IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS AG, NOVARTIS PHARMA AG, NOVARTIS INTERNATIONAL PHARMACEUTICALS LTD, and LTS LOHMANN THERAPIE-SYSTEME AG, Plaintiffs, v. ACTAVIS SOUTH ATLANTIC LLC, and ACTAVIS, INC., Defendants.	C. A. No.: 11-1077-RGA **REDACTED - PUBLIC VERSION**

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS AG, NOVARTIS PHARMA AG, NOVARTIS INTERNATIONAL PHARMACEUTICALS LTD, and LTS LOHMANN THERAPIE-SYSTEME AG, Plaintiffs, v. WATSON LABORATORIES, INC., WATSON PHARMA, INC., and WATSON PHARMACEUTICALS, INC., Defendants.	C. A. No.: 11-1112-RGA

WATSON'S ANSWERING BRIEF IN OPPOSITION TO PLAINTIFFS' MOTION FOR LEAVE TO AMEND THEIR COMPLAINT FOR PATENT INFRINGEMENT

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Defendants, Watson Laboratories, Inc., Watson Pharma, Inc., and Watson Pharmaceuticals, Inc. (collectively "Watson"), respectfully submit this brief in opposition to the Motion for Leave to Amend Plaintiffs' Complaint For Patent Infringement Against Watson filed by Plaintiffs, Novartis Pharmaceuticals Corporation, Novartis AG, Novartis Pharma AG, Novartis International Pharmaceutical Ltd. and LTS Lohmann Therapie-Systeme AG (collectively "Plaintiffs"). As explained in detail below, Plaintiffs' proposed new cause of action is futile and will likely delay resolution of the present action.

NATURE AND STAGE OF THE PROCEEDINGS

Plaintiffs filed their Complaint against Watson on November 9, 2011. (D.I. 1) Watson filed its Answer, Affirmative Defenses and Counterclaim on December 8, 2011, (D.I. 14), and Plaintiffs filed their Reply on December 29, 2011. (D.I. 18) Judge Robinson held a scheduling conference pursuant to Fed. R. Civ. P. 16(b) on January 13, 2012. That same day, Plaintiffs served their First set of Interrogatories and their First Set of Requests for the Production of Documents on Watson (D.I. 23), and Watson served its First Set of Interrogatories and its First Set of Requests for the Production of Documents on Plaintiffs (D.I. 24). The parties exchanged initial disclosures January 23, 2012 and the Scheduling Order was entered by the Court on February 15, 2012. (D.I. 31) Since that time, the parties have conducted a substantial amount of additional written discovery, and all document production has been completed by the parties. The Court held a Discovery Status Conference on June 29, 2012. Approximately one week prior to the status conference, on June 21st, Plaintiffs filed a motion for leave to amend their Complaint to add the '196 patent. (D.I. 66).

SUMMARY OF THE ARGUMENT

Plaintiffs "seek[] to add a cause of action for declaratory judgment that Watson's ANDA Products *will* infringe [U.S. Patent No. 6,054,196 (the "196 patent")]." (D. I. 75 at ¶7.) The

proposed claim is wholly unrelated to the existing case. The present action is based on Watson's certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certifications") in connection with its ANDA [redacted] for certain patents listed by Plaintiffs in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"). The Hatch-Waxman statute provides that Watson's filing of Paragraph IV certifications in an ANDA seeking FDA approval of Watson's generic product before expiration of Plaintiffs' listed patents constitutes an act subject to a charge of patent infringement (35 U.S.C. § 271(e)(2)(A)) and thus confers subject matter jurisdiction.

The '196 patent is not listed in the Orange Book. It is directed to child-proof packaging for active substance-containing transdermal patches. Because the '196 patent does not cover the drug or a method of using the drug, Plaintiffs cannot list it in the Orange Book. *See* 21 U.S.C. § 355(b)(1). Plaintiffs do not—and cannot—allege infringement under 35 U.S.C. § 271(e)(2). Instead, Plaintiffs' proposed claim is for a declaratory judgment of *future* infringement under 35 U.S.C. § 271(a). [redacted]

Unlike the present action under 35 U.S.C. § 271(e)(2)(A), this Court would lack subject-matter jurisdiction over Plaintiffs' proposed new claim. The request for declaratory judgment that Watson will infringe the '196 patent at some indeterminate time in the distant future is speculative and is not of sufficient immediacy to constitute a justiciable controversy. Watson cannot market its ANDA product unless and until it obtains final FDA approval. Not only is that

approval a contingent future event, FDA approval is currently blocked by the 30-month stay resulting from Plaintiffs' filing the present action. 21 U.S.C. § 355(j)(5)(B)(iii). [redacted]

When, as here, claims of alleged future patent infringement under 35 U.S.C. § 271(a) have been brought by patentees against ANDA applicants pursuant to the Declaratory Judgment Act, courts have consistently dismissed such claims, because they do not present an actual controversy. A justiciable controversy of sufficient immediacy does not exist because multiple, contingent future events must occur before any actual act of infringement could possibly occur. Specifically, an actual controversy will exist only *if* the FDA approves the accused product, *if* the defendant decides to market the product, [redacted] For this reason, Watson asks that Plaintiffs' request for leave to amend be denied as futile.

Plaintiffs' request should also be denied for a second, independently sufficient reason. Contrary to Plaintiffs' assertions at the June 29, 2012 Discovery Conference, the addition of a

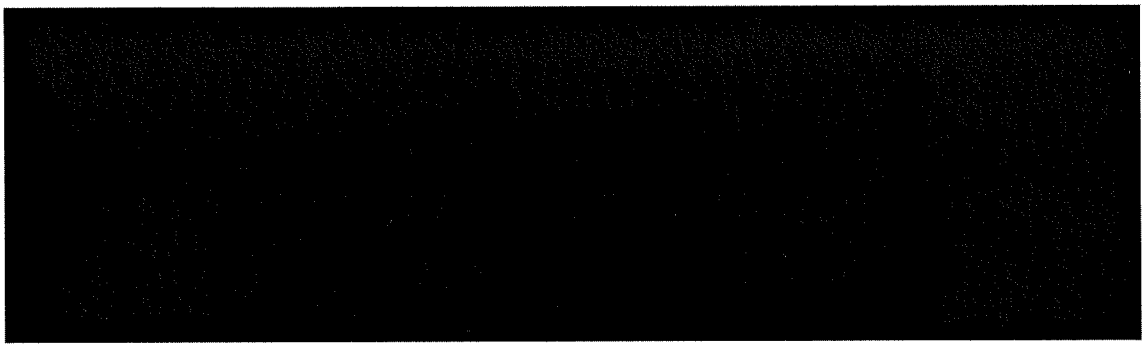
new, unrelated patent at this stage in the litigation will delay this case and will prejudice Watson. Plaintiffs informed the Court that, from their perspective, "[t]here is not a lot of discovery left on that patent." (D.I. 77 at p. 9, l. 24.) Plaintiffs base this assertion on the fact that Watson has produced its ANDA and other documents and samples of its product. But Plaintiffs' one-sided assessment of the need for discovery does not account for the discovery that Watson would need if litigation of the '196 patent were to go forward. If the Court were to grant Plaintiffs' motion, Watson would assert invalidity and non-infringement defenses, both of which would require additional discovery—including document production, contention interrogatories and depositions—on this unrelated patent that claims neither a drug nor method of using a drug. Inasmuch as Watson has not yet requested and Plaintiffs have not yet produced any documents or disclosures concerning the '196 patent, this additional discovery would likely delay both fact and expert discovery, and consequently resolution of the entire case, thereby prejudicing Watson. Therefore, Watson asks that the Court deny Plaintiffs' request for this additional, independent reason.

STATEMENT OF FACTS

Plaintiffs are the apparent holders of approved New Drug Application ("NDA") No. 022083 for Exelon® Patch (rivastigmine transdermal system).[1] On July 1, 2010, Watson submitted ANDA [redacted] o the FDA under 21 U.S.C. § 355(j), seeking approval to engage in commercial manufacture, use and/or sale of generic, bioequivalent versions of Exelon® Patch before the expiration of U.S. patents 5,602,176 (the "'176 patent"), 6,316,023 (the "'023 patent")

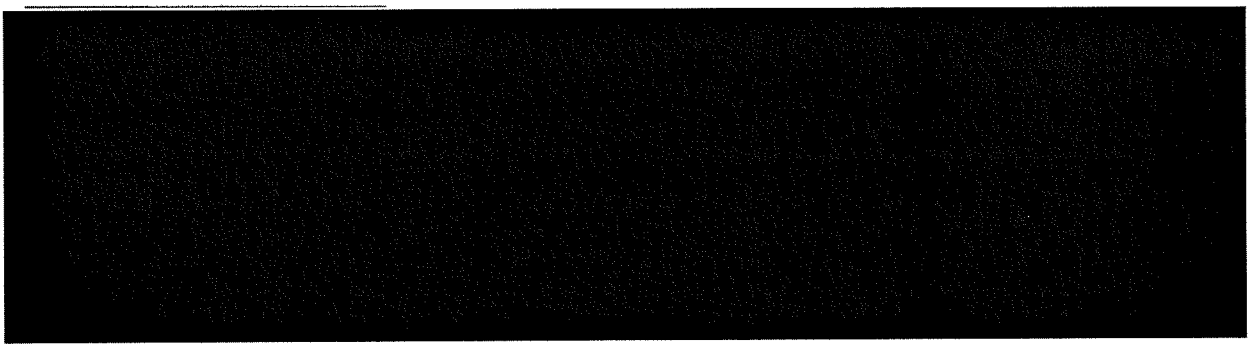
[1] The Exelon® Patch is marketed in two dosages: a 4.6 mg/24 hours patch containing 9 mg rivastigmine in a 5 cm transdermal system (the "4.6 mg/24 hr dosage"); and a 9.5 mg/24 hours patch containing 18 mg rivastigmine in a 10 cm transdermal system (the "9.5 mg/24 hr dosage").

and 6,335,031 (the "'031 patent") (collectively "the Exelon patents").[2] These patents claim rivastigmine and pharmaceutical compositions of rivastigmine (including transdermal patches) that contain effective amounts of antioxidants and are listed in the Orange Book in connection with the Exelon® Patch.



Watson also offered Plaintiffs confidential access to its ANDA pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III). Plaintiffs declined to review Watson's ANDA, and instead, on November 9, 2012, sued Watson for infringement of the '176 patent, the '023 patent and the '031 patent. Notwithstanding Plaintiffs' refusal to review Watson's ANDA prior to filing this lawsuit, Watson promptly produced it after discovery commenced, and Plaintiffs have now had it since February 2012. The ANDA describes the Watson patch and its packaging in detail.

On June 20, 2012, more than seven months after the lawsuit was filed and more than four months after receiving Watson's ANDA, Plaintiffs filed the present motion seeking to add a claim for declaratory judgment of future infringement of the '196 patent.[3] Plaintiffs now assert



that they are entitled to a declaratory judgment "that the packages for Watson's ANDA Products *will* infringe one or more claims of the '196 patent." (D.I. 75-3 at ¶52.) (emphasis added). Plaintiffs allege that Watson would manufacture, market, and/or sell a rivastigmine transdermal system "if approved by the FDA." (D.I. 75-3 at ¶27.) Plaintiffs further allege that "Watson has taken active steps towards the commercial manufacture, use, offer for sale, sale and/or importation of the infringing packages, including filing Watson's ANDA." (D.I. 75-3 at ¶51.)

ARGUMENT

I. LEGAL STANDARD

A. Leave to Amend is Not Automatic Under Fed. R. Civ. P. 15, Because There Are Many Reasons For Denial Such as Futility and Undue Prejudice to the Non-Moving Party

Whether to grant leave to amend "rest[s] within the sound discretion of the trial court under Fed. R. Civ. P. 15." *Massarsky v. General Motors Corp.*, 706 F.2d 111, 125 (3d Cir. 1983). While leave to amend should be freely given where justice so requires, "[it] is not automatic." *Lorah v. Home Helper's Inc.*, 813 F. Supp. 2d 620, 627 (D. Del. 2011) (citation omitted). Grounds for refusal include, *inter alia*, undue delay, dilatory motive by the movant, prejudice to the non-moving party, and futility. *See Foman v. Davis*, 371 U.S. 178, 182 (1962).

Regarding futility, it is well-settled that "[t]he trial court may properly deny leave to amend where the amendment would not withstand a motion to dismiss." *Massarksy*, 706 F.2d at 125. For example, "[a] proposed claim is . . . futile if the court lacks subject matter jurisdiction pursuant to Fed. R. Civ. P. 12(b)(1)." *United States v. Sensient Colors, Inc.*, No. 07-1275, 2009 U.S. Dist. LEXIS 11070, at *9 (D.N.J. Feb. 13, 2009) (Schneider, Mag. J.), *aff'd*, 649 F. Supp. 2d 309 (D.N.J. 2009).

Two types of challenges to subject-matter jurisdiction are available under Fed. R. Civ. P. 12(b)(1): facial and factual. *AstraZeneca Pharms. LP v. Mylan Pharms. Inc.*, MDL No. 08-1949,

2008 U.S. Dist. LEXIS 96289, at *31 (D. Del. Nov. 24, 2008) (Stark, Mag. J.), *aff'd*, 2009 U.S. Dist. LEXIS 1844 (D. Del. Jan. 12, 2009). Watson's opposition to Plaintiffs' motion to amend is, in part, a factual challenge. A factual challenge involves "a claim 'that the court in fact lacks subject-matter jurisdiction, no matter what the complaint alleges.'" *Coulter v. East Stroudsburg Univ.*, No. 11-2065, 2012 U.S. Dist. LEXIS 83332, at *6 (M.D. Pa. June 15, 2012) (quoting *NE Hub Partners, L.P. v. CNG Transmission Corp.*, 239 F.3d 333, 341 (3d Cir. 2001)). Under a factual challenge:

> [T]he Court is not confined to the allegations of the complaint, and the presumption of truthfulness does not attach to the allegations in the complaint. Instead, the Court may consider evidence outside the pleadings, including affidavits, depositions and testimony, to resolve any factual issues bearing on jurisdiction. Once the Court's subject matter jurisdiction over a complaint is challenged, Plaintiff bears the burden of proving jurisdiction exists.

AstraZeneca Pharms. LP, 2008 U.S. Dist. LEXIS 96289, at *46-48 (internal quotations and citations omitted).

Watson also challenges Plaintiffs' motion to amend because of undue delay, dilatory actions by Plaintiffs, and the prejudice such an amendment imposes on Watson. Indeed, "prejudice to the non-moving party is the touchstone for the denial of an amendment." *Cornell & Co., Inc. v. Occupational Safety and Health Review Comm'n*, 573 F.2d 820, 823 (3d Cir. 1978).

B. Declaratory Judgment of Infringement is Not an Independent Basis for Subject Matter Jurisdiction

Plaintiffs' proposed Amended Complaint asserts a violation of the ordinary prohibition against infringement pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. However, the Declaratory Judgment Act is not an independent basis for subject-matter jurisdiction. *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1335 (Fed. Cir. 2008) (citing *Skelly Oil Co. v. Phillips Petroleum Co.*, 339 U.S. 667, 671-72 (1950)). Instead, it provides a

remedy only if the court has jurisdiction from some other source. *Prasco, LLC*, 537 F.3d at 1335 (citing *Cat Tech LLC v. Tube-Master, Inc.*, 528 F.3d 871, 879 (Fed. Cir. 2008)). In patent infringement cases, jurisdiction arises under the Patent Act. *See id.* at 1335 n.3. While Plaintiffs do not provide a specific infringement theory, they necessarily must rely on 35 U.S.C. § 271(a) based on the reference to "manufacture, use, offer for sale, sale and/or importation . . . ."[4] (D.I. 75-3 at ¶51.) Regardless of its infringement theory, however, there is no justiciable controversy regarding the '196 patent.

C. In Hatch-Waxman Cases, Courts Have Consistently Denied Declaratory Judgment Claims Against ANDA Applicants

"A claim is not ripe for adjudication if it rests upon 'contingent future events that may not occur as anticipated, or indeed may not occur at all.'" *Texas v. United States*, 523 U.S. 296, 300 (1998) (quoting *Thomas v. Union Carbide Agricultural Prods. Co.*, 473 U.S. 568, 581 (1985)). As applied to declaratory judgment actions brought by the patent holder against ANDA applicants and alleged future infringers, the law is clear – where a controversy will only materialize *if* the FDA approves the accused drug and *if* the defendant decides to market the drug *without change*, there is no controversy of sufficient immediacy and reality to support jurisdiction. *See, e.g.*, *Intermedics v. Ventritex Co.*, No. 92-1076, 1993 U.S. App. LEXIS 3620, at *13-15 (Fed. Cir. Feb. 22, 1993) (unpublished) (affirming dismissal of declaratory judgment count because there was no actual controversy); *Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1527 (Fed. Cir. 1992) (affirming dismissal of declaratory judgment count because there was no actual controversy). *See also, e.g.*, *AstraZeneca Pharms. LP*, 2008 U.S. Dist. LEXIS 96289, at *46-48 (recommending that the motion to dismiss the declaratory

[4] 35 U.S.C. § 271(a) defines infringement as the unauthorized making, using, offering to sell, or selling of a patented invention within the United States, or the unauthorized importing in the United States of a patented invention. Plaintiffs cannot rely on 35 U.S.C. § 271(e)(2) as the '196 patent claims neither a drug nor use of a drug.

judgment count be granted because there was not a controversy of "sufficient immediacy" under § 271(a)); *Eisai Co. v. Mut. Pharm. Co.*, No. 06-3613, 2007 U.S. Dist. LEXIS 93585, at *59-74 (D.N.J. Dec. 20, 2007) (dismissing declaratory judgment count for lack of subject matter jurisdiction); *Abbott Diabetes Care, Inc. v. DexCom, Inc.*, No. 05-590, 2006 U.S. Dist. LEXIS 57469, at *9-10 (D. Del. Aug. 16, 2006) (dismissing declaratory judgment count because no controversy of sufficient immediacy and reality existed at the time Abbott filed its complaint); *Abbott Labs. v. Zenith Labs.*, 934 F. Supp. 925, 937-39 (N.D. Ill. 1995) (dismissing declaratory judgment count because "a controversy will only materialize if the FDA approves the accused drug and if Defendant decides to market the drug"). In these cases, the declaratory judgment plaintiff lacks standing to bring suit because there is no actual or imminent injury, and the case is not ripe for adjudication because the claim rests on contingent future events. *See, e.g.*, *Intermedics, Inc*, 1993 U.S. App. LEXIS 3620, at *13-15; *Telectronics Pacing Sys., Inc.*, 982 F.2d at 1527. *See also*, *e.g.*, *AstraZeneca Pharms. LP*, 2008 U.S. Dist. LEXIS 96289, at *46-48; *Eisai Co.*, 2007 U.S. Dist. LEXIS 93585, at *59-74; *Abbott Diabetes Care, Inc.*, 2006 U.S. Dist. LEXIS 57469, at *9-10; *Abbott Labs.*, 934 F. Supp. at 937-39.

Courts have consistently found that they lack subject-matter jurisdiction over declaratory judgment claims against ANDA applicants both before and after the Supreme Court's ruling in *Medimmune, Inc. v. Genentech, Inc.*, which clarified that an injury-in-fact sufficient to create an actual controversy can exist even when there is no apprehension of suit. *See Medimmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (declaratory judgment jurisdiction requires the Court to consider whether the "facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy

and reality to warrant the issuance of a declaratory judgment"). For example, in *Eisai Co. v. Mutual Pharmaceutical Co.*, a post-*Medimmune* case, the court concluded:

> These allegations, combined with the post-Complaint stipulation, do not present the immediacy necessary for declaratory judgment jurisdiction. The alleged future infringement depends on two contingent future events: FDA approval of Mutual's ANDA, and Mutual's decision to market a generic version of Aricept® ODT pursuant to that ANDA. At least until the ANDA is approved, however, the controversy is not sufficiently immediate.

Eisai Co., 2007 U.S. Dist. LEXIS 93585, at *62.

The United States District Court for the District of Delaware reached the same outcome in *AstraZeneca Pharms. LP v. Mylan Pharms. Inc.* based on a slightly different line of reasoning:

> There is not a present controversy of "sufficient immediacy" . . . to permit a declaratory judgment to be awarded under § 271(a). The filing of these lawsuits triggered the automatic 30-month stay of FDA approval of each of Defendants' ANDAs. The Defendants cannot manufacture, import, market, or sell their proposed generic drug in the United States without FDA approval . . . .

AstraZeneca Pharms. LP, 2008 U.S. Dist. LEXIS 96289, at *46-47.

II. THIS COURT LACKS SUBJECT MATTER-JURISDICTION OVER PLAINTIFFS' DECLARATORY JUDGMENT CAUSE OF ACTION BECAUSE THERE IS NO CASE OR CONTROVERSY

Watson requests that Plaintiffs' request for leave to amend their complaint be denied, because no case of *actual* controversy presently exists with regard to whether Watson's generic product infringes the '196 patent under 35 U.S.C. § 271(a). Plaintiffs' proposed second cause of action is based entirely on allegations regarding what Watson may do in the future [redacted] Section 271(a) provides a claim for infringement for the unauthorized making, using, offering to sell, selling, or importing of a patented invention. 35

U.S.C. § 271(a). It is undisputed that Watson has not and does not engage in any of such acts.[5] Nor is there any definite date in the future when Watson will do so.

Indeed, there are at least three contingent future events on which a case of *actual* controversy hinges:

(1) will the FDA approve ANDA [redacted]

(2) will Watson's product will be marketed at all; and

[redacted]

Unless and until all three of these contingencies are removed, there is no actual controversy under 35 U.S.C. § 271(a) of sufficient immediacy to create subject-matter jurisdiction. *See, e.g., Intermedics, Inc*, 1993 U.S. App. LEXIS 3620, at *14-15; *Telectronics Pacing Sys., Inc.*, 982 F.2d at 1527. *See also, e.g., AstraZeneca Pharms. LP*, 2008 U.S. Dist. LEXIS 96289, at *46-48; *Eisai Co.*, 2007 U.S. Dist. LEXIS 93585, at *59-64; *Abbott Diabetes Care, Inc.*, 2006 U.S. Dist. LEXIS 57469, at *9; *Abbott Labs.*, 934 F. Supp. at 937-39.

A. The FDA's Approval of Watson's ANDA Application is a Future, Not Immediate Event

Plaintiffs' proposed Amended Complaint does not even attempt to guess at when the FDA may approve ANDA [redacted] As a minimum, Plaintiffs' original Complaint triggered a 30-month stay meaning the FDA cannot approve Watson's ANDA until at least [redacted] As stated by the court in *Eisai Co.*, "until the ANDA is approved . . . the controversy is not sufficiently immediate." *See Eisai Co.*, 2007 U.S. Dist. LEXIS 93585, at *62. *See also Intermedics, Inc.*, 1993 U.S. App. LEXIS 3620, at *14-15 ("it was impossible to know when the FDA might make

[5] Watson's activities related to its ANDA [redacted] are protected by the safe harbor provision of 35 U.S.C. § 271(e)(1).

such a determination in response to Ventritex's application"); *Abbott Labs.*, 934 F. Supp. at 937-39 ("there is no guarantee that the FDA approval will be forthcoming on any particular date in the future"); *Abbott Diabetes Care, Inc.*, 2006 U.S. Dist. LEXIS 57469, at *9 ("Abbott could not predict when, or if, the FDA would approve the product . . . .").

Until Watson's ANDA is approved, the controversy alleged by Plaintiffs' in the second cause of action of their proposed Amended Complaint is not sufficiently immediate to establish subject-matter jurisdiction, and thus their request for leave to amend should be denied as futile.

[redacted]

Telectronics Pacing Sys., Inc., the Federal Circuit affirmed the district court's dismissal of the case, opining that "[t]here was no certainty that the device when approved would be the same device that began clinical trials; product changes during testing are contemplated by statute." 982 F.3d at 1527 (further noting that in this case Ventritex in fact did modify its device during clinical trials). *See also Intermedics, Inc.*, 1993 U.S. App. LEXIS 3620, at *14-15 (explaining that sometimes the FDA requires ANDA applicants to make changes before approval is given). The Federal Circuit has further noted, "[t]he greater the variability of the subject of a declaratory-judgment suit, particularly as to its potentially infringing features, the greater the chance the that the court's judgment will be purely advisory, detached from the eventual, actual content of that subject,--in short, detached from eventual reality." *Sierra Applied Sciences, Inc. v. Advanced Energy Indus., Inc.*, 363 F.3d 1361, 1379 (Fed. Cir. 2004).

Here, the facts are even more compelling. [redacted]

[redacted] Because of these contingent future events, [redacted], there is no actual controversy under 35 U.S.C. § 271(a) of sufficient immediacy and reality to confer subject-matter jurisdiction on this Court.

Plaintiffs' proposed second cause of action is, therefore, futile.

III. WATSON REQUESTS THAT PLAINTIFFS' REQUEST FOR LEAVE TO AMEND BE DENIED FOR THE INDEPENDENTLY SUFFICIENT REASON THAT THE PROPOSED AMENDMENT IS BROUGHT FOR THE PURPOSE OF DELAYING THE PRESENT ACTION WHICH WILL PREJUDICE WATSON

Watson also challenges Plaintiffs' motion to amend because of undue delay -- conduct by Plaintiffs having the effect of delaying progress of this case, and the prejudice such an amendment imposes on Watson. Indeed, "prejudice to the non-moving party is the touchstone for the denial of an amendment." *Cornell & Co., Inc. v. Occupational Safety and Health Review Comm'n*, 573 F.2d 820, 823 (3d Cir. 1978). Here, Plaintiffs' motion is consistent with a pattern of conduct having the effect of delaying the action, including, for example, their failure to engage in timely third-party discovery, their failure to complete document production by the June 11, 2011 deadline, and their request for an additional three months of discovery. It is well-settled that parties may not file motions to amend in order to cause delay. *Otsuka Pharm. Co. v.*

Barr Labs., Inc., No. 07-1267, 2008 U.S. Dist. LEXIS 99214, at *13 (D.N.J. Dec. 5, 2008) ("The federal courts have often admonished the filing of vexatious litigation, even where the legal and factual grounds are not of a frivolous nature.")(citations omitted).

Despite Plaintiffs' statements to the contrary, the addition of the '196 patent to the present action *will* have a high likelihood of causing delay. That is because the '196 patent is unrelated to the other patents-in-suit and thus will require additional discovery from Plaintiffs relating to Watson's invalidity and non-infringement defenses. Such discovery will include document requests, contention interrogatories and inventor depositions—all of which are necessary because the '196 patent is completely unrelated to the current patents-in-suit. Moreover, delaying the present action may result in a delay of resolution of the current dispute beyond expiration of the 30-month stay. The Hatch-Waxman scheme was designed to permit resolution of patent disputes within the 30-month stay period, and imposes an obligation on the parties to cooperate in reasonably expediting the patent litigation. *See* 21 U.S.C. § 355(j)(5)(B)(iii). Plaintiffs' request for leave to amend will have the effect of delaying this and cause prejudice Watson.

CONCLUSION

For the foregoing reasons, Watson respectfully requests that Plaintiffs' motion for leave to amend be denied.

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Dated: July 11, 2012

01:12277139.1

EXHIBIT 1

WATSON'S ANSWERING BRIEF IN OPPOSITION TO PLAINTIFFS' MOTION FOR LEAVE TO AMEND THEIR COMPLAINT FOR PATENT INFRINGEMENT

FILED UNDER SEAL

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS AG, NOVARTIS PHARMA AG, NOVARTIS INTERNATIONAL PHARMACEUTICALS LTD. and LTS LOHMANN THERAPIE-SYSTEME AG, Plaintiffs, v. WATSON LABORATORIES, INC., WATSON PHARMA, INC., and WATSON PHARMACEUTICALS, INC. Defendants.	Case No. 1:11-cv-01112 (RGA) [redacted]

DECLARATION OF GISELA SHARP IN SUPPORT OF THE WATSON'S OPPOSITION TO PLAINTIFFS' MOTION FOR LEAVE TO AMEND THEIR COMPLAINT FOR PATENT INFRINGEMENT AGAINST WATSON

I, Gisela Sharp, hereby declare as follows:

1. I am the Manager of Regulatory Affairs at Watson Laboratories, Inc. ("Watson"). As part of my duties, I am responsible for ensuring regulatory compliance with the requirements set by the Food and Drug Administration ("FDA") regarding Watson's ANDA [redacted] for a bioequivalent, generic version of Exelon® Patch (rivastigmine transdermal system).

2. [redacted]

3. Assuming the FDA approves Watson's ANDA [redacted], and assuming Watson decides to market a rivastigmine patch, [redacted]

[redacted]

4. I am familiar with FDA regulations and guidances for amendment of ANDAs. Under those regulations and guidances, [redacted]

I declare under penalty of perjury that the foregoing is true and correct.

Executed on July 10, 2012.

Gisela Sharp