IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH HOLDINGS CORPORATION, WYETH-AYERST LEDERLE LLC, and WYETH LLC,	)	
Plaintiffs and Counterclaim-Defendants,	)	
v.	)	Civ. Action No. 09-955-RGA-CJB
SANDOZ, INC.,	)	
Defendant and Counterclaim-Plaintiff.	)	

REPORT AND RECOMMENDATION[1]

Pending before the Court in this patent case is a motion by Defendant Sandoz, Inc. ("Sandoz") for summary judgment of invalidity of U.S. Patent No. 7,879,828 ("the '828 patent") for obviousness-type double patenting in light of claim 97 of U.S. Patent No. RE40,183 ("the '183 patent"). (D.I. 96) Plaintiffs Wyeth Holdings Corporation, Wyeth-Ayerst Lederle LLC, and Wyeth LLC (collectively, "Wyeth") oppose Sandoz's motion, and argue that the asserted claims of the '828 patent are patentably distinct from claim 97 of the '183 patent, or, at a minimum, that genuine issues of material fact preclude entry of summary judgment in Sandoz's favor. (D.I. 108)

For the reasons discussed below, I recommend that the Court DENY Sandoz's motion.

I. BACKGROUND

A. Procedural Posture

[1] Absent unanimous consent of the parties to the jurisdiction of a United States Magistrate Judge, a Magistrate Judge's authority as to the resolution of a motion for summary judgment pursuant to Rule 56 is limited to making a Report and Recommendation to the District Court. 28 U.S.C. § 636(b)(1)(B); D. Del. LR 72.1(a)(3).

This case arises from Sandoz's filing of Abbreviated New Drug Application ("ANDA") No. 91-620 with the United States Food and Drug Administration ("FDA"). Sandoz's ANDA seeks to market an injectable form of tigecycline, an antibiotic that Wyeth currently markets under the brand name Tygacil®. (D.I. 1 at ¶ 10) Wyeth asserts that the '828 patent and the '183 patent (collectively, "the patents-in-suit") are valid and infringed by Sandoz. (D.I. 1) Both of the patents-in-suit are listed in the FDA's Approved Drug Products with Therapeutic Evaluations as covering Tygacil®. (D.I. 108 at 1) Sandoz has stipulated that its submission of ANDA No. 91-620 and the commercial manufacture, use, and/or sale of generic tigecycline antibacterial products would infringe the asserted claims of the patents-in-suit, if any of those claims are found valid and enforceable. (D.I. 62 at 5, ¶ 16; 6, ¶ 24) Sandoz challenges, *inter alia*, the validity of both of the patents-in-suit. (*Id.* at 7, 21)

No *Markman* hearing was held in this case. The parties initially disputed the meaning of a single phrase from the '828 patent: "pH of the composition in a solution." (D.I. 35) However, they were later able to agree on the appropriate construction of the phrase. (D.I. 36)

Fact discovery closed on October 19, 2011. (D.I. 59) Expert discovery is nearly complete.[2] On March 5, 2012, this case was reassigned to Judge Richard G. Andrews, and remains before me on referral to resolve all pre-trial matters, up to and including case dispositive motions. (D.I. 75) A final pre-trial conference is scheduled for May 11, 2012, and a bench trial is scheduled to begin on June 4, 2012. (D.I. 23 at 6–7)

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[2] On March 14, 2012, the Court denied a motion by Wyeth to strike an expert report of Sandoz's, and granted-in-part a motion to strike one of Wyeth's expert reports. (D.I. 115) As a result of the Court's decision, at least two additional expert depositions may occur in advance of trial. Neither expert is cited in the parties' submissions relating to the present motion.

B. The Patents-in-Suit

1. The '183 Patent

The '183 patent was issued to Plaintiff Wyeth Holdings Corporation on March 25, 2008, and is a reissue of U.S. Patent No. 5,494,903 ("the '903 patent").[3] ('183 patent at 1) The '183 patent is entitled "7-Substituted-9-Substituted Amino-6-Demethyl-6-DeoxyTetracyclines," and lists five individuals as inventors (Joseph J. Hlavka, Phaik-Eng Sum, Yakov Gluzman, Ving J. Lee, and Adma A. Ross). (*Id.*) This patent is generally directed to tetracycline derivatives with antibacterial properties. Although the overwhelming majority of the '183 patent claims are directed to tetracycline compounds with various substitutions, claim 97 of the '183 patent claims a "pharmaceutical composition of matter" that includes a tetracycline compound as well as a "pharmaceutically acceptable carrier." (*Id.* at col. 151:62–64) Tigecycline is among the "numerous compounds" within the scope of claim 97. (D.I. 108 at 7)

2. The '828 Patent

The '828 patent was issued to Plaintiff Wyeth LLC on February 1, 2011,[4] and is based on Application No. 11/374,330 ("the '330 application"). It is entitled "Tigecycline Compositions and Methods of Preparation," and lists three individuals (Mahdi B. Fawzi, Tianmin Zhu, and Syed M. Shah) as inventors.[5] ('828 patent at 1) Tigecycline is a well-known antibiotic in the

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[3] The application that led to the '903 patent was filed on August 4, 1994, and the '903 patent was issued on February 27, 1996.

[4] Although the '183 patent was issued to a nominally different entity than the '828 patent, there does not appear to be any dispute that the patents-in-suit are commonly owned. (*See, e.g.*, D.I. 97 at 7 n.4)

[5] None of the inventors of the '828 patent are listed as inventors of the '183 patent, and the '828 patent does not claim priority to the '183 patent (or the '903 patent).

tetracycline family. (*Id.* at col. 1:23–25; col. 2:55–65) It is a particularly effective intravenous treatment against certain strains of drug-resistant bacteria. (*Id.* at col. 1:24–29, 45–47) Tigecycline is typically dissolved in water and then freeze-dried or "lyophilized" into a powder form before being shipped to end users, such as hospital pharmacies. (*Id.* at col. 1:55–63) Prior to being administered to patients, the powder is mixed with saline or another form of diluent and placed into intravenous bags for delivery. (*Id.* at col. 1:66–2:7)

During this process, tigecycline is subject to two countervailing degradative pathways. First, tigecycline in solution form is susceptible to rapid oxidation, which typically occurs at a slightly basic pH (about 7.8). (*Id.* at col. 2:26–35) To avoid this oxidative degradation, the pH of the solution can be lowered by adding an acid or buffer. (*Id.* at col. 2:44–48) However, lowering the pH triggers a second degradative process, known as epimerization. (*Id.* at col. 2:48–50) Under acidic conditions, the standard "*cis*" form of tigecycline is converted into the "*trans*" isomer. This epimerized product is non-toxic, but also exhibits low antibacterial efficacy. (*Id.* at col. 3:16–21) Thus, according to the '828 patent, there was a need to develop a composition that minimizes both the propensity of tigecycline to oxidize and its tendency to epimerize. (*Id.* at col. 3:62–65) It is through the addition of lactose that a stable balance against the countervailing degradative pathways is purportedly achieved. (*Id.* at col. 4:49–59)

All of the '828 patent claims are directed to compositions that include tigecycline, lactose, and an acid. (D.I. 65 at 1, 3) Wyeth asserts 17 of the '828 patent claims: 1–4, 6–8, 10–12, 14, 16–18, 20 and 22–23. (D.I. 40 at 1) Two of those claims (1 and 12) are independent, while the remaining 15 asserted claims are dependent. Claim 1 of the '828 patent is representative, and is reproduced below:

> 1. A composition comprising tigecycline, lactose, and an acid selected from hydrochloric acid and gentisic acid, wherein the molar ratio of tigecycline to lactose is between 1:0.2 and about 1:5 and the pH of the composition in a solution is between about 3.0 and about 7.0.

The remaining asserted claims of the '828 patent include various modifications to the elements recited in claim 1, such as restricting the type of acid to hydrochloric acid, narrowing the pH and molar ratios, and limiting the composition to solid form. (D.I. 108 at 4; D.I. 118 at 2)

C. The Prosecution History of the '828 Patent

The '330 application—the application that eventually led to the issuance of the '828 patent—was filed on March 13, 2006, claiming priority to an earlier provisional application filed on March 14, 2005. ('828 patent at 1) As originally filed, the claims of the '330 application were broader than those that ultimately issued, with the original independent claim 1 directed to "[a] composition comprising tigecycline, at least one suitable carbohydrate, and an acid or buffer." (D.I. 108 at 4 (quotation marks omitted)) These claims were amended to specifically identify lactose, instead of the more generic reference to a "suitable carbohydrate." (D.I. 98, ex. 4 at SDZ(14)0227158)

The amended claims were rejected as obvious over the Applicant's admission of the prior art in combination with U.S. Patent Appl. Pub. No. 2005/0148553 ("Testa"), which taught a method of treating infections by administering a pharmaceutical composition including tigecycline and various excipients, including lactose. (*Id.*) Although Testa did not teach a lyophilized composition of tigecycline and lactose, the PTO examiner concluded that it would have been *prima facie* obvious for a person of ordinary skill in the art to lyophilize the composition, prior to adding an acid in order to lower the pH and combat oxidation. (*Id.* at

SDZ(14)0227158–59) In response to this rejection, the Applicant argued that while Testa referred to lactose as one of a number of excipients that might be combined with tigecycline, Testa did not teach lactose as a stabilizer against epimerization. (*Id.* at SDZ(14)0227206) As such, in the Applicant's view, the Examiner "failed to articulate a reason why the claimed invention . . . would have been obvious over Testa," and thus failed to articulate a *prima facie* case of obviousness. (*Id.*) The Applicant argued that the person of ordinary skill in the art would not have expected to achieve a more stable form of tigecycline by lowering pH, because the resulting acidic solution would have reduced oxidation while increasing epimerization. (*Id.* at SDZ(14)0227206–07) The Examiner was not persuaded by these arguments, and maintained his obviousness rejection. (*Id.* at SDZ(14)0227222–23)

However, the '828 applicants persisted in their view that the claimed compositions were not obvious. In an interview with the Examiner, the Applicant highlighted the allegedly improved attributes of the claimed tigecycline composition, including its success in combating epimerization, as set forth in the data provided in the '330 application. (D.I. 109, ex. B at WT02266015) After the interview, and at the Examiner's request, the Applicant submitted a declaration of Christian Ofslager, Wyeth's Director of Parenteral New Products & Process Development. (D.I. 98, ex. 4 at SDZ(14)0227234; D.I. 109, ex. C) In this declaration, Mr. Ofslager elaborated on the allegedly unexpected stabilization results that were observed when tigecycline and lactose were combined in an acidic composition. (D.I. 109, ex. C) This ultimately persuaded the Examiner to withdraw the rejection in light of Testa, concluding that "the claimed composition unexpectedly reduces . . . unwanted epimerization and thus stabilizes tigecyline." (D.I. 98, ex. 4 at SDZ(14)0227636)

The '828 applicants cited several prior art references during prosecution of the '828 patent; among those references was the '903 patent, which is the patent that was reissued as the '183 patent. (D.I. 109, ex. D) The Examiner never rejected the claims of the '330 application for statutory or nonstatutory double-patenting, and no terminal disclaimers were entered during prosecution of the '828 patent.

D. Sandoz's Motion for Summary Judgment

On February 10, 2012, Sandoz moved for partial summary judgment pursuant to the equitable doctrine of obviousness-type double patenting, arguing that the asserted claims of the '828 patent are invalidated by claim 97 of the '183 patent. (D.I. 97) Briefing was completed on March 16, 2012, (D.I. 116), and the Court heard oral argument on Sandoz's motion on March 27, 2012 (D.I. 125). Sandoz's motion is thus ripe for resolution.

II. STANDARD OF REVIEW

A. Summary Judgment Standard

A grant of summary judgment is appropriate where "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 n.10 (1986). "Facts that could alter the outcome are 'material', and disputes are 'genuine' if evidence exists from which a rational person could conclude that the position of the person with the burden of proof on the disputed issue is correct." *Horowitz v. Fed. Kemper Life Assurance Co.*, 57 F.3d 300, 302 n.1 (3d Cir. 1995) (internal citations omitted). A party asserting that a fact cannot be—or, alternatively, is—genuinely disputed must support the

assertion either by citing to "particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for the purposes of the motion only), admissions, interrogatory answers, or other materials"; or by "showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." Fed. R. Civ. P. 56(c)(1)(A) & (B).

If the moving party has demonstrated the absence of a genuine dispute of material fact, the nonmovant must then "come forward with specific facts showing that there is a genuine issue for trial." *Matsushita*, 475 U.S. at 587 (internal quotation marks and emphasis omitted). The Court will "draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence." *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000). However, to defeat a motion for summary judgment, the non-moving party must "do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita*, 475 U.S. at 586. The "mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment"; a factual dispute is genuine only where "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247–48 (1986) (emphasis omitted). If the nonmoving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, then the moving party is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

B. Obviousness-Type Double Patenting

The doctrinal prohibition against double patenting prevents a patentee from using a later-issued patent to effectively extend the period of exclusivity for a single invention set forth in an earlier-issued patent. *Takeda Pharm. Co. v. Doll*, 561 F.3d 1372, 1375 (Fed. Cir. 2009). The proscription against double patenting takes two forms. The first is statutory double patenting, which stems from 35 U.S.C. § 101 and prohibits a later patent from covering identical subject matter as an earlier patent. *Id.* The second is nonstatutory, or "obviousness-type" double patenting. This is a judicially created doctrine, designed to foreclose claims in separate patents that do not recite the same invention, but that nonetheless claim inventions so alike that granting both exclusive rights would effectively extend the life of patent protection. *Id.* Under the obviousness-type double-patenting doctrine, a patentee is prohibited "from obtaining an extension of the right to exclude through claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent." *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 967 (Fed. Cir. 2001).

An obviousness-type double-patenting inquiry involves two steps. First, a court must construe the claims-at-issue from both the earlier patent and the later patent, identifying any differences. *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 518 F.3d 1353, 1363 (Fed. Cir. 2008). Second, a court must determine "whether those differences render the claims patentably distinct." *Id.* "A later patent claim is not patentably distinct . . . if the later claim is obvious over, or [is] anticipated by, the earlier claim," in which case the later claim is invalid. *Id.* (internal quotation marks and citations omitted); *see also Barr Labs.*, 251 F.3d at 967. In undertaking the second step of this analysis, the Court must ask whether any identified differences render the claims of

the later patent non-obvious to a person of ordinary skill in the art. *Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1361–62 (Fed. Cir. 2009) (citing *In re Kaplan*, 789 F.2d 1574, 1580 (Fed. Cir. 1986)). This second step is generally analogous to an obviousness analysis under 35 U.S.C. § 103, except that the earlier patent is not considered prior art. *Id.* (citing *In re Longi*, 759 F.2d 887, 892 n.4 (Fed. Cir. 1985)). The party asserting obviousness-type double patenting must prove by clear and convincing evidence that the claims at issue are not patentably distinct—a "heavy and unshifting burden." *Symbol Techs. Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1580 (Fed. Cir. 1991).

III. DISCUSSION

A. Differences Between the Construed Claims of the '183 Patent and the '828 Patent

1. Construction of Claim Terms-At-Issue

As part of the first step of analyzing whether the asserted '828 patent claims are invalid in light of claim 97 of the '183 patent, the Court must construe the terms of the claims-at-issue. In this case, as noted above, the parties did not present any disputed claim terms to the Court for construction at a *Markman* hearing, and do not appear to dispute the meaning of any claim terms at issue in Sandoz's motion. However, the Court must still construe the claims-at-issue, so as to determine whether and to what extent those claims differ.

A claim term should be interpreted as having the ordinary and customary meaning that would be understood by a person of skill in the relevant art, unless the patentee specifically defined that term in the patent specification. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (*en banc*). In discerning the meaning that would be ascribed to a claim term by a

person of ordinary skill in the art, courts should look to "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning scientific principles, the meaning of technical terms, and the state of the art." *Id.* at 1314 (internal quotation marks and citations omitted). The patent specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Id.* at 1315 (internal quotation marks and citations omitted).

Claim 97 of the '183 patent depends from claim 1, and describes "[a] pharmaceutical composition of matter comprising a compound according to claim 1 in association with a pharmaceutically acceptable carrier." ('183 patent at col. 151:62–64) To determine the scope of this claim, the Court must determine (1) what constitutes a "compound according to claim 1" and (2) what constitutes a "pharmaceutically acceptable carrier."

Sandoz does not suggest a particular definition for the phrase "compound according to claim 1," but does assert that it is "beyond dispute that tigecycline is" such a compound. (D.I. 97 at 8) Wyeth likewise does not suggest a particular definition for this phrase, noting instead that "[c]laim 1 is directed to compounds of two generic formulae having various substituents," and that "[t]igecycline is one of numerous compounds included" in the scope of that claim. (D.I. 108 at 7) Claim 1 of the '183 patent refers to a genus of tetracycline derivatives. In light of the plain language of claim 1 and the parties' statements, the Court therefore construes the "compound" term in claim 97 to mean "a tetracycline derivative of the formulae set forth in claim 1, including but not limited to tigecycline."

As for what constitutes a "pharmaceutically acceptable carrier," the parties again appear to agree that lactose is such a carrier, but as with the preceding phrase, neither suggests an actual

definition. (D.I. 97 at 8; D.I. 108 at 7–8, 10) Both parties do, however, direct the Court to a portion of the '183 patent specification, which notes that "[w]hen the [claimed] compounds are employed as antibacterials, they can be combined with one or more *pharmaceutically acceptable carriers*, for example, solvents, diluents and the like." ('183 patent, col. 114:33–35 (emphasis added)) The '183 patent describes a number of solid carriers that may be used for oral administration and intravenous, intramuscular, or subcutaneous routes, "includ[ing] starch, *lactose*, dicalcium phosphate, microcrystalline cellulose, sucrose and kaolin." (*Id.* at col. 114:66–67 (emphasis added)) The '183 patent also describes a number of liquid carriers, including "sterile water, polyethylene glycols, non-ionic surfactants and edible oils." (*Id.* at col. 115:1–3) These carriers should be "appropriate to the nature of the active ingredient and the particular form of administration desired." (*Id.* at col. 115:3–5) In light of these teachings from the '183 patent specification, the Court construes "pharmaceutically acceptable carrier" to mean "any solid or liquid, including but not limited to lactose, that may be combined with a tetracycline derivative of the formulae set forth in claim 1, and that results in an antibacterial formulation."

As for the asserted claims of the '828 patent, all of the claim terms have well-established meanings, and refer to known chemical compounds (tigecycline, lactose, hydrochloric acid and gentisic acid) with discrete chemical formulae and clear pH ranges (between about 3.0 and 7.0).

2. Comparison of Claims-At-Issue

Having considered the meaning of the claim terms of the patents-in-suit, the Court next identifies the differences between these claims. There are five key differences between claim 97

of the '183 patent and the asserted independent claims (1 & 12) of the '828 patent:[6]

1. Claim 97 is broadly drawn to numerous tetracycline derivatives, while claims 1 and 12 of the '828 patent refer to only a single tetracycline derivative—tigecycline. Although neither Wyeth nor Sandoz has attempted to precisely quantify the number of compounds within the scope of claim 1, it appears that, at minimum, thousands of tetracycline compounds are included in that claim, in contrast to the single, specific tetracycline compound in claims 1 and 12. (D.I. 97 at 1; D.I. 125 at 11, 73–74)

2. Claim 97 is broadly drawn to pharmaceutically acceptable carriers, which encompass over a dozen different solids and liquids appropriate for combination with the thousands of different claimed tetracycline derivatives that may be used as antibacterials. In contrast, claims 1 and 12 identify only a single pharmaceutically acceptable carrier—lactose.

3. Claims 1 and 12 of the '828 patent identify hydrochloric and/or gentisic acids as part of the claimed composition; claim 97 of the '183 patent includes no reference to an acidic element.

4. Claim 1 and 12 of the '828 patent specify particular molar ratios of tigecyline to lactose, while claim 97 does not describe any particular compositional ratios between the generic tetracycline compound and the generic carrier.

5. Claims 1 and 12 of the '828 patent specify that the claimed composition must be acidic, with a pH of "between about 3.0 and about 7.0." Claim 97 of the '183 patent does not recite any pH range for the claimed composition.

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[6] The Court has confined its analysis to the two independent asserted claims of the '828 patent; because the dependent claims inherently incorporate all of the limitations of the independent claims, the Court's conclusions (as set forth below) are equally applicable to all the asserted claims of the '828 patent. 35 U.S.C. § 112 ("A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.").

B. There is a Genuine Issue of Material Fact as to Whether the Differences Between Claim 97 of the '183 Patent and the Asserted Claims of the '828 Patent Render These Claims Patentably Distinct

Having identified several differences among the claims-at-issue, the Court next turns to the second step of the obviousness-type double-patenting analysis—whether Sandoz has proven by clear and convincing evidence that these differences fail to render the '828 patent claims patentably distinct from claim 97 of the '183 patent. *Opticon*, 935 F.2d at 1580. Before considering the extent of those differences, however, the Court must first resolve a dispute among the parties as to what evidence is relevant to the second step of the analysis.

1. Obviousness Analysis In A Nonstatutory Double-Patenting Inquiry

As this Court has noted, "[i]n general, the same type of analysis is used for an obviousness-type double patenting inquiry as for a Section 103 obviousness inquiry." *Proctor & Gamble Co. v. Teva Pharms. USA, Inc.*, 536 F. Supp. 2d 476, 497 (D. Del. 2008). As one part of the standard Section 103 obviousness inquiry, courts generally must assess whether secondary indicia demonstrate that claims appearing at first glance to be similar to the prior art should nonetheless be considered nonobvious. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406–07 (2007). Secondary considerations may include evidence of commercial success, long felt but unsolved needs, the failure of others to achieve similar results, skepticism or disbelief of success, copying or praise of the claimed invention, and unexpected results. *Zoltek Corp. v. U.S.*, 95 Fed. Cl. 681, 691 (Fed. Cl. 2010) (citations omitted).

While the Section 103 obviousness inquiry is similar to an obviousness-type double-patenting inquiry, there are differences as well. The Federal Circuit has identified at least three such distinctions:

1. The objects of comparison are very different: Obviousness compares claimed subject matter to the prior art; nonstatutory double patenting compares claims in an earlier patent to claims in a later patent or application;

2. Obviousness requires inquiry into a motivation to modify the prior art; nonstatutory double patenting does not;

3. *Obviousness requires inquiry into objective criteria suggesting non-obviousness; nonstatutory double patenting does not.*

Geneva Pharms., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1378 n.1 (Fed. Cir. 2003) (emphasis added).

Sandoz argues, citing the third-listed distinction in *Geneva*'s footnote one, that "secondary considerations of nonobviousness, such as unexpected results, *should not be considered in the nonstatutory double patenting analysis*." (D.I. 97 at 14 (emphasis added); *see also* D.I. 118 at 8 (citing *Geneva* and asserting that secondary considerations are "not relevant" to an obviousness-type double-patenting inquiry)) Wyeth disagrees with this characterization of *Geneva*, arguing that Sandoz "misstates the law of double patenting" by "boldly suggest[ing] that this Court should ignore" this type of evidence, which would include the "unexpected results obtained by the '828 patent inventors." (D.I. 108 at 15; *see also id.* at 16 n.6)

This Court has made different statements as to whether, in light of the Federal Circuit's opinion in *Geneva*, secondary considerations of non-obviousness are relevant to a nonstatutory double-patenting inquiry. In *Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, C.A. No. 08-335-GMS, 2011 WL 3236037, at *1 n.1 (D. Del. July 28, 2011), this Court cited the above-referenced passage in *Geneva* for the proposition that "secondary considerations are not relevant to the analysis of invalidity for obviousness-type double patenting." *Id.* (citing *Geneva*, 349 F.3d at 1378 n.1). As a result, the *Teva* Court rejected plaintiff's proposed findings of fact and

conclusions of law pertaining to secondary considerations, while nevertheless issuing a post-trial ruling in the plaintiff's favor that its patent was not invalid for obviousness-type double patenting. *Id.* at *1 n.1 & *4. However, in *Boehringer Ingelheim Int'l. GMBH v. Barr Laboratories, Inc.*, 562 F. Supp. 2d 619, 639–40 (D. Del. 2008), *rev'd on other grounds*, 592 F.3d 1340 (Fed. Cir. 2010), another judge of this Court took a different view of the meaning of the above-cited passage from *Geneva*, explaining that:

> While the Court understands this statement [from *Geneva*] to indicate that secondary indicia of nonobviousness are not required to be considered in the nonstatutory double patenting inquiry, the Court does not read this statement to suggest that secondary indicia of nonobviousness are irrelevant. Rather, the Court believes there is discretion to be applied between the idea of maintaining the focus on what is claimed rather than what is disclosed, while simultaneously considering factors beyond the scope of the claim language like secondary indicia of nonobviousness.

Id. For the reasons set forth below, I agree with the *Boehringer Ingelheim* Court that no precedent forecloses consideration of secondary indicia of nonobviousness as part of the nonstatutory double-patenting inquiry.

First, there is nothing in the *Geneva* Court's statement to suggest that a district court is *precluded* from considering evidence of secondary considerations in an obviousness-type double-patenting analysis. In noting that a Section 103 obviousness inquiry "requires inquiry into objective criteria suggesting non-obviousness" while nonstatutory double patenting "does not," the Federal Circuit appears to have used intentionally permissive language. *Geneva*, 349 F.3d at 1378 n.1. If the *Geneva* Court meant to exclude all evidence of secondary considerations as irrelevant in any nonstatutory double-patenting case, then it could have said so directly. The fact that it did not is telling. *Cf. Ortho-McNeil-Janssen Pharms., Inc. v. Watson Labs., Inc.*, Civil Action No. 08-5103 (SRC), 2011 WL 254313, at *6 n.1 (D.N.J. Jan. 25, 2011) (finding "no

support for the proposition that secondary considerations must be excluded from the nonstatutory double patenting analysis," and noting that any suggestion to the contrary "is incorrect"); *In re Glaxo '845 Patent Litig.*, 450 F. Supp. 2d 435, 438 (S.D.N.Y. 2006) ("The plain language of the footnote [in *Geneva*] makes it clear that it does not preclude the proffer and consideration of evidence of objective criteria (another term for secondary considerations) where relevant.").

Second, reading *Geneva* to allow for (though not require) consideration of secondary considerations of non-obviousness better tracks the way in which the Federal Circuit has addressed the significance of this type of evidence. Time and again, the Federal Circuit has recognized that, in an obviousness analysis, "secondary considerations are often some of the best 'independent evidence of nonobviousness.'" *Rolls-Royce, PLC v. United Techs. Corp.*, 603 F.3d 1325, 1339 (Fed. Cir. 2010) (quoting *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1365 (Fed. Cir. 2008)). Indeed, courts frequently look to secondary considerations, such as unexpected results, when considering the validity of a patent in the "chemical arts," like the patents-in-suit. *See, e.g.*, *Allergan, Inc. v. Sandoz Inc.*, --- F. Supp. 2d ---, 2011 WL 3809882, at *34 (E.D. Tex. Aug. 22, 2011) (citing cases).

Sandoz argues, to the contrary, that allowing for any consideration of this evidence would impermissibly broaden the scope of the nonstatutory double-patenting inquiry, which is meant to be narrowly focused "entirely on what is claimed in an issued patent." *In re Barfield*, 925 F.2d 1450, 1453 (Fed. Cir. 1991) (cited in D.I. 118 at 9); (*see also* D.I. 125 at 48–50). Yet while the *focus* of the nonstatutory double-patenting inquiry is on what is claimed in the respective patents, there are many different *types of evidence* that may be relevant to a court's analysis of that issue. The words of the respective claims are certainly the starting point. But it is beyond dispute that

other evidence may also be considered by a court in certain circumstances—from the prosecution history, *see Geneva,* 349 F.3d at 1380, to expert testimony as to what one skilled in the art would understand the difference in claim scope to be, *see Teva*, 2011 WL 3236037 at *3. Sandoz does not persuasively explain why, in appropriate circumstances, evidence of secondary considerations (such as unexpected results) could not shed similarly helpful light on whether what is claimed in a later patent is patentably distinct from what is claimed in an earlier patent. *Cf. Boehringer Ingelheim,* 562 F. Supp. 2d at 639–40 (concluding that a district court could simultaneously maintain a focus on what is claimed in a nonstatutory double-patenting analysis, while still considering evidence beyond the claim language, such as secondary indicia of non-obviousness).

Third, Federal Circuit decisions prior to and after *Geneva* suggest that evidence of secondary considerations may be considered in a nonstatutory double-patenting analysis. One such case is *In re Longi*, 759 F.2d 887 (Fed. Cir. 1985), a case decided many years before *Geneva.* In *Longi*, the Federal Circuit upheld a decision by the Patent and Trademark Office Board of Appeals that certain claims in a patent application entitled "Polymerization Catalyst" were properly rejected on obviousness-type double-patenting grounds, in light of the claims of four previously issued patents. *Id.* at 889. The applicants had argued during prosecution that a declaration filed by the inventor of one of the prior patents, which had "outlined the unexpected results obtained from the applicant's claimed invention," should defeat the nonstatutory double-patenting claim. *Id.* at 891. In analyzing this argument, the *Longi* Court determined that the declaration at issue "fails to provide the unexpected results necessary to rebut the *prima facie* case of obviousness," as there was "nothing to show that the results [described] in the declaration were unexpected." *Id.* at 896. Far from declaring evidence of "unexpected results" irrelevant,

the *Longi* Court considered such evidence, but simply found the strength of that evidence wanting. *See Glaxo*, 450 F. Supp. 2d at 437–38 (citing *Longi* and other Federal Circuit cases for this proposition); *see also Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 364 F. Supp. 2d 820, 911–12 (S.D. Ind. 2005) (same).

The Federal Circuit's approach in a post-*Geneva* case, *Amgen v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1362 (Fed. Cir. 2009), is also instructive. In *Amgen*, the Federal Circuit undertook a nonstatutory double-patenting analysis of certain claims of two patents ("the '868 patent" and "the '698 patent") relating to processes for producing the protein erythropoietin. *Id.* at 1359. The Court examined whether these claims were patentably distinct from a claim of an earlier patent ("the '008 patent"), which the *Amgen* Court described as reciting the starting materials necessary to execute the processes recited in the claims of the '868 patent and the '698 patent. *Id.* at 1361. In conducting this obviousness inquiry, the Federal Circuit considered whether a skilled artisan would have perceived a "reasonable expectation of success" in making the invention described in the claims at issue in the '868 patent and the '698 patent, in light of what was disclosed in the relevant claims of the earlier-filed '008 patent. *Id.* at 1362. This familiar "reasonable expectation of success" analysis appears to be substantively coextensive with the "unexpected results" analysis; the distinctions between these inquiries appear to be largely semantic or procedural. As such, *Amgen* further supports the idea that evidence of unexpectedly reduced levels of degradation and increased antibacterial efficacy (which a skilled artisan allegedly would not have reasonably expected to have had success in achieving) should be considered when assessing nonstatutory double patenting.

In light of this precedent, and in line with the majority of courts outside this jurisdiction

to have considered the question,[7] I will examine relevant evidence of objective criteria suggesting non-obviousness in determining whether Sandoz is entitled to summary judgment.[8]

2. There is a Genuine Issue of Material Fact as to Whether Differences Among the Claims-At-Issue Render Them Patentably Distinct

As discussed above, the '828 patent claims-at-issue differ from claim 97 of the '183 patent in at least five significant respects. Sandoz acknowledges these differences, but contends that they are "superficial" and insufficient to render the '828 claims patentably distinct. (D.I. 97 at 8) Sandoz essentially makes two arguments as to why the differences among these claims do not confer patentability: (1) two elements of the '828 patent's claimed composition (tigecycline and lactose) fall within the scope of the broader claims of claim 97; and (2) the remaining elements of the '828 patent claims (disclosing certain molar ratios, the inclusion of a particular acid, and the

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[7] At least four district courts outside of this jurisdiction have concluded that secondary considerations need not be categorically excluded from a nonstatutory double-patenting analysis. *See, e.g., Ortho-McNeil-Janssen Pharms.*, 2011 WL 254313 at *6 n.1; *Glaxo*, 450 F. Supp. 2d at 437–38; *Pfizer Inc. v. Synthon Holdings BV*, No. 1:05CV39, 2006 WL 2553370, at *21 (M.D.N.C. Aug. 31, 2006); *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 364 F. Supp. 2d 820, 911–12 (S.D. Ind. 2005). In contrast, at least two other district courts have appeared to conclude that evidence of secondary considerations is irrelevant to the nonstatutory double-patenting analysis. *See Applera Corp. v. MJ Research Inc.*, 363 F. Supp. 2d 261, 264 (D. Conn. 2005) (noting, without further analysis, that "the double patenting inquiry . . . [does not] involve inquiry into objective criteria suggesting non-obviousness") (citing *Geneva*, 349 F.3d at 1378 n.1); *Astellas Pharma, Inc. v. Ranbaxy Inc.*, Civil Action No. 05-2563 (MLC), 2007 WL 576341, at *4 (D.N.J. Feb. 21, 2007) (same).

[8] Evidence of nonobviousness does not always fit neatly into a single, discrete category of secondary considerations. In this case, as discussed below, certain evidence relates to whether a person of skill in the art would have expected to achieve a stable pharmaceutical composition with the particular combination claimed in the '828 patent. This evidence implicates issues of unexpected results, but also could be said to encompass the concepts of "skepticism or disbelief of success," and/or "long felt but unsatisfied need." Whatever nominal classification is assigned to this evidence, the Court is convinced that it would improper to ignore it when considering the merits of Sandoz's motion.

inclusion of a particular compositional pH) are insignificant and obvious modifications to claim 97.

a. Genus vs. Species Claims

As to Sandoz's first argument, the mere fact that a composition with tigecycline and lactose falls within the broader scope of the claims-at-issue in the '183 patent is not dispositive for purposes of the nonstatutory double-patenting analysis. Claim 97 of the '183 patent claims a large genus in two different respects—a genus of tetracycline derivatives, and a genus of pharmaceutically acceptable carriers. The claims of the '828 patent are species claims in the same two respects—they claim a species of tetracycline derivatives (tigecycline) and a species of pharmaceutically acceptable carrier (lactose). As this Court has made clear, "[i]n the context of double patenting, an earlier patent claiming a large genus of pharmaceutical compounds does not preclude a later patent from claiming a species within that genus, so long as the species is novel, useful, and nonobvious." *Brigham & Women's Hosp. Inc. v. Teva Pharms. USA, Inc.*, 761 F. Supp. 2d 210, 224 (D. Del. 2011); *see also Eli Lilly & Co. v. Bd. of Regents of the Univ. of Wash.*, 334 F.3d 1264, 1270 (Fed. Cir. 2003) ("[E]arlier disclosure of a genus does not necessarily prevent patenting a species member of that genus.").[9] Under those circumstances, "the genus or 'dominant' patent will expire while claims to the patentably distinct species or selection invention will continue into the future." *Brigham*, 761 F. Supp. 2d at 224. Absent

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[9] In its reply brief, Sandoz cites *Eli Lilly & Co. v. Barr Laboratories, Inc.*, 251 F.3d 955, 972 (Fed. Cir. 2001), as an example of a situation where the Federal Circuit "revers[ed the] denial of [a] motion for summary judgment on invalidity for obviousness-type double patenting where the claims at issue were not patentably distinct." (D.I. 118 at 2) But *Barr Labs.* involved the converse of the situation encountered here. In that case, the Federal Circuit determined that a later genus was anticipated by a particular, earlier species claim—not that an earlier genus claim renders obvious all later species claims. *Barr Labs.*, 251 F.3d at 971.

invalidation, that is what will happen with the patents-in-suit, with the genus claims of the '183 patent expiring in 2016, and the species claims of the '828 patent expiring later. (D.I. 97 at 1)

At times in its briefing, Sandoz appears to suggest that because certain later-disclosed species fall within the scope of the earlier-disclosed genus, this constitutes *per se* evidence of invalidity. (D.I. 97 at 1 ("By applying for the claims of the '828 patent—which covers the identical tigecycline formulations disclosed in claim 97 of the '183 patent—plaintiffs have secured an *additional* 13 years of exclusivity for these formulations."); *id.* at 5 (arguing that because "claim 97 [of the '183 patent] covers the very pharmaceutical formulations claimed in the '828 patent" Wyeth has "impermissibl[y] exten[ded]" its patent exclusivity through the life of the '828 patent)). However, such a position would be contrary to the established law, and cannot be used to satisfy Sandoz's burden of proof at this stage.

This was made clear in *Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 405 F. Supp. 2d 495 (D. Del. 2005), *rev'd on other grounds*, 457 F.3d 1284 (Fed. Cir. 2006), a case where this Court encountered a factual scenario similar to that in the instant case. In *Pfizer*, the defendants asserted that claims 12 and 14 of U.S. Patent No. 5,003,080 ('the '080 patent") invalidated later-issued claim 6 of U.S. Patent No. 5,273,995 ("the '995 patent"). *Id.* at 513. The *Pfizer* Court characterized Claim 12 of the '080 patent as "genus claim" that encompassed "a broad variety of compounds," while claim 6 of the '995 patent was "appropriately characterized as a species claim, because it is directed to a single specific compound," namely, atorvastatin calcium, that was a part of the larger genus. *Id.* at 514. The *Pfizer* Court noted that "[c]ourts have recognized that later species claims are typically not invalidated in light of earlier genus claims on the basis of double patenting." *Id.* (citing cases). After reviewing the evidence adduced during a bench

trial, the *Pfizer* Court went on to find that "[a]lthough the process described in claim 12 [of the '080 patent] [could] be used to make atorvastatin calcium if the right starting products are selected, there [was] nothing in the '080 patent that would lead one to select the chemicals needed to produce" that specific compound in the later-issued patent. *Id.* As a result, claim 6 of the '995 patent was "patentably distinct" from the earlier-issued claims of the '080 patent.[10]

Just as in *Pfizer*, here the fact that the later-issued claims of the '828 patent disclose a species of compound and carrier that are subsumed within a larger genus set forth in the earlier-issued '183 patent claims is, in and of itself, dispositive of nothing. As the *Pfizer* Court did, this Court must go on to analyze the scope of the claims in greater depth, in order to fully evaluate the merits of the instant motion.

b. Molar Ratios and Acidic Conditions in the '828 Claims

In addition to arguing that the genus-species distinction is inadequate to render the '828 claims patentable in light of claim 97 of the '183 patent, Sandoz also claims that the remaining elements of the '828 patent claims (relating to molar ratios of tigecycline to lactose, pH levels, and the inclusion of particular acids) likewise confer no patentable distinctions. (D.I. 97 at 9–12) The Court considers each of these limitations, and their impact on the nonstatutory double-

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[10] *See also Zenith Goldline*, 364 F. Supp. 2d at 830, 844, 910 (rejecting an invalidity defense of nonstatutory double patenting, where prior patent claims disclosed a genus of compounds used to treat psychotic conditions, and later-issued patent claims disclosed a particular species of the genus—a drug used to treat schizophrenia—in finding that the "enormous genus" of the earlier patent, along with the secondary considerations of long-felt need and unexpected results, demonstrated that the selection of a single compound from the earlier disclosed genus would not have been obvious); *cf. In re Baird*, 16 F.3d 380, 383 (Fed. Cir. 1994) (noting, in a Section 103 obviousness inquiry, that "[a] disclosure of millions of compounds does not render obvious a claim to three compounds, particularly when that disclosure indicates a preference leading away from the claimed compounds").

patenting analysis, in turn.

Claims 1 and 12 of the '828 patent require that the molar ratio of tigecycline to lactose in the claimed composition be "between about 1:0.2 and about 1:5." Sandoz argues that this limitation "appears to be an arbitrary range added in response to the Examiner's suggestion," and that "these ratios do not render claims 1 and 12 patentably distinct from claim 97." (D.I. 97 at 9)

Sandoz does not, however, cite any evidence or expert testimony from one skilled in the art that supports its view that this range is "arbitrary." Instead, in an effort to support its assertion of arbitrariness, Sandoz cites only to portions of the '828 patent's prosecution history. (*Id.* (citing D.I. 98, Ex. 4 at SDZ(14)0227234, SDZ(14)0227342)) Yet these citations appear to highlight merely that, in response to a request from a PTO Examiner, Wyeth provided information about the ratios of tigecycline to lactose that it claimed had the effect of simultaneously stabilizing the rate of oxidation and epimerization in tigecycline. Wyeth now responds that these proffered ratios were truly "commensurate in scope with the unexpected results" that it observed from the composition claimed in the '828 patent, and thus "were key to patentability." (D.I. 108 at 14–15 (citing D.I. 98, ex. 4 at SDZ(14)0227234)) And indeed, the evidence that Wyeth provided to the Examiner appears to have been of sufficient impact that it (along with other evidence Wyeth put forward) convinced the Examiner to remove his obviousness-based rejection.

In addition, Wyeth noted that the asserted molar ratios disclosed in claims 1 and 12 roughly correlate to the tables set forth in '828 patent's specification. (D.I. 125 at 108–09 (citing '828 patent, col. 14:1–34)) These tables, in turn, purport to demonstrate the manner in which the claimed compositions simultaneously stabilized the rate of oxidation and epimerization in tigecycline. Sandoz does not dispute the accuracy of the stabilization data in the '828 patent

specification, and offers no evidence to contradict the purported correlation between these data and the claimed molar ratios.

In the absence of any evidence from an expert or person of skill in the art, and given the conflicting evidence cited by Wyeth, Sandoz's bare argument does not rise to the level of clear and convincing evidence. *See, e.g.*, *LP Matthews LLC v. Bath & Body Works, Inc.*, 458 F. Supp. 2d 198, 208 (D. Del. 2006) (rejecting a motion for summary judgment where "despite all the attorney argument of record, the record [was] neither clear nor convincing" as to whether there were distinctions between different chemical cleaning agents).

Sandoz next argues that the '183 patent "discloses much, if not all, of the claimed [molar] range," in claims 1 and 12 of the '828 patent. (D.I. 97 at 9) In essence, Sandoz's claim is that the '183 specification refers to particular weighted percentages of the active ingredient (spanning anywhere from 5% to 90% of that ingredient), which is to be combined with a carrier making up the remaining percentage of the total formulation. (*Id.*) Therefore, Sandoz argues that: (1) because the '183 patent discloses a broadly defined mixture of a compound (which could be tigecycline) and a carrier (which could be lactose); and (2) because claims 1 and 12 of the '828 patent disclose a more specific mixture of tigecycline and lactose that fall within those expansive parameters; then (3) the claims-at-issue in the '828 patent are not patentable.[11]

The problem with this argument is that it again implicates the genus-species distinction discussed above. In other words, the '183 patent discloses the unsurprising concept that the

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[11] Wyeth disputes whether it is even appropriate to consider the specification of the '183 patent in this regard, asserting that this would constitute an "improper use of hindsight knowledge'" (D.I. 108 at 9 (internal citations and quotation marks omitted)) The Court need not resolve this question because, as discussed herein, even to the extent this evidence is considered, it does not satisfy Sandoz's clear and convincing burden of proof.

thousands of claimed compositions it recites can also vary by the percentage of their constituent elements. This unremarkable fact does not demonstrate how the precise molar ranges disclosed in the '828 patent are, or are not, patentably distinct from the broader universe of ranges contemplated by the '183 patent. While Sandoz may ultimately present evidence (from, for instance, a third-party expert or a party-witness) demonstrating that the subset of molar ratios claimed in the '828 patent are obvious, Sandoz has marshaled no such evidence at this stage.

The same is true for the "acid"-related limitations (requiring hydrochloric or gentisic acid to produce acidic pH) of the '828 patent. Claims 1 and 12 of the '828 patent require the claimed composition to have a pH of between "about 3.0 and about 7.0," and that either hydrochloric or gentisic acid be used in the composition to achieve such an acidic pH. Sandoz again simply repeats the attorney argument that "these pH ranges have no apparent significance." (D.I. 97 at 10) Sandoz also makes much of the fact that claim 3 of the '183 patent encompasses hydrochloric salts of tetracycline derivatives, asserting that in solution, hydrochloric salt becomes hydrochloric acid. (*Id.* at 11) It then argues that using "hydrochloric acid to reduce the pH of the composition would have been *prima facie* obvious over the admitted prior art and is specifically encompassed by claim 97 of the '183 patent." (*Id.*)

Yet Sandoz provides no real evidence—let alone clear and convincing evidence—that the particular combination of tetracycline derivative, acid, and carrier (in the required proportions) would have been an obvious step from the vast universe of theoretical possibilities claimed in the '183 patent. Indeed, neither claim 97 (nor claim 1, from which claim 97 depends) make any mention of an acidic component of the claimed composition, and the '183 patent never refers to the desirability (or even possibility) of adjusting the pH of the claimed compounds in solution to

achieve greater stability. (D.I. 109, ex. E at 100)

Sandoz tries to fill this gap by again focusing on the prosecution history of the '828 patent.[12] It contends that during prosecution, the '828 "applicants admitted that oxidation of tigecycline at basic pH was a well-known phenomenon in the prior art and that reducing the pH would mitigate the problem."[13] (D.I. 97 at 10) Yet, Sandoz need not look to the prosecution history for evidence of this proposition; the '828 patent itself notes this problem. ('828 patent, col. 2:27–29) However, as Wyeth highlights in its opposition brief, that is only half the story. (D.I. 108 at 10) When tigecycline is placed in an acidic solution, that does in fact reduce oxidation—but it simultaneously creates the separate problem of epimerization, where tigecycline's typical antibacterial activity is reduced as it is converted into a different isometric form. ('828 patent, col. 2:44–50; 3:16–21) It is this more nuanced problem that the '828 patent was meant to address, and Sandoz points to no evidence that claim 97 of the '183 patent foreshadowed Wyeth's later-proffered solution to that problem.

For these reasons, Sandoz has not put forth clear and convincing evidence that this

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[12] If anything, the prosecution history of the '828 patent supports the Court's conclusion that Sandoz has failed to meet its burden of proof at this stage. Claim 97 of the '183 patent was also before the PTO during prosecution (as part of the '903 patent, which was later reissued as the '183 patent). Thus, the Examiner could have rejected the claims of the '828 patent on the precise grounds that Sandoz urges the Court to embrace here. However, not only did the Examiner fail to reject the '828 patent claims on that basis, but the Examiner affirmatively determined that of the art cited (including claim 97), a different reference (Testa) was the "closest" prior art to the claimed '828 patent. (D.I. 98, ex. 4 at SDZ(14)0227635)

[13] Wyeth repeatedly contends that "[t]he applicants did not contest the Examiner's conclusion, effectively admitting the *prima facie* obviousness of the pending claims." (D.I. 97 at 3; *see also* D.I. 125 at 114) As noted above, the Applicant never admitted that a *prima facie* case of obviousness had been made, and instead offered evidence of unexpected results only assuming "*arguendo* [that] the combination of tigecycline and a suitable carbohydrate is *prima facie* obvious over Testa." (D.I. 98, ex. 4 at SDZ(14)0227206)

particular combination—with the particular pH range claimed in the '828 patent—would have been obvious to a skilled person in the art, in light of the '183 patent claims-at-issue.

3. Evidence of Unexpected Results

Although it is not its burden to bear, Wyeth has also identified evidence demonstrating that the particular combination of lactose, tigecycline, and acid claimed in the '828 patent was hardly a self-evident choice for a pharmaceutical composition, in light of the teachings of the '183 patent (or any other reference). For instance, Wyeth cites the testimony of Dr. Mahdi Fawzi, the first-named inventor of the '828 patent. (D.I. 108 at 13–14) When confronting the problem of how to stabilize tigecycline, Dr. Fawzi testified that he tried antioxidants, other acids, and chelating agents first, as the more obvious choices for stabilization, before trying "unconventional excipients" like lactose. (D.I. 109, ex. F at 29–31) Wyeth also cites to the previously-referenced laboratory results that it provided to the Examiner, purportedly documenting the "unexpected results" obtained by Wyeth's researchers when using this "unconventional excipient" in combination with tigecycline and certain acids. (D.I. 108 at 16)

Drawing all reasonable inferences in Wyeth's favor, as the Court must at this stage, Wyeth's evidence suggests that there is unexpected antibacterial synergy that comes from the particular combination of elements claimed in the '828 patent. According to Wyeth, it is not enough for a generic tetracycline derivative to be combined with a pharmaceutical carrier; it takes a particular combination of elements to achieve the new and unexpected results disclosed in the '828 patent (*i.e.*, a compound that has increased antibacterial properties due to a decrease in degradative and inactive forms of tigecycline). As such, the evidence indicates that the claims of the '828 patent are more than just "[t]he combination of familiar elements according to known

methods . . . [that] does no more than yield predictable results." *KSR*, 550 U.S. at 416; *accord Callaway Golf Co. v. Acushnet Co.*, 576 F.3d 1331, 1339–40 (Fed. Cir. 2009) (affirming District of Delaware jury's verdict of non-obviousness where there was evidence that golf ball composition "'produce[d] a synergy and an important new result'") (citation omitted).

Sandoz may ultimately be able to demonstrate, through cross-examination or other evidence, that the allegedly "unconventional" choice of lactose (in combination with acidic conditions) was merely the application of "conventional" and obvious principles. But it has not done so at this juncture. Instead, Sandoz has relied solely on the idea that "unexpected results cannot overcome the invalidity of the asserted claims of the '828 patent." (D.I. 97 at 13) Yet as discussed above, there is no precedent that forecloses consideration of unexpected results (or any other type of secondary considerations) in the nonstatutory double-patenting analysis.

In its reply brief, Sandoz characterizes Wyeth's argument relating to the unexpected properties of the '828 claimed composition as "rest[ing] primarily on reading *unclaimed* features into the claims of the '828 patent." (D.I. 118 at 1 (emphasis in original)) In particular, Sandoz contends that Wyeth asks the Court to "import[] unclaimed attributes related to stabilizing tigecycline against epimerization and oxidation . . . into the claims of the '828 patent." (*Id.* at 7) However, the Court need not expressly construe the claims of the '828 patent to require that the claimed formulation be "stable" or "unexpectedly stable," in order to consider whether evidence of unexpected stability objectively indicates that the claimed combination was non-obvious. Evidence of unexpected compositional stability can be considered regardless of whether there is an explicit claim limitation referring to such stability. *See, e.g.*, *Genetics Institute, LLC v. Novartis Vaccines & Diagnostics, Inc.*, 655 F.3d 1291, 1302–09 (Fed. Cir. 2011) (recognizing

evidence of secondary considerations of unexpected protein stability in obviousness analysis where composition claims-at-issue did not explicitly refer to such stability); *accord Unigene Labs., Inc. v. Apotex Inc.*, 655 F.3d 1352, 1362–63 (Fed. Cir. 2011). As the above discussion indicates, the Court has not construed any of the claim limitations-at-issue to incorporate unclaimed language from the specification.

IV. CONCLUSION

For the foregoing reasons, the differences between claim 97 and the claims-at-issue of the '828 patent are sufficient to create a genuine issue of material fact as to the validity of the '828 patent, thus precluding the grant of summary judgment. Sandoz has not demonstrated by clear and convincing evidence that the '828 patent impermissibly and unjustifiably extends the term of the '183 patent. Therefore, I recommend that the Court DENY Sandoz's motion.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the district court. *See Henderson v. Carlson*, 812 F.2d 874, 878–79 (3d Cir. 1987); *Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006).

The parties are directed to the Court's Standing Order In Non-Pro Se Matters For Objections Filed Under Fed. R. Civ. P. 72, dated November 16, 2009, a copy of which is available on the District Court's website, located at http://www.ded.uscourts.gov.

Because this Report & Recommendation may contain confidential information, it has been released under seal, pending review by the parties to allow them to submit a single jointly

proposed redacted version of the Report & Recommendation. Such redacted version shall be submitted no later than **April 12, 2012**, for review by the Court. The Court will subsequently issue a publicly-available version of its Report & Recommendation.

Dated: April 5, 2012

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE