IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANTARUS, INC., and THE CURATORS OF THE UNIVERSITY OF MISSOURI, Plaintiffs, v. PAR PHARMACEUTICAL, INC., Defendant.	)	C.A. No. 07-551-GMS

MEMORANDUM

I. INTRODUCTION

In this consolidated patent infringement action, plaintiffs Santarus, Inc. ("Santarus") and the Curators of the University of Missouri (the "University") (collectively, "the plaintiffs") allege that defendant Par Pharmaceutical, Inc.'s ("Par") proposed generic pharmaceutical product infringes the asserted claims of the patents-in-suit. (D.I. 1.) The court held a five-day bench trial in this matter on July 13 through July 17, 2009. (D.I. 168-172.) After the fourth day of trial, the court ruled that Par's proposed products infringed the asserted claims of the patents-in-suit. (See D.I. 171 at 936-941.) Presently before the court are the parties' post-trial proposed findings of fact and conclusions of law concerning the validity and enforceability of the patents-in-suit. (D.I. 173-174.)

Pursuant to Fed. R. Civ. P. 52(a), and after having considered the entire record in this case and the applicable law, the court concludes that: (A) the patents-in-suit are invalid due to obviousness; (B) the patents-in-suit are not unenforceable due to inequitable conduct; and (C) an award for attorneys' fees and costs is not warranted in this case. The court further concludes that

certain asserted claims of the patents-in-suit are invalid because they lack a written description, or are not entitled to the filing date of earlier applications because the disclosures in the prior applications do not meet the written description requirement. These findings of fact and conclusions of law are set forth in further detail below.

II. FINDINGS OF FACT

A. The Parties

1. Plaintiff Santarus, Inc. is a corporation organized and existing under the laws of Delaware, and has its principal place of business at 3721 Valley Centre Drive, San Diego, CA 92130. (D.I. 152, Tab 1 at ¶ 1.)

2. Plaintiff The Curators of the University of Missouri is the governing body of the University of Missouri, which is a public corporation and body politic having a principal place of business at 321 University Hall, Columbia, Missouri 65211. (Id. at ¶ 2.)

3. Defendant Par Pharmaceutical, Inc. ("Par") is a corporation organized and existing under the laws of Delaware, having a principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677. (Id. at ¶ 3.)

B. The Patents In Suit

i. *Prosecution History*

4. On January 4, 1996, Dr. Phillips filed U.S. Provisional Application No. 60/009,608 (hereinafter "the Provisional Application"). (See JTX-31.)

5. The Provisional Application describes a pharmaceutical composition "referred to as simplified omeprazole solution (SOS)." (Id. at 8.)

6. On July 15, 1996, Dr. Phillips filed U.S. patent application Ser. No. 08/680,376 (hereinafter, the "'737 Application"), which issued as U.S. Patent No. 5,840,737 (hereinafter, the "'737 patent") on November 24, 1998. (See JTX-33.)

7. On October 30, 1998, Dr. Phillips filed U.S. patent application Ser. No. 09/183,422 (hereinafter, the "'422 Application"). (See JTX-32.)

8. The Provisional Application, the '737 Application, and the '422 Application (collectively, "the priority applications") share the following features:

- Each application describes the invention as a "pharmaceutical composition" (JTX-31 at 8; JTX-32 at 16; JTX-33 at 21.)
- The "DETAILED DESCRIPTION OF THE INVENTION" section of each application states that the pharmaceutical composition is prepared by mixing:
    - Omeprazole or other substituted proton pump inhibitors; and
    - A bicarbonate salt of a Group IA metal

(JTX-31 at 8; JTX-32 at 17; JTX-33 at 21.) The preferred bicarbonate salt is sodium bicarbonate (JTX-31 at 9; JTX-32 at 17; JTX-33 at 22.)

ii. The Patents

9. On December 3, 2002, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 6,489,346 (the "'346 Patent"), entitled "Substituted Benzimidazole Dosage Forms and Method of Using Same" to the University, the named assignee of the named inventor Jeffrey O. Phillips ("Dr. Philips"). (D.I. 152, Tab 1 at ¶ 4.)

10. The face of the '346 Patent states that "[t]his application is a continuation-in-part of U.S. patent application Ser. No. 09/183,422 filed on Oct. 30, 1998, now abandoned, which is a

continuation-in-part of U.S. patent application Ser. No. 08/680,376 filed on Jul. 15, 1996, now U.S. Pat. No. 5,840,737, which claims priority to U.S. Provisional Application Serial No. 60/009,608 filed on Jan. 4, 1996. This application claims priority to all such previous applications, and such applications are hereby incorporated herein by reference." The face of the '346 Patent states that it is subject to a terminal disclaimer. (Id. at ¶ 5.)

11. On November 11, 2003, the PTO issued U.S. Patent No. 6,645,988 (the "'988 Patent"), entitled "Substituted Benzimidazole Dosage Forms and Method of Using Same" to the University, the named assignee of the named inventor Dr. Phillips. (Id. at ¶ 6.)

12. The face of the '988 Patent states that "[t]his application is a continuation-in-part of U.S. patent application Ser. No. 09/481,207, filed on Jan. 11, 2000, now U.S. Pat. No. 6,489,346 which is a continuation of U.S. patent application Ser. No. 09/183,422, filed Oct. 30, 1998, now abandoned, which is a continuation-in-part of U.S. patent application Ser. No. 08/680,376, filed on Jul. 15, 1996, now U.S. Pat. No. 5,840,737, which claims priority to U.S. Provisional Application Ser. No. 60/009,608 filed on Jan. 4, 1996. This application claims priority to all such previous applications, and such applications are hereby incorporated herein by reference to the extent permitted by law." The face of the '988 Patent states that it is subject to a terminal disclaimer. (Id. at ¶ 7.)

13. On March 2, 2004, the PTO issued U.S. Patent No. 6,699,885 (the "'885 Patent"), entitled "Substituted Benzimidazole Dosage Forms and Methods of Using Same" to the University, the named assignee of the named inventor Dr. Phillips. (Id. at ¶ 8.)

14. The face of the '885 Patent states that "[t]his application is a continuation-in-part of U.S. patent application Ser. No. 09/901,942, filed on Jul. 9, 2001, which is a continuation-in-

part of U.S. patent application Ser. No. 09/481,207, filed on Jan. 11, 2000, now U.S. Pat. No. 6,489,346, which is a continuation-in-part of U.S. patent application Ser. No. 09/183,422, filed on Oct. 30, 1998, now abandoned, which is a continuation-in-part of U.S. patent application Ser. No. 08/680,376, filed on Jul. 15, 1996, now U.S. Pat. No. 5,840,737, which claims priority to U.S. Provisional Application Serial No. 60/009,608, filed on Jan. 4, 1996. This application claims priority to all such previous applications, and such applications are hereby incorporated herein by reference." The face of the '885 Patent states that it is subject to a terminal disclaimer. (Id. at ¶ 9.)

15. On or about August 22, 2005, a third party requested that the PTO reexamine the '885 Patent. On September 18, 2007, after concluding reexamination proceedings, the PTO issued an Ex Parte Reexamination Certificate for the '885 Patent. (Id. at ¶ 10.)

16. On August 24, 2004, the PTO issued U.S. Patent No. 6,780,882 (the "'882 Patent"), entitled "Substituted Benzimidazole Dosage Forms and Methods of Using Same" to the University, the named assignee of the named inventor Dr. Phillips. (Id. at ¶ 11.)

17. The face of the '882 Patent states that "[t]his application is a continuation of U.S. patent application Ser. No. 09/481,207, filed on Jan. 11, 2000, now U.S. Pat. No. 6,489,346 which is a continuation of U.S. patent application Ser. No. 09/183,422, filed Oct. 30, 1998, now abandoned, which is a continuation-in-part of U.S. patent application Ser. No. 08/680,376, filed on Jul. 15, 1996, now U.S. Pat. No. 5,840,737, which claims priority to U.S. Provisional Application Ser. No. 60/009,608, filed on Jan. 4, 1996. This application claims priority to all such previous applications, and such applications are hereby incorporated herein by reference." The face of the '882 Patent states that it is subject to a terminal disclaimer. (Id. at ¶ 12.)

18. On July 15, 2008, the PTO issued U.S. Patent No. 7,399,772 (the "'772 Patent"), entitled "Substituted Benzimidazole Dosage Forms and Method of Using Same" to the University, the named assignee of the named inventor Dr. Phillips. (Id. at ¶ 13.)

19. The face of the '772 Patent states that "[t]his application is a continuation of U.S. patent application Ser. No. 10/068,437 filed Feb. 5, 2002 now abandoned, which is a continuation of U.S. patent application Ser. No. 09/481,207 filed Jan. 11, 2000, now U.S. Pat. No. 6,489,346, which is a continuation-in-part of U.S. patent application Ser. No. 09/183,422 filed Oct. 30, 1998, now abandoned, which is a continuation-in-part of U.S. patent application Ser. No. 08/680,376, filed Jul. 15, 1996, now U.S. Pat. No. 5,840,737, which claims priority to U.S. Provisional Patent Application No. 60/009,608 filed Jan. 4, 1996. This application claims priority to all such previous applications, and such applications are hereby incorporated herein by reference." (Id. at ¶ 14.)

20. On November 24, 1998, the PTO issued United States Patent No. 5,840,737 ("the'737 Patent"), entitled "Omeprazole Solution and Method for Using Same" to the University, the named assignee of the named inventor Dr. Phillips. (Id. at ¶ 15.)

21. The face of the '737 Patent states that "[t]his application is a continuation-in-part of U.S. Prov. App. Ser. No. 60/009,608 filed on Jan. 4, 1996." (Id. at ¶ 16.)

22. Santarus holds an approved New Drug Application ("NDA") for NDA Nos. 21-706 (40mg Zegerid® Powder for Oral Suspension), 21-636 (20mg Zegerid® Powder for Oral Suspension), and 21-849 (20mg & 40mg Zegerid® Capsules). (Id. at ¶ 17.)

23. Zegerid® is sold by Santarus under an exclusive license to the patents-in-suit from the University of Missouri. (See JTX-8.)

24. Zegerid® is a non-enteric-coated drug containing omeprazole and sodium bicarbonate. (D.I. 152, Tab 1 at ¶ 18.)

25. The '885, '346, '988 and '772 Patents are listed in the United States Food and Drug Administration's (the "FDA") Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, in connection with Santarus' Zegerid® (omeprazole/sodium bicarbonate) Capsules 20 mg and 40 mg products. (Id.)

26. The '737, '885, '346, '988, '882 and '772 Patents are listed in the FDA's Orange Book in connection with Santarus' Zegerid® (omeprazole/sodium bicarbonate) Powder for Oral Suspension 20 mg and 40 mg products. (Id. at ¶ 19.)

27. None of the patents-in-suit expire before July 16, 2016. (Id. at ¶ 20.)

28. Jeffery Owen Phillips is named as the inventor on each of the patents-in-suit. (Id. at ¶ 34.)

C. The Accused Products

29. Par has submitted Abbreviated New Drug Application No. 78-966 (the "Capsule ANDA") to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The Capsule ANDA seeks approval to engage in the commercial manufacture, use and/or sale of generic omeprazole and sodium bicarbonate capsules. Zegerid® was named in the Capsule ANDA as the reference listed drug. (Id. at ¶ 21.)

30. Par's proposed products in the Capsule ANDA have 20 mg omeprazole/1100 mg of sodium bicarbonate or 40 mg omeprazole/1100 mg sodium bicarbonate. (Id. at ¶ 22.)

31. Par has requested the FDA to approve the Capsule ANDA before the July 16, 2016 expiration of the '885, '346, '988, and '772 Patents. (Id. at ¶ 23.)

32. Par has submitted Abbreviated New Drug Application No. 79-182 (the "Powder ANDA") to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The Powder ANDA seeks approval to engage in the commercial manufacture, use and/or sale of generic omeprazole and sodium bicarbonate powder for oral suspension. Zegerid® was named in the Powder ANDA as the reference listed drug. (Id. at ¶ 24.)

33. Par's proposed products in the Powder ANDA have 20 mg omeprazole/1680 mg of sodium bicarbonate or 40 mg omeprazole/1680 mg sodium bicarbonate. (Id. at ¶ 25.)

34. Par has requested the FDA to approve the Powder ANDA before the July 16, 2016 expiration of the '885, '346, '988, '882, and '772 Patents. (Id. at ¶ 26.)

35. Plaintiffs received a letter dated August 2, 2007, from Par notifying them that Par's Capsule ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "First Capsule Paragraph IV Certification") that, in Par's opinion, the '885, '346, and '988 Patents are invalid, unenforceable or will not be infringed by the commercial manufacture, use or sale of the Proposed Capsules. (Id. at ¶ 27.)

36. Plaintiffs alleged that the filing of Par's Capsule and Powder ANDAs constituted patent infringement pursuant to 35 U.S.C. § 271(e)(2) and that the commercial manufacture, use, sale, offer for sale and/or importation of Par's proposed Capsule and Powder ANDA products would infringe one or more claims of the '885, '346, '988, '882, and/or '772 Patents. (Id. at ¶ 28.)

37. Plaintiffs received a letter dated November 13, 2007, from Par notifying them that Par's Powder ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in Par's opinion, the '885, '346, '988, and '882 Patents are invalid, unenforceable or will not be

infringed by the commercial manufacture, use or sale of the Proposed 20 mg Powder. (Id. at ¶ 30.)

38. Plaintiffs received a letter dated December 6, 2007, from Par notifying them that Par's Powder ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in Par's opinion, the '885, '346, '988, and '882 Patents are invalid, unenforceable or will not be infringed by the commercial manufacture, use or sale of the Proposed 20 mg and 40 mg Powder. (Id. at ¶ 31.)

39. Plaintiffs received a letter dated September 30, 2008, from Par notifying them that the Capsule and Powder ANDAs include a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "'772 Patent Paragraph IV Certification") that, in Par's opinion, the '772 Patent is invalid, unenforceable or will not be infringed by the manufacture, use or sale of the Proposed 20 mg and 40 mg Powder and Capsule Products. (Id. at ¶ 33.)

D. Procedural History

40. Plaintiffs filed a first complaint for patent infringement against Par on September 13, 2007, and a first amended complaint against Par on October 2, 2007. (Id. at ¶ 29.)

41. In a separately-captioned action, C.A. No. 07-827, Plaintiffs filed a second complaint for patent infringement against Par on December 20, 2007. The cases were consolidated on March 4, 2008. (Id. at ¶ 32; *see also* Minute Entry for March 4, 2008.)

42. Plaintiffs filed a second amended complaint for patent infringement against Par in the consolidated action on October 17, 2008. (D.I. 152, Tab 1 at ¶ 34.)

43. At trial, the plaintiffs asserted the following claims were infringed by Par's Capsule and Powder ANDA products:

- '346 Patent: Claims 26, 37, 38, 49, 50, 58, 59, 60, 66, 68, 80, 81, 82
- '772 Patent: Claims 1, 4, 5, 8, 10, 12, 14, 15, 20, 21
- '882 Patent: Claims 11, 12, 15, 27
- '885 Patent: Claims 2, 9, 11, 15, 16, 17, 18, 41
- '988 Patent: Claim 29

(*See* D.I. 174 at viii (hereinafter the "asserted claims").)

44. After the fourth day of trial, the court held that the Capsule and Powder ANDA products infringed the asserted claims of the patents-in-suit. (*See* D.I. 171 at 936-941.)

III. CONCLUSIONS OF LAW

The court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331, 1338 and 2201. Venue is proper in this court under 28 U.S.C. §§ 1391 and 1400(b). After having considered the entire record in this case, the substantial evidence in the record, the parties' post-trial submissions, and the applicable law, the court concludes that: (A) the patents-in-suit are invalid due to obviousness; (B) the patents-in-suit are not unenforceable due to inequitable conduct; and (C) an award for attorneys' fees and costs is not warranted in this case. The court further concludes that certain asserted claims of the patents-in-suit are invalid because they lack a written description, or are not entitled to the filing date of earlier applications because the disclosures in prior applications do not meet the written description requirement. The court's reasoning follows.

A. Written Description and Priority

Par argues that a number of the asserted claims of the patents-in-suit are invalid because they do not meet the written description requirement. (See D.I. 173 at 24-27.) Par further asserts that these claims and several other asserted claims are not entitled to the priority date of earlier-filed applications because the written descriptions of those applications do not support the

asserted claims. (Id. at 2-7.) To meet the written description requirement, the applicant must "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). One skilled in the art, reading the disclosure, "must immediately discern the limitation at issue in the claims." *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000). Thus, support in the written description must be based on what actually is disclosed, and not on an obvious variant of what is disclosed. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1571 (Fed. Cir. 1997). The party challenging the sufficiency of a written description must establish by clear and convincing evidence that the claim is invalid or not entitled to an asserted filing date. *See Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1329-30 (Fed. Cir. 2008).[1]

Table 1 (see following page) summarizes the court's findings as to the priority dates of the asserted claims of the patents-in-suit.

[1] In its post-trial briefing, Par states that where the written descriptions of the priority applications do not support the disputed claim limitations, "the earliest effective priority date for the asserted claims of the patents-in-suit is January 11, 2000, the filing date of the '346 patent." (D.I. 173 at 7.) Consequently, the court will use January 11, 2000 as the effective priority date for asserted claims that are not supported by any of the priority applications.

Table 1[2]

Asserted claims entitled to filing date of January 4, 1996 (Provisional Application)	All asserted claims of the patents-in-suit not listed below
Asserted claims entitled to filing date of July 15, 1996 ('737 Application)	'346 Patent • Claim 81 (see § III.A.iii) • Claims 37, 38, 49 (see § III.A.iv) • Claim 50 (see §§ III.A.iii & III.A.iv) '772 Patent: Claim 2 (see § III.A.iii) '988 Patent: Claim 29 (see § III.A.iii)
Asserted claims entitled to filing date of January 11, 2000 ('346 Application)	'346 Patent • Claims 37, 38, 66, 68, 80, 81, 82 (see § III.A.ii) • Claim 26 (see § III.A.v) • Claims 49, 50 (see §§ III.A.ii & III.A.v) '772 Patent: All claims (see § III.A.vi) '885 Patent: All claims (see § III.A.vii) '988 Patent: Claim 29 (see §§ III.A.iii and III.A.v)

i. Types of Proton Pump Inhibitors

Claims 24 and 57 of the '346 Patent and claim 29 of the '988 Patent each claim a group of seven proton pump inhibitors ("PPIs"): omeprazole, lansoprazole, rabeprazole, esomeprazole, pantoprazole, pariprazole, and leminoprazole. Par asserts that the priority applications do not support this limitation because the applications only disclose a subset of the claimed group. The court disagrees. The Provisional Application states that the pharmaceutical composition "can include . . . omeprazole *or other substituted benzimidazoles* such as lansoprazole, and derivatives thereof . . . ." (Prov. App. at 8.) Similarly, the '737 and '422 applications states that the composition "can include . . . omeprazole or other substituted benzimidazoles which are proton pump inhibitors such as lansoprazole, pantoprazole, rabeprazole, dontroprazole, perprazole, habeprazole, and derivatives thereof . . . ." ('422 App. at 16.) The court finds that a person of

[2] Where a claim is listed in multiple rows in the table, the claim is entitled only to the latest filing date for which it is listed.

ordinary skill in the art would have understood from these disclosures that the inventor possessed the claimed PPIs.

ii. Types of Buffers

Par also contends that claims 24 and 57 of the '346 Patent cannot claim the filing dates of the priority applications because they claim types of buffers – specifically magnesium and calcium salts – that are not disclosed in the priority applications. (See Tr. 643-44; D.I.173 at 3.) The section of Santarus' post-trial brief discussing this issue is both devoid of citations to the transcript and unavailing. (See D.I. 174 at 25.) Santarus makes no argument that any portion of the provisional or '737 applications supports the claiming of magnesium or calcium salts. With respect to the '422 Application, Santarus asserts that two of the original claims in the '422 Application disclose calcium salts. However, the '422 Application claims cited by Santarus refer to "calcium," not calcium salts, and Santarus presented no evidence that this reference to "calcium" refers to calcium salts rather than calcium ions. Furthermore, the claims cited recite calcium as an additive that acts not as a buffer, but as a chelating agent; there is no indication that this disclosure of calcium was meant to encompass the use of calcium salts as buffering agents in place of sodium bicarbonate, and Santarus certainly presented no evidence that the claim should be so construed. Moreover, the written description requirement cannot be satisfied by making reference to *claims* in the prior application, but rather must be satisfied by disclosure in the *specification* of the prior application. *See, e.g., TurboCare Div. of Demag Delaval Turbomachinery Corp. v. General Electric Co.*, 264 F.3d 1111, 1119 (Fed. Cir. 2001) "When the applicant adds a claim or otherwise amends his specification after the original filing date . . . the new claims or other added material must find support in the original *specification.*") (emphasis

added).

Santarus' other post-trial arguments with respect to the disclosure of calcium and magnesium salts in the '422 Application are also unsupported by transcript citations and, in any case, unavailing. The fact that the '422 Application indicates that the *prior art* included "salts of carbonic acid, which include carbonates" (see D.I. 174 at 25, citing '422 App. at 9:1-4) is not sufficient to indicate that the *inventor* contemplated or possessed a composition wherein non-Group IA salts were substituted. The final sentence of Santarus' argument on this issue – that "given the small number of therapeutically relevant carbonate buffering agents, an artisan would understand that the inventor disclosed the claimed salts" – is not supported by citation to any source, much less evidence in the record of this case. In short, Santarus points to no source, and certainly no testimony, indicating that calcium or magnesium salts are properly disclosed in any of the priority applications. Consequently, claims 24 and 57 of the '346 Patent cannot claim the filing date of the priority applications. Since asserted dependent claims 37, 38, 49, 50, 66, 68, and 80-82 do not further limit this claim element, they also are not entitled to priority.

iii. Types of Solid Dosage Forms

Par also challenges whether the written descriptions in the priority applications support the types of solid dosage forms claimed in claims 50 and 81 of the '346 Patent, claim 29 of the '988 Patent, and claim 2 of the '772 Patent. Those claims read, in pertinent part, as follows:

- '346 Patent claims 50 and 81 are dependent on claims 24 and 57, respectively, of the '346 Patent. Claims 24 and 57 both include a "solid pharmaceutical composition in a dosage form that is not enteric coated." Claims 50 and 81 then specify the claimed dosage forms as "selected from the group consisting of a

tablet, powder, suspension tablet, chewable tablet, capsule, effervescent powder, effervescent tablet, pellets, and granules."

- '988 Patent claim 29 is an independent claim that includes a "non-enteric coated solid oral pharmaceutical dosage form." The possible dosage forms are specified as "a powder, tablet, suspension tablet, chewable tablet, capsule, two-part tablet, two-part capsule, effervescent powder, pellet, granule or effervescent tablet."
- '772 Patent claim 2 is dependent on claim 1 of the '772 Patent. Claim 1 includes "a solid pharmaceutical composition." Claim 2 specifies the composition as "a solid dosage form selected from the group consisting of a tablet, a chewable tablet, a capsule, a troche, and a lozenge."
- '882 Patent claim 1 is an independent claim that includes a "powder for suspension."

In its claim construction order, the court construed the terms "solid pharmaceutical composition in a dosage form" and "solid oral pharmaceutical dosage form" identically. (See D.I. 82.) Under the court's construction, both terms refer to "a solid dosage form that is pharmaceutically acceptable for storage, shipping, and administration, including a powder that can be combined with an aqueous medium then orally administered." (Id.)

The invention as described and claimed in the Provisional Application is an aqueous solution. The only reference to solid dosage forms in the Provisional Application is that "formulations of the present invention can be manufactured in a concentrated form, such as an effervescent tablet, so that upon reaction with water, the aqueous form of the solution would be produced for oral or enteral administration." (Prov. App. at 12.) All other descriptions,

examples, and claims in the Provisional Application refer exclusively to the aqueous solution. In other words, there is no indication in the Provisional Application that the inventor possessed or was even aware of the ability to convert the omeprazole/bicarbonate solution into the disputed solid dosage forms. Indeed, the background section of the application indicates that a major drawback of then-available formulation of omeprazole as compared to the claimed invention was that some patients were unable to swallow solid dosage forms such as capsules and tablets:

> [I]n its current form, (capsules containing an enteric-coated granule formulation of omeprazole), omeprazole can be difficult or impossible to administer to patients . . . who are unwilling or unable to swallow tablets or capsules. Therefore, it would be desirable to formulate an omeprazole solution which can be enterally delivered to a patient thereby providing the benefits of omeprazole without the drawbacks of the current capsule dose form.

(Prov. App. at 4.) The invention's ability to deliver omeprazole enterally as well as orally is emphasized throughout the background and description sections of the Provisional Application as an advantage of the claimed invention over the prior art. (See id. at 5-6, 10, 11, 12.) In all examples provided in the application, the solution was administered through a nasogastric tube to most or all patients. (See id. at 14-30.) The Provisional Application's references to solid dosage forms besides effervescent tablets were disparaging. The court finds that a person of ordinary skill in the art reading the Provisional Application would not believe that the inventor possessed – or even contemplated – the composition in a capsule, non-effervescent tablet, granule, chewable tablet, pellet, troche, or lozenge form, as listed in the disputed claims from the '346, '988, and '772 Patents. Since support for these dosage forms does not appear in the Provisional Application, claims 50 and 81 of the '346 Patent, claim 29 of the '988 Patent, and claim 2 of the '772 Patent cannot claim priority to the Provisional Application.

While the '737 and '422 Applications also include statements emphasizing the importance of enteral administration capability, those applications include additional disclosures pertaining to solid forms of the composition. Both the '737 and '422 Applications contain a paragraph stating that it is possible to form the PPI/bicarbonate solution "into a tablet, capsules, or granules, by methods well known to those skilled in the art." ('422 App. at 23-24; '737 App. at 28-29.) The disclosure of possible solid formulations in the '422 Application is even more expansive, stating that the invention "can include an aqueous solution/suspension, *or dry formulation*" ('422 App. at 16 (emphasis added)) and that "the composition includes dry formulations." (Id. at 17.) Similarly, the summary of the '422 Application makes reference to "a dry formulation of" the composition, whereas both the Provisional Application and the '737 Application describe only an "aqueous solution." (*Compare* '422 App. at 15 *with* Prov. App. at 6-7 and '737 App. at 19.) The '422 Application's written description of "dry" and "solid" formulations of the invention would indicate to a person of ordinary skill in the art that the inventor contemplated and possessed the ability to make a wide variety of solid dosage forms. The "other suitable solid dosage form" language further indicates that the inventor possessed the ability to make solid dosage forms beyond those specifically listed. Given these statements, the court finds that a person of ordinary skill in the art would have known from the description in the '422 Application that the inventor possessed the solid dosage forms listed in the disputed claims of the '346, '988, and '772 Patents.

The '737 Application is intermediate with respect to the other priority applications in its disclosures of solid dosage forms. In addition to the effervescent tablets disclosed in the Provisional Application, the '737 Application discloses that it is possible to form the

omeprazole/bicarbonate solution into some non-effervescent solid dosage forms, specifically tablets, capsules, or granules. ('737 App. at 28-29.) Unlike in the '422 Application, however, the '737 Application's written description does not include an open-ended statement stating that the composition could be made into solid dosage forms other than those explicitly described. The '737 Application also does not include the references to dry formulations that appear in the summary and at the beginning of the description in the '422 Application. Furthermore, the '737 Application includes the statements in the background section of the Provisional Application describing the disadvantages of orally administering tablets, capsules, and granules. ('737 App. at 10.)

Nonetheless, the court finds that Par has not shown by clear and convincing evidence that the written description of the '737 Application is insufficient to support the dosage forms recited in the disputed claims of the patents-in-suit. The '737 Application's disclosure that the composition "can be formed into a tablet, capsules, or granules" is sufficient to convey with reasonable clarity to those skilled in the art that, as of the filing date of the '737 Application, Dr. Phillips was in possession of solid dosage forms. *Vas-Cath*, 935 F.2d at 1563-64. This specific disclosure more than counterbalances the concerns expressed in the background section regarding the oral administration of solid dosage forms, and a person of ordinary skill in the art would conclude that Dr. Phillips possessed the ability to form the composition into solid dosage beyond those specifically listed. Under these circumstances, the court finds that a person of ordinary skill in the art would know from the disclosures in the '737 Application that the inventor was in possession of the solid dosage forms recited in the disputed claims.

iv. Amount of Buffer

Par also asserts that several asserted claims of the patents-in-suit include limitations regarding the amount of buffer in the composition that are not supported by the priority applications. (See D.I. 173 at 4-5.) Par further asserts that the originally-filed application for the '346 Patent does not support these limitations, thus rendering the claims invalid for lack of written description. (See D.I. 173 at 24-25.) Specifically, Par argues that the following claim limitations are not disclosed:

- '346 Patent
  - Claim 24: "a buffering agent in an amount of approximately 1.0 mEq to approximately 150 mEq"
  - Claim 57: "a buffering agent . . . in an amount more than about 40 times the amount of" the PPI
- '772 Patent
  - Claim 1: "sodium bicarbonate in an amount of 0.2 mEq to 5 mEq per 2mg omeprazole"
- '882 Patent
  - Claim 1: "buffering agents in an amount of about 0.1 mEq to about 2.5 mEq per mg of" the PPI
- '885 Patent
  - Claim 1: "buffering agents in an amount of about 0.1 mEq to about 2.5 mEq per mg of" the PPI and "a total buffering agent to total [PPI] weight ratio of greater than 20:1"
  - Claim 26: "buffering agents in an amount of about 0.1 mEq to about 2.5 mEq per mg of" the PPI
- '988 Patent
  - Claim 1: "at least one Primary Essential Buffer and at least one optional Secondary Essential Buffer in a total amount of approximately 0.1 mEq to approximately 2.5 mEq per mg of" PPI

Each of the priority applications and the '346 Patent disclose that "[t]he concentration of the bicarbonate salt of the Group 1A metal in the composition generally ranges from approximately 5.0% to approximately 60.0%." (Prov. App. at 9; '737 App. at 22; '422 App. at 17; '346 Patent col. 14:18-21.) The same documents also disclose a preferred range of 7.5% to

10%, and a preferred embodiment of 8.4%. (Prov. App. at 9; '737 App. at 22; '422 App. at 17; '346 Patent col. 14:21-26.) Other portions of these documents list the amount of buffer in terms of mEq or mEq per mg of PPI rather than in percentage concentration.

It is undisputed that 1 mEq of sodium bicarbonate weighs 84mg (see, e.g., D.I. 153, Ex.12 at 177), and the court finds that a person of ordinary skill in the art would know this equivalence. Once that equivalence is established, simple arithmetic confirms that the priority applications disclose most of the buffer amount recited in the asserted claims. For instance, as noted above, the priority applications all disclose a sodium bicarbonate concentration as low as "approximately 5%." The priority applications and '346 Patent also disclose a 10 mL solution.[3] (E.g., 'Prov. App. at 19; '737 App. at 25:4; '422 App. at 20:8; '346 Patent col. 25:61-64 & col. 32:64-67.) A 5% sodium bicarbonate solution would contain 5 g of sodium bicarbonate per 100 mL of water, or 500 mg per 10 mL. Furthermore, the priority applications disclose an omeprazole concentration as high as "approximately 6 mg/ml." (Prov. App. at 8:19; '737 App. at 21:21; '422 App. at 17:12.) Thus, 10 mL of a 5% sodium bicarbonate solution with this concentration of omeprazole would contain 5.95 mEq (500 / 84) sodium bicarbonate and 60 mg of omeprazole. This, in turn, would translate to 0.099 mEq of sodium bicarbonate per mg of omeprazole – almost exactly the lower end (0.1 mEq/mg) of the claimed range in claim 1 of the

[3] The court notes that sodium bicarbonate is a solid white-colored substance in its "natural" state, and typically appears as a fine powder. (*See, e.g.*, Tr. 661-662 (witness testifying that "sodium bicarbonate occurs as a powder prior to combination with an aqueous medium").) Consequently, the amount of sodium bicarbonate typically is provided in units of mass (e.g. grams or milligrams) or amount of substance (moles or millimoles) rather than in terms of liquid volume. References to the volumes of "sodium bicarbonate solution" therefore are a reference to the volume of an aqueous solution containing sodium bicarbonate, and not a reference to the amount of sodium bicarbonate in the solution.

'882, claim 1 of the '772 Patent,[4] claims 1 and 26 of the '885 Patent, and claim 1 of the '988 Patent. Similarly, using the same 10 mL volume of solution, a 10% sodium bicarbonate concentration (Prov. App. at 9; '737 App. at 22; '422 App. at 17) and a 0.5 mg/ml concentration of omeprazole (Prov. App. at 8:19; '737 App. at 21:21; '422 App. at 17:12) would yield 2.38 mEq of buffering agent per mg of omeprazole – just below the higher end (2.5 mEq/mg) of the claimed range in those claims. The court thus finds that the priority applications support the claimed mEq/mg ranges mEq/mg in claim 1 of the '882, claim 1 of the '772 Patent, claims 1 and 26 of the '885 Patent, and claim 1 of the '988 Patent.

Claim 24 of the '346 Patent calls for "a buffering agent in an amount of approximately 1.0 mEq to approximately 150 mEq." For the upper limit, the priority applications and '346 Patent disclose a 20 mL solution (Prov. App. at 19; '737 App. at 35; '422 App. at 29; '346 Patent col. 32:64-67) with a 60% concentration of sodium bicarbonate (Prov. App. at 9; '737 App. at 22; '422 App. at 17; '346 Patent col. 14:18-21), which would yield 12000 mg – or 142 mEq – of sodium bicarbonate. The court finds that this is within the "approximately 150 mEq" upper limit specified in claim 24 of the '346 Patent. In claim 57 of the '346 Patent and claim 1 of the '885 Patent, the amount of buffer is provided in relation to the relative weight of buffer and PPI in the composition. Support for the 40:1 ratio provided in claim 57 of the '346 Patent can be found by dividing the preferred concentration of sodium bicarbonate (an 8.4% solution, which yields 84 mg/ml of sodium bicarbonate) by the 2 mg/ml standard concentration of omeprazole in the

[4] The '772 patent uses mEq per 2 mg of omeprazole rather than mEq per 1 mg of omeprazole to set the limits of buffer amount.

solution, both of which are provided in the priority applications and the '346 Patent.[5] The resulting ratio – 42:1 – is sufficient to support a limitation of "more than about" 40:1. Similarly, using the upper end of the preferred concentration of omeprazole – 4 mg/ml (Prov. App. at 8; '737 App. at 22; '422 App at 17) – yields a weight ratio of 21:1, which is sufficient to support the "ratio of greater than 20:1" limitation in claim 1 of the '885 Patent.

The only claimed buffer amount for which there does not appear to be numerical support in each of the priority applications is the lower end of the claimed range in claim 24 of the '346 Patent, which specifies a lower limit of "approximately 1.0 mEq" of buffering agent. The '737 and '422 Applications both state that "[t]he dosage range of omeprazole or other substituted benzimidazoles and derivatives thereof can range from approximately 2 mg/day to approximately 100 mg/day." ('737 App. at 24; '422 App. at 20.) The '346 Patent discloses a range of "approximately <2 mg/day to approximately 300 mg/day" of PPI ('346 Patent col. 12:65-13:1) and later mentions a concentration of 100 mg/day of IV-administered omeprazole as the lower limit of typical adult dosage. (Id. col. 10:65-67.) These documents also state that "[t]he amount of the sodium bicarbonate used in the solution/suspension of the present invention is approximately 1 mEq (or mmole) sodium bicarbonate per 2 mg omeprazole." ('737 App. at 28; '422 App. at 23; '346 Patent col. 14:27-31.) The court concludes from these two disclosures that a person of ordinary skill in the art would understand from the '737 and '422 Applications that Dr. Phillips was in possession of buffer amounts as low as approximately 1 mEq. The

[5] The '737 and '422 Applications and the '346 patent explicitly state that 2 mg/ml of omeprazole in the solution is standard, within a broader preferred range of 1 to 4 mg/ml. ('737 App. at 22; '422 App at 17; '346 Patent col. 13:40-43.) The Provisional Application only recites the preferred range of 1 to 4 mg/ml, but the court finds that this is sufficient to support the claimed ratio. (Prov. App. at 8.)

Provisional Application, however, does not appear to include comparable disclosures of the dosage range of omeprazole or the approximate amount of sodium bicarbonate relative to omeprazole used in the invention, and Santarus does not assert in its post-trial brief that such a disclosure is present in the Provisional Application or that a person of skill in the art could deduce from the Provisional Application that Dr. Phillips possessed buffer amounts as low as 1 mEq in his invention. Consequently, the court finds that Provisional Application does not support the lower end of the range of buffer amount claimed in claim 24 of the '346 Patent. This claim thus is not entitled to the priority date of the Provisional Application. Dependent asserted claims 37, 38, 49, and 50 of the '346 Patent thus can claim priority only to the filing date of the '737 Application.

v. ***Amount of PPI***

Par also asserts that the priority applications do not support limitations relating to the amount of PPI provided in claim 24 of the '346 Patent and claim 29 of the '988 Patent. Specifically, the disputed claims provide for "approximately 5 mg to approximately 300 mg" of a PPI in the claimed composition. Par's challenge appears to relate primarily to the upper end of the claimed range. (See D.I. 173 at 3-4.) Santarus asserts that the 300 mg figure can be found by taking 6.0 mg/ml – the upper limit of PPI concentration recited in the priority application (Prov. App. at 8:19; '737 App. at 21:21; '422 App. at 17:12) – and multiplying it by 50 ml.

The court finds, however, that the priority applications do not support a claim limitation based on the administration of a 50 ml volume of solution that could contain up to 300 mg of omeprazole, and is not aware of any other basis for the "300 mg" limitation. The pages of the '422 Application that Par cites to support its claim do not describe a 50 ml solution being used to

administer Dr. Phillips' invention in a way that allows for PPI amounts as high as 300 mg. For instance, one of the cited pages describes a study that administered divided doses of 20 ml, 20 ml, and 10 ml of the claimed composition spaced several hours apart, and even the total amount of omeprazole (100mg) in the divided doses was well below 300 mg. (See '422 App at 29.) Another page states that the total drug cost for the composition as used in one study was calculated using "the average institutional cost[] of . . . 50 ml sodium bicarbonate vials" (id. at 35), but the amount of solution actually administered to patients was either 10 ml or 20 ml. (Id. at 32.) Furthermore, the description of the invention in the '737 and '422 Applications specifically disclose a much lower upper limit of PPI amount (100 mg/day). (See id. at 20; '737 App. at 25.) Thus, the court finds that the priority applications do not support the claimed range. Consequently, claim 29 of the '988 Patent, claim 24 of the '346 Patent, and asserted dependent claims 26, 49, and 50 of the '346 Patent are not entitled to the filing date of the priority applications.[6]

vi. "No sucralfate"

Par further asserts that the negative limitation "wherein the composition contains no sucralfate" included in claim 1 of the '772 Patent is not supported by the priority applications or by the written description of the '772 Patent. (D.I. 173 at 6; Tr. 653:24-654:4.) In response, Santarus asserts that the specification of the patents-in-suit and the priority applications "teach[] an artisan that sucralfate has adverse effects and that avoiding sucralfate is desirable." (D.I. 174 at 22 (citing Tr. 949:20-951:20, 953:19-955:4).) Consequently, Santarus argues that [a]n artisan

[6] Asserted dependent claims 37 and 38 of the '346 Patent further limit the claimed amount of PPI to amounts supported in the priority applications, and Par does not challenge the priority date of these claims.

would understand that sucralfate is contraindicated" with regard to Dr. Phillips' inventions. (Id.)

The Provisional Application states that "H2 antagonists, antacids, and sucralfate . . . have certain disadvantages associated with their use . . . . Omeprazole represents an advantageous alternative to the use of H2 antagonists, antacids, and sucralfate . . . ." (Prov. App. at 3-4.) While this indicates that omeprazole is preferable to sucralfate, the same statements indicate with no less force that omeprazole is preferable to antacids such as sodium bicarbonate. Nonetheless, sodium bicarbonate, an antacid, is listed as the preferred carrier or buffer in the disclosed invention. Thus, it cannot be true that the priority applications' disclosure of the disadvantages of sucralfate, by itself, implies that its use in the invention is contraindicated.

Santarus further notes that the background sections of the '737 and '422 applications and the '772 Patent include additional information regarding the potentially serious adverse effects of sucralfate. (See '737 app. 8:1-13; '422 app. 6:1-11; '772 Patent col. 11:1-5.) These documents also included, however, a paragraph discussing the increased risk of pneumonia associated with antacids. ('737 app. 13:4-14:2; '422 app. 10:5-11:2; '772 Patent col. 5:37-6:15.) Santarus asserts, citing the testimony of Dr. Gilbert Banker, that a person of ordinary skill in the art would understand from these disclosures regarding the adverse effects of sucralfate that its use was contraindicated in Dr. Phillips' invention. (See D.I. 174 at 22; Tr. 949:20-951:20, 965:11-968:12.) The court did not find this testimony persuasive. Neither the priority applications nor Dr. Banker provided information regarding the frequency of the adverse effects associated with sucralfate relative to other therapies. One of the adverse incidents cited by Santarus consists of a single patient in a single study.[7] Dr. Banker also testified that the adverse effects associated with

[7] See Tr. 951:1-5 ("[T]here was a study by Driks and coworkers that compared sucralfate to

sucralfate – such as "diarrhea, flatulence, [and] GI disease" – are "pretty socially unacceptable." (Tr. 951:6-9.) Again, however, neither the priority applications nor Dr. Banker indicated the frequency of these effects. In addition, Dr. Banker did not explain why the "social unacceptability" of sucralfate's side effects should be considered more troublesome than pneumonia or the other adverse affects associated with antacids. Certainly, no evidence was presented as to why a person of ordinary skill in the art reading the application would believe that sucralfate was "contraindicated" in the claimed composition. Consequently, the court finds that neither the priority applications nor the specification of the '772 Patent support the "no sucralfate" limitation. Since this limitation is not supported and claim 1 is the only independent claim of the '772 Patent, the asserted claims of the '772 Patent are only entitled to the filing date of the '346 application, and are also invalid for lack of written description.

vii. Initial serum concentration

Claims 1, 2, and 26 of the '885 Patent include limitations that identify minimum serum concentrations of the PPI that must be obtained "within about 30 minutes of administration." Specifically, claims 1 and 26, the only independent claims of the '885 Patent provide that "an initial serum concentration of the [PPI] greater than about 0.1 μg/ml [be] obtained at any time within about 30 minutes after administration of the composition." Claim 2, which is dependent on claim 1, further limits the initial serum concentration to "greater than about 0.15 μg/ml." Par asserts that these limitations are not supported by the priority applications (see D.I. 173 at 6), or the specification of the '885 Patent itself. (See id. at 24-25.)

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conventional therapies of H2-antagonist antacids and H2-antagonist plus antacids, the only patient whose death was attributed to stress-related upper GI bleeding was in the sucralfate arm."); see also '737 App. at 8, '422 App. at 6; '772 App. col. 4:24-28.

A Santarus witness did testify at trial that these serum concentrations were sufficiently disclosed in the written description of the '885 Patent itself. Nevertheless, Santarus does not cite any evidence presented at trial that would support a finding that information regarding initial serum concentrations was disclosed in any of the three priority applications. Furthermore, in its post-trial brief, Santarus does not contend that these concentrations were disclosed prior to the '885 Patent application. The specification of the '885 Patent does contain tables disclosing the initial PPI serum concentrations of patients using the claimed composition, so the disputed claims themselves are not invalid for lack of written description. '885 Patent col. 54-55. These tables do not, however, appear in the priority applications' written descriptions, and Santarus does not contend that any tables or paragraphs disclosing initial serum concentrations are present in the priority applications. Consequently, the court finds that the priority applications do not support the initial serum concentration limitations. As a result, none of the asserted claims of the '885 Patent are entitled to the filing dates of the priority applications.

viii. "A commercially stable powder for suspension"

Lastly, Par asserts that the priority applications and the written description of the '882 Patent do not support the "commercially stable powder for suspension" limitation in claim 1 of the '882 Patent. (D.I. 173 at 6; Tr. 654:8-14.) To the extent that Par's objection is to the "powder for suspension" portion of this limitation, the court finds that the priority applications support this dosage form limitation for the reasons stated in section III.a.iii, *supra*. As for the "commercially stable" portion of this limitation, the court finds that a person of ordinary skill in the art reading the priority applications and the '882 Patent would recognize that the inventor contemplated and possessed a commercially stable formulation. Consequently, the priority

applications support this limitation in claim 1 of the '882 Patent.

B. Obviousness

Par challenges the validity of each of the asserted claims as anticipated by or obvious in light of the prior art. The court finds that Par has established by clear and convincing evidence that the patents-in-suit are, indeed, obvious. This is true regardless of which filing date is used for the asserted claims, because even at the time that the Provisional Application was filed, the available prior art rendered the patents-in-suit obvious.

i. Legal Standard

35 U.S.C. § 103(a) provides that a patent may not be obtained "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious to a person having ordinary skill in the art." Obviousness is a question of law that is predicated upon several factual inquiries. *Richardson-Vicks v. Upjohn Co.*, 122 F.3d 1476, 1479 (Fed. Cir. 1997). Specifically, the trier of fact must consider four issues: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed subject matter and the prior art; and (4) secondary considerations of non-obviousness, such as commercial success, long felt but unsolved need, failure of others, and acquiescence of others in the industry that the patent is valid, and unexpected results. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).

A party seeking to challenge the validity of a patent based on obviousness must also demonstrate by "clear and convincing evidence" that the invention described in the patent would have been obvious to a person of ordinary skill in the art at the time the invention was made.[8]

[8] "Clear and convincing evidence is evidence that places in the fact finder 'an abiding conviction

Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348, 1359-60 (Fed. Cir. 2007). However, in determining what would have been obvious to one of ordinary skill in the art at the time of invention, the use of hindsight is not permitted. *See KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 421, 127 S. Ct. 1727, 1742, 167 L. Ed. 2d 705, 724 (2007) (cautioning against "the distortion caused by *hindsight bias*" and "arguments reliant upon *ex post reasoning*" in determining obviousness) (emphasis added).

In *KSR*, the Supreme Court rejected a rigid application of the principle that there should be an explicit "teaching, suggestion, or motivation" in the prior art, the nature of the problem, or the knowledge of a person having ordinary skill in the art, in order to find obviousness. *See KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. at 415. The *KSR* Court acknowledged, however, 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." *Takeda Chem. Indus. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356-57 (Fed. Cir. 2007) (quoting *KSR*, 550 U.S. at 418).

ii. <u>The Level of Ordinary Skill in the Art</u>

A person with an ordinary level of skill in the art to which the patents in suit pertain would be (i) a person with, for example, at least a bachelors degree in pharmacy, chemistry, biochemistry, biology, pharmaceutics, or a comparable field and multiple years of relevant work experience; or (ii) a person with an advanced degree in pharmacy, chemistry, biochemistry,

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that the truth of [the] factual contentions are 'highly probable.'" *Alza Corp. v. Andrx Pharms., LLC*, 607 F. Supp. 2d 614, 631 (D. Del. 2009) (quoting *Colorado v. New Mexico*, 467 U.S. 310, 316 (1984)).

biology, pharmaceutics, or a comparable field.[9]

iii. Scope and Content of Prior Art and Differences Between Claimed Subject Matter and Prior Art

a. Published Studies Using Omeprazole/Sodium Bicarbonate Solutions

The prior art at the time of the filing of the Provisional Application includes buffered, non-enteric-coated solutions or suspensions containing omeprazole and sodium bicarbonate. One such reference is an abstract by Lamers et al. that was presented at the annual meeting of the *British Society of Gastroenterology* in 1985 and published in the peer-reviewed *Gut* journal the same year. *See* JTX-93; pdf available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1432933/pdf/gut00383-0136.pdf (scroll to page A1134). The Lamers abstract briefly describes a study that used two different preparations containing 80 mg omeprazole and sodium bicarbonate: "an enteric-coated preparation together with 250 ml (40 mmol) sodium bicarbonate [and an] uncoated preparation with sodium bicarbonate." (JTX-93 at A1134.) A third formulation used in the study consisted of enteric-coated omeprazole administered with 250 ml saline. (Id.) The abstract revealed that:

> There was wide variation in omeprazole absorption with the enteric-coated preparation and saline. Ingestion of enteric-coated omeprazole with sodium bicarbonate resulted in significantly greater absorption. Omeprazole absorption after uncoated omeprazole with sodium bicarabonate was slightly greater than that with the enteric-coated preparation and saline, but not significantly different from that with enteric-coated omeprazole and sodium bicarbonate. . . .
>
> We therefore conclude that addition of alkali accelerates absorption of omeprazole in patients with Zollinger-Ellison syndrome resulting in early inhibition of acid secretion.

[9] This definition was proposed by Santarus in its pre-trial proposed findings of fact. (See D.I. 153, Ex. 12 at 106; Tr. 512:6-16.) Par did not offer a different definition at trial or in its pre-trial or post-trial briefs.

(Id. at A1135 (parenthetical statistical data omitted).) Lamers therefore teaches that the use of a sodium bicarbonate buffer is effective in preventing omeprazole from being deactivated by gastric acid, even in the absence of enteric coating.

Another reference that disclosed buffered omeprazole/sodium bicarbonate suspensions was a study by Pilbrant et al. published in the *Scandanavian Journal of Gastroenterology* in 1985. See DTX-167; Aring Pilbrant et al., *Development of an oral formulation of omeprazole*, 20 SCAND. J. GASTROENTEROLOGY 113 (1985). Santarus attempts to distinguish Pilbrant from the patents-in-suit by asserting that Pilbrant involved the administration of "multiple, additional large doses of sodium bicarbonate solution" along with omeprazole as opposed to the single dose of sodium bicarbonate buffered omeprazole, as in Dr. Phillips' invention. (See, e.g. D.I. 153, Ex. 12 at 116.) However, Santarus' focus on the volume of liquid consumed is somewhat misleading. It is sodium bicarbonate, and not water, that neutralizes gastric acid and acts as a pH buffer in the various pharmaceutical compositions at issue.[10] Santarus does not explain why a person of ordinary skill in the art would view the amount of liquid used in a preparation as taking such paramount importance. The court finds, based on the evidence presented at trial, that a person of ordinary skill in the art would find the amount of *sodium bicarbonate* rather than the amount of water or other liquid to be most relevant when examining the use of buffers in the

[10] Furthermore, Santarus' characterizations of Lamers and Pilbrant as involving "large doses" of sodium bicarbonate solution is misleading because the volumes of liquid administered were not particularly large. 50 ml is approximately equal to 1.7 liquid ounces or 3.4 tablespoons. Even in the case of Pilbrant, which involved the administration of five 50 ml liquid doses, the court does not view the consumption of five 50 ml doses to be a particularly "large" quantity of liquid for a patient to consume. Santarus did not explain at trial why the seemingly modest amount of liquid administered in Pilbrant should be deemed so large that a person of ordinary skill in the art would not consider it relevant to the development of a buffered omeprazole composition.

prior art. In this regard, the amount of sodium bicarbonate administered in Pilbrant is well within the range of with the amounts specified in the asserted claims of the patents in suit. Each dose of sodium bicarbonate solution administered in Pilbrant contained 8 mmol of sodium bicarbonate, and five doses of this solution were given over the course of approximately 40 minutes. This total of 40 mmol – which translates to 40 mEq or 3360 mg – of sodium bicarbonate administered along with 60 mg omeprazole in the Pilbrant study is within the range of buffer specified in the asserted claims of the patents-in-suit.[11] Under these circumstances, the fact that the sodium bicarbonate is provided in divided doses rather than a single dose is not such a significant difference as to render the Pilbrant reference irrelevant. On the contrary, the court finds that a skilled artisan would find Pilbrant highly relevant to the subject matter of the patents-in-suit.

Santarus also attempts to persuade the court that a person of ordinary skill in the art would view Pilbrant as teaching away from Dr. Phillips' invention because Figure 5 in the Pilbrant publication indicates that there may be a "rapid washout" of omeprazole in buffered solutions. (See D.I. 153, Ex. 12 at 118.) The court, however, is more persuaded by Dr. Roy Charles Orlando's testimony that for the purposes of inhibiting acid production, the serum concentration of omeprazole at any given time is less important than the total amount of omeprazole reaching general circulation. (See Tr. 815-817.) In mathematical terms, on a graph

[11] Specifically, the patients in the Pilbrant study were given a total of 40 mEq of sodium bicarbonate (within the 1.0 to 150 mEq range specified in claim 24 of the '346 patent), which is equivalent to 0.67 mEq per mg of omeprazole (within the 0.1 to 2.5 mEq/mg range specified in claim 1 of the '772, '882, '885, and '988 patents, and claim 9 of the '885 patent); and the total weight ratio of sodium bicarbonate to omeprazole was 56 to 1 (within the "more than about 40 times" and "greater than 20:1" ranges specified in claim 57 of the '346 patent and claim 1 of the '885 patent, respectively).

indicating the blood concentration of omeprazole over time, the shape of the curve is less important than the area under the curve ("AUC"). (See id.) Indeed, the Pilbrant reference explicitly states:

> The effect of omeprazole is long lasting. The effect is not a direct function of blood concentration of omeprazole at any time, but is rather a function of the total amount of omeprazole reaching the general circulation, i.e., directly proportional to the AUC. This means that the pharmacological effect is achieved with dosage forms of omeprazole producing equal AUCs. The shape of the plasma concentration-time curves are of no importance.

(DTX-167 at 118; see also Tr. 817:1-818:10.) The Pilbrant reference therefore does not teach away from the use of sodium bicarbonate buffers on this basis. On the contrary, the court finds that the Pilbrant reference as a whole strongly indicates that buffering omeprazole with sodium bicarbonate is a possible alternative approach to enteric coating for the administration of omeprazole.[12]

The Pilbrant and Lamers references described aqueous solutions, in contrast to the solid compositions claimed in the patents-in-suit. But while this distinction is sufficient to render the Pilbrant and Lamers references non-anticipatory with respect to the patents-in-suit, it does not render them irrelevant to the obviousness analysis. The prosecution history of the patents-in-suit begins with applications that described and claimed aqueous solutions. The '737 and '422 Applications both state that the described composition could "be formed into a tablet, capsules, or granules, by methods well known to those skilled in the art." '737 App. at 28-29; '422 App.

[12] Furthermore, even if the more rapid washout of omeprazole is a disadvantage of a buffered and non-enteric coated formulation, this fact does not "teach away" from its use altogether. As Santarus asserted repeatedly at trial, enteric coated formulations of omeprazole have the disadvantage of delayed bioavailability, a quality of enteric coating that was known at the time of the invention. (See, e.g., Tr. 39:8-9.) Santarus does not claim, however, that the existence of this disadvantage "teaches away" from the use of enteric coating in omeprazole formulations.

at 23-34. Thus, Dr. Phillips himself recognized that the transition from liquid to solid dosage forms was well within the knowledge and capacity of persons of ordinary skill in the art.

The Lamers and Pilbrant references teach that uncoated omeprazole formulations containing a sodium bicarbonate buffer could be used as an alternative to enteric coating in order to protect omeprazole from degrading in the stomach. For the reasons stated above, a person of skill would consider these references highly relevant to the subject matter of the patents-in-suit. As Santarus itself stated in a 505(b)(2) filing in connection with Zegerid's NDA: "Pilbrant published the first study of sodium bicarbonate as an API protectant for omeprazole in 1985. This technology was then patented by Phillips in 1996 for all proton pump inhibitors." (Tr. 145:9-12; D.I. 17 at Santarus0000216 (internal citations omitted).) The court finds that even in isolation, these references render the patents-in-suit obvious. Additional prior art references at the time of the filing of the Provisional Application confirm this finding.

b. The Makino and Yamasaka Patents

The prior art also includes references disclosing solid pharmaceutical compositions containing both sodium bicarbonate and benzimidazole compounds such as the PPIs included in the patents in suit. Two such references are United States Patent No. 5,093,132 (hereinafter, the "Makino Patent"), issued on March 3, 1992; and United States Patent No. 5,294,439 (hereinafter, the "Yamasaka Patent"), issued on March 15, 1994. Both of these patents are prior art with respect to all claims of the patents-in-suit because they were issued more than one year prior to the filing of the Provisional Application.

The Makino Patent describes solid oral pharmaceutical compositions containing both

alkali inorganic salts such as sodium bicarbonate[13] and benzimidazole compounds such as omeprazole that "exhibit[] excellent gastric antisecretory, gastric mucosa-producing, and antiulcer activities." Makino Patent col. 11:38-41. The Makino Patent states that the resulting mixture:

> can be made up into dosage forms suited for oral administration, such as tablets, capsules, powders, granules, and fine granules, by per se known means.
>
> Tablets, granules and fine granules may be coated by a per se known method for the purpose of masking of the taste or providing them with enteric or sustained release property.

Makino Patent col. 11:1-8. The Yamasaka patent describes solid oral pharmaceutical compositions containing both alkali salts such as sodium bicarbonate and benzimidazole compounds that "show[] a prominent inhibitory action on secretion of gastric acid."[14] *See*

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[13] Both the Makino Patent and the Yamasaka Patent use the term "sodium hydrogen bicarbonate," an alternative name for sodium carbonate. *See* Makino Patent col. 6:5-6; Yamasaka Patent col. 5:31.

[14] Santarus asserts that Dr. Allen, one of Par's expert witnesses, testified that "there there are substantial differences between omeprazole and leminoprazole." (D.I. 174.) This is, at best, a highly misleading statement and is one of the more egregious examples of the distortions of the record contained in Santarus' post-trial briefing. The portion of the transcript that Santarus cites for its characterization of Dr. Allen's testimony contains two questions that call for some comparison between leminoprazole and omeprazole. The first question and its response consisted of the following:

> Q. You would agree that Leminoprazole is substantially different from omeprazole; correct?
> A. It is a ben --
> Q. Thank you, sir.

Tr. 710:19-22. The second question, as reworded after an objection by Par's counsel, discussed a hypothetical, abstract patent containing leminoprazole and asked whether, for the purposes of the *doctrine of equivalents* rather than non-obviousness, the substitution of omeprazole would constitute a "substantial difference" such that it would not infringe under the doctrine of equivalents. (Tr. 711:5-25.) To that abstract, hypothetical question concerning a wholly

Yamasaka Patent col. 6:20-21.

Santarus attempts to distinguish the Makino and Yamasaka patents on two grounds. First, Santarus asserts that the purpose of the inorganic salts in these patents is to improve storage stability rather than to neutralize gastric acid in the stomach to protect a PPI, and that a person of ordinary skill in the art would thus not have been motivated to select the "operative ranges and ratios in the asserted claims." (See D.I. 174 at 8.) This is not sufficient to distinguish these patents, however, because both patents plainly contemplated eventual oral administration of the compositions. *See, e.g.*, Makino Patent col. 11:1-8; Yamasaka Patent col. 6:22-25. The amounts of buffer and PPI disclosed in the Makino and Yamasaka patents overlap with those of the asserted claims. (*E.g.* Makino Patent col. 10:29-34, 11:49-52; Yamasaka Patent col. 5:7-14, 6:38-40.) While neither patent explicitly states that sodium bicarbonate would prevent or inhibit the acid degradation of the benzimidazole, the antacidic properties of such salts are inherent and well-known to those skilled in the art. (See, e.g. Tr. 146:8-147:6.) The same alkali salts that

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different area of patent law, Dr. Allen answered "I believe that is true." *Id.* at 712:1. The court is troubled that on this basis, Santarus asserts in the context of its obviousness argument that Dr. Allen "testified" that leminoprazole and omeprazole were substantially different.

Sadly, such distortions are not confined to these examples – both at trial and in the post-trial briefing. At trial, counsel for Santarus implied that one of Par's witnesses was "embarrassed" by his opinion in this case based on the witness's statement during deposition that he hoped the confidentiality of his participation in the case would be respected. (See Tr. 909-910.) In its proposed findings of fact and conclusions of law, Santarus' counsel represented to the court that Dr. Orlando was unable to explain the meaning of an article at trial. (See D.I. 174 at 12-13.) Counsel neglects to mention, however, that the testimony cited was in response to a question that counsel withdrew after Dr. Orlando asked to see the sentence in context. (See Tr. 917-18.) Furthermore, both parties' briefs cite portions of the transcript that provide no support for the propositions for which they are cited. These tactics make it far more difficult and time-consuming for the court to examine the record when preparing its findings of fact and conclusions of law. Both the court and the parties suffer undue inconvenience when counsel engages in such tactics. Equally important, counsel who engage in such sharp practices run the risk of severely damaging their credibility and, thus, their effectiveness in the place and at the time when they most need to be viewed as honest and ethical brokers of the facts and the law.

increase the stability of the benzimidazoles in storage also lower gastric pH and thus increase the stability of the benzimidazoles in the acidic environment of the stomach. The court finds that a person of ordinary skill in the art would recognize these qualities of Makino and Yamasaka's inventions even though Makino and Yamasaka may not have fully appreciated its potential importance. Thus, at least with respect to the composition claims of the patents-in-suit, the Makino and Yamasaka patents are not distinguishable on this basis.

Santarus also notes that the claims of the Makino Patent all require an enteric coating and states that the patent teaches that an enteric coating is "essential in the manufacture of oral preparations." (D.I. 174 at 8 (*quoting* Makino Patent 1:68-2:1).) The teachings of a patent are not limited only to what is claimed, however, but also include what is disclosed in the specification. *See, e.g.*, *Sun Studs v. ATA Equip. Leasing*, 872 F.2d 978, 983-84 (Fed. Cir. 1989) (holding that "the entire disclosure of [a prior patent's] specification is effective as a reference"); *Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335, 1349-50 (Fed. Cir. 2009) (using disclosures in the specifications of two prior art patents to find obviousness). Furthermore, the court is persuaded by the testimony presented at trial that the Makino patent as a whole does not teach that an enteric coating is required for *all* types of solid oral dosage forms containing benzimidazoles such as omeprazole. When the Makino specification discusses preparations of the claimed composition in detail, it is clear that use of enteric coating was both optional and only contemplated for certain dosage forms. *See* Makino Patent 11:5-8 ("Tablets, granules and fine granules *may be coated* by a per se known method for the purpose of . . . providing them with enteric or sustained release property.") (emphasis added). There is no indication that other described solid dosage forms, such as capsules or powders, could – much less must – be prepared

with an enteric coating. Read in the context of the patent as a whole, the portions of the Makino patent cited by Santarus do not teach an artisan that the presence of enteric coating is required for solid oral dosage forms of omeprazole.[15] Certainly, read in combination with the Pilbrant and Lamers references, the court does not believe that Makino or Yamasaka teach that enteric coating is essential for the oral administration of omeprazole. On the contrary, a person of ordinary skill in the art reading these references would conclude that the patents-in-suit are obvious in light of the prior art.

c. Other Prior Art as of January 4, 1996

The prior art as of January 4, 1996, the time of the filing of the Provisional Application also included numerous pharmaceutical compositions that a person of ordinary skill in the art would find relevant to the subject matter of the patents in suit. Sodium bicarbonate has long been known for its antacidic properties. (Tr. 961:12-14). Antacids, a group of drugs also including calcium carbonate (well-known under such trade names as Tums), are often used as the first-line treatment for immediate relief of symptoms associated with excessive gastric acid. (See, e.g., Tr. 827:2-9.) While sodium bicarbonate is not commonly used by itself for immediate relief of acid-related symptoms (Tr. 292:10-16), the prior art includes pharmaceutical formulations including other active ingredients in which sodium bicarbonate is included for its

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[15] As the Federal Circuit has stated:

> It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art.

Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 796 F.2d 443, 448 (Fed. Cir. 1986) (*quoting In re Wesslau*, 353 F.2d 238, 241 (CCPA 1965)).

ability to neutralize stomach acid rapidly. For instance, Alka-Seltzer contains aspirin, sodium bicarbonate, and citric acid, and the sodium bicarbonate is included in the formulation as an antacid. (See Tr. 224:21-225:8, 530:10-533:9).

In contrast to antacids, which operate primarily by neutralizing already-produced gastric acid, PPIs such as omeprazole act to inhibit the *production* of gastric acid, thus providing a sustained increase in gastric pH. (See, e.g., Tr. 37:8-12.) The idea of combining an acid secretion inhibitor with an antacid was not new at the time of the invention. Before the development of PPIs, drugs known as H2 blockers were a leading class of drugs designed to inhibit acid production (e.g. Tr. 805:23-25), and the prior art includes co-administration of antacids and H2 blockers.[16] (Tr. 292:2-9). Furthermore, in the 1991 *Physician's Desk*

[16] The court notes that one such antacid/H2 blocker combination was the subject of recent patent litigation in the United States District Court for the Southern District of New York. *See McNeil-PPC, Inc. v. Perrigo Company*, 516 F. Supp. 2d 238 (S.D.N.Y. 2007). In that case, the court examined patents underlying the NDA for "a single-layer tablet containing, inter alia, 10mg of coated famotidine [an H2 blocker] and 165mg of magnesium hydroxide [an antacid]. The tablets are marketed over-the-counter under the trade name Pepcid Complete." *Id.* at 245. The court in *McNeil-PPC* held that the patents at issue were obvious in light of the prior art. *Id.* at 255. One of the prior art references that the court relied on in its obviousness analysis was U.S. Patent No. 5,229,137, which was issued in 1993. That patent claimed, among other things:

> An oral pharmaceutical medication for providing immediate and sustained relief from pain, discomfort and/or symptoms associated with episodic heartburn in a human, said oral pharmaceutical medication consisting essentially of:
>
> an antacid in an amount effective to substantially neutralize gastric acid;
>
> a histamine H2-receptor antagonist in an amount effective to substantially inhibit or block gastric acid secretion . . . .

U.S. Patent No. 5,229,137 col. 8:7-16 (filed May 6, 1992). The issues surrounding the prior art differences between pharmaceutical compositions and patents discussed in *McNeil-PPC* differed materially from those in this case in a number of ways. Nonetheless, the case is further indication that the idea of combining antacids and acid secretion inhibitors to provide both

Reference, the monograph entry for PRILOSEC – an enteric-coated omeprazole formulation and the best-known brand name formulation of omeprazole – states that "antacids were used concomitantly with PRILOSEC" (Tr. 660:8-20; DTX-1027 at 1484), and mentions "a buffered solution of omeprazole." (DTX-1027 at 1482.) These references further confirm the obviousness of combining sodium bicarbonate with omeprazole to neutralize gastric acid and inhibit its production.

d. The '737 Patent

To the extent that the patents-in-suit cannot claim priority to the priority applications,[17] the court finds that they are obvious in light of Dr. Phillips' '737 patent, which issued on November 24, 1998. The '737 patent claims "a method for treating gastric acid disorders" by administering an aqueous solution or suspension of omeprazole and sodium bicarbonate. '737 Patent col. 22:40-48. The specification of the '737 patent states that this composition "can be formed into a tablet, capsules, or granules, by methods well known to those skilled in the art." '737 Patent col. 10:31-34. These disclosures either anticipate or render obvious each asserted claim of the patents-in-suit.[18]

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immediate and sustained relief from gastric acid symptoms was hardly new at the time Dr. Phillips filed his Provisional Application.

[17] *See* section III.A, *supra*.

[18] Specifically, the '737 Patent renders obvious those claims that are only entitled to the filing date of the '346 application. *See supra*, Table 1. Santarus asserts in its post-trial briefing that "the manner in which Par's experts have concluded that the '737 Patent contains enabling disclosure that anticipates (expressly or inherently) each asserted claim would necessarily establish that the '737 Patent provides priority for each asserted claim." D.I. 174 at 9. The court does not necessarily agree that the standards for anticipation, enablement, and priority are coterminous, and Santarus cites no legal authority for that proposition. The court further notes that even if Santarus' assertion were legally correct, the standards for *obviousness* and priority

iii. Secondary Considerations

The evidence in the record on several relevant secondary considerations does not undermine the court's finding that the patent is obvious in light of the prior art. On the contrary, the weight of the evidence as to the relevant secondary considerations confirms the court's finding in this regard. *See Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983) (noting that "evidence of secondary considerations may often be the most probative and cogent evidence in the record"). Once a *prima facie* case of obviousness has been established, the burden shifts to the applicant to come forward with evidence of secondary considerations of non-obviousness to overcome the *prima facie* case. *E.g.*, *In re Huang,* 100 F.3d 135, 139 (Fed. Cir. 1996). Secondary considerations can include evidence of commercial success, long felt but unsolved needs, and failure of others, *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966), as well as unexpected results created by the claimed invention, unexpected properties of the claimed invention, licenses showing industry respect for the invention, and skepticism of skilled artisans before the invention. *See In re Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1998).

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are not coterminous; a disclosure in a published patent may render a claim obvious even if the same statement appeared in an application to which the disputed claim asserts priority. The reasoning behind such a distinction is to encourage applicants to disclose their application as completely and early as possible, thereby avoiding uncertainty as to the scope and priority dates of their claims:

> Entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. It extends only to that which is disclosed. . . . The question is not whether a claimed invention is an obvious variant of that which is disclosed in the specification. Rather, a prior application itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought.

Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1571-72 (Fed. Cir. 1997).

"Evidence of commercial success, or other secondary considerations, is only significant if there is a nexus between the claimed invention and the commercial success." *Ormco Corp. v. Align Technology, Inc.*, 463 F.3d 1299, 1311-12 (Fed. Cir. 2006).

a. Commercial Success and Nexus

Santarus argues that Zegerid has achieved considerable commercial success. Zegerid's sales grew from $46 million in 2006 to over $100 million in 2008, a pace of growth that Santarus asserts "far outpaced the combined rest of the branded PPI market." (D.I. 174 at 15-16.) Santarus further asserts that Zegerid's sales "cannot be explained away by marketing expenditures" because sales increased despite Santarus "reducing its marketing expenses and sales force, which were dwarfed by those of its competitors." (Id. at 16.) Par counters that Zegerid has not achieved commercial success, citing evidence of Zegerid's continued small market share relative to other prescription PPI drugs. (See D.I. 173 at 22-24.) Par further asserts that this modest market share is largely attributable to Santarus' unusual discounting and pricing on Zegerid. (Id.)

The court agrees with Par that Zegerid has not achieved commercial success. While the Zegerid sales and growth figures provided by Santarus might seem impressive in isolation, the evidence presented at trial showed that Zegerid's sales and prescriptions remained dwarfed by those of other PPIs at the end of 2008, four years after the product was launched. Furthermore, Zegerid apparently was no longer showing signs of growth in the most recent quarters for which evidence was presented at trial. Zegerid's share of PPI prescriptions was 0.8% in the last two quarters of 2007, and was just 0.9% in each of the four quarters of 2008. (See Tr. 413; PTX 112.) Zegerid's sales seem even more modest when one considers that these percentages do not

include Zegerid's sales compared to the PPI market as a whole, which would include over-the-counter sales of enteric-coated omeprazole (trade name Prilosec). Furthermore, even the entirety of the PPI market does not include sales of other classes of drugs aimed at reducing or neutralizing gastric acid, such as H2 blockers and antacids. Lastly, Zegerid's sales fell far short of Santarus' own expectations. Santarus had at one time projected sales of $2 billion by 2008 (Tr. 86:22-24), approximately twenty times actual Zegerid sales for that year. (Tr. 388:20-23).[19] In this context, Zegerid's less-than-1% share of the prescription PPI market is not persuasive evidence of commercial success.

Similarly, placing Zegerid's growth in the context of the broader PPI prescription market illustrates that the growth in Zegerid's sales is not as robust as Santarus asserts. One of Santarus' own trial exhibits shows that PPI prescriptions increased by nearly 40% between February 2004 and December 2008. (See PTX 86.) During this period, approximately 2.5 million Zegerid prescriptions were written (Tr. 389), but the total number of PPI prescriptions increased by 33.2 million during the same period, from 85.9 million in 2004 to 119.1 million (118 million excluding Zegerid) in 2008. (See PTX 86.) Santarus has made much of the fact that Zegerid was the first – and so far only – non-enteric coated PPI to come to market. It is neither persuasive nor even surprising that a start-up company with a newly-launched drug would show strong sales growth relative to long-established competitors in its first few years. Santarus notes that Zegerid's net sales increased substantially between *2006* and 2008 (e.g. Tr. 388:20-23), but

[19] Par also cites the fact that Santarus had yet to have a profitable year at the time of trial as evidence of Zegerid's lack of commercial success. (E.g., D.I. 173 at 22.) Even though Zegerid remains Santarus' primary product, the court does not find this to be persuasive evidence given the number of factors bearing on the profitability of a company as a whole that are unrelated to the technical merits of a particular product.

Santarus did not present comparable evidence of sales growth between *2007* and 2008. Other evidence presented at trial regarding Zegerid's sales provides an explanation for this approach. Zegerid's share of the PPI prescription market did not grow between 2007 and 2008, which indicates that growth was not continuing as of the most recent reporting periods discussed at trial.[20]

Furthermore, the evidence did not reveal a close nexus between the asserted merits of the invention and the sales and growth of Zegerid. Rather, the court finds it likely that a substantial portion of Zegerid's sales are due to preferential pricing and other marketing and sales tactics by Santarus. Santarus has offered unusually high discounts and rebates on Zegerid (Tr. 574:12-25), and has offered Zegerid at prices lower than that of competing PPIs. (Tr. 575:8-25.) Like traditional advertising and marketing, such pricing tactics can have a significant effect on the sales of a commercial pharmaceutical product unconnected to the merits of the underlying invention. Thus, the court finds that even the modest sales that Zegerid has achieved are largely attributable to factors unrelated to the merits of the patents-in-suit.

The court recognizes that Santarus is a relative newcomer to the pharmaceutical industry and that Zegerid was launched into a market with a number of established and well-known products sold by companies older and many times larger than Santarus. These factors do not, however, outweigh the fact that even four years after its launch, Zegerid had yet to gain more than a fractional share of the PPI market. According to the most recent sales figures presented at trial, enteric-coated PPIs still retained more than 99% of the PPI market share, and thus were still

[20] The growth from 2006 to 2007 is no doubt due in large part to the launch of the capsule form of Zegerid in 2006; before that, the only form of Zegerid available was a powder form. (See Tr. 467:9-13, 576:5-8.)

prescribed more than one hundred times as often as Zegerid. (See Tr. 586:11-15; PTX-112.) The evidence presented at trial further indicated that Zegerid's share of the PPI prescription market was no longer growing as of the most recent sales reporting period. (See Tr. 586:20-22; PTX-112.) For these reasons, the court finds that Zegerid has not achieved commercial success.

b. Unmet Needs

Santarus asserts that Dr. Phillips' patents addressed several long-felt but unmet needs in the relevant art: (1) Minimizing variability in pharmacokinetics and pharmacodynamics, (2) more rapid and sustained acid control, (3) improved nocturnal acid control, and (4) dosing independent of meals. The evidence Santarus cites for these propositions, however, is not persuasive. Santarus cites no evidence indicating that these needs were "long-felt" or considered particularly significant among skilled artisans at the time of invention in light of then-existing prior art, nor does Santarus assert that others had tried and failed to come up with formulations that addressed these needs. Further, as to the fourth asserted need, there are other PPIs on the market with labeling indicating that it can be taken prior to a meal. (See Tr. 517:2-6.) The labeling for Zegerid, however, indicates that it should be taken on an empty stomach and at least one hour before a meal. (See Tr. 133:13-17, 516:12-517:14.) As to the second asserted need, Zegerid is not indicated for the immediate relief of gastric acid symptoms. (See Tr. 516:15-16.) The court thus finds it questionable whether Zegerid has, in fact, addressed the alleged needs significantly better than the prior art.

Also, the court does not perceive a nexus between the claimed merits of the patents-in-suit and the fulfillment of any legally cognizable need. To extent that the claimed benefits of Zegerid stem from the immediate reduction in antacid, this is easily explained by the antacidic

properties of the sodium bicarbonate in the formulation. To the extent that the benefits stem from the long-term reduction in gastric pH, this is explained by the long-lasting effects of the omeprazole – effects that last even after the blood concentration of the omeprazole diminishes. (See, e.g., DTX 167 at 118; Tr. 817:1-818:10.) These attributes of sodium bicarbonate and omeprazole, respectively, were known to those of ordinary skill well before the earliest effective filing date of the patents-in-suit. Lastly, the Pilbrant and Lamers prior art references show that buffering omeprazole with sodium bicarbonate in quantities within the range claimed in the patents-in-suit allowed for rapid absorption of omeprazole. Thus, the court does not perceive an unmet need that existed in the prior art that was resolved by the subject matter of the patents-in-suit.

If there was a "need" in the PPI market that Zegerid resolved, the need was not for advancements on the existing prior art, but rather for a drug manufacturer to recognize the commercial potential of what already existed in the prior art. Indeed, one of the sections of testimony Santarus cited in support of its position on this secondary consideration was in response to a question about "Santarus's marketing goals in differentiating Zegerid as a product." (See D.I. 174 at 14; Tr. 132:3-133:17.) Moreover, as indicated in the court's discussion of commercial success, even this commercial and marketing "need" has not proven to be substantial, since Zegerid's sales continue to be dwarfed by sales of enteric-coated PPIs.[21] Consequently, the court concludes that the patents-in-suit do not address any previously unmet

[21] The Federal Circuit has long recognized the relevance of commercial success to the question of whether an "unmet need" has been met. *See, e.g.*, *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546 (Fed. Cir. 1998) ("It was undisputed that the product met an unsolved need and was quickly adopted by the automotive industry, this commercial success also weighing against obviousness.").

needs in the relevant art.

c. Skepticism

Santarus asserts that before the patents-in-suit, there was "a long-held belief that buffered approaches were unworkable and that enteric coating was essential for solid dosage forms" of omeprazole. (D.I. 174 at 10.) In light of the evidence before it, the court finds this argument unavailing. Santarus has repeatedly cited a statement made in 2004 by Dr. George Sachs expressing his skepticism regarding the then-ongoing research using Zegerid. (See, e.g., Tr. 23:1-20 (Santarus' counsel quoting Dr. Sachs during his opening statement at trial); D.I. 174 at 10.) Specifically, Dr. Sachs stated that:

> The principle of Santarus is to give essentially, if you like, a bicarbonate or carbonate buffer to the omeprazole solution. And so you don't have enteric coating and it comes in a gelcoat or gelcap. We thought about that a long time ago at Astra. . . . [M]an is a continuous acid secretor; the amount of acid man makes is not really predictable and [so] you're not really able to particularly buffer the omeprazole solution in the stomach. So as soon as the solution starts to fall below pH 5, which would happen with a high degree of frequency, you simply destroy the omeprazole and it will no longer work. So I think the Santarus principle, though well-founded – you know, in terms of the idea of stabilizing, simply doesn't work in man.

(See PTX-10.) For a number of reasons, the court does not find this statement of skepticism persuasive. First, Dr. Sachs was not a witness in the present action; instead, Santarus had his statement read into evidence by one of its experts and submitted an email containing the quote as evidence at trial. The context of the statement thus was never presented at trial. This is significant given that Dr. Sachs apparently made his statement at an "R&D Technology Review" (PTX-10 at SANTARUS000995442) or "investor day" (id. at SANTARUS000995469-A) for Allergan, Inc. while Zegerid's FDA approval was pending. (See Tr. 66:14-67:6.) At the time,

Dr. Sachs was a consultant for Allergan, which was developing a potentially competing product at the time of the statement. (Tr. 69:18-23.) Without either the context of the statement or any testimony by Dr. Sachs, the court simply does not find the statement to be credible or persuasive evidence of skepticism in the industry or among persons of skill generally.

Furthermore, the timing of the statement reduces its impact. The statement was made in 2004, nearly two decades after Astra's initial research into omeprazole, eight years after Dr. Phillips filed the first priority applications and, most importantly, a year after the first of the patents-in-suit was issued. While post-invention skepticism can be used as evidence of non-obviousness, *see, e.g.*, *Knoll Pharmaceutical Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 367 F.3d 1381, 1384-85 (Fed. Cir. 2004), the court does not believe that this particular expression of skepticism was indicative of the general view of sodium bicarbonate/omeprazole combinations at the time of the present invention. The court does not dispute that Dr. Sachs is an accomplished researcher in his field, but even accomplished researchers may have incomplete knowledge or imperfect recollection of the state of the art with respect to the claimed inventions. Indeed, Santarus' exhibit quoting Sachs' statement shows that Santarus wrote Allergan in 2004 to ask it to remove Dr. Sachs' statement from their website, pointing to a number of publicly-available sources showing the "positive results" of Zegerid in clinical trials.[22] (See PTX-10.)

The other evidence of skepticism that Santarus cites in its post-trial brief is similarly unavailing. Santarus President and Chief Executive Officer Gerry Proehl testified that "[t]here was a lot of skepticism within the medical community" when Santarus first presented clinical

[22] Furthermore, it is neither surprising nor uncommon for persons of skill to publicly disagree about the efficacy or prospects of an invention, particularly in the months immediately before a product goes to market. If the mere existence of skepticism among some persons of skill were considered a reliable indicator of non-obviousness, courts would have a difficult time indeed

evidence of Zegerid's effectiveness, but he cited no examples except Dr. Sachs' statement and an out-of-court oral statement by Santarus' Chief Medical Officer. (Tr. 62:3-17; see also Tr. 39:22-40:3.) Emerson Ballard, another Santarus executive, testified that unnamed "clinicians" requested more information regarding Zegerid's safety and efficacy before its launch. (Tr. 130:9-131:23.) Besides Dr. Sachs' statement, however, Santarus cites no specific examples of persons of skill expressing skepticism and no published statements of skepticism whatsoever. Furthermore, the statements Santarus cites in its brief all appear to have been made in 2000 or later.

At most, the court finds that the evidence presented at trial shows that some persons of skill in the art believed enteric-coated formulations of PPIs would be clinically superior to buffered formulations. It does not show that there was a widespread belief that the claimed invention was "unworkable" rather than simply inferior to enteric-coated formulations.[23] *See In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994) ("A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use.") Thus, the court finds that Santarus failed to produce persuasive evidence of skepticism.

d. Unexpected Results

Santarus also argues that Dr. Phillips' inventions produced "unique and surprising results." (See D.I. 174 at 10-14.) Santarus specifically cites the coupling of immediate and sustained acid control, enhanced nighttime acid control, and a "more rapid and predictable pharmacokinetic profile" as allegedly surprising and unique features of the invention embodied

[23] To the extent that commercial sales are an index of clinical superiority, the continued market dominance of enteric coated PPIs would seem to confirm this belief.

by the patents-in-suit. Par asserts that the results of studies using Zegerid were neither surprising nor unique in light of the prior art. (See D.I. 173 at 18.)

The court agrees with Par that the composition claimed and described by these patents did not produce unexpected results. In order to establish this secondary consideration, a party must produce evidence demonstrating "substantially improved" results that are unexpected in light of the prior art. *In re Soni*, 54 F.3d 746, 751 (Fed. Cir. 1995). This evidence should be weighed against contrary evidence indicating that the results were not unexpected or not a substantial improvement over the prior art. *Id.*; *see also In re Geisler*, 116 F.3d 1465, 1470-71 (Fed. Cir. 1997). In this case, the court finds that the allegedly "unexpected" properties of Zegerid were neither unexpected nor surprising in light of the prior art. It was already known to a person of ordinary skill in the art by the time of the alleged invention that a combination of sodium bicarbonate and omeprazole provided faster absorption than enteric-coated omeprazole while having a comparable duration of effect. *See, e.g.*, Tr. 827:12-828:7; 831:13-22; DTX-167 at Fig. 5. A clinical trial report for Zegerid sponsored by Santarus states that the immediate increase in gastric pH associated with Zegerid was due to the neutralization of gastric acid by the sodium bicarbonate, DTX-299 at 55, and the antacidic properties of sodium bicarbonate were known long before the time of the invention. Tr. 146:25-147:8. The long duration of effect on gastric pH associated with omeprazole was also known at the time of the invention. Indeed, the concluding section of the clinical trial report states that "*[a]s anticipated*, [Zegerid] was found to be bioequivalent to Prilosec on Day 1 and Day 7 of dosing with regard to AUC[] and percent decrease from baseline in integrated gastric acidity over 24 hours." Tr. 831:13-17; DTX-299 at 62. The Pilbrant and Lamers studies further indicated to a personal of ordinary skill in the art

that an omeprazole/sodium bicarbonate combination would produce a combination of immediate and sustained increase in gastric pH. For the remaining results that Santarus argues were "unexpected" – prevention of nocturnal acid breakthrough, predictable pharmacodynamic profile, and greater dosing flexibility – the court finds that the evidence presented at trial did not indicate that these results were "unexpected" in light of the known prior art. The court thus finds that the results achieved by Zegerid were not surprising or unexpected.

e. Copying

The only alleged example of copying that Santarus cites is Par's accused ANDA product. Santarus asserts that Par "reviewed the patents and reverse engineered Zegerid . . . and derived its formula from this process." (D.I. 174 at 15.) As several courts have noted, however, a showing of copying is not compelling evidence of non-obviousness in Hatch-Waxman cases due to the nature of the ANDA process. *See, e.g., Purdue Pharma Products L.P. v. Par Pharmaceutical, Inc.*, 642 F. Supp. 2d 329, 373-74 (D. Del. 2009) ("[A] showing of copying, which Plaintiffs have provided here, is not compelling evidence of non-obviousness in the Hatch-Waxman context."); *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, No. IP 99-38-C H/K, 2001 WL 1397304, at *14 (S.D. Ind. Oct. 29, 2001) ("[T]he ANDA procedures established by the Hatch-Waxman Act require generic drug manufacturers to copy the approved drug. Variations undermine the FDA's ability to assume that if the patented drug is safe and effective, the generic competitor will also be safe and effective."). Thus, even assuming Par's conduct in reverse engineering Zegerid amounted to "copying" of the patents-in-suit, such conduct is not persuasive objective evidence of non-obviousness.

f. Industry Recognition

Santarus also asserts that Dr. Phillips' inventions received substantial industry recognition, citing sublicenses that three pharmaceutical companies obtained from Santarus for the patents-in-suit. (See D.I. 174 at 14-15.) The court finds that this evidence is not sufficient to establish widespread industry recognition of the patents-in-suit. Santarus was the first company to take a license out on the patents-in-suit, which are held by the University of Missouri, and did so at a time when Santarus had no other products on the market. (Tr. 73:19-22.) Three companies entered sublicense agreements with Santarus on Dr. Phillips' inventions, and two of these sublicenses remained in force at the time of trial. (Tr. 48:8-25.) As the Federal Circuit has noted, however, a number of factors that may go into the decision to take a license on a product are highly variable, and may turn on factors unrelated to the merits of the patents-in-suit:

> When . . . the PTO issues a patent because the examiner did not consider prior art teaching the very technique essential to the claimed invention . . . it is not unusual to see astute businessmen capitalize on it by erecting a temporarily successful licensing program thereon. Such programs are not infallible guides to patentability. They sometimes succeed because they are mutually beneficial to the licensed group or because of business judgments that it is cheaper to take licenses than to defend infringement suits, or for other reasons unrelated to the unobviousness of the licensed subject matter.

EWP Corp. v. Reliance Universal, 755 F.2d 898, 907-08 (Fed. Cir. 1985). Santarus cites evidence discussing the existence of the sublicenses, the revenues that Santarus obtained under them, and the opinion of Mr. Proehl that the patents-in-suit were important to each sublicense. (See D.I. 174 at 14-15 (citing Tr. 47:18-48:7, 96:4-97:9).) Santarus also states that other companies did not take licenses "for strategic reasons, such as competing product launches." (D.I. 174 at 14-15.) Santarus does not explain, however, why the three sublicenses Santarus did

obtain were not also created for "strategic reasons," nor does the court find Mr. Proehl's testimony on the importance of the patents-in-suit persuasive given the dearth of evidence presented on the sublicenses. The court therefore finds that Santarus has not presented evidence sufficient to persuade it that the patents-in-suit have gained substantial industry recognition or acceptance, or that any acceptance it has achieved has a nexus to the merits of the claimed inventions.

C. Inequitable Conduct

Par also asserts that the patents-in-suit are unenforceable due to inequitable conduct by Dr. Phillips. Par asserts that the evidence presented at trial establishes that for several years prior to the filing of the Provisional Application, Dr. Phillips publicly used and disclosed the combination of sodium bicarbonate and omeprazole claimed in the priority applications, and that Dr. Phillips and his legal representatives intentionally withheld this information from the PTO. For the reasons that follow, however, the court concludes that Par did not establish by clear and convincing evidence that Dr. Phillips or his legal representatives engaged in inequitable conduct.

A party alleging inequitable conduct must establish by clear and convincing evidence that the applicant: (1) made an affirmative misrepresentation of material fact, failed to disclose material information, or submitted false material information to the PTO; and (2) intended to deceive the PTO. *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008). These two elements are often shortened to "materiality" and "intent to deceive." *See, e.g., id.* ("[A]t least a threshold level of each element – i.e., both materiality and intent to deceive – must be proven by clear and convincing evidence."). "Information is material when a reasonable examiner would consider it important in deciding whether to allow the application to

issue as a patent." *Symantec Corp. v. Computer Associates Intern., Inc.*, 522 F.3d 1279, 1297 (Fed. Cir. 2008) (internal citation omitted). Intent "need not, and rarely can, be proven by direct evidence. Rather, intent to deceive is generally inferred from the facts and circumstances surrounding the applicant's overall conduct." *Impax Labs., Inc. v. Aventis Pharm. Inc.*, 468 F.3d 1366, 1375 (Fed. Cir. 2006) (quoting *Merck & Co., Inc. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418, 1422 (Fed. Cir. 1989)). In order to establish the requisite intent, "the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive." *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988).

In this case, the court finds that while Par has met its burden with respect to materiality, it has not established that Dr. Phillips or his representatives acted with the requisite intent. With respect to materiality, the evidence showed that Dr. Phillips extensively used simplified omeprazole solution ("SOS"), the aqueous solution of omeprazole and sodium bicarbonate described in the priority applications, at least as early as 1990. (See, e.g., Tr. 316:22-317:5; 310:2-7.) The SOS was administered by nurses and given to patients without any limitation, restriction, or obligation of secrecy and the administration of the solution was open to observation by residents, medical students, nurses, hospital staff, patient family, and others (see Tr. 307:7-310:1), thus making these uses public. *See, e.g., Netscape Communications Corp. v. Konrad*, 295 F.3d 1315, 1320 (Fed. Cir. 2002). Indeed, the evidence at trial showed that someone else wrote "60 milligrams [omeprazole] in eight cc sodium bicarbonate" on Dr. Phillips' physician order form for a patient receiving SOS. (See Tr. 307:16-21.) Further, it appears that the SOS was administered to patients who were not enrolled in any clinical study

(Tr. 302:9-303:10), and that the SOS was administered during the course of Dr. Phillips' salaried employment as a physician. (310:13-311:7.)

Dr. Phillips also disclosed his use of SOS to a number of medical and scientific professionals before 1995. In 1994, Dr. Phillips prepared an abstract that mentioned his use of SOS, and two scientists contacted Dr. Phillips about how to make the product. (See Tr. 321:21-323:13.) Dr. Phillips provided them with the requested information (Tr. 323:14-18), apparently without any discussion concerning confidentiality. (Tr. 323:19-324:13.) Dr. Phillips also made presentations to fellow medical and scientific professionals in the years preceding the filing of his applications during which he disclosed his use of SOS, including information about its preparation and dosing. (See, e.g., Tr. 325:12-326:3; DTX 109 at 7.)

Dr. Phillips testified that there were unwritten "understandings" or "agreements" of confidentiality regarding his disclosures of SOS. (See, e.g., Tr. 274:4-22; 282:14-24; 318:3-9; 326:22-25.) For the various uses of SOS in patients, Dr. Phillips similarly asserts that individuals with access of the information either were not aware that SOS was being administered or were in some way ignorant of the nature of the drug being administered. (E.g., Tr. 307:22-308:16.) Dr. Phillips' testimony on these points was not corroborated by either documentary or testimonial evidence, and the court does not find it credible. It does not appear that Dr. Phillips entered into any formal confidentiality agreements regarding the subject matter of the patents-in-suit until December 1995, a month before the filing of the Provisional Application. (See Tr. 321:10-14; see also Tr. 318:3-9.) Similarly, the evidence presented at trial indicated that the SOS was administered to patients on a number of occasions where numerous persons under no obligation of secrecy were able to observe the preparation and administration

of the SOS. The evidence clearly and convincingly established that Dr. Phillips publicly and repeatedly used and disclosed the composition described in the priority applications more than a year before the filing of the Provisional Application. The court finds that a reasonable examiner would have found this information important and material to the prosecution of the applications that led to the issuance of the patents-in-suit.

The court finds, however, that Par has not established that Dr. Phillips or his legal representatives acted with the requisite intent to deceive. Dr. Phillips indicated in his testimony at trial that he believed at the time he prosecuted the patents-in-suit that his duty to disclose did not extend to uses and disclosures of his invention that were not both printed and published. (See, e.g., Tr. 279:7018; 327:10-14.) Joseph Mahoney, the prosecution counsel who filed the continuation-in-part application that became the '346 Patent, testified that he did not become aware of Dr. Phillips' earlier disclosures and uses of SOS until 2000-2001. (See Tr. 160-63). In December 2001, he filed a supplemental disclosure statement that disclosed at least some of the prior uses and disclosures that Par asserts as a basis for inequitable conduct. (See id.) Given that the provisional and '737 Applications were filed in 1996 and Mr. Mahoney became involved in their prosecution in the fall of 1999 (see Tr. 157:9-11), the court admits that Dr. Phillips' and Mr. Mahoney's testimony strains credibility. It seems unlikely that for five years, Dr. Phillips was not aware that his early uses and disclosures of SOS might be relevant to patentability, and that his attorneys remained ignorant of this information throughout the same period. Nonetheless, the court finds that the evidence presented is not sufficient to establish by clear and convincing evidence that Dr. Phillips acted with an affirmative intent to deceive.

Par also asserts that Dr. Phillips and his legal representatives engaged in inequitable

conduct by failing to disclose the so-called "Critical Care Abstract." (See D.I. 173 at 28-32.) The parties dispute when this publication became publicly available. (Compare id. with D.I. 174 at 28-29.) The court finds that Dr. Phillips and his legal representatives may reasonably have believed that it was not published until after January 4, 1995, and thus was not potentially invalidating prior art under § 102 or § 103. Thus, even if the abstract was material, the court finds that Par has not established the requisite intent to deceive. For these reasons, the patents-in-suit are not unenforceable due to inequitable conduct.

D. Attorney's Fees

Santarus also moved at trial for an award of attorneys' fees pursuant to 35 U.S.C. § 285. Because the court does not find this case to be exceptional by clear and convincing evidence as required by § 285, the court will not award attorneys' fees and costs. In deciding whether to award attorney's fees, the court must undertake a two-step inquiry. *Interspiro USA, Inc. v. Figgie Intern. Inc.*, 18 F.3d 927, 933 (Fed. Cir. 1994). First, the court "must determine whether there is clear and convincing evidence that the case is 'exceptional.'" *Id.* (quotation omitted). Second, the court must determine whether "an award of attorney fees to the prevailing party is warranted." *Id.* Exceptional cases include: "inequitable conduct before the PTO; litigation misconduct; vexatious, unjustified, and otherwise bad faith litigation; a frivolous suit or willful infringement." *Epcon Gas Sys., Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1034 (Fed. Cir. 2002) (citation omitted). An award of attorney fees under § 285 is not intended to be an "ordinary thing in patent cases," and should be limited to circumstances in which it is necessary to prevent "a gross injustice" or bad faith litigation. *Forest Labs., Inc. v. Abbott Labs.*, 339 F.3d 1324, 1329 (Fed. Cir. 2003); *see also Aptix Corp. v. Quickturn Design Sys., Inc.*, 269 F.3d 1369,

1375 (Fed. Cir. 2001) (affirming an award of attorney fees under § 285 for the "extreme litigation misconduct" of falsifying evidence); *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547 (Fed. Cir. 1989) (affirming an award under § 285 following repeated violations of a permanent injunction and a district court finding of a "strategy of vexatious activity").

None of the parties' conduct in this case rises to a level of bad faith or vexatious litigation that warrants an award of attorneys' fees and costs. *See Forest Labs., Inc. v. Ivax Pharms., Inc.*, No. 03-891-JJF, 2008 U.S. Dist. LEXIS 14623, at *6-7 (D. Del. Feb. 26, 2008) (noting that "hard-fought" litigation does not necessarily constitute "vexatious or bad faith litigation" for purposes of awarding attorney fees under § 285). The court therefore finds that none of the parties are entitled to an award for attorneys' fees and costs in this case.

IV. CONCLUSION

For the reasons stated above, the court concludes that: (A) the patents-in-suit are invalid due to obviousness; (B) the patents-in-suit are not unenforceable due to inequitable conduct; and (C) an award for attorneys' fees and costs is not warranted in this case. The court further concludes that the claims of the '772 Patent are invalid for lack of written description, and that certain other asserted claims of the patents-in-suit are not entitled to the filing date of earlier applications because the disclosures in one or more of the priority applications do not meet the written description requirement. *See* Table 1, *supra*. An appropriate order will follow.

Dated: April 14, 2010

CHIEF, UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANTARUS, INC., and THE CURATORS OF THE UNIVERSITY OF MISSOURI, Plaintiffs, v. PAR PHARMACEUTICAL, INC., Defendant.	)	C.A. No. 07-551-GMS

ORDER

At Wilmington, this 14th day of April, 2010, IT IS HEREBY ORDERED THAT:

1. The patents-in-suit are invalid as obvious in light of the prior art.

2. An award for attorneys' fees and costs is not warranted in this case.

3. The Clerk of Court is directed to enter judgment in favor of Par and against the plaintiffs.

CHIEF, UNITED STATES DISTRICT JUDGE