IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

APOTEX INC., Plaintiff,	:	CIVIL ACTION
v.	:	No. 2:06-cv-2768
CEPHALON, INC., et al., Defendants.	:	

Goldberg, J. **November 7, 2011**

AMENDED MEMORANDUM OPINION[1]

At issue in this case is the validity and enforceability of Defendant, Cephalon, Inc.'s, RE'516 patent for Provigil®, a drug commonly prescribed for sleep disorders. After careful review and consideration of the evidence presented at a bench trial, I find that Plaintiff, Apotex, Inc., has met its burden in proving the invalidity of this patent. Specifically, I find that: (1) The invention claimed was on sale more than one year prior to the date of the application for the patent, 35 U.S.C. § 102(b); (2) The claimed invention was actually invented by a French company, Laboratoire L. Lafon (hereinafter, Lafon); (3) The subject matter at issue as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art, 35 U.S.C. § 103(a); and (4) The patent is invalid for failing the written description requirement of 35 U.S.C. § 112.[2] I also find that the patent is unenforceable due to inequitable conduct on the part of Cephalon. This Opinion explains the basis for these conclusions.

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[1] This Amended Opinion is issued only to correct a few typographical errors on pages 28, 45 and 47. It is, in all other respects, the same as the October 31, 2011 Opinion (doc. no. 513).

[2] Apotex has withdrawn its claims for invalidity based on public use and enablement. Therefore, those claims will not be addressed. (Apotex Post-Trial Memo., p. 1 n. 1.)

I. Introduction

Apotex, a generic drug manufacturer, commenced this declaratory action in June 2006, alleging non-infringement, invalidity and unenforceability of Cephalon's RE'516 patent for Provigil®. This lawsuit is a result of Apotex's continuing efforts to gain approval of its Abbreviated New Drug Application (hereinafter "ANDA") 77-677 and enter the market with a generic version of Provigil®.

After completion of discovery, the Court bifurcated for trial Apotex's invalidity and unenforceability claims from its non-infringement claim. (See doc. no. 426.) A bench trial on Apotex's invalidity and unforceability claims was held first from March 29 - April 7, 2011. A subsequent bench trial on Apotex's non-infringement claims was held July 12 - 20, 2011, and the Court's decision on that issue is forthcoming.

Both the invalidity and infringement disputes revolve around a claimed invention for smaller particle size of the primary chemical compound, modafinil, that positively affected the bioavailability and dissolution of the drug. The pertinent portion of the claim states:

> A pharmaceutical composition comprising a substantially homogeneous mixture of modafinil particles, wherein at least about 95% of the cumulative total of modafinil particles in said composition have a diameter of less than about 200 microns (μm).

While Apotex pressed numerous theories at the invalidity trial, its primary argument was that the RE'516 patent is invalid and unenforceable because Lafon invented the claimed subject matter. Apotex stresses that Lafon was consistently manufacturing and then selling modafinil with smaller particle size. Apotex further urges that Cephalon's claim regarding the discovery of the significance of smaller particle size as it relates to the issues of bioavailability and dissolution is immaterial because "unexpected results" are irrelevant to determining derivation. Finally, Apotex claims

invalidity through an "on-sale bar" and further raises issues regarding alleged material misrepresentations to the United States Patent and Trademark Office (hereinafter "PTO"), obviousness and inadequate written description.

Cephalon does not dispute that it received smaller particle size modafinil from Lafon and that such particle size fell within the claims of the RE'516 patent. Cephalon also unequivocally concedes that it did not change, modify or manipulate the modafinil it received from Lafon. Rather, Cephalon rests almost its entire case on the proposition that its "invention" is the appreciation of the significance of smaller particle size. Cephalon also explains that the modafinil it received from Lafon was not "on sale" because it was used for clinical testing, and thus, was experimental. According to Cephalon, during these clinical tests, it discovered the significance of improved bioavailability and dissolution achieved from smaller particle size, which is a significance Lafon never appreciated.

Prior to setting forth my reasoning in finding in favor of Apotex, I note that many of the underlying facts in this case are undisputed.[3] Moreover, most of the testimony presented at trial was through expert witnesses. Thus, to the extent that some of the following "findings of fact" may appear to be more "legal" than "factual," those findings reflect the Court's acceptance of the experts' opinions.

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[3] I recognize that Counsel had previously been advised that the Court's ruling would be delivered through an opinion, without findings of fact and conclusions of law and thus, proposed submissions from the parties along those lines would not be received. Upon further consideration, I have determined that it is clearer to communicate my reasoning through findings of fact. Because most of these facts are uncontested, it remains my view that proposed factual findings submissions by the parties are unnecessary.

II. Findings of Fact

A. Background

1. Plaintiff Apotex Inc. is a corporation organized and existing under the laws of Canada, with its principal place of business at 150 Signet Dr., Weston, Ontario M9L1T9. (Stip., doc. no. 438.)

2. Defendant Cephalon, Inc. is a corporation organized and existing under the laws of the state of Delaware, with its principal place of business at 41 Moores Road, Frazer, Pennsylvania 19355. (Stip., doc. no. 438.)

3. Laboratoire L. Lafon was a French company founded by Louis Lafon that was purchased by Cephalon on December 28, 2001, and is now known as Cephalon France. (Stip., doc. no. 438.)

4. Lafon discovered modafinil in 1976, and as of 1993, Lafon had a stable and bioavailable dosage form of modafinil that was approved for sale in Europe. (N.T. 4/1/11, pp. 42, 45-46.)

5. The '290 patent was issued to Louis Lafon and assigned to Lafon on December 4, 1979, for the chemical modafinil. (N.T. 3/29/11, p. 121.)

6. The '290 patent claimed 200 mg as the dosage for humans. (N.T. 3/29/11, p. 122.)

7. Lafon's '290 patent on modafinil does not include any references to particle size. (N.T. 3/30/11, p. 10; PTX 5.)

8. Cephalon filed an Investigational New Drug Application for modafinil tablets on June 30, 1993. Cephalon filed a New Drug Application ("NDA"), No. 20-717, for Provigil® on December 26, 1996. The U.S. Food and Drug Administration ("FDA") approved the NDA on December 24, 1998, and Cephalon began marketing Provigil® in February 1999. (Stip.,

doc. no. 438.)

9. Cephalon filed U.S. Patent Application No. 08/319,124 with the PTO on October 6, 1994. That application issued on April 8, 1997 as U.S. Patent No. 5,618,845 ("the '845 patent") with six claims. The '845 patent is titled "Acetamide derivative having defined particle size," and names inventors Peter E. Grebow, Vincent Corvari and David Stong. (Stip., doc. no. 438.)

10. On April 1, 1999, Cephalon filed U.S. Patent Application No. 09/285,166 seeking a reissue of the '845 patent. The PTO issued U.S. Reissue Patent No. 37,516 ("the RE'516 patent") on January 15, 2002, with twenty-six claims.[4] The RE'516 patent is titled "Acetamide derivative having defined particle size," and also names inventors Peter E. Grebow, Vincent Corvari and David Stong. In pertinent part, the RE'516 patent claims:

> [a] pharmaceutical composition comprising a substantially homogeneous mixture of modafinil particles, wherein at least 95% of the cumulative total of modafinil particles in said composition have a diameter less than about 200 microns (μm).

(Stip., doc. no. 438; JTX 1.)

11. The RE'516 patent was listed in the "Approved Drug Products With Therapeutic Equivalence Evaluations," an FDA publication more commonly known as the "Orange Book." (Stip., doc. no. 438.)

12. On March 30, 2005, Apotex filed ANDA No. 77-667, seeking FDA approval for its generic

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[4] A reissue patent application is made by someone who already has a patent, but has then decided that it does not cover the claims the way it should. The claims are either too narrow or too broad. The reissue is a mechanism to correct those errors. Filing a reissue patent application puts the entire patent, including the original claims, at risk. If the reissue patent is granted, then the patentee must surrender the original patent. However, the patent term continues to run from the date of the original application. (N.T. 4/6/11, pp. 117-19.)

version of Provigil®. That ANDA included a Paragraph III certification to the RE '516 patent. (Stip., doc. no. 438.) Under the Hatch Waxman Act, a Paragraph III certification is a statement by a generic drug manufacturer that a name brand drug exists, has a valid patent, and that the generic drug manufacturer will not sell its product until the patent expires. 21 U.S.C. § 355(j)(2)(A)(vii).

13. On March 9, 2006, Apotex changed its Paragraph III certification to a Paragraph IV certification. A Paragraph IV certification is a technical act of infringement by the generic drug manufacturer, which alleges that the patent is invalid and/or that the generic drug will not infringe on the patent. A Paragraph IV certification allows the name brand manufacturer to sue the generic manufacturer for infringement. Glaxo Group, Ltd. v. Apotex, Inc., 376 F.3d 1339, 1351 (Fed. Cir. 2004); see also (Stip., doc. no. 438).

14. Apotex filed its original declaratory judgment complaint on June 26, 2006 and subsequently filed amended and second amended complaints, which seek, inter alia, declaratory judgments that the RE'516 patent is not infringed, invalid and unenforceable.[5] (Stip., doc. no. 438.)

B. Experts

15. Dr. David Beach, who testified for Apotex, is an expert in pharmaceutical manufacturing and pharmaceutical formulation. (N.T. 3/29/11, pp. 99-100.)

16. At the subsequent infringement trial,[6] Dr. Beach acknowledged that between 1994 and 2004 he was the President and a member of the Board of Directors at Torpharm, a subsidiary of

[5] This matter was reassigned to me on April 28, 2009. (Doc. no. 82.)

[6] The parties agreed that, to the extent it is relevant, evidence elicited at the infringement trial may be considered in the invalidity trial.

Apotex. In 2004, when Torpharm was absorbed by Aptoex, Dr. Beach entered into a separation agreement with Aptoex that called for him to transition out of his role at the company. Dr. Beach eventually left Apotex altogether in 2006. (N.T. 7/19/11, pp. 129-131.) The separation agreement also provided that Apotex would pay Dr. Beach $1 million in severance pay, and buy his equity interest in the company. Additionally, if Apotex were to be sold any time prior to the end of 2012, Dr. Beach would be paid the difference between the value of his ownership interest at the time of the sale and what he was paid for that interest when he left the company. (N.T. 7/19/11, pp. 130-31.)

17. A finding that the RE'516 patent is invalid will allow Apotex to enter the market and could result in an increased valuation of Apotex. If Apotex were sold before the end of 2012, that could also result in an increased payout for Dr. Beach under the separation agreement described above. While I have considered that this scenario provides a financial incentive for Dr. Beach to testify in favor of Apotex, his credibility is not essential to my determination, which, as set out infra, rests almost entirely upon documents, agreed-upon facts and lay witness testimony.

18. Dr. David Feifel, an Apotex witness, is an expert on narcolepsy, pharmacological profiles of drugs and analyzing the results of pre-clinical and clinical trials. (N.T. 3/30/11, pp. 86, 102.)

19. Dr. Palmieri, an Apotex witness, is an expert in the field of pharmaceutics, which includes the production and examination of pharmaceutical dosage forms. (NT. 3/31/11, pp. 28-29, 49-50; PTX 109.)

20. George Gerstman, an Apotex witness, is an expert on the PTO's practices and procedures,

and patent prosecution. (N.T. 4/1/11, pp. 97-124.)

21. Dr. Eugene Cooper, a Cephalon witness, is an expert in the field of pharmaceutical formulation and pharmaceutical dosage forms. (N.T. 4/6/11, pp. 5-18; DTX 155.)

22. Dr. Baranski, a Cephalon witness, is an expert on the physical and psychological effects of modafinil on humans and the interpretation of results of testing involving modafinil. (N.T. 4/4/11, pp. 40-41, 54, 61.)

23. Cephalon's expert on the PTO's practices and procedures is Bruce H. Stoner, who also testified as an expert in patent law and what types of information would be important in the prosecution of patents. (N.T. 4/6/11, pp. 98, 110; DTX 157.)

C. Lafon's Work/Derivation

24. Consideration of particle size by Lafon occurred as far back as 1986, when Lafon intentionally crushed modafinil particles in order to better compress the loose powder into tablet form. Lafon knew that they were crushing the particles to a median of 90 microns. Lafon then retested once they were able to increase compression and decided to remain at the 200 micron size. (Leyder Depo., 3/30/04, pp. 41-43.)

25. Prior to 1993, Lafon conducted 125 total studies on modafinil, involving over 2,000 patients and using 9 different lots of tablets made from 30 different batches of modafinil. (N.T. 4/1/11, pp. 73-77; PTX 65.)

26. Lafon also conducted a number of studies in 1979, 1981, 1989, 1990, and 1992 on the effect of modafinil on narcoplesy. All of these tests were conducted before Lafon shipped modafinil to Cephalon in 1993. The articles published about these studies detailed the results from the testing of 50 to 700 mg of modafinil and evaluated issues such as dosage, abuse

potential and side effects. (N.T. 3/29/11, pp. 124-26; N.T. 3/30/11, pp. 115-25; JTX 1, col. 1; PTX 17; PTX 31; PTX 43.)

27. Lafon conducted extensive clinical studies and received French regulatory approval for the treatment of narcolepsy with modafinil in February, 1992. (N.T. 3/29/11, pp. 128-29; PTX 64A, Bates CPH-PLD_00001869.)

28. Lafon manufactured and tested several different active pharmaceutical ingredient ("API") batches and tablet lots over the course of its development of modafinil. The following chart sets forth different modafinil API batches and tablet lots produced by Lafon and shipped to Cephalon from 1986 to 1993, and notes the relevant particle size characteristics found in each batch/lot. (PDX 2.)

Lafon Modafinil Batch No.	**RE'516 Patent Designation**	**Batch Measurement Date**	**Approximate 95% Cumulative Value (µm)**	**Median Diameter (µm)**	**Tablet Lots**
5/1939	E-A	September 1986	> 327	202.7	
5/2171	E-B	September 1986	> 260	164.6	
5/2236	E-C	December 1986	260	76.2	
5/2435	not disclosed	January 1989	< 130	49.6	12 845, 12 975
1/0103	not disclosed	January 1993	< 164	71.0	
001	not disclosed	October 1993	< 164	70.8	
002A	E-D	January 1993	206-260	98.2	M005
003	L-1	May 14, 1993	130	37.2	M006
004	not disclosed	April 15, 1993	130	26.3	
005	L-2	April 15, 1993	< 130	30.7	

29. From October 1989 to June 1991, Lafon used Batch 5/2435 in clinical study MOD-25, which evaluated the effect of small particle modafinil on narcoleptic patients. (N.T. 3/29/11, pp. 154-56; PTX 104.)

30. In May-June 1991, Lafon used Batch 5/2435 in another clinical study, MOD-29, evaluating the predictive effects of abuse liability in modafinil as compared to amphetamine, caffeine and placebo. The fact that Lafon was using this material in clinical studies establishes that they were aware it was an effective drug. (N.T. 3/29/11, pp. 150-51, 160-61; N.T. 3/30/11, pp. 113-24; PTX 65, Bates CPH-FTC 00036028; PTX 79; PTX 96b, Bates CPH_PLD_00039070; PTX 104, Bates CPH_PLD_00071298.)

31. The particle size of several batches shipped from Lafon to Cephalon between 1989 and 1993 fell squarely within the claims of the RE'516 patent. Batch 5/2435 had 99.8 percent of the particles less than 206.36 microns and a median particle size of 49.56 microns, which also falls within the RE'516 claims. Batch 003 had 98.62 percent of its particles less than 206.36 microns. The median of that lot was 37.2 microns, and thus that entire lot falls within Claims 1-14 and 16 of the RE'516 patent.

32. In a memo from Jacquelyn Naduad at Lafon dated November 10, 1993, to Dr. Grebow, the alleged inventor at Cephalon, Lafon conveyed its particle size analysis of different batches. This information was communicated to Grebow prior to Lafon shipping Batch 003 to Cephalon. Additionally, Batch 005 had 99.8 percent of the particles less than 206.36 microns, with a median of 30.7 microns. This is also within the claimed range of the RE'516 patent. (N.T. 3/29/11, pp. 138-47; PTX 83, Bates CPH-FTC 00032133, 00032136-37, 00032140.)

33. Cephalon concedes, as they must, that Lafon made batches of modafinil tablets that fell within the RE'516 patent claims. (N.T. 3/29/11, pp. 58-59.)

34. The trend in the data from Lafon's test results on modafinil API batches establishes that Lafon was purposefully decreasing particle size. From January 1989 to July 1993, six out of the seven modafinil API batches produced by Lafon fell within claim 1 of the patent and four out of seven batches fell within claim 2 of the patent. (N.T. 3/29/11, pp. 162-67; PDX 2, PDX 6; PTX 7; Moachan Depo., 5/27/04, pp. 278-79; Moisan Depo., 4/1/04, pp. 46-47.)

35. Lafon and Cephalon started meeting in 1992 to discuss Cephalon as a licensee of modafinil in the United States. Prior to the formalization of their relationship, and as part of those meetings, Lafon supplied technical information about its modafinil to Cephalon. (N.T. 4/4/11, p. 174.)

36. Lafon provided Cephalon with data from 1989 tests which showed that Lafon achieved better dissolution rates with modafinil that was ground into smaller particles than with non-ground. (N.T. 3/29/11, pp. 168-70; PTX 20a; PTX 131b.)

37. After a visit to Lafon in October 1992, Dr. Grebow noted that there had been a change in the formulation of the modafinil during development which involved decreasing particle size. (N.T. 4/5/11, pp. 141-42; PTX 36.)

38. In October 1992, Lafon conveyed to Cephalon that they decreased the particle size of modafinil and conducted all clinical trials with small particle modafinil. Lafon also conveyed that their recommended dosage was early morning and early afternoon for a total of 300 mg, which they had found to be successful in treating narcolepsy in clinical studies. (N.T. 3/29/11, pp. 172-74; N.T. 3/30/11, pp. 115-18; PTX 36, Bates CPH_PLD_ 00046185; PTX 43, Bates AI 0000604.)

39. In November 1992, Lafon conveyed to Cephalon that they knew particle size related to

solubility and that they would be measuring the particle size of the bulk API to be supplied for Cephalon's clinical studies. (N.T. 3/29/11, pp. 175-77; PTX 37, Bates CPH_PLD _00050278-80.)

40. On February 26, 1993, Cephalon sent Lafon a fax requesting particle size information. Lafon responded that 300-315 microns was their specification for the modafinil API, which was the range approved by the French regulatory agency. (N.T. 4/4/11, pp. 201-10, 218; PTX 197, CPH-FTC 00023337; DTX 52; DTX 54.)

41. In March 1993, Lafon conveyed to Cephalon that the recommended dosage was a range of 200 to 400 mg a day with 300 mg being the most used. Lafon also acknowledged that it had conducted various particle size tests in accordance with the United States and European Pharmacopedia. (N.T. 3/29/11, pp. 177-79; PDX 19; PTX 56, Bates CPH_PLD_00018794, 97.)

42. A Phase I study is a study conducted in normal volunteers to assess maximum tolerated dosage, drug interaction, effect of food on the medication, etc. This study provides a baseline for the drug so it can be studied in patients. (N.T. 4/4/11, p. 230.)

43. Lafon conducted a Phase I study where increasing dosages of modafinil were administered to patients. That study revealed that modafinil, particularly at high dosages of 800 and 1,000 mg, increased heart rate and blood pressure. Despite having received this information from Lafon, Cephalon subsequently informed the PTO that there were "no statistically significant changes in heart rate or blood pressure." (N.T. 3/30/11, pp.138-52; JTX 4, Bates CPH_PLD_00000331; PDX 20; PTX 53.)

44. In meetings held on March 29 and 30, 1993, Lafon communicated to Cephalon that its

clinical investigations showed that the maximum tolerable dosage was 600 mg. (N.T. 3/30/11, pp. 154-56; N.T. 4/4/11, pp. 109, 137-40; PDX 19; PTX 51, Bates CPH_PLD_00050336-37; PTX 56, Bates CPH_PLD_00018795.)

45. On April 19, 1993, Lafon sent Cephalon a memorandum advising that side effects from modafinil could be seen in normal healthy patients. (N.T. 4/4/11, pp. 125-27; PTX 60.)

46. Lafon's P-1421 study showed statistically significant changes in blood pressure with increased dosages of modafinil, and a report on that study was sent to Cephalon in May 1993. (N.T. 4/4/11, pp. 143-55; PTX 193, Bates CPH-FTC 00028364.)

47. Cephalon learned about the safety and efficacy of modafinil from Lafon's French clinical studies. (N.T. 4/4/11, p. 194.)

48. Cephalon received and reviewed all of Lafon's clinical trial data from January to June 1993. (N.T. 4/4/11, p. 219; N.T. 4/5/11, p. 15.)

49. Dr. Grebow noted Lafon's clinical test results as set forth in a June 14, 1993, investigative brochure, which is one of the documents filed with an Investigational New Drug Application (hereinafter "IND").[7] (N.T. 3/29/11, pp. 156-57; PTX 62.)

50. All of the characteristics of the modafinil claimed in the patent were already present when it was manufactured by Lafon and shipped to Cephalon in July 1993. (N.T. 4/5/11, p. 135.)

51. Lafon observed the regular decrease in the median value for particle size, except for the recrystallized batch, and conveyed that information to Cephalon in October 1993. (N.T. 4/5/11, pp. 98-99; PTX 83, Bates CPH-FTC 00032133.)

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[7] An IND seeks approval from the FDA to ship a drug which has not yet been approved for marketing across state lines to conduct clinical trials. See Integra Lifesciences I, Ltd. v. Merck KGA, 496 F.3d 1334, 1336 (Fed. Cir. 2007).

52. Lafon supplied Cephalon with particle size measurements for all of its batches on November 15, 1993. (N.T. 4/5/11, p. 101.)

53. Lafon recommended Batch 5/2236 (early Lot C) to Cephalon on November 25, 1993, as the reference lot having the appropriate specifications for use in manufacturing Cephalon's proposed version of the drug. (N.T. 4/5/11, pp. 54-58; DTX 106.)

54. Cephalon responded on November 29, 1993, noting that they wished to use a specification more similar to Batch 003 – 005, not 5/2236. That was the specification later agreed upon. (N.T. 4/5/11, pp. 62-64; DTX 107; Shek Depo., 8/5/04, pp. 196-97.)

55. Lafon later admitted that their recommendation to use Batch 5/2236 as the reference lot was strictly a business decision in an attempt to not jeopardize their French regulatory filings. However, Lafon was using Batch 003 as their good manufacturing practices standard batch. (N.T. 4/5/11, pp.114-118; PTX 63B, 84.)

56. Mr. Michel Moisan from Lafon acknowledged that Lafon measured the particle sizes of modafinil in the scaled-up lots, wherein the particle size of modafinil had been decreased, and found that there was a demonstrated relationship between particle size and bioavailability. (N.T. 3/30/11, pp. 71-77; Moisan Depo., 4/1/04, pp. 46-50.)

D. <u>License and Supply Agreement/On-Sale Bar</u>

57. On January 20, 1993, Cephalon entered into Supply and License Agreements with Lafon. (Stip., doc. no. 438; N.T. 3/29/11, pp. 129-30; PTX 48, Bates CPH_PLD_00023471; PTX 49.)

58. In a letter from a senior regulatory affairs director at Cephalon to the FDA, Cephalon advised that it received a license from Lafon to develop and market modafinil in the United States.

(N.T. 3/29/11, pp. 128-29; PTX 64A, Bates CPH_PLD_00001869.)

59. Pursuant to the Supply Agreement, on July 13, 1993, Lafon sent Cephalon 25 kg of Batch 003 modafinil API and 50,000 tablets from Lot M006. The API and tablets were received by Cephalon on July 23, 1993. (Stip., doc. no. 438.)

60. The Supply Agreement states that Lafon will supply Cephalon with modafinil free of charge in exchange for Cephalon paying for clinical testing in the U.S. In exchange for the "free supply," Cephalon would pay Lafon 11% of the net sales. (N.T. 3/29/11, pp. 130-33; N.T. 4/4/11, pp. 185-87; PTX 48; DTX 71.)

61. Pursuant to the Supply Agreement, Lafon began sending Cephalon commercialized shipments of modafinil in 1999, and Cephalon paid for those shipments. (Heacock Depo., 1/27/04, pp. 25-26.)

62. The License Agreement provided that Cephalon would use reasonable efforts to file the IND for modafinil in the United States and that they would work to do this as expeditiously as possible. (N.T. 4/4/11, pp. 188-89; PTX 49; DTX 72.)

63. The on-sale bar critical date is October 6, 1993, one year prior to the filing of the '845 patent. (N.T. 3/29/11, p. 109; N.T. 4/6/11, p. 133.)

E. <u>Cephalon's Work/Unexpected Results</u>

64. Cephalon concedes that the API and tablets it tested were manufactured by Lafon. (N.T. 4/5/11, pp. 93-94.)

65. Cephalon measured the particle size of modafinil from the API, not the tablet. (N.T. 3/29/11, p. 107; N.T. 4/5/11, p. 144.)

66. The clinical testing necessary to bring modafinil to market in the United States was estimated

to cost over a million dollars. (N.T. 4/5/11, p. 124.)

67. In 1993, Cephalon conducted a Phase I study, CEP-2101, wherein it administered increasing dosages of modafinil to patients. Cephalon concluded that because of adverse cardiovascular effects seen in one patient at the 800 mg dosage, the study had to be stopped and that the maximum tolerable dosage was 600 mg. In the patent, Cephalon claims that the "elevations in heart rate [in this study] were totally unexpected." (N.T. 3/30/11, pp. 152-59; N.T. 4/4/11, pp. 92-93; PTX 101a, Bates AI 0005820; DTX 99, Bates CPH_PLD_00019893.)

68. Cephalon's Phase I study was conducted in August 1993 in healthy males, ages 21-30. The study was a double blind study so neither the volunteers nor the administrators knew who was getting placebo or medication. (N.T. 4/4/11, p. 235.)

69. Cephalon's Phase I study was stopped two to three days after the volunteers received 800 mg of modafinil when one patient's blood pressure and heart rate were elevated for a sustained period of time after the dose administration. (N.T. 4/5/11, pp. 8-12; PTX 197; DTX 99.)

70. Cephalon conveyed to Lafon the results of the patient with elevated heart rate and blood pressure in a fax, where it was noted that Cephalon "anticipated these effects" based on the extensive Lafon database. (N.T. 4/5/11, pp. 21-24; PTX 69.)

71. Cephalon first noted that it wanted to investigate particle size distribution on October 8, 1993. (N.T. 4/5/11, pp. 29-30.)

72. In October 1993, Cephalon began to conduct a number of experiments, including dissolution testing and photographing of particle size. Cephalon also conducted a test on the effects of modafinil of different particle sizes on the blood plasma levels in dogs. (N.T. 4/5/11, pp. 46-50.)

73. In its ANDA, Cephalon represented to the FDA that "the variation in the median particle size from 50.18 microns to 94.05 microns did not affect oral absorption of modafinil in dogs," while conversely stating to the PTO in the RE'516 patent that there is increased potency with smaller particles because the "median particle size of 50.18 microns resulted in a higher peak plasma concentration than with larger particles." (N.T. 3/30/11, pp. 128-36; JTX 1, Bates AI 0005271; PDX 21; PTX 96a, Bates CPH-FTC 00045337.)

74. On October 20, 1993, Cephalon wrote to Lafon advising that they had confirmed the effect of particle size on intrinsic dissolution. (N.T. 4/5/11, pp. 41-46; PTX 72.)

75. On October 26, 1993, twenty days after stopping its clinical trial, Cepahlon claims to have done its particle size analysis with a Hiac/Royko. However, the summary of that analysis does not include any actual particle size measurements. (N.T. 4/5/11, pp. 153-57; DTX 98, Bates CPH_PLD_17817-17823.)

76. The first time Cephalon conducted Hiac/Royko testing to measure the particle size of modafinil was on February 16, 1994. (N.T. 4/5/11, p. 126.)

77. On October 5, 1994, Cephalon's patent attorney noted that one of Cephalon's scientists reanalyzed the modafinil lots so that they would not have to rely on Lafon's data. (PTX 91.)

78. Dr. Grebow claims to have made the discovery, which is the basis for the patent, in the fourth quarter of 1993. (N.T. 4/5/11, p. 74.)

79. Dr. Grebow described the invention as modafinil with a threshold particle size of about 200 microns resulting in reproducible dissolution results and consistent bioavailability. (N.T. 4/4/11, pp. 173-74; N.T. 4/5/11, p. 134.)

80. The claimed "invention" was very simple - modafinil with 95 percent of its particles smaller

than about 200 microns. Modafinil with those characteristics was manufactured by Lafon and used by Cephlaon without change or improvement. (N.T. 4/6/11, pp. 20-22, 48-49; Shek Depo., 8/5/04, pp. 196-97, 250-51.)

81. Lafon was surprised that Cephalon patented the particle size because Lafon was the "owner" of the molecule and Cephalon was its client for use of the molecule in the United States. (Moisan Depo., 4/1/04, pp. 171-72.)

F. Prior Art/Obviousness

82. A person of ordinary skill in the art is a person with a bachelor's degree in chemistry, either in chemical engineering or pharmaceutical sciences. Such person would also most likely have a Ph.D. in pharmaceutical sciences or a related field and would be familiar with preformulation, formulation and the FDA and other regulatory bodies. A person skilled in the art would also have lab experience, would be familiar with particle size, and would know why measuring particle size is important, and how particle size affects dissolution and bioavailability. That person would also be a medical doctor who has treated conditions such as narcolepsy, which modafinil is known to affect. (N.T. 3/31/11, pp. 79-80; N.T. 4/6/11, p. 27.)

83. The obviousness inquiry considers materials publically available one year prior to the date of the '845 patent application - October 6, 1993, and earlier. Modafinil was known to treat narcolepsy in October 1993. (N.T. 4/6/11, pp. 73-74.)

84. A person of skill in the art would have known that modafinil was effective to treat the conditions listed in the RE'516 patent in the early 1990's. (N.T. 3/31/11, p. 81.)

85. There were articles published in the early 1990s which showed that drugs could be

reformulated to have a smaller particle size and achieve better therapeutic results and/or the same results with a smaller dosage. (N.T. 3/31/11, pp. 126-29; PTX 32; PTX 41.)

86. Once API is past the laboratory stage, particle size analysis is typically one of the first tests undertaken because it plays a key role in performance of the drug and dissolution rate. Literature available in the early 1990s suggested that new drugs be ground to a diameter of 30 microns, or at least between 10 to 40 microns. (N.T. 3/29/11, pp. 101-04; N.T. 3/31/11, pp. 93-96; PTX 6, Bates AI0088870.)

87. A person skilled in the art would have known, as early as 1966, that reducing particle size increases surface area, which increases the dissolution rate of pharmaceutics. (N.T. 3/31/11, pp. 85-92; PTX 1.)

88. The unique relationship between particle size and dissolution is an inherent property, and is therefore an inherent property of modafinil. (Shek Depo., 8/5/04, pp. 22-23.)

89. It was known to people skilled in the art in 1993/1994 that reducing particle size increased bioavailability. (N.T. 4/6/11, pp. 30-32.)

90. Increasing bioavailability is not always positive and does not always lead to the desired result. Decreasing particle size, and, thus, increasing bioavailability, can lead to toxicity, the particles could dissolve too fast to be absorbed into the body, and static electricity has a greater impact on smaller particles. (N.T. 4/6/11, pp. 34-38; PTX 6, Bates AI0088870.)

91. A person skilled in the art in the early 1990's would have known that reducing the particle size of modafinil would allow for increased potency and/or reduced dosage. (N.T. 3/31/11, pp. 81, 128.)

92. Based on the information available in the early 1990s, a person of ordinary skill in the art

would have ground modafinil and would have arrived at a particle size that fell within the claim limitations of the RE'516 patent. (N.T. 3/31/11, pp. 108-09; PTX 6.)

93. Figure 6 in the RE'516 patent is a classical dissolution curve where the dissolution rates of one early lot with large particle modafinil and one late lot with small particle modafinil are represented. Figure 7 in the RE'516 patent is a classical dissolution curve representing the dissolution rates of two early lots of large particle modafinil and one late lot of small particle modafinil. The graphs are exactly what someone skilled in the art prior to October 6, 1994, would expect in that smaller particles dissolve faster than larger particles. (N.T. 3/31/11, pp. 55-57, 62, 132; JTX 1, Bates AI 0005265.)

94. Anyone skilled in the art who had the capability of measuring particle size on July 26, 1993, would have been able to determine that Batch 003 had a 95 cumulative value under 220 mircrons. (N.T. 4/5/11, p. 122.)

95. A 1987 FDA publication recognized that particle size is important in terms of dissolution and bioavailability of poorly water soluble drugs such as modafinil. (N.T. 3/31/11, pp. 119-22; PTX 16, Bates AI0089407, 89457-58.)

96. A person skilled in the art would have known that modafinil was poorly water soluble in the early 1990s and would have sought to reduce its particle size if it received the chemical with a median particle size substantially larger than 40 microns. (N.T. 3/31/11, pp. 82-84, 95; N.T. 4/1/11, pp. 54-55; PTX 6 at Bates AI88870; PTX 27.)

97. A person skilled in the art would have known the clinically effective dosages of modafinil in the early 1990s. (N.T. 3/31/11, pp. 81-82; PDX 42.)

98. The prior art shows that 100 to 200 mg of modafinil is safe and effective to treat narcolepsy.

(N.T. 4/4/11, p. 121.)

99. The 1990 U.S. Pharmacopedia, which is the compendium for drug standards in the U.S., allowed 85 to 115 percent weight variation from the amount claimed. For example, a 100 mg tablet could actually have 85 mg to 115 mg of the claimed ingredient. (N.T. 3/31/11, pp. 113-16; PTX 26, Bates AI0088717.)

100. The claim of an additional 10 to 15 percent of modafinil as stated in claims 13 and 14 of the RE'516 patent would have been obvious to one skilled in the art in the early 1990s. (N.T. 3/31/11, p. 117; N.T. 4/5/11, p. 146.)

G. Written Description

101. The patent only describes the particle size measurement of the modafinil API, not the measurement of modafinil in the finished tablet. (JTX 1; N.T. 3/30/11, pp. 57-60; Heacock Depo., 1/27/04, pp. 87-88.)

102. One of ordinary skill in the art would not know if the particle size in the finished Provigil® tablet was the same as the measurement of the modafinil API, pre-tabletting. (JTX 1; N.T. 3/30/11, pp. 57-60; Heacock Depo., 1/27/04, pp. 87-88.)

H. The Patent Office

103. The Manual of Patent Examining Procedure (MPEP) sets out rules for both patent examiners and patent practitioners. (N.T. 4/1/11, p. 103; PTX 142; PTX 239.)

104. After a patent is filed, it is classified by subject matter. New patent applications are typically reviewed chronologically. Once a patent comes up for examination, which could take up to two years, the examiner searches through previous patents within the appropriate classes of

subject matter. The examiner looks for prior art in previously filed patents that meets the language of the patent up for review. (N.T. 4/1/11, pp. 143-44.)

105. In a memo to various executives on October 5, 1994, regarding Cephalon's patent application, Cephalon's in-house patent attorney stated, "this application is 'unusual' in the sense that we did not want to include any of Lafon's data so as to avoid disclosing their 'confidential' information; thus, the task of 'disclosure' of the invention was unique." (N.T. 4/5/11, p. 84; PTX 91, Bates CPH-FTC 00045117; Burgoon Depo., 10/27/10, pp. 237-38.)

106. Cephalon never disclosed to the PTO that: Lafon was the manufacturer of Batch 003; that Lafon had measured the particle size of that batch prior to providing it to Cephalon; that Lafon had manufactured and tested several modafinil lots that fell within the claim limitations; or that the two companies had both supply and license agreements. (N.T. 3/29/11, pp. 181-83; N.T. 4/1/11, pp. 116, 146-47; PTX 239, pp. 2100-27; Burgoon Depo., 7/23/04, pp. 159-60.)

107. On June 27, 1995, the PTO issued an office action (an official communication from the PTO), rejecting all of the claims under 35 U.S.C. § 103 as obvious. The examiner concluded that there were references to the smaller particle sizes in connection with the old modafinil, and that while the early lots had larger particles, it would have been obvious to make them smaller. The examiner further concluded that it was obvious that if particle size is reduced, potency, bioavailability and dissolution rate are increased, and there are higher peak plasma levels. (N.T. 4/1/11, pp. 23-27, 146; JTX 4, Bates CPH_PLD_00000245-47.)

108. After receiving the office action rejecting the patent for obviousness, Cephalon's patent attorneys requested an in-person interview with the examiner. In an attempt to rebut the

obviousness rejection, Cephalon filed a pre-interview submission which included a declaration by Dr. Shek. (N.T. 4/1/11, pp. 153-54; JTX 4, Bates CPH_PLD_00000253.)

109. Cephalon also filed a formal response wherein they asserted that "it is probative of non-obviousness that the materials which are the subject of the invention and had long been known, but had never before been modified as the inventors had done." (N.T. 4/1/11, pp. 157-58; JTX 4, Bates CPH_PLD_00000343.) As noted previously (Fact 80), Cephalon never modified the modafinil it received from Lafon.

110. In response to subsequent office actions wherein the patent was again rejected as obvious, Cephalon asserted that prior foreign studies on modafinil's bioavailability do not suggest that one of ordinary skill in the art would be motivated or expected to manipulate the particle size of modafinil. (N.T. 4/1/11, pp. 160-61; JTX 4, Bates CPH_PLD_00000437, 441.)

111. On September 5, 1995, approximately 11 months after Cephalon applied for the patent, it submitted another declaration by Dr. Shek. This declaration contained a graph representing the dissolution rates of large particle, early lot, modafinil and small particle, late lot, modafinil. When compared to the dissolution data present in the patent itself (Figures 6 and 7), only two of the data points on the Shek declaration graph can be considered because the other information is not disclosed in the data or is from a recrystallized lot. Those two data points, E-B and L-1, do not allow one skilled in the art to come to the conclusion that about 200 microns was the critical breakpoint for particle size of modafinil. (N.T. 3/31/11, pp. 63-65, 68-77; JTX 4a, Bates CPH_FTC 00021653; JTX 4C.)

112. In Dr. Shek's third declaration to the patent office, Cephalon also represented that it had "manipulate[d] the particle size of the drug substance." (N.T. 4/1/11, pp. 157, 160; JTX 4, Bates CPH_PLD_00000343, 347.)

113. Cephalon did not modify, manipulate or improve any aspect of the product they received from Lafon, which is in direct contradiction to their representation to the patent office. (N.T. 4/1/11, pp. 158, 160, 162; N.T. 4/6/11, p. 75; Clark Depo., 12/21/04, pp. 207-08; Shek Depo., 8/5/04, pp. 196-97, 250-51.)

114. The patent does not contain any data that the claimed small particle modafinil is safer or more effective than large particle modafinil. (N.T. 3/30/11, pp. 150-52; JTX 1.)

115. The RE'516 patent does not contain claims regarding solubility or bioavailability, and on December 5, 1995, the inventors specifically disavowed to the PTO that they were claiming such properties. (N.T. 3/29/11, pp. 99-101, 118-19; JTX 4B, Bates CPH_PLD_00000398.)

116. The Supply Agreement between Cephalon and Lafon was not disclosed to the PTO. A reasonable examiner would want to know if the product being claimed was the subject of a supply agreement because the examiner would need to evaluate that agreement for anticipation and the on-sale bar. (N.T. 4/1/11, p. 151; PTX 142, Bates CPH-FTC 00018917.)

III. Legal Analysis

A. Patent Invalidity

Patents are presumed to be valid. 35 U.S.C. § 282. The burden of establishing invalidity by clear and convincing evidence is on the party asserting such invalidity. Microsoft Corp. v. i4i Ltd. P'ship, 131 S.Ct. 2238, 2242 (2011). "[T]he ultimate question of patent invalidity is one of law . . . ." Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17 (1966) (citations omitted).

As noted previously, Apotex has challenged the validity of Cephalon's RE'516 patent on the grounds that: it was on sale more than one year before the patent application; Cephalon did not invent the claimed subject matter; the claimed subject matter of the invention was obvious; and it lacked a written description.

1. On-Sale Bar

"A person shall be entitled to a patent unless . . . the invention . . . was on sale in this country more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b). An invention is on sale within the meaning of § 102(b) if it was sold, or the subject of a commercial offer for sale, and ready for patenting prior to the critical date.[8] Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 67-68 (1998).

Apotex posits that the claimed invention was on sale when Lafon and Cephalon entered into license and supply agreements in 1993, resulting in Lafon shipping modafinil to Cephalon starting in July 1993. Cephalon counters that its claimed invention was not on sale prior to the on-sale bar date because Lafon supplied Cephalon with modafinil for free in 1993 for experimental purposes.

a. On Sale

As § 102(b) only requires that the invention be on sale, not actually sold**,** a contract to sell satisfies the on-sale requirement. Buildex Inc v. Kason Indus., Inc., 849 F.2d 1461, 1464 (Fed. Cir. 1988). Additionally, there is no requirement that the invention be delivered and/or money change hands prior to the critical date. Weatherchem Corp. v. J.L. Clark, Inc., 163 F.3d 1326, 1333 (Fed. Cir. 1998).

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[8] The critical date is one year prior to the application date for patent. Scaltech, Inc. v. Retec/Tetra, L.L.C., 269 F.3d 1321, 1327 (Fed. Cir. 2001).

In determining whether a particular transaction is commercial or, as Cephalon claims, experimental in nature, the relevant inquiry is "whether the primary purpose of the inventor at the time of the sale, as determined from an objective evaluation of the facts surrounding the transaction, was to conduct experimentation." Allen Eng'g Corp. v. Bartell Indus., Inc., 299 F.3d 1336, 1352 (Fed. Cir. 2002). The entire transaction must be considered, and a transaction will not be found to be for experimental use simply because the "invention was under development, subject to testing, or otherwise still in its experimental stage at the time of the asserted sale." Id.

Three cases from the United States Court of Appeals, Federal Circuit, decided between 2002 and 2005, provide further guidance as to when an agreement to sell satisfies the on-sale requirement. These cases generally instruct that the on-sale bar inquiry is very fact specific.

In the first case, In re Kollar, 286 F.3d 1326, 1330-31 (Fed. Cir. 2002), the court concluded that the parties' agreement did not constitute a sale because it focused on potential products resulting from the potential commercialization of a claimed process. In Kollar, the parties entered into a "definitive agreement" whereby in exchange for technical information about the claimed process and a license to commercialize that process, the potential licensor, Celanese, would pay Kollar royalties. While the process at issue had been reduced to practice, and thus, was ready for patenting, the court focused on the agreement's language and noted that its primary purpose was to "conduct research and development in the [f]ield" with the goal of achieving a commercial plant within five years. Id. at 1329-30. The court focused on the contingency that if, and when, the commercial phase was reached, Celanese would receive an exclusive license to operate the plant using the claimed process to sell resultant products. Id. In ruling that there was no sale, the court gave little credence to the

plans to sell potential products in the future and concluded that the agreement did not provide for a sale of the claimed process. Id. at 1331.

In Elan Corp. v. Andrx Pharms., Inc., 366 F.3d 1336 (Fed. Cir. 2004), the court also found that there was no sale for the purposes of the on-sale bar. The alleged offer for sale in Elan was a letter from Elan to Lederle Laboratories wherein Elan expressed their plan to file an IND. the following year. The letter also expressed an interest in seeking a licensing partner in exchange for certain fees and concluded, "we would value having Lederle as a partner in this project, and [we] look forward to having [Lederle's] decision in this matter." Id. at 1337-38. The court found that this letter was not a contract for sale, or offer for sale, because of its speculative nature and lack of details commonly found in commercial offers. Id. at 1341. In finding that the letter lacked the necessary material terms to be considered an offer for sale, the court noted the lack of "any mention of quantities, time of delivery, place of delivery, or product specifications," and the fact that the monetary amount discussed was not intended as payment for a product but a licensing fee. Id.

Finally, in 2005, the Federal Circuit issued Enzo Biochem, Inc. v. Gen-Probe Inc., 424 F.3d 1276 (Fed. Cir. 2005), which is most analogous to the case at hand. In Enzo, the court did find that there was a commercial offer for sale. Id. at 1278. The contract language at issue stated that, "ENZO shall supply to ORTHO and ORTHO shall purchase from ENZO for use in Licensed Products no less than ninety percent (90%) of ORTHO's United States requirements or seventy-five percent (75%) of ORTHO's worldwide requirements of Active Ingredients." Id. at 1279. The contract further stated that "ENZO shall supply ORTHO at ENZO's fully allocated cost with all quantities of any Licensed Product reasonably required by ORTHO or any Affiliate for its own

research, development, and test marking, including that required to perform all preclinical and clinical studies." Id.

While the court recognized that the contract provided for the "free" supply of product for clinical testing, which in and of itself was not a commercial offer for sale, it found that the other language unequivocally provided for a requirements contract once the product was commercialized. Id. at 1281-82. The court reasoned that this requirements contract was not illusory or speculative because the parties had a duty under general contract law to act reasonably and in good faith to set prices and order goods. Id. The facts presented in Enzo were distinguished from those in Kollar in that Kollar involved the alleged sale of a process to make a product, whereas the contract in Enzo concerned the sale of an actual, tangible product. Id. at 1282. Accordingly, the court concluded that, when read as a whole, the contractual language provided for a requirements contract that was a commercial offer for sale under § 102(b). Id. at 1281-82.

With this precedent in mind, for the following reasons, I conclude that the Supply Agreement between Lafon and Cephalon constituted a commercial offer for sale.

Lafon and Cephalon entered into a Supply Agreement on January 20, 1993. That agreement was signed in conjunction with a license agreement wherein Cephalon received "a license to make, have made, market and otherwise sell pharmaceutical products containing the compound modafinil." Following an acknowledgment of the License Agreement, the Supply Agreement states "LAFON is prepared and has the right to sell modafinil, a pharmaceutically active compound . . . and CEPHALON wishes to purchase the Compound from LAFON." Under the category "product supply" the agreement states that "LAFON . . . will sell such Compound to CEPHALON."

The pertinent terms of this agreement regarding pricing state:

> a) All quantities of Compound and matching placebo necessary to CEPHALON for carrying clinical tests in calendar year 1993 and thereafter up to the date of the first FDA approval in the U.S.A. of a Licensed Product including the Compound as an active ingredient, shall be supplied free of charge. The specifications for the Compound and matching placebo in finished tablet form shall be agreed to by the parties in writing.
>
> b) All quantities of the Compound other than those mentioned under (a) above shall be supplied at a price equal to eleven percent (11%) of CEPHALON's Net Sales of Licensed Productions in the Territory, provided that if CEPHALON's finishing costs (including formulation, tabletting and packaging costs), exceed 3 % of Net Sales, CEPHALON and LAFON shall meet to determine whether an adjustment in the price of the Compound under this Agreement is appropriate.

(PTX 48.)

Pursuant to the Supply Agreement, Lafon supplied Cephalon with both API and tablets for Cephalon to conduct clinical testing starting in 1993. (Fact 59.) In 1999, Lafon began supplying the compound to Cephalon for the commercial sale of Provigil® in return for payment in the amounts specified above. (Fact 60.) The Supply Agreement also includes a process for placing firm orders and addresses shipping, warranties, and the right of rejection. (PTX 48.)

While Kollar, Elan and Enzo addressed factual scenarios involving the sale of a product in the future, it is the contractual language itself that was outcome determinative. Here, the parties' Supply Agreement starts out with language indicating that this is a contract "to sell" and "to purchase" modafinil. The remainder of the contract language at issue most closely mirrors that found in Enzo, 424 F.3d 1276. Both the Enzo contract and the Lafon/Cephalon contract provide for a "free" supply of product for clinical testing. Id. at 1279. Both agreements also contain language akin to a requirements contract, wherein one party provides the actual transfer of money for product under the requirements contract portion of the agreement, as opposed to the "free" provision of the

product for research and development that might occur in the future, ostensibly after the on-sale bar date. While the contracts may contemplate some clinical or experimental testing by Cephalon, that testing is incidental to the primary commercial purpose of the contract to provide for the sale of a modafinil product in the U.S. market. The fact that Cephalon agreed to conduct the testing necessary for approval of the drug by the FDA in no way demonstrates that the "primary purpose" of the contract was experimental. Given the striking similarities between the contractual language in the Supply Agreement here and that in Enzo, and the Federal Circuit's clear statement that a requirements contract for a future product can satisfy the on-sale bar requirement, I find that there was a commercial offer for sale in Cephalon and Lafon's Supply Agreement.[9]

b. Ready for Patenting

In addition to the requirement that there be a commercial offer for sale, the subject of that offer must be ready for patenting in order for the on-sale bar to apply. Pfaff, 525 U.S. at 67-68. An invention is ready for patenting when it has been reduced to practice. Abbott Labs. v. Geneva Pharms., Inc., 182 F.3d 1315, 1318 (Fed. Cir. 1999). An invention has been reduced to practice when the subject matter of the sale embodies all of the claims of the patent and it has been determined that the invention works for its intended purpose. In re Omeprazole Patent Litig., 536 F.3d 1361, 1373 (Fed. Cir. 2008) (citations omitted). There is no requirement that there be proof of conception for the claimed invention, as "there is no requirement that a sales offer specifically identify all the characteristics of an invention offered for sale or that the parties recognize the

[9] I also note that in addition to the concrete terms related to quantity and price, the Supply Agreement includes material terms such as the process for ordering, shipping information, warranties and the right of rejection, which are material terms the court in Elan, 366 F.3d 1336, noted were relevant to determining whether an offer constituted a commercial offer for sale under § 102(b). Id. at 1341.

significance of all of these characteristics at the time of the offer." Abbott, 182 F.3d at 1319. Rather, "[i]f a product that is offered for sale inherently possesses each of the limitations of the claims, then the invention is on sale." Id.; see also Scaltech, 269 F.3d at 1329.

Lafon shipped modafinil API and tablets to Cephalon in 1993, which were then used by Cephalon for clinical testing. (Facts 27, 60.) It was from these tests that Cephalon claims to have arrived at their invention. However, as noted previously, nothing was done to the product shipped to Cephalon by Lafon. (Facts 54, 80.) While there was no modification or manipulation of the API or tablets shipped, Cephalon nonetheless claims that it appreciated a characteristic, namely the 220 micron threshold, that Lafon did not appreciate. However, this is irrelevant to an on-sale bar analysis. Scaltech, 269 F.3d at 1330 ("appreciation of the invention is not a requirement to trigger the statutory bar."). Regardless of appreciation or conception, the fact that Cephalon used the modafinil it received from Lafon as the basis for its patent application, without any change or modification whatsoever, demonstrates that the product shipped to Cephalon in 1993 inherently possessed each of the claim limitations. (Facts 32, 33.) Further, the "invention" had been reduced to practice at the time of the sale because Lafon was manufacturing and selling it in France. (Facts 40, 41.) Batch 003, some of which was shipped to Cephalon, was Lafon's good manufacturing practices standard batch. (Fact 55.) Modafinil was known to be effective in the treatment of narcolepsy long before Cephalon entered into the Supply Agreement with Lafon, and Lafon had been selling it commercially in France for that purpose. (Facts 26, 27.) It was well known that the compound shipped to Cephalon worked for its intended purpose. Accordingly, because the API and tablets shipped to Cephalon in 1993 inherently possessed all of the claim limitations and had been

reduced to practice by Lafon, the "invention" was ready for patenting when it was shipped to Cephalon.[10]

For the reasons set forth above, I conclude that there was a commercial offer for sale on January 20, 1993, when Cephalon and Lafon entered into their Supply Agreement. I further conclude that the invention was ready for patenting when it was shipped. Accordingly, Apotex has proved by clear and convincing evidence that the modafinil Cephalon claims as its invention was on sale before the critical date of October 6, 1993, one year prior to the filing of the '845 patent.

2. Derivation

Pursuant to § 102(f), a patent is invalid if the inventors named in the patent did not actually invent the claimed invention. 35 U.S.C. § 102(f). One cannot claim or reproduce the invention of another and obtain a patent on that "invention." OddzOn Prods., Inc. v. Just Toys, Inc., 122 F.3d 1396, 1401-02 (Fed. Cir. 1997). To invalidate the RE'516 patent by derivation, Apotex must show by clear and convincing evidence that the claimed subject matter was conceived by someone else and there was communication of that conception to Cephalon. MacMillan v. Moffett, 432 F.2d 1237, 1239 (C.C.P.A. 1970).

Apotex maintains that Cephalon derived its claimed invention from Lafon because Lafon scientists conceived small particle modafinil and communicated that information to Cephalon.

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[10] I note that the experimental use exception to the on-sale bar is not applicable here because Cephalon's claimed "invention" had been reduced to practice by Lafon. Clock Spring, L.P. v. Wrapmaster, Inc., 560 F.3d 1317, 1327 (Fed. Cir. 2009). The experimental use doctrine is intended only to allow the inventor to perfect his discovery through testing without losing his right to obtain a patent. Id. Cephalon entered into the supply and license agreements with Lafon in order to conduct testing in the United States for FDA approval. Cephalon was not perfecting the product, and in fact, did nothing to change its composition, so the experimental use exception is inapplicable.

Cephalon responds that its claimed invention was not derived from Lafon because the Lafon scientists did not appreciate the significance of the smaller particle, 220 micron threshold.

a. Conception

Conception is the formation in the inventor's mind of a definite and permanent idea which constitutes the complete and operative invention as it is then to be applied in practice. Solvay S.A. v. Honeywell Int'l, Inc., 622 F.3d 1367, 1377 (Fed. Cir. 2010). Conception requires the contemporaneous recognition and appreciation of the invention. (N.T. 4/6/11, p. 132; PTX 239, section 2138.04.) Accidental and unappreciated duplication of an invention does not constitute conception under § 102(f). Invitrogen Corp. v. Clontech Labs., Inc., 429 F.3d 1052, 1063 (Fed. Cir. 2005).

The question of conception focuses on whether the alleged original inventor appreciated what he had made. Dow Chem. Co. v. Astro-Valcour, Inc., 267 F.3d 1334, 1341. The original inventor must have understood the features of his invention, however, the original inventor need not recognize his "invention in the same terms as those recited in the [claims]" as the invention is not the claim language, but, rather, the subject matter of those claims. Invitrogen, 429 F.3d at 1064; Silvestri v. Grant, 496 F.2d 593, 599 (C.C.P.A. 1974). The inventor must have "recognized and appreciated 'a compound corresponding to the compound defined by the [claims].'" Teva Pharm. Indus. Ltd. v. AstraZeneca Pharms. LP, 748 F.Supp.2d 453, 466 (E.D.Pa. 2010) (quoting Silvetri 496 F.2d at 599). It follows that "the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. IRECO Inc., 190 F.3d 1342, 1347 (Fed. Cir. 1999); see also Abbott Labs., 182 F.3d at 1368. Therefore, a pharmaceutical

composition is conceived when one knows of its specific chemical structure, has a method for making it, and appreciates that it has a utility. Burroughs Wellcome Co. v. Bar Labs., Inc., 40 F.3d 1223, 1229 (Fed. Cir. 1994).

Cephalon concedes that Lafon manufactured and shipped smaller particle modafinil API and tablets starting in July 1993. (Fact 29.) The API and tablets shipped to Cephalon in 1993 came from Batch 003, which had been measured by Lafon to have 98.62 percent of its particles smaller than 206.36 microns. (Facts 29, 32.) The median particle size of that lot was 37.2 microns. Lafon had measured the particle size of Batch 003 and all of the others it produced, and those results reflected that Lafon was consistently decreasing the particle size of its API. (Fact 34.) While Lafon was manufacturing and commercially selling pills from Batch 5/2236, which had a 95% cumulative value of approximately 260 microns (and was the batch which received French regulatory approval), Lafon used Batch 003 as their good manufacturing practices standard. (Facts 28, 31, 55, 59.) Lafon also conducted numerous tests with batches of API that fell within the claim limits, and found that those batches, specifically 5/2435, were effective in the treatment of narcolepsy. (Facts 30, 31.) These undisputed facts establish that Lafon was aware of the compound's specific structure and particle size, that Lafon had developed a manufacturing method for the compound, and that Lafon appreciated the compound's utility.

Teva Pharm. Indus. Ltd., 748 F.Supp.2d 453, supports my conclusion that Lafon was the true inventor and presents a similar factual scenario. In Teva, the Plaintiff, Teva Pharmaceutical Industries, claimed that its invention was not anticipated by Defendant, Astrazeneca Pharmaceuticals, because there was no evidence that Astrazeneca appreciated the "stabilizing nature" of one of the chemicals in the claimed formulation. Id. at 465. Despite the fact that Astrazeneca

conceded that its researchers did not appreciate the specific attributes of one of the chemicals in the formulation, the court held that the formulation had been conceived first by Astrazeneca because it had appreciated that the formulation as a whole was stable. Id. The court emphasized that recognizing which chemical in the formulation created stability was not necessary for conception because the formulation as a whole was stable. Id. The court further reasoned that the stabilizing nature of one chemical in the formulation was an inherent characteristic which, once discovered, did not render an old formulation newly patentable. Id. at 469. Consequently, Astrazeneca was found to have conceived the formulation when they made it, as Astrazeneca knew of the compound's chemical structure and recognized its use as a pharmaceutical drug. Id.

In so ruling, the Teva court relied heavily upon Titanium Metals Corp. of America v. Banner, 778 F.2d 775 (Fed. Cir. 1985), which is also instructive. The claims at issue there defined titanium base alloys consisting of nickel and molybdenum in specified proportions, the resulting alloy being "characterized by good corrosion resistance in hot brine environments." Id., 778 F.2d at 776. An appeal was taken after the PTO Board of Appeals denied Titanium Metals's patent application on the grounds that a prior article disclosed alloys falling within the patent claims. Although the article in question did not mention the "good corrosion resistance in hot brine environments" of the alloy, the PTO affirmed the denial of a patent, holding that the "fact that a particular property or the end use for this alloy as contemplated by [Titanium Metals] was not recognized by the article is of no consequence." Id. at 777.

After the district court reversed and ordered issuance of the patent, the PTO Commissioner appealed. The United States Court of Appeals, Federal Circuit, reversed, holding the proposed claims unpatentable. The court emphasized that "patent law imposes certain fundamental conditions

for patentability, paramount among them being the condition that what is sought to be patented, as determined by the claims, be new." Id. at 780. Thus, "it is immaterial, on the issue of their novelty, what inherent properties the alloys have or whether these applicants discovered certain inherent properties." Id. at 782.

Here, Cephalon claims it is the inventor as Lafon did not appreciate that smaller particle size produces better dissolution and bioavailability. Had Lafon not measured particle size, Cephalon's argument may carry more weight. However, Lafon performed those measurements and was aware that the API and tablets it manufactured and sent to Cephalon contained more than 95% of particles with a diameter less than 220 microns. (Facts 29, 32.) Cephalon's argument ignores the fact that the exact product Dr. Grebow claims he invented had been previously tested, manufactured and used by Lafon for the treatment of narcolepsy. In short, Lafon manufactured modafinil that met the claim limitations, was aware of the compound's chemical structure and particle size, and recognized its use as a pharmaceutical drug.

As in Teva, someone other than the patent applicant had previously conceived the claimed invention when the applicant manufactured it. Cephalon's alleged "discovery" of the 220 micron threshold is more akin to an inherent property, or scientific explanation, of the compound Lafon had previously conceived. As the court in Teva noted, "the Federal Circuit has held invalid for anticipation numerous patents claiming what amount to newly discovered properties of prior art compositions, where the missing characteristic was necessarily present, or inherent, in the prior art, even though there was no recognition of the missing characteristics in the prior art."[11] I thus

[11] See Abbott Labs., 471 F.3d at 1368-69 (patent disclosing a composition of water-saturated sevoflurane anticipated later patent disclosing a composition comprising sevoflurane mixed with water or another Lewis acid inhibitor in an amount effective to prevent degradation by a Lewis acid,

conclude that Lafon's development, manufacture and transmittal of the late-lot modafinil to Cephalon is enough to meet the conception and communication requirements. (N.T. 4/1/11, pp. 179-80, 183-84.)

Cephalon relies upon Silvestri v. Grant, 496 F.2d 593 (C.C.P.A.1974), to press the point that appreciation of the invention, specifically the importance of the 220 micron threshold, is required to prove derivation. In Silvestri, the court found that there was no appreciation of the invention when the inventors made a new form of a chemical compound but did not know that they had made a new form until a later date. Id. at 597 (citing Heard v. Burton, 333 F.2d 239, (C.C.P.A. 1964); and Langer v. Kaufmann, 465 F.2d 915 (C.C.P.A. 1972)). Silvestri is entirely distinguishable because,

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even though earlier patent did not teach that the mixture would prevent sevoflurane from degrading in the presence of Lewis acids); EMI Group N. Am., Inc. V. Cypress Semiconductor Corp., 268 F.3d 1342, 1349-50 (Fed. Cir. 2001) (patents claiming a structure for a metallic fuse for semi-conductor chips, and a method for fabricating and blowing such a fuse, both of which recited a theoretical explosive mechanism for blowing the fuse, were anticipated by earlier patents that disclosed the same fuse structure but not the explosive mechanism where explosive mechanism was "a scientific explanation for the process of blowing the claimed fuse structure" that was inherent in fuses of the same structure); Atlas Powder Co., 190 F.3d at 1348-49 (patents disclosing blasting compositions were anticipated by earlier patents disclosing compositions containing the same ingredients in overlapping amounts, notwithstanding that earlier patents lacked limitation that there be "sufficient aeration . . . entrapped to enhance sensitivity to a substantial degree": "[b]ecause 'sufficient aeration' was inherent in the prior art, it is irrelevant that the prior art did not recognize the key aspect for Dr. Clay's invention - that air may act as the sole sensitizer of the explosive composition"); accord In re Omeprazole Patent Litig., 483 F.3d 1364, 1371-73 (Fed. Cir. 2007) (patent reciting a process for making a pharmaceutical formulation composed of an omeprazole core, a water soluble separating layer, and an enteric coating layer, wherein the separating layer was created by causing an *in situ* reaction involving the other two layers, was anticipated by an earlier patent application that contained all elements of the later patent except the *in situ* formation of the separating layer - and that expressly disavowed a subcoating - where the *in situ* formation was inherent); Verdegaal Bros., Inc. v. Union Oil Co. of Cal., 814 F.2d 628, 633 (Fed. Cir. 1987)(patent disclosing a process for making certain known urea-sulfuric acid liquid fertilizer products, in which a previously made batch of liquid fertilizer known as a "heel" served as a "heat sink" to absorb the heat of the reaction, was anticipated by an earlier patent disclosing the same process, even though earlier patent did not recognize that the heel functioned as a heat sink).

as explained above, Lafon knew the chemical structure and particle size of the late-lot modafinil based upon its own measurements. Further, Cephalon did not make a new form of the chemical compound, and in fact, did nothing to it at all.

Finally, I note that the evidence reflects that Lafon did appreciate the significance of smaller particle size and the 220 micron threshold for the 95% cumulative value.[12] However, whether Lafon had this appreciation is immaterial. It is sufficient that the compound Lafon manufactured and shipped to Cephalon in July 1993 was of the same chemical structure as that claimed in Cephalon's patent, and Lafon was aware of that chemical structure, including particle size.

b. Communication

A party alleging invalidity for derivation must also prove by clear and convincing evidence that the invention conceived was communicated to the patentee prior to date of the patent application. MacMillan, 432 F.2d at1239. The communication must be sufficient to enable one of skill in the art to make the patented invention. Gambro Lundia AB v. Baxter Healthcare Corp., 110 F.3d 1573, 1578 (Fed. Cir. 1997).

Because the modafinil received by Cephalon on June 23, 1993, had the exact chemical properties as that which Cephalon patented, the shipping of the compound itself is more than sufficient to constitute a communication. Anyone skilled in the art of pharmaceutical compositions would have been able to measure the particle size of the modafinil API shipped from Lafon to Cephalon, and thus, would have been capable of making that compound. (Fact 94.)

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[12] See e.g., PTX-036-October 6, 1992, Grebow memo regarding meeting with Lafon research staff which acknowledges the Lafon formulations changed through "decreasing the particle size;" April 1, 2004 deposition of Michel Moisan, Lafon scientist, acknowledging that Lafon measured particle size and their objective was to achieve smaller particle size; PTX-057, Grebow, April 2, 1993, email summarizing meeting with Lafon noting "faster dissolution in smaller particle size."

In addition to Cephalon actually receiving several lots that fell squarely within the claim, on numerous occasions Lafon provided Cephalon with additional information which establishes "communication." Lafon started providing Cephalon with technical information about its modafinil in 1992. (Facts 35, 38.) Specifically, Cephalon was advised that Lafon's 1989 tests showed that ground modafinil, having smaller particles, produced better dissolution rates than non-ground particles, and this grinding was part of the manufacturing process. (Facts 35, 36, 37.) Lafon also told Cephalon in October 1992 that all of their clinical trials were conducted with small particle modafinil, and that the recommended dosage was 300 mg. (Fact 38.) A month later, Lafon advised Cephalon that they knew particle size related to solubility. (Fact 39.) In March 1993, Lafon again suggested the most common dosage of 300 mg, with a range of 200 to 400 mg, and a maximum tolerable dosage of 600 mg. (Facts 41, 56.) In June 1993, Cephalon shared Lafon's clinical test results in an investigative brochure. (Fact 56.)

While all of the above-referenced communications omit any direct reference to a 220 micron threshold, they nonetheless clearly demonstrate that Lafon had manufactured and tested modafinil API meeting that threshold and shared that information with Cephalon. The provision of detailed particle size measurements and dosage recommendations to Cephalon by Lafon only serves to bolster my finding that the shipping of the modafinil API to Cephalon in July of 1993 satisfies the communication requirement under § 102(f).

Accordingly, the conception of the chemical compound possessing the properties claimed in the patent by Lafon, and Lafon's communication of that chemical compound and its specific properties to Cephalon no later than July 1993, invalidates the patent under § 102(f).

3. Obviousness

A patent is invalid under 35 U.S.C. § 103(a) for obviousness 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 at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a). This is a legal determination based on four factors: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) any secondary considerations such as unexpected results or commercial success." Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966). The patent challenger must prove obviousness by clear and convincing evidence and faces the enhanced burden of overcoming deference to the PTO when the obviousness inquiry is based on the same evidence presented to the PTO. Tokai Corp. v. Easton Enterprises, Inc., 632 F.3d 1358, 1367 (Fed. Cir. 2011). Apotex alleges that the claimed invention is invalid for obviousness because it is identical to the prior art. Cephalon responds that its claimed invention was not obvious because Cephalon identified the 220 micron threshold as significant given unexpected dissolution and bioavailability data they discovered in clinical and laboratory tests.

a. Scope of the Prior Art

"Prior art has been defined as follows: '[t]he existing state of knowledge in a particular art at the time an invention is made. It includes the issued patents * * *, publications, and all other knowledge deemed to be common thereto such as trade skills, trade practices, and the like,'" available a year or more before the patent filing date. Trio Process Corp. v. L. Goldstein's Sons, Inc., 461 F.2d 66, 69 n.3 (3d Cir. 1972) (quoting A. Smith, PATENT LAW, CASES, COMMENTS AND MATERIALS 2 (1964)); see also, (N.T. 4/6/11, pp. 110-11).

Under the MPEP, section 2112.01, a prima facie case of either anticipation or obviousness is established when the material supplied to the party claiming the invention is identical to that of the claimed invention. Section 2112 states that a product that was previously known does not become patentable upon the discovery of a new property. (N.T. 4/1/11, pp. 147-48; PTX 239, p. 2100-27.)

Here, modafinil was widely known as a chemical compound effective in the treatment of narcolepsy prior to 1994. (Facts 84, 85.) The extensive information detailed in Section II, A, 2, supra, regarding Lafon's communications to Cephalon about modafinil, can be considered as prior art. See also (Facts 34, 35, 36, 37, 38, 39, 41, 44, 47, 48.) Indeed, the API that was shipped from Lafon to Cephalon is also prior art. OddzOn, 122 F.3d at 1401-02. With Cephalon's actual receipt and possession of the compound, and all of the communications from Lafon to Cephalon detailing the compound, a person skilled in the art would have been motivated to measure the particle size of the modafinil as part of the FDA process, which requires such information for approval of new drug substances. (Fact 95**,** 96.) Accordingly, the communications, as detailed above, and the inherent properties of the modafinil, which would have and could have been tested by someone skilled in the art, establish that the scope of the prior art was: a pharmaceutical composition of modafinil API having 95% of its particles with a diameter less than 220 microns.

I further note that publications available prior to 1994 made it known to those skilled in the art that modafinil was poorly water soluble. (Facts 95**,** 96.) Thus, if one skilled in the art received modafinil and intended to formulate it into a pharmaceutical composition, one skilled in the art would have measured the particle size of the modafinil API. (Facts 95**,** 96.) That person would have then sought to reduce the median particle size of the modafinil to approximately 10 to 40

microns if it was not already that size, resulting in a drug wherein 95% of the particles would have a diameter of less than 220 microns. Therefore, even if Cephalon's claimed invention was not derived directly from prior art, and thus also rendered obvious for that same reason, additional prior art publications demonstrate that one skilled in the art would have sought small particles of modafinil prior to formulating a pharmaceutical composition.

b. Person of Ordinary Skill in the Art

A person of ordinary skill in the art would be a person with a bachelor's degree in chemistry, either in chemical engineering or pharmaceutical sciences. That person would also most likely have a Ph.D. in pharmaceutical sciences or a related field and would certainly be familiar with preformulation, formulation and the FDA and other regulatory bodies. A person skilled in the art would have lab experience and would know about particle size, why measuring particle size is important, and how particle size affects dissolution and bioavailability. Alternatively, a person skilled in the art could be a medical doctor who has treated conditions such as narcolepsy, which modafinil is known to effect. (Fact 82.)

c. Differences Between Invention and Prior Art

Without belaboring the point, as set forth under Section II, A, 2 – Derivation, and briefly addressed above in Section II, A, 3, a – Scope of the Prior Art, infra, there are no differences between Cephalon's claimed invention and the information communicated to Cephalon by Lafon, which constitutes prior art.

d. Secondary Considerations

Secondary considerations such as commercial success and unexpected results can be offered to rebut obviousness. KSR Intern. Co. v. Teleflex Inc., 550 U.S. 398, 406 (2007). The proponent

of non-obviousness must establish a connection between the merits of the claimed invention and evidence of secondary considerations in order for them to be afforded any substantial weight. In re GPAC Inc., 57 F.3d 1573, 1580 (Fed. Cir. 1995).

Cephalon argues that two different secondary considerations support non-obviousness. First, Cephalon posits that the Shek declaration which was submitted to the PTO to initially thwart an obviousness rejection demonstrates unexpected results. For the reasons explained in Section II, B – Unenforceability, infra, I decline to credit the Shek declaration and the unexpected results it purports to represent. Second, Cephalon argues that Lafon's inability to appreciate the significance of the 220 micron threshold renders the patent non-obvious. While I cannot determine which appropriate § 103 test this argument is made under, it nonetheless fails for the reasons set forth in Section II, A, 2 – Derivation, supra.

While not argued in its post-trial brief, Cephalon pressed at trial that the one negative cardiovascular event in its Phase I clinical trial was unexpected and thus probative of non-obviousness. (Facts 67, 68, 69, 70.) I decline to find that this evidence is probative of non-obviousness because Lafon had told Cephalon which dosages were appropriate for use in humans, and that cardiovascular side effects could be seen at high dosages. Moreover, after the clinical trial, Cephalon noted in a communication to Lafon that these results were "expected." (Facts 43, 44, 45, 46, 70.)

Accordingly, given the lack of secondary considerations and the lack of any differences between the prior art and the invention claimed by Cephalon, I find that Apotex has proven by clear and convincing evidence that the patent is invalid for obviousness under § 103.

4. Written Description

A patent may be invalid under 35 U.S.C. § 112 for lack of a written description. "[T]he test for written description is 'whether the disclosure of the application . . . reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." Eli Lilly & Co. v. Teva Pharms. USA, Inc., 619 F.3d 1329, 1345 (Fed. Cir. 2010) (citing Airad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010)). Possession is more accurately defined as requiring the specification to "describe an invention understandable to [a person of ordinary skill in the art] and show that the inventor actually invented the invention claimed." Airad, 598 F.3d at 1351. This is a fact based inquiry, and the party seeking to invalidate the patent "must show that the claims lack a written description by clear and convincing evidence." Id.; Hynix Semiconductor, Inc. v. Rambus, Inc., 645 F.3d 1336, 1351 (Fed. Cir. 2011).

Apotex argues that the RE'516 patent is invalid for lack of written description because the patent does not specify the claimed particle size of the modafinil in tablet form. Cephalon responds that there is no requirement that a measurement of modafinil post-tabletting be described in the patent, and it is sufficient that the patent included particle size measurement techniques that could be applied post-tabletting. (Cephalon Post-Trial Memo., pp. 36-38.)

In Eli Lilly & Co. v. Teva Pharms. USA, Inc., 619 F.3d 1329, 1345 (Fed. Cir. 2010), the court upheld the district court's finding that the patent was invalid for failure to comply with the written description requirement. The patent at issue only disclosed the particle size of the bulk chemical, and did not disclose the particle size of the chemical once composed in pill form. Id. In determining that the patent did not have an adequate written description, the district court relied upon, in part, expert testimony that a person of skill in the art reading the patent would not know

whether the particle size increased, decreased or remained the same in the final pharmaceutical composition. Id. While noting that there generally is no requirement that a patent describe all of the steps that may be used to prove infringement, such as a test for measuring particle size in the finished composition, the United States Court of Appeals for the Federal Circuit concluded that there was no clear error in the district court's decision based on the lack of such a description. Id. Here, I first note that only a few minutes of testimony were presented on the issue of written description. During this brief testimony, Dr. Beach testified that the patent did not describe a measurement of the modafinil particle size once formulated into a tablet. (JTX 1; Facts 11, 101.) He also noted that while it may be possible to conduct tests to determine the particle size of modafinil in the finished tablet, based on a review of the patent alone, one of ordinary skill in the art would not know whether the particle size was the same pre- and post-tabletting. (JTX 1; Fact 102.) Dr. Beach further stated that because the patent did not specify, and it was impossible to know based on the information disclosed therein, he had to assume that the particle size was the same pre and post-tabletting in his analysis of the respective test results reviewed at trial. (N.T. 3/30/11, pp. 57-60.) Without any evidence to the contrary in the record, I conclude that the patent does not specify the particle size of the modafinil post-tabletting and does not contain sufficient information to allow someone skilled in the art to make such a determination. In addition to Dr. Beach's testimony, the four corners of the patent also demonstrate that it does not specify the particle size of modafinil in the finished pharmaceutical composition. (JTX 1); Airad, 598 F.3d at 1351. As in Eli Lilly, the patent does not provide sufficient information to allow a person skilled in the art to determine the particle size in the finished pharmaceutical composition as claimed, and the patent is invalid for failing the written description requirement of § 112.

B. Patent Unenforceability

To prevail on a claim of inequitable conduct, it must be demonstrated that the patent applicant: (1) misrepresented or omitted certain information in applying for the patent; (2) that information was material; and (3) the misrepresentation or omission was made with the specific intent to deceive the PTO. American Calcar, Inc. v. American Honda Motor Co., Inc., 651 F.3d 1318, 1334 (Fed. Cir. 2011). Earlier this year, the Court of Appeals for the Federal Circuit made it more difficult for an accused infringer to prove inequitable conduct. See Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276 (Fed. Cir. 2011). Recognizing that such claims have become prolific and burdensome on the courts, have discouraged settlement and expanded discovery, and have inspired patent applicants to "bury PTO examiners with a deluge of prior art references, most of which have marginal value," the court adjusted both the intent and materiality standards. Id. at 1289-92. A party alleging inequitable conduct must now demonstrate that the patent applicant acted with the specific intent to deceive the PTO, and that but for its omission or misrepresentation the PTO would not have issued the patent. Id.

Intent to deceive must be shown by clear and convincing evidence, but in assessing materiality, "the court should apply the preponderance of the evidence standard and give claims their broadest reasonable construction." Id. If a threshold showing of materiality and intent has been made, the court must balance the equities to determine whether the fraudulent conduct justifies barring enforcement of the patent. Cargill, Inc. v. Canbra Foods, Ltd., 476 F.3d 1359, 1364 (Fed. Cir. 2007).

In evaluating whether conduct was inequitable, I note that the PTO imposes a duty of candor on all individuals associated with the filing of a patent. 37 C.F.R. § 1.56(a). This duty includes an

obligation to disclose all material information known at the time of filing. 37 C.F.R. § 1.56(b); see also (N.T. 4/1/11, pp. 134-35; N.T. 4/6/11, pp. 149-50; Burgoon Depo., 10/27/10, pp. 129-30; PTX 142, Bates CPH-FTC 00018915).

Based on the same facts supporting the on-sale bar and derivation findings, Apotex maintains that Cephalon committed inequitable conduct in its application to the PTO. Cephalon responds that the information regarding Lafon's manufacturing of modafinil and research on that product was not material because that modafinil was not prior art. Cephalon also argues that even if Apotex establishes the materiality of Lafon's involvement, Apotex has failed to show that Cephalon intended to deceive the PTO by not disclosing this information.

1. Failure to Disclose Material Information

Following Therasense, the materiality requirement is met only if the party challenging the patent is able to demonstrate that "the PTO would [not] have allowed the claim if it had been aware of the undisclosed reference." The court recognized that, in certain circumstances, this determination will be "congruent" with that of the validity of the patent. It noted that "if a claim is properly invalidated in district court based on the deliberately withheld reference, then that reference is necessarily material because a finding of invalidty in a district court requires clear and convincing evidence, a higher evidentiary burden than that used in prosecution at the PTO." Therasense, 649 F.3d at 1292.

Materiality is not limited to prior art, but includes any information a reasonable patent examiner would be substantially likely to consider important in deciding to issue a patent. Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., 326 F.3d 1226, 1233 (Fed. Cir. 2003); see also (N.T. 4/1/11, p. 135). Material information subject to the mandatory disclosure under 37 C.F.R.

1.56 includes, but is not limited to, information on possible prior public uses, sales, offers to sell, derived knowledge, prior invention by another, and inventorship conflicts. Atlanta Attachment Co. v. Leggett & Platt, Inc., 516 F.3d 1361, 1368 (Fed. Cir. 2008); see also (N.T. 4/1/11, p. 136; PTX 142, Bates CPH-FTC 00018917).[13]

The duty of disclosure continues from the date of filing to the date of issuance, and also through a reissue application. (N.T. 4/1/11, pp. 141-42; PTX 142.) While a patent applicant is not required to go out and do a search for material information, the applicant is required to disclose material information it is aware of that relates to the matter before the PTO. (N.T. 4/6/11, pp. 111-15; PTX 142, Bates CPH-FTC 00018915.) The applicant can disclose material information to the PTO in several different ways. The applicant can file an information disclosure statement, which is essentially a letter listing the references. The applicant can also file a Form 1449, include the information in the specification of the application, or include the information as part of an affidavit or declaration. (N.T. 4/6/11, pp. 115-16.)

Here, Cephalon never disclosed to the PTO that: (1) Lafon was the manufacturer of Batch 003; (2) Lafon had measured the particle size of that batch prior to providing it to Cephalon; (3) Lafon had manufactured and tested several modafinil API batches and tablet lots that fell within the claim limitations; or (4) that the two companies had both supply and license agreements. (Fact 106.)

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[13] Information is also material to patentability when:

> (b) . . . [I]t is not cumulative to information already of record or being made of record in the application, and
>
> > (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
> >
> > (2) It refutes, or is inconsistent with, a position the application takes in:
> >
> > > (i) Opposing an argument of unpatentability relied on by the Office, or
> > >
> > > (ii) Asserting an argument of patentability.

37 C.F.R. § 1.56.

As discussed supra, Lafon's small particle modafinil, specifically Batch 003 and Lot 006, was prior art which should have been, but was not, disclosed to the PTO. The Supply Agreement should also have been disclosed to the PTO because, as discussed supra, it establishes both anticipation and the on-sale bar. Atlanta, 516 F.3d at 1368; see also (Fact 116.) Additionally, all of Lafon's test results and data regarding small particle modafinil that were shared with Cephalon demonstrated derivation. As discussed earlier, these withheld references establish the invalidity of the RE '516 patent. Our finding of invalidity based on those references also establishes their materiality. Therasense, 649 F.3d at 1292.

It is also probative of materiality that the information which Cephalon failed to disclose related to obviousness, an issue that was repeatedly raised by the patent examiner. Cargill, 476 F.3d at 1366. Cephalon failed to disclose to the PTO any of the information relating to Lafon's substantial role in Cephalon's claimed invention. Had the PTO been aware of this information, it would not have allowed the patent to issue.

2. Intent to Deceive

As noted previously, a party claiming inequitable conduct must also demonstrate by clear and convincing evidence that the patentee acted with the specific intent to deceive the PTO. Therasense, 649 F.3d at 1290 (citing Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1366 (Fed. Cir. 2008)). As patent applicants rarely admit intentionally misleading the patent office, intent to deceive can be inferred from the facts and circumstances surrounding the conduct at issue. Merck & Co., Inc. v. Danbury Pharmacal, Inc., 873 F.2d 1418, 1422 (Fed. Cir. 1989); Cargill, 476 F.3d at 1364. Where intent is inferred from indirect and circumstantial evidence, the clear and convincing standard is met only when the intent to deceive is "the single most reasonable inference able to be

drawn from the evidence." Therasense, 649 F.3d at 1290 (quoting Star, 537 F.3d at 1366). Said another way, the evidence "must be sufficient to *require* a finding of deceitful intent in light of the circumstances." Id., (quoting Kingsdown Medical Consultants, Ltd. v. Hollister Inc., 863 F.2d 867 (Fed. Cir. 1988) (emphasis added)).

Here, Cephalon failed to inform the PTO about Lafon's role as manufacturer, supplier of product and years of technical data behind that product, and profit beneficiary. (Fact 106.) I find that the complete concealment of another company's extensive involvement in the product which is the subject of the claimed invention definitively establishes Cephalon's deception by clear and convincing evidence. Further, in addition to concealing Lafon's role as manufacturer and supplier of the product being claimed in the patent, Cephalon affirmatively told the PTO that it had modified particle size when in fact it had done nothing whatsoever to change, modify or improve the modafinil it received from Lafon. (Facts 111, 112.)

The claim history with the PTO is also probative of Cephalon's intent. The PTO initially rejected Cephalon's patent application as obvious. (Fact 107.) The examiner concluded that the prior art included smaller particle modafinil, and the scientific references in the field suggested that it would have been obvious to reduce particle size to achieve better bioavailability, dissolution, potency, and higher peak plasma levels. (Fact 107.) In response to that office action, and subsequent office actions continuously rejecting the application as obvious, Cephalon asserted that the prior art and studies on that art would not have motivated one of ordinary skill in the art to modify or manipulate the particle size of the drug substance like Cephalon's inventors had done. (Facts 109, 110, 112.) This response not only served to further conceal Lafon's role, despite the fact that it was central to the examiner's challenge, but was an affirmative misrepresentation in that, as has been

mentioned previously, Cephalon did not modify, manipulate or improve any of the modafinil it received from Lafon. (Fact 113.) Without a logical explanation for making such misrepresentations, I conclude that Cephalon made those unsupported claims with the intention of convincing the patent examiner to change his mind and issue the patent. See Cargill, 476 F.3d at 1366. Thus, Cephalon acted with the intent to deceive when it represented that it undertook a course of action which never in fact occurred.[14]

I further note that even Cephalon's in-house patent attorney stated that "this application is 'unusual' in the sense that we did not want to include any of Lafon's data so as to avoid disclosing their 'confidential' information; thus, the task of 'disclosure' of the invention was unique." (Fact 105.) While there may have been some concern over the confidentiality of Lafon's manufacturing process, that does not explain Cephalon's decision to omit any mention of Lafon's role in its application. When viewed in conjunction with the enormity and materiality of Cephalon's omissions, and the misleading statements made to the PTO, this statement is probative of Cephalon's intent to deceive. Finally, aside from challenging the materiality of the information at issue, Cephalon has not offered any alternative explanation for these misrepresentations and omissions. See Cargill, 476 F.3d at 1366. I conclude that Apotex has proven that Cephalon acted with the specific intent to deceive the PTO.

As the Federal Circuit has noted, a finding of inequitable conduct carries serious consequences, which I have carefully considered. Therasense, 649 F.3d at 1288-89. Unlike a finding of invalidity or non-infringement, inequitable conduct "renders the entire patent

[14] I further note that the Shek declaration submitted to the PTO to rebut an obviousness rejection presented data which had not in fact been disclosed to the PTO and therefore was misleading in its conclusion. (Fact 113.) This further contributes to our finding that Cephalon acted with the intent to deceive as it related to the PTO's obviousness inquiry.

unenforceable," "cannot be cured by reissue . . . or reexamination," may "spawn antitrust and unfair competition claims" and can lead potentially to an award of attorneys' fees. Id. Nonetheless, given the unmistakable importance of the Lafon information, the inexplicable concealment of that information from the PTO, even after the examiner's obviousness challenge unequivocally alerted Cephalon to its importance, as well as the direct misrepresentations made by Cephalon to the PTO, the only reasonable inference to be drawn is that Cephalon made a deliberate choice to deceive the PTO about the origin of its claimed invention. Such conduct warrants a finding of inequitable conduct and justifies rendering the patent unenforceable.

IV. Conclusion

For the reasons set forth above, Cephalon's RE'516 patent is invalid pursuant to the on-sale bar, for derivation, for obviousness, and for lack of written description. Furthermore, Cephalon's RE'516 patent is unenforceable due to Cephalon's inequitable conduct in its prosecution of the patent.

An appropriate Order follows.