supp. 2d at 1127. Regardless of the characterization, the fact remains that the recent change in the law of obviousness under *KSR* makes the application of issue preclusion unfair and inappropriate in this case.[13]

Under *Steen*, issue preclusion will not be applied when (1) the issues decided in the first case were legal (as opposed to factual) in nature and (2) the intervening change in the law presents a *significant* change in the legal climate. (Mem. at 19:15-25); *Steen v. John Hancock Mut. Life Ins. Co.*, 106 F.3d 904, 914 (9th Cir. 1997). Both conditions are satisfied here.

First, it is well established that "obviousness is a question of law based on underlying facts." *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1302 (Fed. Cir. 2005). Since this Court addressed obviousness in *Syntex I*, it made both legal and factual findings. While Plaintiffs state that "[n]o change in law could disturb the preclusive effect of these factual findings" (Mem. at 19:21-22), they ignore the fact that under the flexible and expansive approach to the obviousness inquiry under *KSR*, these factual determinations would be interpreted differently and would likely lead to a finding of obviousness as shown in Apotex' Petition for Certiorari. (Gupta Decl., Ex. C).

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[13] Plaintiffs reliance on *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, --- F.3d ---, 2007 WL 1839698 (Fed. Cir. June 28, 2007) for discounting the "change in law" argument based on *KSR* is misplaced. (*See* Mem. at 22:5-20). *Takeda* did not concern an issue preclusion inquiry based on the change in law in *KSR*. That is, in *Takeda* the issue was not whether defendant's defenses should be re-litigate or re-evaluated in view of *KSR*.

Second, "[t]he Supreme Court's unanimous decision in *KSR* has been described by commentators as 'one of the most significant patent rulings in decades' representing a 'sea change' in patent law turning established precedent 'upside down'." *Izzo Golf, Inc. v. King Par Golf, Inc.*, 2007 WL 1987789, at *19 (W.D.N.Y. July 5, 2007) (allowing defendant to supplement its motion for summary judgment to raise obviousness "[b]ecause *KSR* has substantively changed the law of obviousness with respect to the validity of a patent, defendant should be allowed to present an obviousness defense to the court if it so chooses") (internal citations omitted). The American Bar Association has commented that the "decision in *KSR International Co. v. Teleflex, Inc,* criticized and modified the obviousness standard that has been used in patent cases for decades. Many observers believe that the *KSR* decision may dramatically change patent law and make it more difficult to obtain new patents, and protect existing patents." (Gupta Decl., at Ex. D). Courts from coast to coast have echoed this observation as they have begun to interpret anew the obviousness standard in the wake of *KSR*. "In KSR...the Supreme Court rejected the 'teaching, suggestion, motivation" test ('TSM') for obviousness under 35 U.S.C. §103 promulgated by the Federal Circuit Court of Appeals. More specifically, the Court rejected the 'rigidity' of the TSM test as applied by the Federal Circuit...[T]he Court found no reason to use such a restricting test for the primary reason of preventing hindsight bias." *Single Chip Sys. Corp. v. Intermec IP Corp.*, 2007 WL 1970877, at *8 (S.D. Cal June 29, 2007) (emphasis added). The simple fact is that "*KSR* casts doubt on the continuing validity of Federal Circuit precedent on the issue of obviousness." *McNeill-PPC Inc. v. Perrigo Company*, 2007 WL 1933931, at *15 (S.D.N.Y. July 3, 2007).

These holdings from the District Courts of Western and Southern Districts of New York, the Southern District of California, as well as the Eastern District of Virginia[14] and the District of Minnesota[15] clearly and unequivocally demonstrate that commentators and courts across the country

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[14] *MercExchange, LLC v. Ebay, Inc.*, 2007 WL 2172587, at *13 (E.D.Va, July 27, 2007) (*KSR* "plainly raised the bar as to what qualifies as non-obvious").

[15] *Ecolab Inc. v. FMC Corp.*, 2007 WL 1582677, at *3 (D.Minn. May 30, 2007) ("The Court will endeavor to feel its way through the thickets of obviousness."[after *KSR*]).

believe that the legal landscape with regard to obviousness has changed significantly between the time of *Syntex I* and the present matter. The District Court of Delaware also agrees, stating that *KSR* "proscribed the Federal Circuit's narrow and inflexible application of its 'teaching, suggestion, or motivation' test for obviousness" and reminds us that "the Supreme Court requires that its holdings be given 'full retroactive effect in all cases still open on direct review.'" *Praxair, Inc. v. ATMI, Inc.*, 2007 WL 1732205, at *2 (D. Del. June 14, 2007) citing *KSR*; quoting *Harper v. Virginia Dep't of Taxation*, 509 U.S. 86, 97 (1993).

Furthermore, it is a significant stretch to read *Steen* as definitive of the magnitude of a change in the law that is necessary to preclude collateral estoppel. The Ninth Circuit in *Steen* made much of the fact that the intervening decision in *Harris Trust* "did not discount any prior case law," *Steen* 106 F.3d at 914, and that the judges of the Ninth Circuit "ha[d] cited *Harris Trust* only once in a published opinion." *Id.* at 914 n. 6. In stark contrast, the Supreme Court's decision in *KSR*, which is approximately 3½ months old, has been cited at least 537 times, including 36 court opinions, over 300 administrative decisions, over 100 secondary sources and six Petitions for Certiorari. (Gupta Decl., Ex. E). *KSR* is precisely what *Harris Trust* was not: a landmark decision with far-reaching and substantive effects on the state of the law at issue.

Thus, there has been a substantive change in the law of obviousness since *Syntex I* was decided and therefore collateral estoppel should not apply. This certainly raises a material issue of fact as to whether issue preclusion applies and therefore Plaintiffs' Motion seeking validity and enforceability of the '493 patent should be denied.

C. Should the Court deny Plaintiffs' Motion for Summary Judgment, an Order specifying the material facts not subject to reconsideration at trial (as requested by Plaintiffs) should be denied.

Should the Court deny Plaintiffs' request for application of claim preclusion or issue preclusion, Plaintiffs request, in the alternative, an Order pursuant to Fed.R.Civ.P. 56(d) "establishing at least the fact that Defendants have already litigated numerous invalidity and enforceability arguments in a previous case that the parties are precluded from relitigating in this case." (Mem. at 1:22-23; *see also* Mem. at 23:1-5). That is not the purpose of a Rule 56(d) Order. As pointed out in

the 1948 Advisory Committee Note to Rule 56, a subdivision (d) order is not a judgment at all but "merely practical adjudication" that certain issues of fact "shall be deemed established for the trial of the case." 1948 Advisory Comm. Note to Rule 56. Thus, while it is true that Apotex previously litigated its defenses of invalidity and unenforceability of the '493 patent in *Syntex I*, a Rule 56(d) Order cannot be used to preclude Apotex from raising various defenses in this case.

According to Rule 56(d), if a court finds that summary judgment cannot be granted because there are genuine issues of material fact to be tried, it is empowered, when it would be practicable to save time and expense and to simplify the trial, to issue an order that specifies the ***facts*** that appear ***without substantial controversy***. Wright, Miller & Kane, Federal Practice and Procedure Civil 3d § 2737. Also, the facts identified in a Rule 56(d) Order shall be determined on the basis of the pleadings as well as the documentary evidence and testimony at a hearing on the summary judgment motion and by interrogating counsel. *Id.*

Here, Plaintiffs misapply Rule 56(d) by requesting the Court to issue an Order which would essentially have the same effect as the Court stating that the doctrines of issue and claim preclusion apply without the Court actually granting Plaintiffs' Motion. Rather than specify the facts that Plaintiffs believe are "without substantial controversy," Plaintiffs improperly attempt to preclude Apotex from litigating several defenses in this case. Those defenses contain several hundred facts, many of which remain in dispute. Thus, for the same reasons set forth above with regard to Apotex' opposition to Plaintiffs' Motion for Summary Judgment, Plaintiffs' request for an order under Rule 54(d) should be denied.

D. The Court should not issue an Order stating that the effective date of any approval of Apotex' 0.4% KT ANDA be a date not earlier than 6 months after the '493 patent expires.

In the event the Court grants Plaintiffs' Motion for Summary Judgment, Plaintiffs ask the Court to overextend its authority and issue a remedy ordering the FDA to withhold final approval of Apotex' ANDA until not earlier than six months after the '493 patent expires. Plaintiffs' request is completely unfounded in the law.

The relief sought by Plaintiffs from this Court is based on a misunderstanding of 35 U.S.C. § 271(e)(4), which lists remedies available to a Plaintiff in a Hatch-Waxman action. Plaintiffs point out that for an act of infringement described in § 271(e)(2) (*i.e.*, submission of an ANDA and Paragraph IV certification), § 271(e)(4)(A) provides that courts are to order that FDA approval of the ANDA is "to be a date which is not earlier than the date of expiration of the patent which has been infringed." (emphasis supplied). Based on the "not earlier than" language in the statute, Plaintiffs incorrectly request that the Court explicitly prohibit the FDA from approving Apotex' ANDA until six months after the '493 patent has expired (*i.e.*, after pediatric exclusivity has expired). However, in enacting § 271(e)(4)(A), Congress did not contemplate granting such broad authority to the courts. Courts have no jurisdiction to enforce expired patents.

Under the FDA laws, there are instances in which the FDA itself has authority, or in some instances, is required, without court intervention, to withhold approval of an ANDA even after expiration of the listed patent. The application of pediatric exclusivity after patent expiration is one such instance. Notably, 35 U.S.C. § 271(e)(4)(A) is silent on the issue of pediatric exclusivity. Although not discussed in the patent laws, the effect of pediatric exclusivity is explained under the FDA laws, codified under Title 21, U.S. Code. Under 21 U.S.C. § 355a(b)(2)(B), the FDA cannot approve an ANDA, for which the listed patent has been adjudged valid and infringed, until six months after the listed patent expires. Section 355a(b)(2)(B) is a statutory mandate directed to the FDA, which automatically takes effect upon a court's finding of validity and infringement of a listed patent. A court order preventing the FDA from approving the ANDA until six months after expiration of the listed patent, while it may be redundant, is not authorized, under § 355a(b)(2)(B).

Since the FDA may, for various reasons, postpone approval of an ANDA even after the listed patent has expired, it follows that the "not earlier than" language of 35 U.S.C. § 271(e)(4)(A) actually limits, rather than expands, a court's authority. Suppose § 271(e)(4)(A) said that courts are to order that FDA approval of the ANDA is to "take place upon" patent expiration. Such language would necessarily invade the province of the FDA, which is authorized, and sometimes required, to postpone approval of an ANDA beyond expiration of the listed patent. To avoid such a conflict,

Congress therefore used the "not earlier than" language, which if recited verbatim in a court's order, does not improperly impose the court's will on the FDA. Rather, a court would merely fulfill its role in protecting a patentee's rights *vis-à-vis* an unexpired patent, and leave the FDA to determine if/how any exclusivity may further affect the patentee's rights. *See Mylan Labs., Inc. v. Thompson*, 332 F. Supp. 2d 106, 118 (D. D.C. 2004) ("issues relating to the ANDA's approval and the applicability of the pediatric exclusivity provisions" are "subject areas that have clearly been entrusted to the FDA by Congress").

Additionally, by requesting an Order directed to the FDA, Plaintiffs in effect seek an injunction as § 271(e)(4)(A) would have the effect of enjoining Defendants from marketing its ANDA product until expiration of the '493 patent. However, Plaintiffs have not made any showing that they are entitled to an injunction under *eBay, Inc. v. MercExchange, L.L.C.*, 126 S.Ct. 1837, 1839 (2006), which held that a plaintiff seeking a permanent injunction in a patent dispute "must" establish:

> (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

eBay, 126 S.Ct. at 1839. Thus, the requested relief is thus inappropriate as a matter of law.

V. CONCLUSION

For all of the foregoing reasons, Plaintiffs' Motion for Summary Judgment should be denied.

Respectfully submitted,

Dated: August 13, 2007

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CERTIFICATE OF SERVICE

I hereby certify that all counsel of record, who are deemed to have consented to electronic service are being served the 13th day of August 2007, with a copy of this document via the Court's CM/EFC system.

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

ROCHE PALO ALTO LLC, formerly known as SYNTEX (U.S.A.) LLC, a Delaware corporation, and ALLERGAN, INC., a Delaware corporation,

Plaintiffs,

v.

APOTEX, INC., a Canada corporation, and APOTEX CORP., a Delaware corporation,

Defendants.

Case No. 3:05-cv-02116-MJJ

PLAINTIFFS' REPLY IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT

Judge: Hon. Martin J. Jenkins
Date: August 31, 2007
Time: 9:30 a.m.
Dept.: Courtroom 11

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INTRODUCTION

Defendants have raised no genuine issue of material fact regarding their infringement of U.S. Patent No. 5,110,493 ("the '493 patent") or their affirmative defenses of invalidity and unenforceability. As a result, Plaintiffs' motion for summary judgment must be granted.

With respect to infringement, Defendants do not—and cannot—dispute that they literally infringe the asserted claims of the '493 patent. Instead, in a last gasp effort to preserve this case, Defendants attempt to recast utility and claim construction arguments that they previously lost as a new "reverse doctrine of equivalents" defense to infringement. Defendants' maneuver fails as a matter of law for several reasons.

As an initial matter, while it is unlikely that the reverse doctrine of equivalents remains viable in any case, it is plainly inapplicable in this case, which involves a chemical composition patent that claims no "purpose" or "function," and an infringing generic copy that represents no technological advance over the patented formulations.

Moreover, even if the reverse doctrine of equivalents *could* apply to this case, Defendants' arguments would still fail as a matter of law. Although it was their burden to show non-infringement under the reverse doctrine, Defendants have adduced *no evidence* from which the Court could conclude that Defendants' generic formulation is changed in "principle" from the patented formulations.

Specifically, Defendants argue that the "principle" of the '493 patented inventions is the use of *one* of the inventions' many ingredients – Octoxynol 40 – in an amount sufficient to achieve "critical micelle concentration." But the *only* sources legally relevant to determining the "principle" of the '493 invention—the patent's claims, specification, file history, and prior art—provide no support for this proposition. First, the terms "micelle" and "critical micelle concentration" do not appear *a single time* in the patent's claims, specification, or its prosecution history; nor have Defendants submitted a single piece of prior art. Second, these sources, and particularly example 3 of the specification—which specifically sets forth a ketorolac tromethamine formulation with the identical amount of Octoxynol 40 used in Defendants' generic formulation (0.004%)—make clear that the principle of the invention, however stated, contemplates a

formulation with 0.004% Octoxynol 40. Third, under well-established principles of issue preclusion, Defendants may not even assert the key contention upon which their argument rests—that the 0.004% Octoxynol 40 in their formulation does not have a stabilizing effect—since this Court explicitly found to the contrary in *Syntex*. Fourth, Defendants cannot create a genuine dispute to preclude summary judgment based on their only evidence, Dr. Mitra's declaration, since that declaration flatly contradicts Dr. Mitra's testimony from *Syntex*. Accordingly, Defendants' reverse doctrine of equivalents argument—on which they bear the evidentiary burden—necessarily fails.

With respect to their other asserted defenses, Defendants fare no better. Defendants essentially concede that they are barred from re-litigating their unenforceability defense, and present *no* authority that contradicts the binding precedent cited by Plaintiffs in support of their claim and issue preclusion arguments regarding invalidity. Therefore, summary judgment must issue barring Defendants from pursuing either of these lines of defense.

ARGUMENT

I. SUMMARY JUDGMENT MUST BE GRANTED ON THE ISSUE OF INFRINGEMENT.

Defendants do not dispute that they literally infringe the asserted claims of the '493 patent. Indeed, they have admitted that their proposed formulation literally includes each element of the patent's claims. Pl. Mem., Appx. A[1]. Rather, Defendants attempt to raise genuine issue of fact regarding infringement by dressing up their unsuccessful utility and claim construction arguments from *Syntex* as a "new" affirmative defense under the so-called "reverse doctrine of equivalents" ("reverse DOE"). Under this obsolete doctrine, literal infringement may be excused "where a device is so far changed in principle from a patented article that it performs the same or similar function in a substantially different way." *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950). Defendants' maneuver fails as a matter of law for numerous reasons.

[1] Plaintiffs refer to their opening memorandum in support of this motion as "Pl. Mem.," and to Defendants' opposition as "Opp."

A. The Reverse DOE is inapplicable to this case.

As an initial matter, it is far from clear whether the obscure reverse DOE remains viable in *any* case. The Federal Circuit recently disparaged the reverse DOE as an "anachronistic exception, long mentioned but rarely applied," and noted that it has *never* affirmed a finding of non-infringement based on the doctrine. *Tate Access Floors, Inc. v. Interface Arch. Res., Inc.*, 279 F.3d 1357, 1368 (Fed. Cir. 2002) (Gajarsa, J.).[2] But the Federal Circuit did not simply describe this state of affairs and leave it at that. Rather, the Court noted that there was "good reason" for the doctrine's demise: "when Congress enacted 35 U.S.C. § 112, after the decision in *Graver Tank*, it imposed requirements for the written description, enablement, definiteness, and means-plus-function claims that are co-extensive with the broadest possible reach of the reverse doctrine of equivalents." *Id.* In other words, if a product literally infringed a patent despite being "far changed in principle" from the patented inventions, the patent would be invalid under one of more of the defenses established by section 112. Defendants litigated and lost a section 112 defense in *Syntex*, and are precluded from re-litigating it in this case. *See* Pl. Mem. at 15-18.

But even if the reverse DOE remained good law in some contexts, it is certainly inapplicable in this case, which involves Defendants' infringement of pure chemical composition claims. As the Federal Circuit has recognized, it is difficult even to conceptualize, under the language of the doctrine, how a chemical composition that falls literally within the patent's claims could perform the same "function" in a substantially different "way" from the claimed invention. *U.S. Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1253 n.9 (Fed. Cir. 1989). This is because "[f]or such products, there is very little leeway to determine that a product *literally* reads on the claim but is so far changed in principle from the claimed compound that it does not infringe." (emphasis in original). *Zenith Labs., Inc. v. Bristol-Myers Squibb Co.*, Civ. A. No. 91-3423, 1992 WL 171910, at *31 (D. N.J. July 21, 1992), *rev'd on other grounds*, 19 F.3d 1418 (Fed. Cir. 1994). Where the composition of the accused formulation is indistinguishable from the

[2] As Defendants note, the Court of Claims affirmed non-infringement based on the reverse DOE in a single case over 30 years ago (not in 1996, as Defendants mistakenly state).

composition of the patented formulation, "the doctrine simply has no applicability." *Id.* at *32.

That is the case here. Plaintiffs have asserted only the composition claims of the '493 patent, none of which prescribe any "principle" other than the combination of various ingredients at various ranges of concentration, and none of which contain any limitations relating to "micelle formation" or even the role of Octoxynol 40. Similarly, as Defendants concede, their proposed formulation consists simply of the combination of ingredients prescribed by the '493 patent's claims, at concentrations taught by those claims. *See* Pl. Mem., Appx. A; Shafroth Decl., Ex. 4.[3] The reverse DOE simply has no applicability in this situation.

Moreover, application of the reverse DOE in this case would directly contravene the equitable purpose the doctrine was created to promote. The reverse DOE is a judge-made doctrine put in place to prevent inventors from overextending the scope of their patents so as to deprive the public of other inventors' creative and significant advances in technology. *See Boyden Power Brake Co. v. Westinghouse*, 170 U.S. 537, 570 (1897) (alleged infringer's invention was a "radical departure"). For this reason, the doctrine "should be saved—and apparently is—for the inventor that *radically,* not just modestly, improves upon the prior art," *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 339 F.Supp.2d 202, 288 (D. Mass. 2004) (emphasis in original), *aff'd in relevant part*, 314 F.3d 1313, 1351-52 (Fed. Cir. 2003), such that the accused device "has been so changed that it is *no longer the same invention.*" *Del Mar Avionics, Inc. v. Quinton Instr. Co.*, 836 F.2d 1320, 1325 (Fed. Cir. 1987) (emphasis added).[4]

The situation in this case is as far removed as possible from the situation contemplated by

[3] "Shafroth Decl." refers to the Declaration of Nathan E. Shafroth in Support of Plaintiffs' Motion for Summary Judgment, filed July 30, 2007 (Dkt. # 53).

[4] *See also Diamond Int'l Corp. v. Maryland Fresh Eggs, Inc.*, 374 F.Supp. 1223, 1247 (D.Md.1974) (noting that it is the "really meritorious improver" who deserves the benefit of the concept of the reverse doctrine of equivalents), *rev'd on other grounds*, 523 F.2d 113 (4th Cir.); Robert Merges, *Intellectual Property Rights and Bargaining Breakdown: The Case of Blocking Patents*, 62 Tenn. L. Rev. 75, 92-94 (1994) (opining that the alleged infringer must show a "radical improvement" or "significant contribution" or "substantial technological improvements"); Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 Tex. L. Rev. 989, 1012-13 (1997) (noting that "[t]he reverse doctrine of equivalents therefore benefits radical improvers at the expense of the original patentee, and so encourages radical improvements").

the reverse DOE. Defendants' 0.4% ketorolac tromethamine formulation made no original contribution to the art whatsoever, much less a "radical departure" from Allergan's identical ACULAR® LS. To the contrary, Defendants' ANDA represents an attempt to free-ride on Allergan's research and development to produce and profit from a generic copy of ACULAR® LS. Thus, there is no "inequity" in holding Defendants liable for their infringement. Nor would such liability deprive the public of any beneficial technological advance at all: Allergan's identical product is *already legally on the market*.

B. Even if the Reverse DOE Could Apply to this Case, It Would Not Provide a Defense to Infringement.

Even if the reverse DOE could theoretically apply to the circumstances of this case, Defendants' arguments would still fail as a matter of law, for three reasons. *First*, the "principle" of the patent cannot be for Octoxynol 40 to provide stability "by forming micelles," since the patent discloses no such thing. *Second*, Defendants are barred by issue preclusion from asserting the key contention upon which their reverse DOE argument is necessarily predicated—namely, that the 0.004% Octoxynol 40 in their infringing formulation does not have a stabilizing effect. And *third*, Defendants cannot create a genuine dispute to preclude summary judgment based on Dr. Mitra's declaration, since it directly contradicts his testimony given at trial in *Syntex*.

1. The "Principle" of the '493 Patent is Not the Use of O_{40} to form Micelles.

Application of the reverse DOE requires that the Court determine the "principle" of the patented inventions, so as to compare that principle to the principle of the accused product. *Ciena Corp. v. Corvis Corp.*, 334 F.Supp.2d 598, 604-05 (D. Del. 2004); *see U.S. Steel Corp.*, 865 F.2d at 1253 n.9 (in those chemical composition cases to which the reverse DOE may even intelligibly apply, such application must be with reference to the "principle" of the invention, rather than its "function" or "way"). Just as in claim construction, "[t]he principle of the claimed invention is defined by reference to the claim language in the first instance," which is then amplified by the specification, prosecution history, and prior art. *Ciena Corp.*, 334 F.Supp.2d at 605.

It is Defendants' burden to make out a reverse DOE defense, *SRI Int'l v. Matsushita Elec. Corp. of America*, 775 F.2d 1107, 1122-23 (Fed. Cir. 1985). Accordingly, in order to defeat this motion for summary judgment, Defendants must introduce sufficient evidence to allow a reasonable

fact finder to return a verdict in favor of Defendants. *See, e.g., Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 254-56 (1986).

Yet Defendants have pointed to *no evidence* in the patent, prosecution history, or prior art regarding any supposed the principle of the '493 patent. Instead, Defendants impermissibly point to findings made by this Court regarding the *utility* of the '493 patent, to propose that the principle of the patented inventions is the use of *one* of the inventions' many ingredients (Octoxynol 40) in an amount sufficient to achieve "critical micelle concentration" and "form[] micelles." Opp. at 8:2-4. Defendants' reverse DOE argument therefore fails at the threshold. *Ciena Corp.*, 334 F.Supp.2d at 606 ("The reverse [DOE] requires the Court to focus in the first instance on the *claimed* invention. Corvis' proposed principle of the invention fails to meet this threshold requirement, because it includes features not claimed in the . . . patent.") (emphasis in original); *see Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 945 (Fed. Cir.1990) (a party cannot establish non-infringement via reverse DOE by referencing additional features not present in the patent's claims). But Defendants' argument would fail in any case, since the terms "micelle" and "critical micelle concentration" do not appear *a single time* in the patent's claims, specification, or prosecution history.

First, the primary source to which the Court must look in determining the "principle" of the inventions—the '493 patent's claims—make no mention of "micelles," or "critical micelle concentration." To the extent Defendants are attempting to bootstrap their principle to the "stabilizing amount" language that appears in claim 1, this is impermissible as a matter of law. This Court has already found that this language is *not a claim limitation* (i.e., is not part of the invention), *see* RJN, Ex. D; Defendants may not collaterally attack that claim construction ruling in the guise of a reverse DOE argument. *Ciena Corp.*, 334 F.Supp.2d at 608 (rejecting reverse DOE defense as an attempt to "reargue claim construction issues which were already rejected by the Court").

Nor may Defendants argue that this Court's claim construction was somehow abrogated by findings regarding the utility of the '493 patent included in this Court's 2003 Findings of Fact and Conclusions of Law, *see* Opp. at 8:5-16, since, as Defendants apparently fail to realize, this same

order reiterated and reconfirmed that "stabilizing amount" is not a claim limitation. *See* RJN, Ex. B at ¶ 17. In any case, the portions of the 2003 order quoted in Dr. Mitra's declaration did not purport to interpret the equitable scope of the '493 patent's claims, and are therefore irrelevant to the reverse DOE analysis. *Ciena Corp.*, 334 F.Supp.2d at 605-06.

Second, the '493 patent's specification also makes no mention whatsoever of "micelles" or their purported role in stabilizing the patented formulations. Moreover, Example 3 in the specification discloses a formulation containing Octoxynol 40 in an amount of 0.004% wt/vol.—the *very amount* that Dr. Mitra states in a sworn declaration *cannot form micelles*. Shafroth Decl., Ex. 1 at col. 7, lns. 25-40; Mitra Decl., ¶¶ 34-37. Thus, in the view of Defendants' own expert, the evidence to which the Court must look in determining the principle of the '493 patent (i.e., the patent itself) is *flatly inconsistent* with Defendants' contention that the patent's central principle is for Octoxynol 40 to stabilize an interaction through micelle formation. In any case, this evidence makes clear that the principle of the invention, however stated, contemplates a formulation with 0.004% Octoxynol 40.

Third, the lengthy prosecution history file for the '493 patent also contains no discussion whatsoever concerning "micelles" or "critical micelle concentration." And *fourth*, Defendants have adduced no prior art evidence *at all*, much less any art relating to Octoxynol 40's ability to form "micelles" or reach "critical micelle concentration."

Finally, the fact that Defendants' proposed "principle" relates to the function of only one of the ingredients (Octoxynol 40) in the multi-ingredient inventions conclusively shows that it is *not* the "principle" of the patented inventions for purposes of the reverse DOE analysis. *Ciena Corp.*, 334 F.Supp.2d at 605-06 ("the Court finds that Corvis' proposed principle of the invention is incomplete, because it ignores the receive side of the system"). Defendants' proposed "principle" makes no reference to the edetate disodium, sodium chloride, sodium hydroxide, sodium hydrochloride, or water, which are all ingredients in the claimed solutions.

The asserted claims claim only the combination of certain ingredients in certain ranges of concentration. Thus, the "principle" of the invention, to the extent that this concept makes sense here, can only be the production of multi-ingredient formulations that allow all of the included

ingredients to coexist for the purpose of treating ocular disease. *See U.S. Steel Corp.*, 865 F.2d at 1253 (stating that the "principle" of a patent for crystalline polypropylene was simply "the production for the first time of crystalline polypropylene"). Because this is also the principle of Defendants infringing ANDA formulation, Defendants' reverse DOE argument fails.

2. Defendants Are Barred by Issue Preclusion from Making their Reverse DOE Argument.

Additionally, Defendants are barred by issue preclusion from making arguing a necessary predicate to their reverse DOE argument. Specifically, Defendants argue that their infringing ANDA formulation differs from the patented inventions because Defendants' formulation contains too low an amount of Octoxynol 40 to have any effect on the interaction between ketorolac tromethamine and benzalkonium chloride—which Defendants contend is somehow a limitation on the patent's equitable scope. But this Court already found—in a finding that formed part of the necessary basis for its judgment of validity in *Syntex*—that Octoxynol 40 *does* have a stabilizing effect in formulations identical to Defendants' accused ANDA formulation.

Defendants' generic formulation contains 0.4% ketorolac tromethamine, 0.0063 % BAC and 0.004% Octoxynol 40. Pl. Mem., Appx. A; Shafroth Decl., Ex. 4. In *Syntex*, this Court explicitly found that that tests run by Allergan scientist Theresa Kuan "that included 0.4% wt/vol ketorolac tromethamine, Octoxynol 40 (tested at concentrations from 0.001% to 0.005% wt/vol), and BAC (tested at concentrations from 0.005% to 0.007% wt/vol) . . . confirmed that Octoxynol 40 minimized th[e] interaction between BAC and ketorolac . . . ." RJN, Ex. B at ¶ 50.[5] Thus, the tested range includes the concentrations of ingredients in Defendants' proposed generic product, and this Court already found that in such a formulation, Octoxynol 40 has the *same* stabilizing effect on BAC and ketorolac tromethamine as it does in other patented formulations. Because Defendants are precluded from re-litigating this question of fact by the doctrine of issue preclusion, and therefore cannot show that their product is "far changed in principle" from the patented formulations, their reverse DOE argument necessarily fails. *See generally* Pl. Mem. at 15.

[5] "RJN" refers to Plaintiffs' Request for Judicial Notice, filed July 30, 2007 (Dkt. # 55).

3. Apotex Has Failed to Raise a Genuine Issue Regarding Infringement Because Dr. Mitra's Declaration Must Be Excluded.

Finally, Plaintiffs are entitled to summary judgment on the further independent ground that Dr. Mitra's declaration must be excluded from the summary judgment record, because it is a sham declaration that flatly contradicts his sworn trial testimony in *Syntex*. *See* Plaintiffs' Objections to the Declaration of Dr. Ashim K. Mitra in Support of Defendants' Opposition to Plaintiffs' Motion for Summary Judgment ("Objections") § III.A, filed herewith. "[A] party cannot create a genuine issue of fact sufficient to survive summary judgment simply by contradicting his or her own previous sworn statement (by, say, filing a later affidavit that flatly contradicts that party's earlier sworn deposition) without explaining the contradiction or attempting to resolve the disparity." *Cleveland v. Policy Mgmt. Sys. Corp.*, 526 U.S. 795, 806 (1999). Accordingly, Dr. Mitra's declaration must be excluded in its entirety, as argued in Plaintiffs' Objections. Because Dr. Mitra's declaration is the only evidence Plaintiffs have submitted to attempt to create a dispute of fact precluding summary judgment, Plaintiffs' are entitled to summary judgment on this separate and independent ground.[6]

II. SUMMARY JUDGMENT MUST BE GRANTED ON THE ISSUES OF VALIDITY AND ENFORCEABILITY.

A. Claim Preclusion Bars Defendants' Validity and Unenforceability Defenses.

1. This Case Involves the Same Claim as *Syntex*.

Defendants argue that they are entitled to relitigate validity and enforceability of the '493 patent because although this case concerns an accused product that contains the same ingredients as the product involved in the prior *Syntex* case, those ingredients are present in slightly different concentrations. But it is irrelevant that the two accused products—Defendants' 0.4% and 0.5% KT

[6] In the alternative, Plaintiffs have objected to paragraphs 24-26, 32-42, 45-47, 49, and 51-53 of Dr. Mitra's declaration on the grounds that Dr. Mitra has failed to lay any foundation that his measurements of critical micelle concentration are based on a reliable methodology under Federal Rule of Evidence 702. *See* Objections § III.B. Plaintiffs have further objected to Exhibit C to Dr. Mitra's declaration, which is a document purporting to state that the critical micelle concentration of Octoxynol 40 is 0.04% on the grounds that it is unauthenticated hearsay. *Id.* § III.C. Even if the Court does not exclude Dr. Mitra's declaration in its entirety as a sham declaration, Plaintiffs are entitled to summary judgment because these paragraphs and Exhibit C to Dr. Mitra's declaration are the only evidence Apotex has submitted to create a dispute of fact regarding whether Octoxynol 40 forms micelles in the accused formulations.

formulations—contain slightly different concentrations of the same ingredients. The concentrations of ingredients in both formulations fall *well within* the ranges claimed by the '493 patent.

It is equally irrelevant to the claim preclusion analysis whether Defendants' 0.4% KT formulation achieves stability in a different manner than its 0.5% KT formulation, or whether micelles are formed in one but not the other formulation. *Cf.* Opp. at 13:8-21. For purposes of the claim preclusion analysis, accused products are "essentially the same" so long as their differences are "unrelated to the *limitations in the claim of the patent*." *Foster v. Hallco Mfg. Co.*, 947 F.2d 469, 480 (Fed. Cir. 1991) (emphasis added). As discussed above, the claims of the '493 patent have no limitations relating to "stability" or to "the formation of micelles." *See supra* Part I.B.1. Thus, any purported differences in these characteristics between Defendants' 0.4% and 0.5% KT formulations are "unrelated to the limitations of the claim of the patent" and do not differentiate the accused formulations for purposes of claim preclusion. *See Contempo Tobacco Prods. Inc. v. McKinnie*, 45 U.S.P.Q.2d 1969, 1973 (C.D. Ill. 1997) (holding that accused product was essentially the same as a product accused of infringing the same patent in a previous suit and applying claim preclusion because the differences between the two products had "absolutely nothing to do with the elements" of the patent's claims); *Colida v. Sony Ericsson Mobile Communications USA, Inc.*, No. 06 Civ. 0257(PAC), 2006 WL 3068669, at *2-3 (S.D.N.Y. Oct. 26, 2006) (same). This case therefore involves the same claim, or cause of action, as *Syntex.*

Finally, Defendants' contention that the purported differences between their 0.5% and 0.4% KT formulations render preclusion of their invalidity and unenforceability defenses "unfair" is a serious overreach. The invalidity and unenforceability defenses Defendants wish to raise in this case have *nothing to do* with the nature of their accused products—they relate only to Plaintiffs' patent. It is precisely for this reason that they all were, or could have been, raised in *Syntex*. *See Foster*, 947 F.2d at 478 ("The general concept of claim preclusion is that when a judgment is rendered in favor of a party to litigation, . . . defenses that were raised or *could have been* raised by the defendant in that action are extinguished.") (citation omitted; emphasis in original).

2. Defendants' Filing of a Writ Petition Does Not Erase the Finality of the Judgment in *Syntex*.

Defendants contend that by merely filing a petition requesting discretionary review by the

Supreme Court in *Syntex*, they have somehow erased the finality of the judgments issued in that case.[7] *See* Opp. at 14:9-19. This is an absurd contention, and Defendants are dead wrong on the law. As Plaintiffs showed in their opening brief, it is a basic proposition of the law of judgments that the finality of a judgment is not changed even by the filing of an appeal *as of right*—much less by the filing of a mere request for discretionary review. *See, e.g., Robi v. Five Platters, Inc.*, 838 F.2d 318, 327 (9th Cir. 1988) ("in federal courts the preclusive effects of a lower court judgment cannot be suspended simply by taking an appeal that remains undecided"); Pl. Mem. at 12 n.8 (citing same).

3. There Is No General "Change in Law" Exception to Claim Preclusion.

As Plaintiffs demonstrated in their opening brief, even if the Supreme Court's decision in *KSR International Co. v. Teleflex Inc.* constituted a major "change in law" under which this Court's judgment in *Syntex* could not stand, claim preclusion would nonetheless apply to bar Defendants from raising any defense of invalidity.[8] *See generally* Pl. Mem. at 12:12-13:15.

Defendants cite *no authority* to the contrary. Nor do they even address the controlling Supreme Court and Ninth Circuit precedents cited by Plaintiffs in their opening brief. *See* Pl. Mem. at 12:22-13:6 (citing *Federated Dept. Stores, Inc. v. Moitie*, 452 U.S. 394 (1981) and *Clifton v. Atty. Gen. of State of Cal.*, 997 F.2d 660 (9th Cir. 1993)). Rather, Defendants vainly attempt to distinguish *four of the six* out-of-Circuit cases cited by Plaintiffs as somehow not standing for the rule they explicitly state. *See* Opp. at 14:21-16:10. Even if Defendants were successful in this endeavor, it would not aid them in resisting summary judgment based on the controlling law. But Defendants' grounds for distinction are all unavailing in any case.

Defendants attempt to discount *U.S. v. Tippett*, 975 F.2d 713 (10th Cir. 1992) on the ground that "the party against whom res judicata was applied had failed to join as a party to a petition for

[7] Defendants also claim that "Plaintiffs fail[ed] to mention" the fact of Defendants' writ petition. This is untrue. Though irrelevant to any aspect of the pending motion, Plaintiffs in fact stated in their opening brief that "[o]n April 11, 2005, Defendants filed a petition for a writ of certiorari with the U.S. Supreme Court . . . ." Pl. Mem. at 5 n.2.

[8] Defendants do not contend that there has been any change in the law of patent enforceability, or that they should be permitted to relitigate their unenforceability defense despite the application of claim preclusion.

writ for certiorari." This factual distinction, however, has nothing to do with the applicability of claim preclusion. *See supra* Part II.A.2. Defendants similarly attempt to distinguish *Erspan v. Badgett*, 659 F.2d 26 (5th Cir. 1981) on the facts, and on the fact that Defendants were unable to find any cases citing it. Again, Defendants' factual distinctions are irrelevant to the operation of claim preclusion; and a simple Westlaw KeyCite search shows that the case has in fact been cited in no less than 49 judicial opinions.

Similarly, Defendants attempt to distinguish *Harrington v. Vandalia-Butler Board of Education*, 649 F. 2d 434 (6th Cir. 1981), solely on the ground that *one* of the 89 cases citing *Harringon* did not apply claim preclusion.[9] In that unreported case, *Ervin v. Medtronic*, 22 Fed. Appx. 462 (6th Cir. 2001), however, the Sixth Circuit declined to apply issue preclusion simply because, unlike here, "there was no decision on the merits" in the previous case. *Erwin* did *not*, as Defendants insinuate, refuse to apply claim preclusion due to a change in law. Rather, the court stated in *dicta* that "it also appears that *issue preclusion* would not apply in this case because the controlling legal principles have significantly changed." *Id.* at 463 (emphasis added).[10] Plaintiffs have already acknowledged that there is a narrow "significant legal change" exception to issue preclusion, *see* Pl. Mem. at 18-20; there is, however, no such exception to *claim preclusion*. The fact that *Erwin* acknowledged a significant legal change but made *no mention* of it in the course of its claim preclusion discussion only reinforces this point.[11]

Finally, Defendants go through tremendous contortions in an attempt to present *Precision*

[9] Defendants mistakenly claim that "only two cases cit[ed] *Harrington* in its 26 year history." Again, a simple Westlaw search shows Defendants' error.

[10] Defendants' counsel's omission of the word "issue" from their incomplete quotation of this case is misleading in the extreme. *See* Opp. at 16:5-8 (quoting the case in the context of claim preclusion as "holding that 'preclusion would not apply in th[e] [present] case because the controlling legal principles have changed significantly.").

[11] *Kearns v. General Motors Corp.*, 94 F.3d 1553 (Fed. Cir. 1996), also cited by Defendants, does not even address a situation in which there has been a controlling change in law following the issuance of a previous judgment. In that case, the Federal Circuit declined to apply claim preclusion to bar causes of action for infringement of sixteen patents on the ground that those causes of action had simply never been pled or included in any previous judgment. *See Kearns*, 94 F.3d at 1556.

Air Parts, Inc. v. Avco Corp., 736 F.2d 1499 (11th Cir. 1984) as a case that is favorable to them. But that case explicitly stated that "[t]he general rule . . . *throughout the nation* . . . is that changes in the law after a final judgment do not prevent the application of res judicata and collateral estoppel, even though the grounds on which the decision was based are subsequently overruled." *Precision Air Parts*, 736 F.2d at 1503 (emphasis added). Defendants cling to language from that case stating that "the *occasional adoption of an exception* to the finality rule when public policy demands does not undermine its general effectiveness." (emphasis in original). *Id.* at 1504. But Defendants neglect to mention that this quote follows a passage in which the Court *distinguished* those "occasional" cases duly excepted from the "general rule" as "involve[ing] momentous changes in important, *fundamental constitutional rights*." *Id*. (emphasis added). This point directly rebuts Defendants' contention that "Plaintiffs [sic] pronouncement that the application or denial of claim preclusion is found only in exceedingly narrow circumstances is simply unsupported." Opp. at 16:20-22.

B. Issue Preclusion Bars Defendants' Invalidity and Unenforceability Defenses.

1. Defendants Concede That They Are Barred from Re-litigating the Issue of the Enforceability of the '493 Patent.

Defendants do not dispute that the inequitable conduct defense they have attempted to raise in this case is identical to the unenforceability defense they litigated and lost in *Syntex*. *Compare* RJN, Ex. C at Counterclaim, ¶¶ 13-37 *with* Amended Answer (Dkt. # 23) at Counterclaim, ¶¶ 13-37. Nor do Defendants contend that there has been any significant change in law that would prevent the application of issue preclusion to bar their relitigation of this defense. Thus, summary judgment must be granted precluding Defendants from pursuing their Sixth Affirmative Defense and Counterclaim in this case.

2. Defendants Are Barred from Re-litigating the Validity of the '493 Patent, Since that Issue Was Already Decided in *Syntex*.

Defendants do not dispute that they already litigated the validity of the '493 patent in *Syntex*. Therefore, Defendants are barred from re-litigating that issue in this case.

As Plaintiffs demonstrated in their opening brief, "the overwhelming weight of authority suggests that the 'issue' to be given issue-preclusive effect to a judgment in the patent context is the ultimate determination on patent validity itself, not the sub-issues or the individual pieces of

evidence and arguments that may have been necessary to support the validity determination." *Crossroads Systems (Texas), Inc. v. Dot Hill Sys. Corp.*, No. A-03-CA-754-SS, 2006 WL 1544621, at *5 (W.D. Tex. May 31, 2006). Defendants do not appear to dispute this—they certainly cite no authority to the contrary. Rather, Defendants argue that because a "technical defect," rather than general forgetfulness, accounted for their failure to raise certain arguments in support of their invalidity defense, they should receive an *ad hoc* exception from the doctrine of issue preclusion.[12] There is absolutely no support for this argument, and Defendants cite none. The rule is clear: because Defendants already litigated the validity of the '493 patent in *Syntex*, they are barred from re-litigating that issue in this case, *regardless* of whether they wish to do so on the basis of arguments they did not litigate in *Syntex*, and *regardless* of why they previously failed to litigate those arguments. *See* Pl. Mem. at 16-18 and cases cited therein.

3. The Federal Circuit Already Rejected the Argument that *KSR* Constitutes a Change in Law Necessitating Reconsideration of the Validity of the '493 Patent.

As Plaintiffs demonstrated in their opening brief, *KSR* does not constitute a change in law necessitating an exception to issue preclusion in this case. This point is clear from the *KSR* opinion itself, in which the Supreme Court did not purport to "change" controlling Supreme Court obviousness jurisprudence, or to overrule or discount a *single* Federal Circuit decision other than the one before it on direct review. *See* Pl. Mem. at 20:17-22:4. This point was reconfirmed in *binding Federal Circuit precedent* in *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, No. 06-1329, 2007 WL 1839698 (Fed. Cir. June 28, 2007). *See* Pl. Mem. at 22:5-20. And most importantly, this point was made specifically with respect to the non-obviousness of the '493 patent involved in *this case* when the Federal Circuit rejected Defendants' "significant change in law" argument to deny Defendant's motion to recall the mandate in *Syntex*. *See* RJN, Exs. K & L.

Defendants do not address *any* of these rulings. Defendants do not even *attempt* to respond

[12] Defendants' purported "technical defect" was in fact this Court's granting of Plaintiffs' motion *in limine* barring Defendants from introducing new invalidity arguments and taking massive new discovery only *ten days* before the case originally went to trial. Thus, even if this were relevant, it would still be highly questionable whether "this [was] not a situation where [Defendants] 'forgot' to raise a defense in the earlier proceeding." Opp. at 18:9-10.

to the fact that the Federal Circuit has *already rejected* the very argument they make here regarding the purported effect of *KSR* on this Court's finding of non-obviousness. Nor do Defendants make any serious attempt to grapple with the Federal Circuit's binding decision in *Takeda* that *prima facie* obviousness post-*KSR* still requires a showing that "the prior art would have suggested making the specific . . . modifications necessary to achieve the claimed invention." *Takeda*, at *4 (internal quotations omitted). Rather, they apparently contend that *Takeda*'s statements to the effect that *KSR* constituted no sea change would only be effectual if *Takeda* explicitly concerned issue preclusion.[13] Defendants do not even address the *KSR* opinion itself.

Instead, in the face of Supreme Court statements in *KSR*, binding Federal Circuit precedent, and a Federal Circuit decision *directly rejecting* Defendants' "change in law" argument with respect to the patent involved *in this case*, Defendants string together a series of de-contextualized and generic quotes from a handful of unreported off-district opinions and articles by interested commentators to the effect that *KSR* was in some indefinite sense "significant." *See* Opp. at 21-22. But it is completely irrelevant to the application of issue preclusion in *this case* what a district court in Minnesota might have thought of *KSR* in the context of an entirely different case. In *this case*, the Federal Circuit has already considered and rejected Defendants' arguments that *KSR* is a significant change affecting the non-obviousness of the '493 patent. *That* decision by the appellate court conclusively disposes of Defendants' arguments to the contrary, regardless of what a few district courts may have held in different cases presenting different issues.

CONCLUSION

For the reasons stated above and in their opening memorandum, Plaintiffs respectfully request that summary judgment be granted in full, and that the court order that the effective date of any approval of ANDA 77-308 be not earlier than the date six months after the expiration of the '493 patent.

[13] Specifically, Defendants contend that *Takeda* is inapt because "the issue was not whether defendant's defenses should be re-litigate [sic] or re-evaluated in view of *KSR*." This attempt at distinction is especially weak. Just like this case, *Takeda* concerned one party's argument that the district court's pre-*KSR* decision that a patent was not invalid for obviousness could not stand in the face of *KSR*. Just as here, the Federal Circuit rejected that argument.

DATED: August 21, 2007

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CERTIFICATE OF SERVICE

I hereby certify that all counsel of record, who are deemed to have consented to electronic service are being served this 21st day of August 2007, with a copy of this document via the Court's CM/ECF system.

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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

ROCHE PALO ALTO LLC ET AL,

Plaintiff,

v.

APOTEX, INC. ET AL,

Defendant.
_____/

No. C05-02116 MJJ

ORDER GRANTING PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

INTRODUCTION

Before the Court is Plaintiffs Roche Palo Alto LLC and Allergan, LLC's Motion For Summary Judgment. (Docket No. 52.)

For the following reasons, the Court **GRANTS** the Motion, as described in more detail below.

FACTUAL BACKGROUND

This case involves the same parties, and the same patent, as a previous matter litigated to judgment before this Court: *Syntex v. Apotex*, Case No. 3:01-cv-02214 MJJ ("*Syntex*"). As with *Syntex*, this case is about Defendants' proposal, in an Abbreviated New Drug Application ("ANDA") filed with the FDA, to make and sell a ketorolac tromethamine ("KT") ophthalmic solution, and whether that solution would infringe U.S. Patent No. 5,110,493 ("the '493 Patent") under 35 U.S.C. § 271(e)(2).

A. The Prior *Syntex* Litigation.

In the earlier *Syntex* litigation, Plaintiffs filed a complaint alleging that Defendants' ANDA 76-109 formulation infringed the '493 Patent. The drug for which Defendants sought approval pursuant to ANDA 76-109 was a 0.5% KT ophthalmic solution that was a generic copy of a 0.5% KT ophthalmic solution marketed by Plaintiffs known as ACULAR®. In *Syntex*, Defendants disputed whether their ANDA 76-109 formulation infringed the '493 Patent, and also argued (in the form of both affirmative defenses and counterclaims) that the '493 Patent was invalid and unenforceable. Specifically, with respect to invalidity, Defendants contended that the '493 patent was invalid on the grounds that it lacked utility, lacked enablement, failed to disclose the best mode, was indefinite, and was obvious. With respect to unenforceability, Defendants contended that Plaintiffs had committed inequitable conduct in prosecuting the '493 Patent.

After issuing a claim construction order, this Court granted summary judgment of infringement in favor of Plaintiffs in *Syntex*. The Court then conducted a bench trial on the issues of invalidity and unenforceability of the '493 Patent, and issued Findings of Fact and Conclusions of Law that determined that the '493 Patent was valid and enforceable.

On an appeal brought by Defendants, the Federal Circuit affirmed this Court's claim construction and determination that there was no inequitable conduct, but remanded the case to this Court for further consideration of obviousness. *See Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d 1371 (Fed. Cir. 2005). After further briefing and hearing on remand, this Court issued further Findings of Fact and Conclusions of Law in which it found, for a second time, that the '493 patent was not invalid based on obviousness. On a second appeal by Defendants, the Federal Circuit subsequently affirmed, in an April 9, 2007 order, this Court's determination that the '493 Patent is not invalid and is non-obvious.

On April 30, 2007, the Supreme Court issued its decision in *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007) addressing the standards by which obviousness should be adjudicated. On May 3, 2007, contending that the *KSR* decision constituted a change in the law of obviousness, Defendants filed a motion with the Federal Circuit requesting that the Federal Circuit recall and stay its mandate in Syntex and accept a petition for rehearing by panel or *en banc*. The

Federal Circuit summarily denied Defendants' motion on June 5, 2007. On July 9, 2007, Defendants filed a petition for a writ of certiorari with the United States Supreme Court, seeking to have the Federal Circuit's April 9, 2007 decision summarily vacated and remanded. That petition is still pending.

B. The Current Litigation.

In 2005, Defendants submitted a second ANDA (ANDA 77-308) to the FDA, seeking approval for an 0.4% KT ophthalmic solution which would be a generic copy of a 0.4% KT ophthalmic solution marketed by Plaintiffs known as ACULAR LS®. Plaintiffs filed the complaint in this action against Defendants in May 2005, alleging that the ANDA 77-308 formulation infringes the '493 Patent. In their amended answer, Defendants contend that the ANDA 77-308 formulation does not infringe. They also again argue (in the form of both affirmative defenses and counterclaims) that the '493 Patent is invalid and unenforceable. With respect to invalidity, Defendants this time contend that the '493 patent is invalid on the grounds that it lacks utility, lacks enablement, fails to disclose the best mode, is indefinite, is obvious, and constitutes obviousness-type double patenting. With respect to unenforceability, Defendants again contend that Plaintiffs committed inequitable conduct in prosecuting the '493 Patent.

LEGAL STANDARD

Rule 56(c) of the Federal Rules of Civil Procedure authorizes summary judgment if there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). The moving party bears the initial burden of demonstrating the basis for the motion and identifying the portions of the pleadings, depositions, answers to interrogatories, affidavits, and admissions on file that establish the absence of a triable issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). If the moving party meets this initial burden, the burden then shifts to the non-moving party to present specific facts showing that there is a genuine issue for trial. Fed. R. Civ. P. 56(e); *Celotex*, 477 U.S. at 324; *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986). The non-movant's bare assertions, standing alone, are insufficient to create a material issue of fact and defeat a motion for summary judgment. *Anderson*, 477 U.S. at 247-48. An issue of fact is material if, under the

substantive law of the case, resolution of the factual dispute might affect the case's outcome. *Id.* at 248. Factual disputes are genuine if they "properly can be resolved in favor of either party." *Id.* at 250. Thus, a genuine issue for trial exists if the non-movant presents evidence from which a reasonable jury, viewing the evidence in the light most favorable to that party, could resolve the material issue in its favor. *Id.* However, "[i]f the [non-movant's] evidence is merely colorable, or is not significantly probative, summary judgment may be granted." *Id.* at 249-50 (internal citations omitted).

ANALYSIS

A. Plaintiffs Are Entitled To Summary Judgment Of Infringement.

Submission of an ANDA is an act of patent infringement if the ANDA seeks approval for a drug that is claimed in a patent or the use of which is claimed in a patent. 28 U.S.C. § 271(e). Determination of patent infringement is a two-step analysis. The first step is to construe, or interpret, a claim of the patent. *See Gart v. Logitech, Inc.*, 254 F.3d 1334, 1339 (Fed. Cir. 2001). The second step is to determine whether every limitation of the properly construed claim is found in the accused device, either literally or under the doctrine of equivalents. *See id.*

1. Defendants Do Not Dispute That Each Limitation Of Claims 1-5, 15 & 16 Literally Reads On The ANDA 77-308 Formulation.

Plaintiffs contend that Defendants have admitted, in responses to requests for admission, that all of the claim limitations contained in claims 1-5, 15 and 16 of the 493 Patent literally read on the ANDA 77-308 formulation. The Court agrees.

Determination of which terms in the '493 Patent claims constitute claim limitations, and construction of those terms deemed limitations, was previously addressed by this Court in *Syntex*. At that time, this Court determined that the Court determined that "stabilizing" and "antimicrobially effective" are not claim limitations, and arrived at constructions of the other limitations. Defendants do not challenge the correctness of this Court's prior claim construction rulings here, and in any event, issue preclusion would prevent Defendants from relitigating these claim construction issues. *See Del Mar Avionics, Inc. v. Guinton Instrument Co.*, 836 F.2d 1320, 1323 (Fed. Cir. 1987). The Court's claim constructions from *Syntex* are binding on Defendants.

Defendants also do not dispute that their responses to Plaintiffs' requests for admission admit that each of the limitations of claims 1-5 & 15-16 of the '493 Patent is literally met by the ANDA 77-308 formulation. (*See* Shafroth Decl., Exh. 4, Admitted Request For Admission Nos. 1-5, 7, 12 (for claims 1-4); *id.*, Admitted Request For Admission Nos. 1-5, 7, 12-14, 16-17, 19-20 (for claim 5); *id.*, Admitted Request For Admission Nos. 2-5, 7, 22 (for claims 15-16).) The Court therefore finds that it is undisputed that each of the limitations of claims 1-5 & 15-16 of the '493 Patent is literally met by the ANDA 77-308 formulation.

2. Because Defendants' Reverse Doctrine of Equivalents Argument Lacks Any Support In The Claims, Specification, Prosecution History or Prior Art, It Fails As A Matter Of Law.

Defendants contend that summary judgment of infringement is nonetheless inappropriate because they have raised a triable issue of fact as to whether the reverse doctrine of equivalents defense precludes a finding of infringement. The Court finds, however, that Defendants' reverse doctrine of equivalents argument lacks any support in the '493 Patent's claims, specification, prosecution history, or prior art, and therefore fails as a matter of law.

Under the reverse doctrine of equivalents, "where a device is so far changed in principle from a patented article that it performs the same or a similar function in a substantially different way, but nevertheless falls within the literal words of the claim, the doctrine of equivalents may be used to restrict the claim and defeat the patentee's action for infringement." *Graver Tank & Mfg. Co. v. Linde Air Prod. Co.*, 339 U.S. 605, 608-09 (1950) (citations omitted). Once a patentee shows claims literally read on accused product, the burden of showing nonequivalence under this doctrine shifts to the accused infringer. *See Del Mar Avionics*, 836 F.2d at 1325 (Fed. Cir. 1987) (finding accused infringer had not "carried the burden of its argument" when invoking the reverse doctrine of equivalents); *Tate Access Floors, Inc. v. Interface Architectural Resources, Inc.*, 279 F.3d 1357, 1368 (Fed. Cir. 2002) (referring to reverse doctrine of equivalents as a "defense to literal

infringement").[1]

The reverse doctrine of equivalents is an equitable doctrine that was judicially created to prevent unwarranted extension of the claims of a patent beyond a fair scope of the patentee's invention. *See Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.3d 1565, 1581 (Fed. Cir. 1991). The equitable scope, or "principle", of the invention must in the first instance be determined from evidence in the public record. *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1581 (Fed. Cir. 1991) ("Application of the [reverse doctrine of equivalents] requires that facts specific to the accused device be determined and weighed against the equitable scope of the claims, ***which in turn is determined in light of the specification, the prosecution history, and the prior art***.") (emphasis added). To prevail on their reverse doctrine of equivalents defense, Defendants must as a threshold matter establish a "principle" of the patented invention by reference to the claim language, specification, prosecution history, and/or prior art that this Court can then compare to the principle of the accused product. *See Ciena Corp. v. Corvis Corp.*, 334 F.Supp.2d 598, 604-05 (D. Del. 2004); *U.S. Steel Corp. v. Phillips Petroleum Co.*, 865 F.3d 1247, 1253 n.9 (Fed. Cir. 1989).

Here, Defendants contend that the "principle" of the '493 invention is the use of Octoxynol 40 to provide "robust" stability to the '493 formulations by forming micelles to prevent interaction between ketorolac tromethamine ("KT") and benzalkonium chloride ("BAC"). Defendants contend that their ANDA 77-308 formulation, in contrast, contains such a low concentration of Octoxynol 40 that it does not produce micelles that solubilize the KT/BAC complex; instead, Defendants contend, the NaCl in their formulation ionically shields the KT and BAC icons, prevents them from interacting, and stabilizes the formulation.

The fundamental problem with Defendants' contention – which this Court considers fatal to Defendants' efforts to withstand summary judgment of infringement – is that Defendants do not

[1] The Court rejects Plaintiffs' contention that the reverse doctrine of equivalents defense is categorically inapplicable to disputes where chemical composition claims and/or generic copies of drugs are involved. While as a matter of logic such disputes leave very little leeway to determine that a product literally reads on the claim but is so far changed in principle from the claimed compound that it does not infringe, *see U.S. Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1253 n.9 (Fed Cir. 1989), the defense still has viability under controlling Federal Circuit precedent. The Court will therefore examine whether Defendants have met their burden of establishing a triable issue of fact regarding applicability of the defense on this record.

identify any support for their proposed "principle" of the '493 invention in the patent's claim language, specification, or prosecution history, nor in the prior art. It is these sources that determine the equitable scope of the claims. *See Scripps Clinic & Research Foundation* 927 F.2d at 1581. Yet Defendants point to nothing in the patent claims, patent specification, prosecution history, or prior art that refer, even indirectly, to the use of Octoxynol 40 to provide stability to the '493 formulations by forming micelles to prevent KT/BAC interaction. Indeed, Defendants are unable to identify any place that the term "micelle" even appears in the patent's claims, specification, or prosecution history.

Defendants' contention regarding the "principle" of the '493 invention is also inconsistent both with the claim language (as construed by the Court in *Syntex*) and the '493 specification. With respect to the claim language, this Court has already ruled that "stabilizing amount" is not a claim limitation (Plaintiff's Request For Judicial notice (hereafter "RJN"), Exh. D), a finding that, as noted above, is binding on Defendants. Defendants' efforts to import into the invention a requirement that Octoxynol 40 be present in an amount that forms micelles and stabilizes the formulation contradicts this ruling, and is tantamount to an improper attempt to "reargue claim construction issues which were already rejected by the Court." *Ciena Corp.*, 334 F. Supp. 2d at 608. Moreover, Example 3 in the specification discloses a formulation containing Octoxynol 40 in an amount of 0.004% wt/vol. (Shafroth Decl., Exh. 1 at 7:25-40), the very concentration that Defendants' expert contends cannot form micelles. (Mitra Decl., ¶¶ 34-37.) Thus, the specification itself is inconsistent with Defendants' underlying contention that the patent's central principle is for Octoxynol 40 to stabilize an interaction through micelle formation.

Defendants rely exclusively on findings made by this Court regarding the utility of the '493 patent in the Syntex matter as their basis for establishing that the principle of the '493 invention is the use of Octoxynol 40 in an amount sufficient to achieve critical micelle concentration and form micelles. Specifically, Defendants and their expert, Dr. Mitra, assert that "a person of ordinary skill in the art reading the Court's December 29, 2003 Findings/Conclusions . . . would interpret them to mean that the function and purpose of O40 is to provide 'robust' stability to the '493 patent formulations by forming micelles to prevent the KT/BAC interaction." (Opp. at 7-8, *see also* Mitra

Decl.¶¶ 25, 48.) This is plainly insufficient to meet Defendants' burden of proof regarding the equitable scope or "principle" of the '493 Patent's claims. The Court's factual findings on the issue of utility, and specifically the Court's factual findings regarding the function of Octoxynol 40 in the patented invention, were not directed towards determining the equitable scope of the '493 Patent's claims. More fundamentally, the Court's findings did not draw on the patent claims, patent specification, prosecution history, or prior art for evidentiary support. To the contrary, the Court's factual findings on the function of Octoxynol 40 were based on the evidence of expert tests, not found in the '493 file wrapper or the prior art, that were introduced by the parties into the record at the bench trial. Such evidence is simply not probative of the equitable scope of the '493 claims as issued. Defendants' reliance on this Court's prior factual findings is misplaced and cannot suffice to meet Defendants' burden of establishing the "principle" of the '493 invention.

Accordingly, Defendants' reverse doctrine of equivalents argument fails as a matter of law.[2] Summary judgment of infringement in favor of Plaintiffs is therefore appropriate.

B. Issue Preclusion Bars Defendants, At A Minimum, From Asserting Unenforceability As Well As All Invalidity Theories Other Than Obviousness.

Plaintiffs contend that issue preclusion bars Defendants from asserting in this action that the '493 Patent is unenforceable or invalid, because these issues were decided in the *Syntex* litigation.

1. The Elements Of Issue Preclusion.

Issue preclusion (sometimes called collateral estoppel) bars relitigation of issues adjudicated in an earlier proceeding if three requirements are met: (1) the issue necessarily decided at the previous proceeding is identical to the one which is sought to be relitigated; (2) the first proceeding ended with a final judgment on the merits; and (3) the party against whom collateral estoppel is asserted was a party or in privity with a party at the first proceeding. *See Reyn's Pasta Bella, LLC v.*

[2] Because Defendants' reverse doctrine of equivalents argument fails at the threshold for the reasons stated above, the Court need not resolve Plaintiffs' objections to the declaration of Dr. Mitra, Defendants' expert, nor Plaintiffs' contention that issue preclusion bars Defendants from asserting their reverse doctrine of equivalents argument. The Court is troubled by the fact that Dr. Mitra's first declaration submitted in support of Defendants' opposition nowhere acknowledges that the critical micelle concentration ("CMC") Octoxynol 40 can vary depending on the ingredients present in the formulation, and contains several potentially misleading statements as a result. (August 13, 2007 Mitra. Decl. at ¶¶ 22-26, 37.) Nonetheless, because Defendants' reverse doctrine of equivalents argument fails for other reasons, the Court does not reach the question of whether Dr. Mitra's declaration rises to the level of a "sham" declaration that must be disregarded.

Visa USA, Inc., 442 F.3d 741, 746 (9th Cir. 2006).

The second and third requirements of this test are clearly met. The Defendants here were also parties to the *Syntex* litigation. In that earlier litigation, this Court decided that the '493 patent is enforceable and not invalid, and entered judgment to that effect. (RJN, Exh. B at 60; Exh. H at 37-38, Exh. F, Exh. I.) After Defendants appealed, the Federal Circuit subsequently affirmed. (RJN, Exh. J.) Defendants' still-pending petition writ of certiorari before the United States Supreme Court does not alter the preclusive effect of this Court's earlier judgment in *Syntex*. *See Robi v. Five Platters, Inc.*, 838 F.2d 318, 327 (9th Cir. 1988).

The applicability of issue preclusion therefore turns on the first element – whether the issue necessarily decided at the previous proceeding is identical to the one which is sought to be relitigated.

With respect to enforceability of the '493 patent, Defendants do not dispute that the inequitable conduct defense/counterclaim they seek to assert in this litigation is identical to the unenforceability defense/counterclaim that they litigated and lost in Syntex. (*Compare* RJN, Ex. C at Counterclaim, ¶ ¶ 13-37 *with* Amended Answer at Counterclaim, ¶¶ 13-37 (Docket No. 23).) Accordingly, all elements of issue preclusion are met with respect to Defendants' unenforceability defense and counterclaim in this action. Issue preclusion therefore prevents Defendants from relitigating the '493 Patent's enforceability.

With respect to invalidity of the '493 patent, Defendants do not dispute that they already litigated the validity of the '493 patent in *Syntex*. However, Defendants contend that, for issue preclusion purposes, the only relevant "issues" that can qualify for issue-preclusive effect are the specific grounds for invalidity that Defendants asserted in *Syntex*. Plaintiffs counter that the relevant "issue" is the ultimate determination on patent validity itself, regardless of which sub-issues or specific grounds were asserted by Defendants in the previous litigation.

The authorities that have considered this question support Plaintiff's view and indicate that the relevant "issue" which Defendants are precluded from relitigating is the ultimate determination on patent validity itself. This Court is persuaded that the reasoning set forth in *Applied Medical Resources Corp. v. U.S. Surgical Corp.*, 352 F. Supp. 2d 1119, 1124-26 (C.D. Cal. 2005)

("*Applied*") regarding the applicability of issue preclusion in the patent invalidity context is correct. In *Applied*, applying Ninth Circuit precedent and the Second Restatement of Judgments, the district court held that the "issue" that the accused infringer was precluded from relitigating because of a prior judgment was the validity of the asserted patent claim. *Id.* at 1124-26 (citing *Kamilche Co. v. United States*, 53 F.3d 1059, 1062 (9th Cir. 1995)). The district court held that what the accused infringer argued were the "issues" – specific arguments such as anticipation by prior sale, best mode, public use, and prior publication – were "just the particular arguments raised in support of [invalidity] in the first case." *Id.* at 1125. Applying Ninth Circuit precedent, *Applied* found that issue preclusion barred the accused infringer not only from re-raising any grounds on which it had argued invalidity in the first litigation, but also the invalidity grounds newly raised in the second litigation, such as prior art anticipation and obviousness. *See id.* at 1127-28. District courts from around the country are in agreement with the result reached in *Applied*.[3] Defendants do not cite any countervailing authority, nor do they attempt to distinguish these cases.

Because it is undisputed that the validity of the '493 Patent was litigated in the *Syntex* action, the Court finds issue preclusion will prevent Defendants from relitigating the '493 Patent's validity unless an exception to the issue preclusion doctrine applies. The two arguments raised by Defendants regarding exceptions to issue preclusion are addressed below.

2. The Effect Of This Court's *In Limine* Ruling In Syntex Barring Obviousness Type Double Patenting And Best Mode Invalidity Arguments.

Defendants assert that issue preclusion should not apply, at least to two of their invalidity arguments, because "there were at least two defenses (obviousness type double patenting and best mode) that Apotex was prepared to litigate in *Syntex* but the Court dismissed those defenses during

[3] *See Crossroads Systems (Texas), Inc. v. Dot Hill Systems Corp.*, 2006 WL 1544621 at *5 (W.D. Tex. May 31, 2006) ("the overwhelming weight of authority suggests that the 'issue' that is to be given issue-preclusive effect to a judgment in the patent context is the ultimate determination on patent validity itself, not the sub-issues or the individual pieces of evidence and arguments that may have been necessary to support the validity determination"); *Advanced Display Sys. v. Kent State Univ.*, 2002 WL 14895555 at *10 (N.D. Tex. July 10, 2002) (applying issue preclusion to earlier validity determination to prevent assertion of even unasserted invalidity arguments); *Pall Corp. v. Fisher Scientific Co.*, 962 F. Supp. 210, 213 (D. Mass. 1997) (finding that for purposes of issue preclusion, a litigant cannot raise different grounds to invalidate a patent in a second suit); *Zip Dee, Inc. v. Dometic Corp.*, 905 F. Supp. 535, 537 (N.D. Ill. 1995) (applying issue preclusion to bar previously unasserted on-sale and public-use invalidity defenses). *Dana v. E.S. Originals, Inc.*, 342 F.3d 1320 (Fed. Cir. 2003), also cited by Plaintiffs, did not directly address the issue before this Court, and this Court does not rely on *Dana* in determining that issue preclusion applies here.

pre-trial due to a technical defect." (Opp. at 18:7-9). Defendants presumably are referring to this Court's May 23, 2003 *in limine* order in *Syntex*, issued approximately ten days before trial, which barred Defendants from asserting obviousness type double patenting or best mode arguments because such theories were not disclosed until the eve of trial, prejudicing Plaintiffs.

To the extent Defendants are contending that the "issues" of obviousness type double patenting and best mode were not litigated in *Syntex*, this argument is unavailing in light of the reasoning set forth in *Applied*. Defendants litigated and lost the issue of invalidity before this Court in *Syntex*, and they are now barred from relitigating that issue, regardless of whether the specific arguments concerning invalidity were raised or not raised in *Syntex*.

To the extent Defendants are contending that they did not have a "full and fair opportunity" to litigate the issue of validity during the *Syntex* litigation because of the Court's *in limine* ruling, the Court finds that Defendants have made an inadequate showing. There is no doubt that "special circumstances-such as reason to doubt the quality, extensiveness, or fairness of procedures followed in prior litigation-may warrant an exception to the normal rules of preclusion. In short, the parties must have had a full and fair opportunity to litigate." *Durkin v. Shea & Gould*, 92 F.3d 1510, 1515 (9th Cir. 1996) (citing *Montana v. United States*, 440 U.S. 147, 155, 164 n.11 (1979)). Here, however, Defendants make no showing that the procedures followed in the *Syntex* litigation that resulted in the exclusion of obviousness type double patenting and best mode arguments – namely, enforcement of the pleading and notice requirements of the Federal Rules of Civil Procedure and this district's Patent Local Rules – were unfair to Defendants. To the contrary, this Court's decision to exclude these specific invalidity arguments from the bench trial in *Syntex* was itself based on considerations of fairness. Moreover, Defendants had an opportunity to challenge these procedural rulings as part of their direct appeal to the Federal Circuit in the *Syntex* matter.

Accordingly, this Court finds that this Court's *in limine* rulings provide no basis to depart from the ordinary rules governing issue preclusion.

3. The Effect Of The Supreme Court's *KSR* Decision Regarding The Obviousness Standard.

Defendants also contend, with respect to their invalidity attack premised on obviousness, that

the Supreme Court's recent decision in *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007) constitutes a change in law necessitating an exception to issue preclusion here. Plaintiffs respond that *KSR* does not constitute a sufficient change in law to trigger this exception to the issue preclusion doctrine.

Issue preclusion will apply to prevent relitigation of previously determined issues "unless there have been major changes in the law." *Montana v. United States*, 440 U.S. 147, 161 (1979). Legal conclusions may be reexamined only if there has been "a significant change in the legal climate." *Kamilche*, 53 F.3d at 1063 n.3; *see also Steen v. John Hancock Mut. Life Ins. Co.*, 106 F.3d 904, 914 (9th Cir. 1997).

The question of whether *KSR* constitutes a major change in the law of obviousness sufficient to preclude application of issue preclusion appears to this Court to be an issue of first impression. In *KSR*, the Supreme Court identified several problems with the "teaching, suggestion, or motivation" ("TSM") test as applied by the Federal Circuit, and found that the Federal Circuit's rigid application of the test in the case before it was inconsistent with Supreme Court precedent. 127 S. Ct. at 1741-43. *KSR*'s actual holding was narrow, as it was limited to the Federal Circuit's application of the TSM test in the matter before it, and did not purport to overrule or overturn any other decisions. Nonetheless, subsequent lower court decisions have regarded *KSR* as a decision that may affect existing Federal Circuit precedent regarding application of the TSM test.[4] None of these decisions, however, expressly considered the question of whether *KSR* is a "major change in law" for purposes of issue preclusion.[5]

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[4] *See, e.g., Izzo Golf, Inc. v. King Par Golf, Inc.*, 2007 WL 1987789 at *19 (W.D.N.Y. July 5, 2007) (permitting supplemental briefing because "KSR has substantively changed the law of obviousness"); *McNeill-PPC. Inc. v. Perrigo Company*, 2007 WL 1933931 at *15 (S.D.N.Y. July 3, 2007) ("KSR casts doubt on the continuing validity of Federal Circuit precedent on the issue of obviousness"); *MercExchange, LLC v. Ebay, Inc.*, 2007 WL 2172587 at *13 (E.D.Va.. July 27, 2007) (*KSR* "plainly raised the bar as to what qualifies as non-obvious").

[5] The Court disagrees with Plaintiffs that the Federal Circuit has already found *KSR* not to constitute a significant change in law in *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. June 28, 2007). *Takeda* did not involve a question of issue preclusion, and the Federal Circuit did not address the question relevant to this Court's inquiry – whether *KSR* constituted a significant change in law from earlier Federal Circuit precedent. Rather, *Takeda* merely applied the standards articulated in *KSR* to its direct review of the district court's findings, found that certain Federal Circuit standards for prima facie obviousness attacks upon chemical compounds remained consistent with *KSR*, and ultimately concluded the district court had not erred in holding that the accused infringer failed to establish a prima facie case of obviousness. *See id.* at 1356-61.

The Court need not resolve this question of first impression today. Even assuming, without deciding, that *KSR* constitutes a change in law sufficient to prevent application of issue preclusion to this Court's prior determination that the '493 Patent is non-obvious, Defendants are nonetheless precluded from relitigating the issue of obviousness under the claim preclusion doctrine, as discussed in more detail below.

Accordingly, the Court finds that issue preclusion bars Defendants from asserting unenforceability of the '493 Patent, and bars Defendants from asserting all invalidity theories other than obviousness. Because (as discussed below) claim preclusion bars Defendants' efforts to relitigate the question of obviousness, the Court does not decide the question of whether issue preclusion also bars this particular invalidity theory.

C. Claim Preclusion Bars Defendants From Asserting Unenforceability or Invalidity In This Litigation.

Plaintiffs contend that, as a result of the *Syntex* litigation, claim preclusion bars Defendants from asserting that the '493 Patent is unenforceable or invalid.

1. The Elements Of Claim Preclusion Are Satisfied.

Under the doctrine of claim preclusion, " [a] final judgment on the merits of an action precludes the parties or their privies from relitigating issues that were or could have been raised in that action." *Federal Dep't Stores, Inc. V. Moitie*, 452 U.S. 394, 398 (1981). Claim preclusion applies when "the earlier suit (1) involved the same 'claim' or cause of action as the later suit, (2) reached a final judgment on the merits, and (3) involved identical parties or privies." *Mpoyo v. Litton Electro-Optical Systems*, 430 F.3d 985, 987 (9th Cir. 2005) (quotations omitted).

The second and third requirements of this test are met. It is not disputed that the parties here were also parties to the *Syntex* litigation. Moreover, the Syntex litigation reached a final judgment on the merits, in which this Court decided that the '493 patent is enforceable and not invalid. (RJN, Exh. B at 60; Exh. H at 37-38, Exh. F, Exh. I.) After Defendants appealed, the Federal Circuit subsequently affirmed. (RJN, Exh. J.) Defendants contend that the resolution in *Syntex* is not yet a "final judgment on the merits" because they have filed a still-pending petition for a writ of certiorari before the United States Supreme Court. This argument is contrary to law. The preclusive effect of

a federal district court judgment is unaffected by any appeals pending therefrom. *See, e.g., Robi v. Five Platters, Inc.*, 838 F.2d 318, 327 (9th Cir. 1988).

The applicability of claim preclusion therefore turns on the first element – whether the *Syntex* lawsuit involved the same 'claim' or cause of action as this lawsuit. Defendants contend that the same claim is not at issue because the 0.4% KT ANDA formulation is materially different from the formulation at issue in *Syntex*. Plaintiffs contend that there is an identity of claims because any differences between the products are unrelated to the limitations of the claims of the '493 Patent.

For purposes of claim preclusion, the same "infringement claim" is raised by a second suit if the accused products in the two suits are "essentially the same." *Foster v. Hallco v. Manufacturing Co., Inc.*, 947 F.2d 469, 479-480 (Fed. Cir. 1991) (applying Ninth Circuit law of claim preclusion). "Colorable changes in an infringing device or changes unrelated to the limitations in the claim of the patent would not present a new cause of action" for purposes of claim preclusion. *Id.* at 480. A new claim is presented, however, if the newly accused products are "materially different" from those in the prior litigation. *See id.*[6]

Here, the undisputed record indicates that the accused products in the *Syntex* litigation and in this litigation are essentially the same. The only colorable changes identified by Defendants are "unrelated to the limitations in the claim of the patent", and therefore cannot prevent the application of claim preclusion. The formulations in the *Syntex* litigation and in this litigation contain the same identical ingredients. While the concentrations of four ingredients in the ANDA 77-308 formulation differs slightly from the formulation involved in *Syntex*, all fall well within the ranges for these ingredients claimed by the '493 Patent. (*See* Shafroth Decl., Exh. 4, Admitted Request For Admission Nos. 1-5, 7, 12 (for claims 1-4); Admitted Request For Admission Nos. 1-5, 7, 12-14, 16-17, 19-20 (for claim 5); Admitted Request For Admission Nos. 2-5, 7, 22 (for claims 15-16)). This evidence satisfies Plaintiffs' burden to demonstrate that the products are "essentially the same."

In an effort to nonetheless establish a material difference between the accused products in the two lawsuits, Defendants rely solely on the declaration of their expert, Dr. Mitra. Dr. Mitra's

[6] Defendants' contentions that the '493 Patent is invalid and unenforceable are not "claims" for purposes of claim preclusion. Instead, such assertions are treated as defenses to the patent owner's infringement claim. *See Foster*, 947 F.3d at 478-79.

declaration contains analysis and descriptions of experiments indicating that Octoxynol 40 is able to form micelles in the 0.5% KT ANDA formulation but not in the 0.4% KT ANDA formulation. (Mitra Decl., ¶¶ 42, 51.) Even if accepted as admissible testimony, however, this evidence does not establish a material difference in the two formulations.[7] The claims of the '493 Patent have no limitations relating to the stability of the formulation or to the formulation of micelles. Because the ability of Octoxynol 40 to form micelles is unrelated to the limitations of the claim of the patent, it cannot differentiate the accused formulations for purposes of claim preclusion. *See Foster*, 947 F.2d at 480; *see also Hallco Mfg. Co., Inc. v. Foster*, 256 F.3d 1290, 1295-98 (Fed. Cir. 2001).

2. No "Change Of Law" Or Fairness Exception Prevents Claim Preclusion Here.

Alternatively, pointing to the Supreme Court's decision in *KSR*, Defendants contend that even if the elements of claim preclusion are satisfied, principles of fairness dictate that claim preclusion should not apply when there has been a change in the law. This contention is contrary to governing law and miscomprehends *res judicata* principles.

Under controlling precedent from the Supreme Court and the Ninth Circuit,[8] the fact that a judgment may have been wrong, or have rested on a since-repudiated legal principle, does not alter the claim preclusive effect of a final judgment. *See Federated Dept. Stores, Inc. v. Moitie*, 452 U.S. 394, 398 (1981) ("Nor are the res judicata consequences of a final, unappealed judgment on the merits altered by the fact that the judgment may have been wrong or rested on a legal principle subsequently overruled in another case."), *Chicot County Drainage Dist. v. Baxter State Bank*, 308 U.S. 371, 374-75 (1940) (claim preclusion applied even though statute upon which prior case was decided was subsequently declared unconstitutional); *Clifton v. Atty. Gen. Of State of Cal.*, 997 F.2d 660, 663 (9th Cir. 1993) ("For us to conclude, under the facts of this case, that the district court's order has become an 'instrument of wrong' merely because it rests on a since repudiated rationale would be to nullify the doctrine of res judicata."); *Government of Guam v. Cruz*, 869 F.2d 1326,

[7] Because Dr. Mitra's testimony would not suffice to establish a material difference in the formulations, the Court need not resolve Plaintiffs' objections to the declaration of Dr. Mitra.

[8] For purposes of analyzing the claim preclusive effect of judgments in patent cases, the law of the regional circuit, not of the Federal Circuit, controls. *See Hartley v. Mentor Corp.*, 869 F.2d 1469, 1471 n.1 (Fed. Cir. 1989); *Foster*, 947 F.2d at 477 n.7.

1327 (9th Cir. 1989) (claim preclusion prevents relitigation of dispute "even if the court in the first litigation was wrong in its determinations").[9]

Defendants cite to no authority supporting their position that principles of fairness create an exception to ordinary claim preclusion principles where a change in law has occurred.[10] To the contrary, the Supreme Court has counseled courts against case-by-case evaluation of the equities when applying claim preclusion principles:

> The doctrine of res judicata serves vital public interests beyond any individual judge's ad hoc determination of the equities in a particular case. There is simply no principle of law or equity which sanctions the rejection by a federal court of the salutary principle of res judicata....[T]he mischief which would follow the establishment of precedent for so disregarding this salutary doctrine against prolonging strife would be greater than the benefit which would result from relieving some case of individual hardship.

Federated Dept. Stores, 452 U.S. at 401-02.

Accordingly, the Court finds that claim preclusion applies here to bar Defendants' contentions that the '493 Patent is invalid and unenforceable, including Defendants' contention that the '493 Patent is invalid for obviousness.

D. Scope Of Order Authorized By 35 U.S.C. § 271(e)(4).

35 U.S.C. § 271(e)(4) provides, in relevant part, that for acts of infringement described in Section 271(e)(2):

> (A) the court shall order the effective date of any approval of the drug . . . involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed.

The parties dispute the appropriate scope of an order under this statutory provision. Plaintiffs cite to 21 U.S.C. § 355a(a)(2)(B), a statutory mandate directed to the FDA, in support of their contention that the Court should issue an order requiring that the effective date of any approval

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[9] *See also* 18 Moore's Federal Practice § 131.12[3] (Matthew Bender 3d ed.) ("The doctrine of claim preclusion is not concerned with whether a prior judgment was right or wrong or whether subsequent changes in the law, the discovery of additional facts, or considerations of fairness should merit a different result in the subsequent litigation").

[10] Defendants did not address, in their opposition, the Supreme Court or Ninth Circuit authority cited by Plaintiffs. Instead, Defendants attempted to distinguish, largely unsuccessfully, certain out-of-circuit decisions that recognize the same principle that a change in law will not prevent application of claim preclusion.

of ANDA 77-308 be not earlier than the date six months after the expiration of the '493 patent.[11] Defendants contend that such an order would exceed the Court's authority by continuing to enforce an expired patent and by invading the province of the FDA, and that the Court should instead issue an order that simply tracks the language of 35 U.S.C. § 271(e)(4)(A).

The Court agrees with Defendants. 21 U.S.C.§ 355a(a)(2)(B) does not provide a sufficient basis for this Court to restrict the FDA's approval of the ANDA beyond the expiration date of the patent. Accordingly, the Court will order, consistent with 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of the drug be a date which is not earlier than the date of the expiration of the patent which has been infringed.

CONCLUSION

For the foregoing reasons, the Court finds that undisputed facts establish that Defendants' filing of ANDA 77-308 infringes claims 1-5, 15-16 of U.S. Patent No. 5,110,493, and **GRANTS** summary judgment in favor of Plaintiffs on Count One of Plaintiff's complaint on that basis. The Court further finds, applying claim and issue preclusion principles as described above, that Defendants may not relitigate this Court's prior judgment the '493 Patent is enforceable and not invalid. Accordingly, the Court **GRANTS** summary judgment in favor of Plaintiffs on Defendants' counterclaim and defenses relating to invalidity and unenforceability.

Pursuant to 35 U.S.C. § 271(e)(2)(A), the Court further **ORDERS** that the effective date of any approval of ANDA 77-308 be a date which is not earlier than the date of the expiration of the '493 Patent.

IT IS SO ORDERED.

Dated: September 11, 2007

MARTIN J. JENKINS
UNITED STATES DISTRICT JUDGE

[11] 21 U.S.C. § 355a(a)(2)(B) provides that where the FDA has granted pediatric exclusivity to the listed drug, as the FDA has done for ACULAR® LS, "the period in which an [ANDA] may not be approved . . . shall be extended by a period of sixth months after the date the patent expires."

United States Court of Appeals for the Federal Circuit

2008-1021

ROCHE PALO ALTO LLC (formerly known as Syntex (U.S.A.) LLC)
and ALLERGAN, INC.,

Plaintiffs-Appellees,

v.

APOTEX, INC. and APOTEX CORP.,

Defendants-Appellants.

Appeal from the United States District Court for the Northern District of California in case no. 05-CV-2116, Judge Martin J. Jenkins.

DECIDED: July 9, 2008

Before MICHEL, Chief Judge, PROST, Circuit Judge, and HOCHBERG, District Judge.[*]

PROST, Circuit Judge.

This is a patent infringement case under the Hatch-Waxman Act. Apotex, Inc. and Apotex Corp. (collectively "Apotex") appeal the grant of summary judgment by the United States District Court for the Northern District of California that the patent held by Roche Palo Alto LLC and Allergan, Inc. (collectively "Roche") is valid and infringed by the formulation covered by Apotex's abbreviated new drug application ("ANDA"). Roche Palo Alto, LLC v. Apotex, Inc., 526 F. Supp. 2d 985 (N.D. Cal. 2007). Because we find

[*] Honorable Faith S. Hochberg, District Judge, United States District Court for the District of New Jersey, sitting by designation.

no error in the court's holding that the reverse doctrine of equivalents is inapplicable and that claim preclusion prohibits Apotex from raising other validity challenges, we affirm.

I

A

Roche is the owner of U.S. Patent No. 5,110,493 ("the '493 patent"), which is directed to a drug formulation for treatment of eye inflammation, such as that caused by glaucoma, conjunctivitis, eye surgery, or eye injury. '493 patent, col. 1, ll. 14-28. The formulation contains a non-steroidal anti-inflammatory drug ("NSAID"), such as ketorolac tromethamine ("KT"); a quaternary ammonium preservative, such as benzalkonium chloride ("BAC"); and the nonionic surfactant, octoxynol 40 ("O_{40}"). Id., col. 3, ll. 13-19, col. 4, ll. 20-41. Claim 1 is representative:

> An opthalmologically acceptable non-steroidal anti-inflammatory drug formulation, comprising:
>
> an opthamologically acceptable non-steroidal anti-inflammatory carboxyl group-containing drug in an effective amount for ophthalmic treatment between 0.001% and 10.00% wt/vol;
>
> a quaternary ammonium preservative in an antimicrobially effective amount between 0.001% and 1.0% wt/vol;
>
> an ethoxylated alkyl phenol that conforms generally to the formula: $C_8H_{17}C_6H_4(OCH_2\text{-}CH_2)_nOH$ where *n* has an average value of 40 [O_{40}] in a stabilizing amount between 0.001% and 1.0% wt/vol; and
>
> an aqueous vehicle q.s. to 100%.

Dependent claim 7 further includes sodium chloride ("NaCl") at a concentration of 0.79% wt/vol.

The last limitation in claim 1, requiring the presence of O_{40}, was added in response to the examiner's obviousness rejection over several prior art references. Accompanying the claim amendment, the applicants submitted the Lidgate Declaration, which stated that O_{40} produced unexpected results over other nonionic surfactants,

such as O_3 and O_5. Specifically, the declaration stated that O_{40} produced a clear solution while the others did not. The examiner allowed the claims based on the unexpected results of O_{40}.

Over the years, Apotex filed two different ANDAs on two different generic drug formulations, each containing a paragraph IV certification that the '493 patent is invalid, unenforceable, or will not be infringed by the generic version of the drug. In 2001, Apotex filed its first ANDA ("ANDA-1"), directed to a generic version of Roche's ACULAR®. Subsequently, in 2005, Apotex filed its second ANDA ("ANDA-2"), directed to a generic version of Roche's ACULAR®LS. The two formulations differ in their compositions as follows:

	ANDA-1 (ACULAR®)	ANDA-2 (ACULAR®LS)
KT	0.5%	0.4%
BAC	0.01%	0.0063%
O_{40}	0.01%	0.004%
NaCl	0.8%	0.8%

Notably, the concentration of O_{40} is reduced in the ANDA-2 formulation as compared to the ANDA-1 formulation, but both are within the range claimed in claim 1 of the '493 patent. The concentration of NaCl is identical in the two formulations and encompassed by at least claim1 of the patent.

B

On June 6, 2001, Roche's predecessor, Syntex (U.S.A.) LLC ("Syntex") sued Apotex for infringement of the '493 patent based on the ANDA-1 formulation. The district court issued a claim construction order. Syntex (U.S.A.) LLC v. Apotex, Inc., No. 01-2214 (N.D. Cal. Nov. 19, 2002). Because claim 1 of the '493 patent expressly states a concentration range for O_{40}, the court held that the claim term "stabilizing amount" is

merely a statement of intended result and not a claim limitation. Id., slip op. at 9. Thereafter, the district court granted Syntex's motion for partial summary judgment that the ANDA-1 formulation literally infringed the '493 patent. Syntex (U.S.A.) LLC v. Apotex, Inc., No. 01-2214, slip op. at 4-5 (N.D. Cal. Mar. 19, 2003). Following a bench trial on Apotex's invalidity defenses of lack of utility, lack of enablement, indefiniteness, and obviousness, and its unenforceablity defense based on inequitable conduct, the court held that the '493 patent was both valid and enforceable. Syntex (U.S.A.) LLC v. Apotex, Inc., No. 01-2214 (N.D. Cal. Dec. 29, 2003) ("Syntex I").

On May 18, 2005, this court affirmed the district court's claim construction and holding of no inequitable conduct, but reversed its holding of validity based on non-obviousness. Syntex (U.S.A.) LLC v. Apotex, Inc., 407 F.3d 1371 (Fed. Cir. 2005) ("Syntex II"). Specifically, we found that the district court clearly erred in some of its factual findings and misapplied certain legal presumptions with respect to its obviousness analysis. Id. at 1378-83. On remand, the district court again held that the '493 patent was not invalid for obviousness, Syntex (U.S.A.) LLC v. Apotex, Inc., No. 01-2214, 2006 WL 1530101 (N.D. Cal. June 2, 2006) ("Syntex III"), and we affirmed without opinion. 221 Fed. Appx. 1002 (Fed. Cir. Apr. 9, 2007).

One day after our mandate issued, the Supreme Court issued its opinion on obviousness in KSR International Co. v. Teleflex Inc., 127 S. Ct. 1727 (2007). Apotex then filed a motion to recall and stay the mandate, and to extend the time to request a rehearing in view of KSR, but the motion was denied. Apotex also filed a petition for writ of certiorari, and that petition too was denied. Apotex, Inc. v. Syntex (U.S.A.) LLC, 128 S. Ct. 209 (2007).

C

On May 24, 2005, Roche sued Apotex for infringement of the '493 patent based on the ANDA-2 formulation. Apotex asserted the defenses of non-infringement; invalidity under 35 U.S.C. §§ 101, 103, and 112; and unenforceability due to inequitable conduct. Thereafter, Roche filed a motion for summary judgment that the ANDA-2 formulation infringes the '493 patent and that the validity and unenforceability defenses should be barred based on the earlier Syntex litigation (Syntex I, Syntex II, and Syntex III) under the doctrines of issue preclusion and claim preclusion. Apotex countered by arguing that the ANDA-2 formulation escapes infringement under the reverse doctrine of equivalents. Apotex further averred that the doctrines of issue preclusion and claim preclusion were inapplicable because the ANDA-2 formulation and the ANDA-1 formulation were distinct, and the change in law exception, in view of KSR, prevented application of those doctrines.

On September 11, 2007, the district court granted Roche's motion for summary judgment. Roche Palo Alto LLC v. Apotex, Inc., 526 F. Supp. 2d 985 (N.D. Cal. 2007). First, the court found that Apotex had failed to properly establish the "principle" of the '493 invention under the first prong of the reverse doctrine of equivalents analysis. Id. at 992-93. Although Apotex contended that the "principle" of the invention was to use O_{40} to provide robust stability to the formulations by forming micelles to prevent interaction between KT and BAC, the court noted that Apotex did not support this "principle" by reference to the claim language, specification, prosecution history, and/or prior art, which are the proper sources to determine the equitable scope of the claims.

Id. Therefore, the court held that Apotex did not meet its burden of establishing a prima facie case of noninfringment under the reverse doctrine of equivalents. Id.

The district court also held that Apotex's invalidity and unenforceablity arguments, with the exception of obviousness, were prevented by issue preclusion because the invalidity of the '493 patent had already been asserted against Roche in the ANDA-1 litigation. Id. at 994-95. Following Ninth Circuit precedent, the court held that issue preclusion barred Apotex from challenging validity on any ground, even grounds that had not been raised in the first litigation. Id. at 995. With respect to the validity challenge on obviousness grounds, the court did not reach whether the Supreme Court decision in KSR constituted a change in law necessitating an exception to issue preclusion because it held that such a challenge was prevented by claim preclusion. Id. at 997.

With respect to claim preclusion, the district court held that the two accused products, ANDA-1 and ANDA-2, are "essentially the same," and thus each of the invalidity claims in the ANDA-2 litigation was prevented by claim preclusion. Id. at 997-99. The court further held that there is no "change of law" or fairness exception to claim preclusion to prevent its application despite the intervening KSR decision. Id. at 999-1000. Hence, the court held that Apotex's invalidity and unenforceability affirmative defenses were barred by claim preclusion. Id. at 1000.

Apotex appeals. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

II

We review a grant of summary judgment of non-infringement de novo, reapplying the standard used by the district court. Innogenetics, N.V. v. Abbott Labs., 512 F.3d

1363, 1378 (Fed. Cir. 2008). Summary judgment is appropriate where, drawing all reasonable inferences in favor of the non-movant, there is no genuine issue as to any material fact and no reasonable jury could return a verdict for the non-movant. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 255 (1986).

The determination of infringement is a two-step process, wherein the court first construes the claims and then determines whether every claim limitation, or its equivalent, is found in the accused device. In re Gabapentin Patent Litig., 503 F.3d 1254, 1259 (Fed. Cir. 2007). While claim construction is a question of law that we review de novo, Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc), non-infringement under the reverse doctrine of equivalents is a question of fact. SRI Int'l v. Matsushita Elec. Corp. of Am., 775 F.2d 1107, 1124 (Fed. Cir. 1985).

We review the district court's application of the doctrine of claim preclusion de novo. Acumed LLC v. Stryker Corp., No. 2007-1115, 2008 WL 2020534, at *2 (Fed. Cir. May 13, 2008); Maldonado v. Harris, 370 F.3d 945, 949 (9th Cir. 2004); Littlejohn v. United States, 321 F.3d 915, 919 (9th Cir. 2003).

III

Apotex does not dispute that the ANDA-2 formulation falls within the literal scope of claim 1 of the '493 patent. Instead, Apotex argues that the district court erred in failing to find non-infringement by the ANDA-2 formulation under the reverse doctrine of equivalents.

The reverse doctrine of equivalents is an equitable doctrine designed "to prevent unwarranted extension of the claims beyond a fair scope of the patentee's invention." Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1581 (Fed. Cir.

1991). According to the Supreme Court:

> [W]here a device is so far changed in principle from a patented article that it performs the same or similar function in a substantially different way, but nevertheless falls within the literal words of the claim, the [reverse] doctrine of equivalents may be used to restrict the claim and defeat the patentee's action for infringement.

Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608-609 (1950) (emphases added). While the patentee bears the burden of proving infringement, if the patentee establishes literal infringement, the burden shifts to the accused infringer to set forth a prima facie case of non-infringement under the reverse doctrine of equivalents. SRI Int'l, 775 F.2d at 1123-24. If the accused infringer is successful in making a prima facie case, the patentee must then rebut that prima facie case. Id. at 1124. The reverse doctrine of equivalents is rarely applied, and this court has never affirmed a finding of non-infringement under the reverse doctrine of equivalents. Tate Access Floors, Inc. v. Interface Architectural Res., Inc., 279 F.3d 1357, 1368 (Fed. Cir. 2002).

Apotex, relying on the declaration of its scientific expert, Dr. Mitra, argues that a person of ordinary skill in the art would recognize that the "principle" of the '493 patent is the use of O_{40} in an amount sufficient to cause the formation of micelles and thereby provide robust stability to the formulation by preventing interactions between KT and BAC. Apotex contends that such a principle is supported by the prosecution history of the '493 patent application in that the examiner ultimately allowed the claims based on the Lidgate Declaration, demonstrating the unexpected results of formulations containing O_{40}. According to Apotex, it is of no consequence that the claims, specification, and prosecution history do not mention "micelles" and that the district court construed "stabilizing amount" to be an intended result, not a claim limitation,

since a person of ordinary skill in the art knows that O_{40} stabilizes the formulation by forming micelles. In contrast to the patented invention, Apotex asserts, the concentration of O_{40} in the ANDA-2 formulation is far below the concentration required to form micelles. Instead, in the ANDA-2 formulation, NaCl acts to ionically shield KT and BAC, preventing them from interacting. Thus, Apotex asserts, the ANDA-2 formulation is stabilized by a completely different ingredient and mechanism, and functions in a "substantially different way" from the formulation claimed in the '493 patent.

Apotex contends that because it has succeeded in making a prima facie showing of non-infringement under the reserve doctrine of equivalents, it is incumbent upon Roche to rebut that prima facie case. According to Apotex, Roche has presented only attorney arguments, not scientific evidence or expert testimony, to rebut Apotex's evidence. Even if the attorney arguments are accepted as contrary evidence, Apotex contends that there is at least a genuine issue of material fact in dispute not amenable to resolution on summary judgment. Thus, Apotex asserts, the district court erred by not drawing all inferences in favor of Apotex and not finding a genuine issue of material fact.

We agree with the district court that Apotex has failed to set forth a prima facie case of non-infringement under the reverse doctrine of equivalents because it does not properly establish the principle of the '493 patent. The "principle" or "equitable scope of the claims" of the patented invention is determined in light of the specification, prosecution history, and the prior art. Scripps Clinic, 927 F.2d at 1581. Here, however, Apotex relies exclusively on the declaration of its expert, Dr. Mitra.

As the district court noted, there is no mention of "micelle" in the claims, specification, or prosecution history of the '493 patent. Further, we previously held that there was no error in the district court's construction of claim 1 of the '493 patent to regard "stabilizing amount" not as a claim limitation, but as an intended result, given that the claim expressly sets forth a concentration range for O_{40}. Syntex II, 407 F.3d at 1378. Thus, there is no support in the claims or specification for micelle formation or for robust stabilization of the formulation by prevention of KT/BAC interactions. The prosecution history is not in evidence in this case and was not relied on by Apotex before the district court in establishing the principle of the invention. Nonetheless, there is no indication that the examiner, in allowing the claims, attributed the unexpected results of O_{40} to its superiority in forming micelles. The intrinsic evidence is therefore inconsistent with Apotex's proffered "principle" of the '493 invention.

The claims and the specification clearly encompass formulations comprising a broad concentration range of O_{40}, from 0.001% to 10% wt/vol.[1] Example 3 discloses a formulation containing O_{40} at a concentration of 0.004% wt/vol, the same concentration as in the ANDA-2 formulation.

For these reasons, we agree with the district court that Apotex did not properly support its alleged "principle" of the patented invention and consequently failed to make out a prima facie case of non-infringement under the reverse doctrine of equivalents.

[1] Apotex asserts that, if the '493 claims are construed to cover the entire claimed O_{40} concentration range, then the claims are invalid under 35 U.S.C. § 112, first paragraph, because they are not enabled throughout their full scope. Alternatively, Apotex argues that, if the claims are so construed, they are invalid as obvious under 35 U.S.C. § 103, because not all concentrations form micelles and thus produce unexpected results. Such arguments go to the validity of the claims of the '493 patent.

Roche, therefore, was not required to rebut the prima facie case. Accordingly, we find no error by the district court in rejecting Apotex's defense under the reverse doctrine of equivalents and in granting summary judgment of literal infringement of the claims of the '493 patent by the ANDA-2 formulation.

IV

Apotex next asserts that the district court erred in holding that its validity challenges to the '493 patent were barred by claim preclusion. Under Ninth Circuit law, claim preclusion applies where: "(1) the same parties, or their privies, were involved in the prior litigation, (2) the prior litigation involved the same claim or cause of action as the later suit, and (3) the prior litigation was terminated by a final judgment on the merits." Cent. Delta Water Agency v. United States, 306 F.3d 938, 952 (9th Cir. 2002) (citing Blonder-Tongue Labs. v. Univ. of Ill. Found., 402 U.S. 313, 323-24 (1971)); Mpoyo v. Litton Electro-Optical Sys., 430 F.3d 985, 987 (9th Cir. 2005).

Apotex does not dispute that the Syntex litigation (Syntex I, Syntex II, and Syntex III) ended in a final judgment and that it involved the same parties or their privies. Rather, Apotex contests only the district court's holding that the instant litigation, pertaining to its ANDA-2 formulation, and the Syntex litigation, pertaining to its ANDA-1 formulation, involved the same claim or cause of action. Whether two claims for infringement constitute the "same claim" is an issue particular to patent law and thus Federal Circuit law applies. Acumed LLC v. Stryker Corp., No. 2007-1115, 2008 WL 2020534, at *2 (Fed. Cir. May 13, 2008); Hallco Mfg. Co. v. Foster, 256 F.3d 1290, 1294 (Fed. Cir. 2001). Under the law of the Federal Circuit, an infringement claim in a

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For the reasons discussed below, we agree with the district court that such validity

second suit is the "same claim" as in an earlier infringement suit if the accused products in the two suits are "essentially the same." Acumed, 2008 WL 2020534, at *3; Foster v. Hallco Mfg. Co., 947 F.2d 469, 479-80 (Fed. Cir. 1991). Accused products "are 'essentially the same' where the differences between them are merely 'colorable' or 'unrelated to the limitations in the claim of the patent.'" Acumed, 2008 WL 2020534, at *3 (citations omitted); Foster, 947 F.2d at 480. The party asserting claim preclusion has the burden of showing that the accused products are essentially the same. Acumed, 2008 WL 2020534, at *3; Foster, 947 F.2d at 480.

Apotex avers that Roche had the burden of establishing that the ANDA-2 formulation at issue in the instant litigation and the ANDA-1 formulation at issue in the Syntex litigation were "essentially the same," yet Roche did not present any expert testimony or other evidence to that effect. In contrast, Apotex provided the Mitra Declaration, which shows that the concentration of O_{40} in the ANDA-2 formulation is insufficient to form micelles and thus the ANDA-2 formulation is materially different from the ANDA-1 formulation. Apotex further contends that the ANDA-2 formulation is not "essentially the same" as the ANDA-1 formulation because the two formulations are stabilized by completely different ingredients and mechanisms. Whereas micelle formation by O_{40} stabilizes the ANDA-1 formulation, ionic shielding by NaCl stabilizes the ANDA-2 formulation. According to Apotex, the fact that it had to file a separate ANDA for the ANDA-2 formulation is additional evidence that the ANDA-2 formulation is materially different from the ANDA-1 formulation. Thus, Apotex asserts that there is at

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challenges are barred by claim preclusion.

least a genuine issue of material fact as to whether the two ANDA formulations are "essentially the same."

We find no error in the district court's analysis. The court determined that the ANDA-1 formulation and the ANDA-2 formulation are "essentially the same" because any differences between them are unrelated to the claims of the '493 patent. Though the court recognized that there are differences in the concentrations of the ingredients in the ANDA-1 and ANDA-2 formulations, it also realized that all of the concentrations are well within the ranges claimed in the '493 patent. The fact that they are stabilized by different mechanisms, even if true, is irrelevant because both formulations are encompassed by the claims of the '493 patent. Thus, any difference in composition between the two formulations is merely colorable and the two formulations are "essentially the same."

In the alternative, Apotex asserts that principles of fairness should prevent application of claim preclusion given the change in the law of obviousness following the Supreme Court's opinion in KSR. In essence, Apotex argues that claim preclusion is not absolute and that this is a case where an exception to the finality rule should apply.

The district court, however, correctly recognized that there is no "change of law" or fairness exception to prevent application of claim preclusion. Federated Dep't Stores, Inc. v. Moitie, 452 U.S. 394, 398 (1981); see also Clifton v. Att'y Gen. of Cal., 997 F.2d 660, 663 (9th Cir. 1993) ("For us to conclude, under the facts of this case, that the district court's order has become an 'instrument of wrong' merely because it rests on a since repudiated rationale would be to nullify the doctrine of res judicata."); Wilson v. Lynaugh, 878 F.2d 846, 850-51 (5th Cir. 1989); Precision Air Parts, Inc. v. Avco Corp.,

736 F.2d 1499, 1503 (11th Cir. 1984) ("The general rule . . . throughout the nation, is that changes in the law after a final judgment do not prevent the application of res judicata and collateral estoppel, even though the grounds on which the decision was based are subsequently overruled."); Hardison v. Alexander, 655 F.2d 1281, 1288-89 (D.C. Cir. 1981). Although there may be a rare exception in cases involving "momentus changes in important, fundamental constitutional rights," Precision Air Parts, 736 F.2d at 1504, no such right is involved here.

As the Supreme Court explained:

> Nor are the res judicata consequences of a final, unappealed judgment on the merits altered by the fact that the judgment may have been wrong or rested on a legal principle subsequently overruled in another case. . . . We have observed that "[t]he indulgence of a contrary view would result in creating elements of uncertainty and confusion and in undermining the conclusive character of judgments, consequences which it was the very purpose of the doctrine of res judicata to avert."

Federated Dep't Stores, 452 U.S. at 398-99 (citations and internal quotations omitted). Thus, the KSR decision does not prevent application of claim preclusion.

Accordingly, the district court did not err in concluding that Apotex's validity challenges to the '493 patent were barred by the doctrine of claim preclusion.[2]

[2] Because we hold that the district court properly determined that Apotex's validity challenges were barred by claim preclusion, we need not reach whether the district court lawfully applied the doctrine of issue preclusion to bar the same validity challenges.

V

For the foregoing reasons, we affirm the district court's grant of Roche's motion for summary judgment that the ANDA-2 formulation literally infringes the claims of the '493 patent and that Apotex's invalidity and unenforceability challenges to the '493 patent are barred by claim preclusion.

AFFIRMED