IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

BOEHRINGER INGELHEIM INTERNATIONAL GMBH and BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,	:	
Plaintiffs,	:	
v.	:	Civil Action No. 05-700-JJF
	:	**CONSOLIDATED**
BARR LABORATORIES, INC. and MYLAN PHARMACEUTICALS, INC.,	:	
Defendants.	:	

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MEMORANDUM OPINION

June 26, 2008
Wilmington, Delaware

Farnan, District Judge.

This action was brought by Plaintiffs, Boehringer Ingelheim International GMBH and Boehringer Ingelheim Pharmaceuticals, Inc. (collectively, "Boehringer"), against Defendants, Barr Laboratories, Inc. ("Barr") and Mylan Pharmaceuticals, Inc. ("Mylan") (collectively, "Defendants"), in connection with the Abbreviated New Drug Applications ("ANDAs") filed by Defendants seeking to market generic versions of MIRAPEX®, a drug developed and sold by Boehringer. Boehringer is the record owner of U.S. Patent No. 4,886,812 (the "'812 patent"), which covers pramipexole dihydrochloride, the active ingredient in MIRAPEX®.

Defendants have stipulated that by filing their ANDAs they have infringed claim 7 of the '812 patent. Boehringer has also alleged infringement of claims 5, 9 and 10 of the '812 patent. Defendants have contested infringement of these claims and assert that claims 3, 4, 5, 7, 9 and 10 of the '812 patent are invalid for nonstatutory double patenting.

The Court conducted a bench trial, and this Memorandum Opinion constitutes the Court's Findings of Fact and Conclusions of Law on the issues tried.

BACKGROUND

I. Procedural History

A. Civil Action No. 05-700

On August 10, 2005 and September 12, 2005, Barr advised Boehringer by letter that it had submitted Abbreviated New Drug

Application No. 77-724 seeking approval to engage in the commercial manufacture, use and sale of generic pramipexole dihydrochloride tablets in 0.125, 0.25, 0.5, 1.0 and 1.5 mg strengths prior to the expiration of the '812 patent and certifying pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '812 patent is invalid and/or not infringed by Barr's proposed generic product. Forty-five days later, Boehringer filed Civil Action No. 05-700 against Barr asserting infringement of both the '812 patent and U.S. Patent No. 4,843,086 (the "'086 patent"). The '086 patent has since expired leaving only the '812 patent at issue in this action.[1]

In response to an Amended Complaint filed by Boehringer, Barr filed an Answer and Counterclaims denying infringement and asserting the defense of invalidity. Barr also counterclaimed for a declaratory judgment of noninfringement and invalidity of the '812 patent. Approximately one year later, Barr filed an Amended Answer and Counterclaims contending that the asserted claims of the '812 patent were unenforceable due to inequitable conduct. By Stipulation the following year, the Court dismissed Barr's inequitable conduct counterclaim with prejudice.

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[1] This action was initially assigned to the Honorable Kent A. Jordan.

B. Civil Action No. 05-854

On October 26, 2005, Mylan advised Boehringer that it had also submitted a similar ANDA to that which was filed by Barr seeking approval to engage in the commercial manufacture, use and sale of generic pramipexole dihydrochloride tablets in the same strength as Barr and certifying that the '812 patent is invalid or not infringed by Mylan's proposed generic product. In response, Boehringer filed Civil Action No. 05-854 on December 12, 2005, alleging infringement of the '812 patent. On January 31, 2006, this action was consolidated with the action pending against Barr.

II. Factual Background

A. The Parties

Plaintiff Boehringer Ingelheim International GmbH is a corporation organized and existing under the laws of Germany, with an office and place of business in Ingelheim, Germany. Plaintiff Boehringer Ingelheim Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business in Ridgefield, Connecticut.

Defendant Barr is a corporation organized and existing under the laws of the State of Delaware with its principal place of business in Pomona, New York. Defendant Mylan is a corporation incorporated under the laws of the State of West Virginia with

its principal place of business in Morgantown, West Virginia.

B. Mirapex® And The Patents At Issue

The '086 patent and the '812 patent share the same specification and same title, "Tetrahydro-Benzthiazoles, The Prepartion Thereof and Their Use as Intermediate Products or as Pharmaceuticals." The '086 patent issued on June 27, 1989, to Dr. Karl Thomas GmbH of Biberach an der Riss, Germany, the assignee of named inventors, Gerhart Griss, Clauss Schneider, Rudolf Hurnaus, Walter Kobinger, Ludwig Pichler, Rudolf Bauer, Joachim Mierau, Diter Hinzen and Gunter Schingnitz. TX 2. The '812 patent also shares the same inventors as the '086 patent, and issued nearly six months later, on December 12, 1989, to the same assignee as the '086 patent. D.I. 190 at Ex. 1, ¶ 5. Plaintiff Boehringer Ingelheim International GmbH is the assignee and record owner of both the '086 and '812 patents.

Mirapex® is the brand name for a pharmaceutical product containing pramipexole dihydrochloride, which is manufactured, marketed and sold by Boehringer in the United States. TX 513 at 56; Trial Tr. (Vol. 1), D.I. 206 at 33:15-17, 223:11-23. Mirapex® is covered by certain claims of the '812 patent. TX 419; TX 99 at BARR909. On July 1, 1997, the United States Food and Drug Administration ("FDA") approved Mirapex® for the treatment and symptoms of idiopathic Parkinson's disease. D.I. 190 at Ex. 1, ¶ 7. In November 2006, the FDA also approved

Mirapex® for the treatment of moderate to severe Restless Leg Syndrome ("RLS"). TX 419. Plaintiff Boehringer Ingelheim Pharmaceuticals, Inc. is the holder of NDA No. 020667 for Mirapex®. TX 406, 426, 509, 546.

C. Prosecution History Of The '812 Patent

1. The '374 Patent/'947 Application

The prosecution history of the '812 patent begins with its "grandfather" application, U.S. Patent Application No. 06/810,947 (the "'947 application") filed on December 15, 1985. TX 46 at 3; TX 786 (Stempel Dep.) 462:2-5, 462:13. The '947 application included 15 claims directed to a variety of compounds, including pramipexole, the methods of using those compounds and the methods of preparation of those compounds. TX 46 at BARR000114-118. On September 4, 1986, the PTO issued a restriction pursuant to 35 U.S.C. § 121 and Section 806.05(h) of the PTO's Manual of Patent Examining Procedure ("MPEP"), which required the applicant to restrict the inventions set forth in the '947 application to one of ten possibilities. Id. at BARR000274-276; TX 786 (Stempel Dep.) 260:23-24; 261:6-25. Grouping these possibilities into categories, the Examiner found that five groups (I-V) were directed to different pharmaceutical compounds, two groups (VI-VII) were directed to the methods of manufacture and three groups (VIII-X) were directed to methods of use. Id. The Examiner further found that the compound groups were distinct from each

other, as well as from the methods of manufacture and methods of use. Id. at BARR000274-278. As a result of this restriction, the Examiner requested the applicants to elect a subset of the then-pending claims and to combine some of the groups stating that the "[a]pplicants must elect either (A) one of the compound groups I-V and one of the utility groups VIII-X (composition and utility to be limited to elected compound type for examination) or (B) one of the process groups VI and VII." Id. at BAR000277 (emphasis added); TX 786 (Stempel Dep.) 263:4-10, 263:21-264:10.

In response to the restriction, Boehringer elected to prosecute the invention described in Group II which was pyrrolidinyl-substituted benzothizoles and the invention described in Group IX which was a method for treating Parkinsonism. Id. at BARR000279. These claims ultimately issued as U.S. Patent No. 4,731,374 (the "'347 patent"). D.I. 190 at Ex. 1, ¶ 7. However, Boehringer also reserved its right to prosecute claims related to the unelected subject matter in later divisional applications. TX 46 at BARR00279.

2. The '086 Patent/'197 Application

One of these divisional applications was U.S. Application No. 07/124,197 (the "'197 application"), which ultimately issued as the '086 patent on June 27, 1989. TX 2, TX 46, TX 286 at 73; D.I. 190 at Ex. 1, ¶ 18. The '197 application contained a complete copy of the '974 application, including the original

fifteen claims asserted in the '947 application. TX 46; TX 286 at BARR00491-495. In the first Office Action by the PTO, some claims were allowed and others were rejected under 35 U.S.C. § 103 and the doctrine of nonstatutory double-patenting in light of the '374 patent. TX 286 at BARR504. However, the applicant responded to this action by canceling all the claims and adding new claims which were directed to methods of using tetrahydrobenzthiazole compounds to treat a variety of medical conditions. Id. at BARR000578-600. These new claims embodied Groups VIII-X as delineated by the Examiner of the '947 application.[2] TX 46 at BARR000275-276; TX 286 at BARR000503, BARR000578-598. In addition, these new claims omitted reference to pyrrolidino compounds with respect to methods of treating Parkinson's disease as set forth in the '374 patent. Id. After noting that "[n]one of the new claims are directed to the subject matter of former claims 1-8," which covered compounds, the applicant "reserved the right to present claims directed to the subject matter of these cancelled claims in a divisional application, under 37 CFR 1.60." Id. at BARR000593. The applicant also responded to the nonstatutory double patenting rejection by arguing that the parent '947 application was subject to a restriction requirement, such that the '374 patent could not

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[2] The '947 application/'347 patent was examined by Examiner Ceperley. The '086 and '812 patents were both examined by Examiner Gerstl.

be used as a reference to support an obviousness-type double patenting rejection. Id. at BARR000595. After assessing the applicant's response, the Examiner lodged no objection to the applicant's plan to pursue the compound claims in subsequent divisional applications, and the Examiner allowed the new claims to issue as the '086 patent. TX 2, TX 286 at BARR601; D.I. 190 at Ex. 1, ¶ 18.

3. The '812 Patent/'671 Application

During the pendency of the '197 application, the same Examiner was also examining the '671 application filed on October 12, 1988, as a divisional application of the then pending '197 application. TX 99 at BARR000674, D.I. 190 at Ex. 1, ¶ 20. The '671 application ultimately issued as the '812 patent. The '671 application included a complete copy of the '197 application, which included the fifteen claims originally set out in both the '197 and '947 applications. TX 99 at BARR000662-66. Shortly after filing the '671 application, the applicant filed a preliminary amendment cancelling all the claims directed to methods of making and using tetrahydrobenzthiazoles (claims 9-15) and amending the remaining compound claims 1-8 to delete all references to the pyrrolidino compounds. Id. at BARR000677. A second preliminary amendment added two additional compound claims which the applicant maintained were directed to a subgeneric aspect of the inventions. Id. at BARR000678-679. As a result of

these preliminary amendments, the '671 application claimed a subset of the inventions originally claimed in the '947 application.

In the first Office Action, the Examiner rejected claims 1-5 and 8 of the '671 application under the doctrine of obviousness-type double patenting in light of claims 1-7 of the '374 patent. Id. at BARR000776. At a May 4, 1989 interview, the applicant reached an agreement with the Examiner that the obviousness-type double patenting rejection would be withdrawn on the basis that the claims were not directed to pyrrolidino compounds, and therefore, were not directed to the same subject matter as the '374 patent. Id. at BARR000786. The applicants further noted during the prosecution of the '671 application that "implicit in the above mentioned restriction requirement was a finding by the examiner in charge of the prior application that the ten inventions set forth in the requirement are not obvious, one over the other, such that the double patenting rejection was improper." Id. The applicants also recited their "understanding . . . that the obviousness-type double patenting rejection will be withdrawn and that no terminal disclaimer need be filed." Id. Shortly thereafter, the claims of the '671 application issued as the '812 patent. TX 3, TX 99 at BARR000789.

DISCUSSION

I. Infringement Of Claims 5, 7, 9 And 10 Of The '812 Patent

A. Applicable Law

A patent is infringed when a person "without authority makes, uses or sells any patented invention, within the United States during the term of the patent . . . ." 35 U.S.C. § 271(a). Determining infringement requires a two step inquiry. Step one requires a court to construe the disputed terms of the patent at issue. Step two requires a court to compare the accused products with the properly construed claims of the patent. Step one is a question of law; step two is a question of fact. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979-81 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996).

Infringement may be proven under either of two theories: literal infringement or the doctrine of equivalents. Literal infringement occurs when each element of at least one claim of the patent is found in the alleged infringer's product. Panduit Corp. v. Dennison Mfg. Co., 836 F.2d 1329, 1330 n.1 (Fed. Cir. 1987). The party asserting infringement has the burden of proof and must meet its burden by a preponderance of the evidence. SmithKline Diagnostics, Inc. v. Helena Lab. Corp., 859 F.2d 878, 889 (Fed. Cir. 1988) (citations omitted).

B. Analysis

Defendants have stipulated that the filing of their ANDAs infringes claim 7 of the '812 patent. With respect to claims 5, 9 and 10 of the '812 patent, Defendants did not contest infringement at trial. However, in their post-trial briefing Defendants contend that their proposed ANDA products do not infringe claims 5, 9 and 10.

1. Claim 5

Defendants contend that claim 5 is not infringed because in its application for a Patent Term Extension, Boehringer did not list claim 5 as a claim that covered pramipexole dihydrochloride. Thus, Defendants contend that Boehringer is estopped from asserting that claim 5 encompasses pramipexole, and therefore, claim 5 cannot be infringed by Defendants' proposed ANDA products.

The prosecution history of a patent constitutes the public record of the patentee's representations concerning the scope and meaning of the claims. Hockerson-Halberstadt, Inc. v. Avia Group Int'l, Inc., 222 F.3d 951, 957 (Fed. Cir. 2000). Competitors are entitled to rely on the representations made during the prosecution of a patent in determining the legality of their conduct. Id. While the prosecution history of a patent limits the interpretation of claims so as to exclude interpretations that were disclaimed during prosecution, Southwall Techs., Inc.

v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir. 1995), the disclaimer or disavowing actions must be both clear and unmistakable. Cordis v. Medtronic Ave., Inc., 511 F.3d 1157, 1177 (Fed. Cir. 2008).

Defendants' argument regarding claim 5 rests solely on the omission of claim 5 from Boehringer's Patent Term Extension application. However, the terms of claim 5 incorporate claim 3, and the Patent Term Extension application indicates that "claim 3 is applicable because it reads on compounds of formula 1a." TX 99 at BARR818. Boehringer further explained in its application that pramipexole dihydrochloride falls within claim 3 because it "is the dihydrochloride salt of a compound of the formula 1a wherein R1 R2 and R3 are all hydrogen and R4 is n-propyl." Id. Thus, the statements that establish that pramipexole dihydrochloride fall within claim 3 are equally attributable to claim 5 which refers to claim 3. In light of these statements, the Court cannot conclude that Boehringer's omission of claim 5 from the Patent Term Extension application is a clear and unmistakable disclaimer that claim 5 encompasses pramipexole.

With respect to the infringement of claim 5, the Court further finds that Dr. Klibanov provided adequate testimony at trial to establish the infringement of claim 5 by the proposed ANDA products. Tr. (Vol. 1), D.I. 206 at 235:1-241:3. Defendants do not claim that any element of claim 5 is missing

from their proposed ANDA products, see D.I. 216 at DFF ¶ 138, and Defendants did not present any evidence during trial to rebut Dr. Klibanov's testimony. Accordingly, the Court concludes that Boehringer has established infringement of claim 5 by a preponderance of the evidence.

2. Claims 9 and 10

Defendants also contend that claims 9 and 10 of the '812 patent do not mention or refer to salts, and therefore, claims 9 and 10 should be limited to the free bases of the specified compounds and should not include acid addition salts. Because Defendants' ANDAs claim pramipexole dihydrochloride, an acid addition salt of pramipexole, Defendants contend that their proposed ANDA products do not infringe claims 9 and 10.

Defendants' argument is essentially a claim construction argument that has been waived as a result of Defendants' failure to press the argument at the time for claim construction proceedings. In fact, the parties raised no disputed terms for claim construction. However, even if Defendants' argument is considered on the merits, the Court concludes that claims 9 and 10 embrace acid addition salts, and in particular pharmaceutically acceptable acid addition salts, because the specification repeatedly incorporates into the compounds of the claimed invention the aforementioned salts. TX 3; see also Tr. (Vol. 1), D.I. 206 at 242:21-246:10; 257:6-24. Moreover, even if

claims 9 and 10 are limited to the free bases of the specified compounds, the Court concludes that the proposed ANDA products would infringe because, as Defendants concede in their post-trial submissions, the administration of the proposed ANDA products to a human produces the free base of pramipexole dihydrochloride. D.I. 216 at DFF ¶ 11; Tr. (Vol. 1), D.I. 206 at 231:14-233:3, 246:10-247:13; Tr. (Vol. 2), D.I. 207 at 489:19-23. As with claim 5 of the '812 patent, Defendants did not rebut Dr. Klibanov's testimony regarding the ANDA products' infringement of claims 9 and 10, and the Court finds his testimony adequate to establish infringement. Tr. (Vol. 1), D.I. 206 at 241:4-250:18. Accordingly, the Court concludes that Boehringer has established infringement of claims 9 and 10 by a preponderance of the evidence.

II. Invalidity Of Claims 3, 4, 5, 7, 9 And 10 of the '812 Patent

Defendants challenge the validity of claims 3, 4, 5, 7, 9 and 10 of the '812 patent on the basis of nonstatutory double patenting. Specifically, Defendants contend that the asserted claims of the '812 patent are expressly and inherently anticipated by the earlier method claims of the '086 patent, and thus, not patentably distinct from the '086 patent. Defendants also contend that the '812 patent is not patentably distinct from the earlier filed '086 patent because the asserted claims of the '812 patent are obvious in light of the method claims of the '086

patent.

In response, Boehringer contends that the claims of the '086 and '812 patents are materially different in several respects such that nonstatutory double patenting does not apply to invalidate the '812 patent. Specifically, Boehringer contends that the '086 and '812 patents claim different statutory subject matter and are directed to different users. Boehringer also contends that secondary indicia of nonobviousness may be considered by the Court, and if considered, support a conclusion that the '812 patent is not invalid.

In addition to these substantive arguments, Boehringer also contends that the issue of nonstatutory double patenting has been rendered moot by Boehringer's filing of a Terminal Disclaimer with the PTO during the trial in this matter. Defendants challenge Boehringer's Terminal Disclaimer as an evidentiary matter[3], and in any event, contend that the Terminal Disclaimer is both untimely and ineffective.

A. The Effect Of The Terminal Disclaimer

Boehringer terminally disclaimed "only the terminal part of the statutory term of the '812 patent which would extend beyond the 1,564 days after the full statutory term of the '086 patent as that term is defined in 35 U.S.C. § 154, so that by virtue of

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[3] The Court will address the parties' evidentiary objections by a separate Memorandum Opinion and Order.

this disclaimer, the '812 patent will expire on October 8, 2010." TX 548. The 1,564 day extension to which Boehringer refers is the extension Boehringer received on the '812 patent term pursuant to 35 U.S.C. § 156. Section 156 allows the term of a patent covering a new drug to be extended for a period of up to five years to compensate the patent holder for time consumed by the regulatory drug approval process which would otherwise deprive the patent holder of the full benefit of the patent's term. As a result of this patent term extension, the original expiration date of the '812 patent, December 12, 2006, was extended to March 25, 2011. By its Terminal Disclaimer, Boehringer disclaimed five and a half months of its term extension. This five and a half months is the period of time between the expiration date of the '086 patent on June 27, 2006, and the original expiration date of the '812 patent, December 12, 2006.

According to Boehringer, Defendants have never contested the validity of the 1,564-day extension it received on the '812 patent. Rather, Boehringer contends that Defendants' only argument is that Boehringer should not have received the additional five and a half months it received because of the alleged double patenting of the '812 patent in light of the '086 patent. Boehringer contends that the '812 patent will now expire on the same date that the '086 patent would have expired if the

Section 156 patent term extension had been applied to it. In advancing this argument, Boehringer points out that the Patent Examiner withdrew his double patenting rejection of the '812 patent, and Boehringer confirmed with the PTO that a terminal disclaimer did not need to be filed. However, Boehringer points out that if such a terminal disclaimer "had . . . been filed at the time vis-á-vis the '086 patent, the addition of the § 156 patent term extension would have resulted in precisely the same expiration date." D.I. 213 at 19.

In response, Defendants contend that the Terminal Disclaimer cannot cure the double patenting issue presented in this case because the '086 patent has already expired. According to Defendants, the disclaimer cannot "remedy the double patenting problem because the '812 patent became incurably invalid when the '086 patent expired and Boehringer continued to prevent the public from freely practicing that invention with a longer patent term." D.I. 211 at 16. Defendants contend that by maintaining the allegedly invalid '812 patent, Boehringer unlawfully withheld from the public rights that expired when the '086 patent expired. Defendants also contend that the Section 156 extension of the '812 patent only applies to FDA-approved uses of pramipexole; however, Boehringer maintained the full scope of the '812 patent for months after the '086 patent expired. Because a patent term extension only extends existing patent rights and does not create

new ones, Defendants contend that if the '812 patent is incurably invalid, there are no patent rights to be extended under Section 156.

Terminal disclaimers allow a patentee or applicant to "disclaim or dedicate to the public the entire term, or any terminal part of the term, of the patent granted or to be granted." 35 U.S.C. § 253. Terminal disclaimers can be used to cure nonstatutory double patenting problems that arise both before the PTO and/or after issuance of the patent. 3A Donald S. Chism, Chism on Patents § 9.04[4][a]-[b] (2005); see e.g., Ventana Med. Sys., Inc. v. Biogenex Labs, Inc., 473 F.3d 1173, 1184 n.4 (Fed. Cir. 2006); Perricone v. Medicis Pharm. Corp., 432 F.3d 1368, 1375 (Fed. Cir. 2005). Specifically, a terminal disclaimer operates to "tie[] the affected patents together" such that they expire on the same date and are enforceable only during the time period in which they share the same owner. Chism, supra § 9.04[5] at 9-115. The filing of a terminal disclaimer is not a concession that the later filed patent is invalid for obviousness-type or nonstatutory double patenting. See e.g., Motionless Keyboard Co. v. Microsoft Corp., 486 F.3d 1376, 1385 (Fed. Cir. 2007); Ortho Pharm. Corp. v. Smith, 959 F.2d 936 (Fed. Cir. 1992); Quad Environmental Techs. Corp. v. Union Sanitary Dist., 20 U.S.P.Q.2d 1392, 1394-1395 (Fed. Cir. 1991).

Section 253 does not state a time period for the filing of a terminal disclaimer, and the case law has not provided a clear answer to this question. Chism, supra § 9.04[4][b] at 9-113. In fact, no Federal Circuit decision has squarely determined whether a terminal disclaimer entered after the issuance of the second patent will cure double patenting. Id. District courts and commentators have taken competing approaches to this question with some refusing to give any weight to disclaimers filed after a double patenting attack has been launched[4] and others giving weight to terminal disclaimers filed as late as after the commencement of an infringement suit.[5] Id. At least one court in the latter camp has also rejected the notion that a disclaimer must be filed without unreasonable delay. Id. (citing Bayer AG v. Barr Labs., 798 F. Supp. 196 (S.D.N.Y. 1992)).

In this case, a dual problem is presented in that the terminal disclaimer was not only filed at or near the conclusion

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[4] See CMI Corp. v. Lakeland Constr. Co., 184 U.S.P.Q. 721, 735 (N.D. Ill. 1975) ("The filing of a terminal disclaimer, three days before trial, does not obviate the vices of double patenting and will not serve as a rebuttal to the double patenting defense in this case."); see also Dunner, Gambrell & White, Patent Law Perspectives Sec. A.6-11 (1975) (discouraging consideration of terminal disclaimers filed after a double patenting challenge).

[5] See Technicon Instruments Corp. v. Coleman Instruments, Inc., 255 F. Supp. 630, 636, 641 (N.D. Ill. 1966), aff'd 385 F.2d 391 (7th Cir. 1967) (considering a terminal disclaimer, even though it was filed after the beginning of trial, and concluding that it was sufficient to cure invalidity).

of trial in this action, but it was also filed after the expiration of the earlier '086 patent.[6] Though not clear holdings, the Federal Circuit has at least suggested in dicta, that for a terminal disclaimer to be effective the earlier filed patent must not have expired at the time of the filing of the disclaimer. In re Lonardo, 119 F.3d 960, 965 (Fed. Cir. 1997) ("With obviousness-type double patenting, however, a terminal disclaimer may overcome that basis for unpatentability, assuming that the first patent has not expired.") (emphasis added); Eli Lilly and Co. v. Barr Laboratories, Inc., 251 F.3d 955, 967 n.5 (Fed. Cir. 2001) (recognizing that a terminal disclaimer could not cure nonstatutory double patenting where earlier patent had already been disclaimed, and therefore, had no remaining patent term).

Boehringer contends that each of these cases is distinguishable from the circumstances here because neither case involved a terminal disclaimer in the context of a Section 156 patent term extension, and no terminal disclaimer was actually filed in either case. Boehringer contends that in this case, the '812 patent has received a second, independent four year term as

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[6] To the extent that Boehringer argues that the PTO confirmed during the prosecution of the '812 patent that a terminal disclaimer need not be filed, the Court notes that this discussion came in the context of a rejection of the '812 patent over the '374 patent. The issue of whether Boehringer needed to file a terminal disclaimer in light of the '086 patent was not clearly addressed.

the result of the Section 156 extension. According to Boehringer, the Court should be guided by Merck & Co. v. Hi-Tech Pharmacal Co., 482 F.3d 1317, 1324 (Fed. Cir. 2007), because Merck involved both a patent term extension under Section 156 and a terminal disclaimer under Section 253.

In Merck, a terminal disclaimer was filed with respect to the '413 patent during its prosecution to overcome the Examiner's rejection on the grounds of obviousness-type double patenting. The terminal disclaimer linked the expiration of the '413 patent to the '115 patent, the patent over which the double patenting rejection was based. The term of the '115 patent was then extended in connection with Uruguay Round Agreements Act, so that its expiration date was reset from June 30, 2004 to December 12, 2004. Merck then obtained from the PTO a Section 156 patent term extension on the '413 patent which resulted in a new expiration date of April 28, 2008. The defendants argued that because the '413 patent was subject to a terminal disclaimer that linked its expiration date to the '115 patent, the '413 patent could not be the recipient of a Section 156 extension. In essence, the defendants argued that "Merck disclaimed any extension of its term beyond the expiration of the '115 patent and is thus foreclosed from obtaining a term extension under § 156." Id. at 1321. The Federal Circuit rejected this argument and concluded that "a patent term extension under § 156 may be applied to a

patent subject to a terminal disclaimer." 482 F.3d at 1317.

The Court does not read Merck to be dispositive of the issue here. In Merck, the earlier patent was not expired at the time the terminal disclaimer was filed, and the later patent was first disclaimed and then extended. In this case, the earlier '086 patent expired well before the disclaimer on the '812 patent was filed, and the '812 patent was extended before the disclaimer was filed. In these circumstances, the Court is not persuaded that Merck supports a departure from the suggestion in Lonardo and Lilly, that a terminal disclaimer may overcome a nonstatutory double patenting rejection only if the earlier patent has not yet expired.[7] Accordingly, the Court concludes that the terminal disclaimer filed by Boehringer is ineffective to moot the double patenting issue raised in this case.[8]

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[7] Boehringer argues that the result of its terminal disclaimer is that the '812 patent expires on "the same date it would have expired had Boehringer applied the patent term extension to the '086 patent." D.I. 213 at 19. However, the fact remains that Boehringer did not seek a Section 156 extension on the '086 patent. It chose to put that extension on the '812 patent. Accordingly, the Court is not persuaded that Boehringer's observation is relevant to the facts here.

[8] While the Court does not rest its holding on the timing of the filing of the terminal disclaimer, the Court is concerned about Boehringer's delay in filing for several reasons. As at least one commentator has noted, an unreasonable delay in filing a terminal disclaimer "'may be a form of the very "extension of monopoly" the terminal disclaimer provision was designed to avoid.'" Chism, supra at § 9.04[4][b] at 9-114 (quoting Dunner, Gambrell & White, Patent Law Perspectives Sec. A.6-11 (1975)). Moreover, extensive delay in filing a document which may ultimately moot a double patenting issue can have harsh effects

B. Whether Defendants' Nonstatutory Double Patenting Defense Is Precluded By 35 U.S.C. § 121

The third sentence of 35 U.S.C. § 121 can shield a patent from an attack based upon nonstatutory double patenting in certain circumstances. The relevant provision of Section 121 is the third sentence, which provides:

> A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application.

35 U.S.C. § 121.

Section 121 is strictly applied. As the Federal Circuit has explained, "§ 121 only applies to a restriction requirement that is documented by the PTO in enough clarity and detail to show consonance. The restriction documentation must identify the scope of the distinct inventions that the PTO has restricted, and must do so with sufficient clarity to show that a particular claim falls within the scope of the distinct inventions." Geneva Pharms., Inc. v. Glaxosmithkline PLC, 349 F.3d 1373, 1382 (Fed. Cir. 2003). The burden is on the patent holder to prove that Section 121 applies. Id. at 1381.

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on the judicial system as a whole resulting in gamesmanship during trial, and/or a waste of the Court's and the parties' resources.

Boehringer contends that Section 121 applies to prevent the '086 patent from being used as a reference. Specifically, Boehringer contends that the '197 application that issued as the '086 patent was filed as a result of the restriction requirement imposed during the prosecution of the '947 application which issued as the '374 patent. Boehringer also contends that the '812 patent application was filed before the issuance of the '086 patent, and therefore the timing requirements of Section 121 are satisfied. Lastly, Boehringer contends that consonance was maintained between the claims of the '812 patent and the restriction requirement because the '812 patent does not claim any subject matter that was elected in either the '374 or '086 patents.

In response to Boehringer's assertions, Defendants contend that Section 121 does not apply in this case for three reasons. First, the '671 application which resulted in the '812 patent was not filed "as a result of" a restriction requirement. Second, the '671 application was filed after the issuance of the '374 patent which was the original patent that was subject to the restriction requirement during its prosecution. Third, the claims of the '812 patent are not consonant with the restriction requirement.

As an initial matter, the parties' disagreement concerning the application of Section 121 centers on whether the '812 patent

itself had to be filed as a result of a restriction requirement or whether the '086 patent being used as a reference against the '812 patent had to be filed as a result of a restriction requirement. Boehringer's argument apparently rests upon the plain language of Section 121. As expressly worded, the "as a result of [a restriction] requirement" language used in Section 121 appears to apply to the patent being "used as a reference" - in this case, the '086 patent. 35 U.S.C. § 121 ("A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference . . ."") (emphasis added). In support of its argument, Boehringer directs the Court to the Federal Circuit's decision in Geneva and this Court's decision in Union Carbide.

In Geneva, the Federal Circuit examined whether three patents referred to as the 2000/01 patents were shielded from a nonstatutory double patenting rejection in light of a third patent referred to as the '720 patent, because the '720 patent issued from a divisional application of a common parent, the '007 application. Ultimately, the Federal Circuit concluded that Section 121 could not be used to shield the 2000/01 patents from invalidation in light of the '720 patent, because the allegedly restricted claims were not pending at the time, and the alleged restriction requirement was not sufficiently memorialized to show

consonance. In discussing the application of Section 121, however, the Federal Circuit explained that "if the 2000/01 patents and the '720 patent trace their lineage back to a common parent which was subject to a restriction requirement, then § 121 intervenes to prevent a nonstatutory double patenting rejection." 349 F.3d at 1378 (emphasis added).

Boehringer uses this sentence from Geneva to support its position that the plain language of Section 121 focuses only on the patent being used as a reference, here the '086 patent. Because there is no dispute that the '086 patent was in common lineage with the '947 application/'347 patent, which was subject to a restriction requirement, Boehringer contends that Section 121 should preclude the '086 patent from being used as a reference. However, the Court understands Geneva to have focused on both the patent being used as a reference, the '720 patent, and the patents subject to invalidation, the 2000/01 patents. More recently, in Bristol Myers Squibb, the Federal Circuit appears to have emphasized that the "as a result of a restriction requirement" language in Section 121 focuses on the patent being subject to invalidation - here the '812 patent. In this regard, the Federal Circuit explained that a patentee "is entitled to invoke the statutory prohibition against the use of the [earlier] patent 'as a reference' against the divisional application that resulted in the [later] patent only if the divisional application

was filed as a result of a restriction requirement and is consonant with that restriction requirement." Bristol-Myers Squibb Co. v. Pharmachemie B.V., 361 F.3d 1343, 1347-1348 (Fed. Cir. 2004) (emphasis added); see also Gerber Garment Tech., Inc. v. Lectra Sys., Inc., 916 F.2d 683, 687 (Fed. Cir. 1990) ("The prohibition against use of a parent application 'as a reference' against a divisional application applies only to the divisional applications that are 'filed as a result of' a restriction requirement.").

The Court understands Boehringer's argument which identifies the tension between the plain language of Section 121 and the manner in which that section has been interpreted by the Federal Circuit. However, the Court must adhere to the interpretation that has been advanced by the Federal Circuit and maintain its focus on the patent subject to invalidation, here the '812 patent.

With the '812 patent as the focus, the parties also raise competing legal and factual arguments. First, Boehringer contends that even if the '812 patent is considered, the '812 patent is the result of a restriction requirement, because like the '086 patent, the '812 patent was in common lineage with the '947 application/'347 patent on which a restriction requirement was originally made by the Patent Examiner. D.I. 231, SCOL ¶ 97.

Boehringer's "common lineage" argument, however, paints too broad a brush stroke. The appropriate inquiry is more narrow. Specifically, the Court must determine whether the '671 application/'812 patent was filed "as a result of" a restriction requirement. The '812 patent was filed as a division of the '197 application which matured into the '086 application. It was not filed as a divisional of the '947 application, which matured into the '374 patent. The 197 application/'086 patent was not itself the subject of any restriction requirement, and the Court is not persuaded, based on the evidence in the record, that the restriction requirement from the '947 application/'347 patent carried over into the '671 application/'812 patent. TX 99; TX 286 at BARR000503; TX 46 at BARR000275-276; TX 786 (Stempel Dep.) at 298:3-21, 470:5-8, 487:11-22, 489:24-490:15, 492:4-493:18, 616:4-617:2, 617:10-12; TX 787 (Hurnaus Dep.) at 196:19-197:10, 197:18-22, 198:3-7, 198:9-16, 198:20-199:2, 199:5-10, 199:13-17; TX 791 (Schneider Dep.) at 162:14-164:6. In fact, the Boehringer attorney responsible for prosecuting the '812 patent acknowledged that the restriction requirement applied only to the '947 application. Moreover, during the prosecution of the '671 application/'812 patent, the Examiner neither referred to the earlier restriction requirement nor imposed any new one.

Boehringer contends that the filing of its preliminary amendment to the claims of the '671 application/'812 patent

demonstrates that the '671 application/'812 patent was filed "as a result of" the earlier restriction requirement. However, the prosecution history of the '812 patent presents a different motive. Specifically, the prosecution history suggests that Boehringer chose to file the preliminary amendment canceling the claims in the '086 patent in order to place them in the later '671 application/'812 patent because of concerns over potentially interfering matter in a patent filed by Eli Lilly, No. 747,748. As Boehringer explained to the PTO during the prosecution of the '086 patent, "[i]n view of the particular pertinence of [the Lilly application] to claims 1-8, these claims have been canceled and will be reinstated in a divisional application . . ." TX 286 at BARR000600. These claims were then placed in the '671 application to "advance the prosecution of the ['086 patent] and [so] that issues presented by [the Lilly application] will be more easily dealt with . . ."[9] Id.; TX 704 (Boehringer's Response to Interrogatory No. 36) at pp. 24-25; TX 786 (Stempel Dep.) at 542:5-543:5, 544:12-16, 544:19-545:6, 558:21-561:7.

As the Federal Circuit recently explained in Pfizer, Inc. v. Teva Pharms. USA, Inc., the purpose of Section 121 is to prevent a patentee who has complied with a division requirement imposed by the PTO from being penalized with a double patenting rejection

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[9] Boehringer's concern over the Lilly patent was also echoed in its internal documents. TX 127; TX 133 at BOE131840.

based on the very same application from which the subsequent application was divided. 518 F.3d 1353, 1361 (Fed. Cir. 2008); Applied Materials, Inc. v. Advanced Semiconductor Materials America, Inc., 98 F.3d 1563, 1568 (Fed. Cir. 1996) ("[W]hen the existence of multiple patents is due to the administrative requirements imposed by the Patent and Trademark Office, 35 U.S.C. § 121 provides that the inventor shall not be prejudiced by having complied with those requirements."). In this case, the record suggests that the claims in the '086 patent which were divided out and placed into the '671 application/'812 patent were not divided so as to adhere to a restriction requirement, but to address concerns related to the Lilly patent and hasten the approval of the '086 patent in light of those concerns.[10] Accordingly, the Court concludes that Boehringer has not satisfied its burden of demonstrating that Section 121 applies to preclude the use of the '086 patent as an invalidating reference.

C. Nonstatutory Double Patenting

1. Applicable Law

The basic premise of double patenting is that the same invention cannot be patented twice. The proscription against double patenting takes two forms: statutory double patenting and

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[10] Having concluded that the '812 patent was not filed "as a result of" a restriction requirement, the Court need not consider the parties' remaining arguments concerning the application of Section 121.

nonstatutory double patenting. Statutory double patenting is rooted in the language of 35 U.S.C. § 101, which provides that "an inventor is entitled to a single patent for an invention." Although Section 101 precludes an inventor from obtaining more than one patent on the same invention, it only prohibits a second patent on subject matter which is identical to that claimed in the earlier patent. Robert L. Harmon, Patents and the Federal Circuit at 1148 (8th ed. 2007). Nonstatutory double patenting, also known as obviousness-type double patenting, is a judicially created doctrine designed "to prevent claims in separate applications or patents that do not recite the 'same' invention, but nonetheless claim inventions so alike that granting both exclusive rights would effectively extend the life of patent protection." Perricone v. Medicis Pharmaceutical Corp., 432 F.3d 1368, 1371 (Fed. Cir. 2005). In this regard, nonstatutory double patenting prevents inventors from obtaining unearned, extended patent protection by drafting claims that vary only slightly from the earlier patent. These principles are consistent with the purpose of patent protection, to protect and reward true innovation.

"Double patenting is altogether a matter of what is claimed." General Foods Corp. v. Studiengesellschaft Kohle mbH, 972 F.2d 1272, 1277 (1992). Claims must be read as a whole in analyzing questions of nonstatutory double patenting. Id.

Importantly, the earlier filed patent is not to be treated as a prior art reference. In other words, the earlier patent's disclosure cannot be used to show nonstatutory or obviousness-type double patenting. In re Metoprolol Succinate Patent Litig., 494 F.3d 1011, 1018 (Fed. Cir. 2007). Herein lies the primary distinction between obviousness and obviousness-type double patenting. Obviousness relates to what is disclosed, regardless of whether or not it is actually claimed, whereas obviousness-type double patenting focuses solely on that which is claimed. Id.; Geneva, 349 F.3d at 1378 n.1.

In examining the scope of what is claimed for purposes of nonstatutory double patenting, the Court applies a two-step analysis:

> First, as a matter of law, a court construes the claim in the earlier patent and the claim in the later patent and determines the differences. Second, the court determines whether the differences in subject matter between the two claims render the claims patentably distinct. A later claim that is not patentably distinct from an earlier claim in a commonly owned patent is invalid for obvious-type double patenting. A later patent claim is not patentably distinct from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim.

Eli Lilly, 251 F.3d at 968 (footnote and citations omitted). The party asserting invalidity based on nonstatutory double patenting must demonstrate invalidity by clear and convincing evidence. Symbol Techs., Inc. v. Opticon, Inc., 935 F.2d 1569, 1580 (Fed.

Cir. 1991).

2. Analysis

The Court's nonstatutory double patenting analysis begins with the basic tenets of claim construction. Claim construction begins with the words of the claims themselves. The words of a claim are generally given their ordinary and customary meaning. Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005). "The ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." Id. The claim language is, in turn, informed by the specification and the prosecution history of the patent.

In this case, the parties have a threshold dispute concerning the qualifications of one of ordinary skill in the art. Defendants contend that a person of ordinary skill in the art for the '086 and '812 patents would possess a combination of skills in chemistry, pharmacology, and/or biological evaluation of pharmaceutical compounds. In contrast, Boehringer contends that the claims of the '086 patent are directed to physicians. Boehringer further contends that this difference between the '086 patent and the '812 patent is a substantial difference relevant to the nonstatutory double patenting inquiry.

The Court has reviewed the testimony of the experts presented on this issue and concludes that a person of ordinary skill in the art for both patents is a person with a combination of skills in chemistry, pharmacology, and/or biological evaluation of pharmaceutical compounds. The Court believes this conclusion is consistent with the testimony of all of the experts who testified, including Defendants' expert, Dr. Anslyn, and Boehringer's expert, Dr. Klibanov. Notably, Dr. Klibanov did not testify regarding the skill in the art vis-á-vis the '086 patent and addressed only the '812 patent. However, the '086 patent and the '812 patent share the same specification and the same inventors, including individuals who were chemists.[11] TX 2; TX 3; TX 787 (Hurnaus Dep.) 9:6-12, 13:4-18, 14:6-10, 15:22-16:6, 36:9-36:16, 36:21-37:9; TX 791 (Schneider Dep.) 8:16-25, 9:14-10:3, 10:20-11:2, 12:9-21, 19:18-20:7. Based on this evidence, the Court is not persuaded that the '086 patent is directed solely to medical doctors. Indeed, such a conclusion would exclude at least some of the inventors of the patent from the definition of one of ordinary skill in the art. Daiichi Sankyo Co., Ltd. v. Apotex, Inc., 501 F.3d 1254, 1527 (Fed. Cir. 2007) (rejecting argument that method of treatment claims were directed

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[11] The Court considers the fact that the patents have the same disclosure in determining the qualifications of one of ordinary skill in the art; however, the Court recognizes that this fact is not dispositive of the nonstatutory double patenting inquiry.

only to medical doctors where inventors had backgrounds in other subjects).

Boehringer directs the Court to the testimony of Defendants' expert, Dr. Anslyn, to support its argument that the '086 patent is directed only to medical doctors. However, Boerhinger's characterization of Dr. Anslyn's testimony on this issue is overstated. While Dr. Anslyn suggested that a medical doctor might be among the people who would be considered skilled in the art, he did not limit the credentials of one skilled in the art to an M.D. degree, and instead described other qualifications consistent with the Court's conclusion. Specifically, Dr. Anslyn referred to a person of skill in the art as including a person with a "Ph.D. in pharmacology, physiology, toxicology, neuroscience and/or an M.D degree with post-graduate training in neurology or equivalent training and experience," along with "some familiarity with or an understanding of the drug discovery and development process as it relates to neuroscience and/or neuropharmacology." Tr. (Vol. 3), D.I. 208, 685:9-685:18. As Dr. Anslyn explained this might include a person with medical training, but it also includes others, like someone with a "more chemical background." Id. at 685:18-686:20. That only a physician might be able to lawfully prescribe to a patient the method for treatment outlined in the '086 patent does not mean that others with the aforementioned background and experience

would be excluded from the definition of a hypothetical person of ordinary skill in the art.

Having established the contours of a person of ordinary skill in the art, the Court turns to the claim language. The plain language of claims 3, 4, 5, 7, 9 and 10 of the '812 patent is directed to pharmaceutical compounds. Specifically, these claims refer to a tetrahydro-benzthiazole compound, or a pharmaceutically acceptable acid additional salt thereof. None of these claims indicate a use or method of use for the described compounds.

In contrast, the claims of the '086 patent, including claims 9, 19, 29 and 39, upon which Defendants base their nonstatutory double patenting argument, are by their express terms directed to a method of use. Specifically, the claims are directed to four particular methods of lowering blood pressure, lowering heart rate, treating Parkinson's disease or Parkinsonism and treating schizophrenia. None of the claims of the '086 patent are directed to the compounds themselves.

In addition, the '812 patent and the '086 patent have different utilities. The utility of the '086 patent is described in the enumerated methods of use claimed in the patent - particularly the treatment of Parkinson's disease, Parkinsonism, schizophrenia, elevated heart rate or high blood pressure. In contrast, the utility of '812 patent lies in the properties of

the claimed compounds, including pramipexole, which can be used to treat several medical conditions which are not listed in the '086 patent.

Although there are differences between the '812 patent and the '086 patent, as discussed above, the Court concludes that those differences are insufficient to support the patentability of the '812 patent in light of the '086 patent. The earlier '086 patent is directed to methods of treatment using tetrahydrobenzthiazoles. Tr. (Vol. 2), D.I. 207 at 471:20-472:21. Tetrahydrobenzthiazoles are the compounds claimed in the later '812 patent. Id. at 480:16-481:5. In fact, the compounds claimed in claim 3 of the '812 patent are identical to the compounds used in the method described in claim 23 of the '086 patent. Id. at 481:6-10, 483:8-484:14. Likewise, the compounds claimed in claim 7 of the '812 patent are identical to the compounds used in the methods of claims 9, 19, 29 and 39 of the '086 patent. Id. at 481:11-482:18, 493:11-20. At trial, Defendants' expert, Dr. Anslyn, testified that it would be impossible for one to practice one or more of seventeen claims of the '086 patent, claims 7-10, 17-20, 23, 27-30 and 37-40, without necessarily using or forming compounds claimed in claims 3, 4, 5, 7, 9 and 10 of the '812 patent. Id. at 482:19-483:7, 484:15-485:1, 485:22-486:20, 487:4-491:1, 493:21-495:10. Thus, one skilled in the art would recognize that in order to practice the

method claims of the '086 patent, one must have the specified compounds. Id. at 477:22-478:19. 482:19-483:7, 484:15-485:1, 485:22-486:20, 488:10-491:1, 493:21-495:10; 570:1-571:6; TX 789 (Mierau Dep.) 64:2-10, 65:9-13, 66:24-67:4, 67:7-14, 67:17-18; TX 790 (Schingnitz Dep.) 159:10-24. Boehringer did not rebut the testimony of Dr. Anslyn on these issues, and instead, focused its cross-examination of Dr. Anslyn on whether one skilled in the art of the '086 patent must have medical degree.

Boehringer also contends that despite the aforementioned similarities, the '086 and '812 patent are distinct because the '086 patent is limited to certain utilities, while the compound claims of the '812 patent have been shown to have use for the treatment of conditions different from those specified in the '086 patent, like RLS, depression, fibromyalgia and the possibility of neuroprotection. However, there is precedent from both the Federal Circuit and its predecessor court, the Court of Customs and Patent Appeals (the "CCPA"), indicating that Boehringer's argument is an insufficient basis to support a conclusion that the patents are distinct. For example, the CCPA has explained:

> It would shock one's sense of justice if an inventor could receive a patent upon a composition of matter, setting out at length in the specification the useful purposes of such composition, manufacture and sell it to the public, and then prevent the public from making any beneficial use of such product by securing patents upon each of the uses to

which it may be adapted.

> In the case at bar, appellant received a patent upon his composition of matter because he had invented something new and useful. He could not have received such a patent unless he had disclosed its utility. Such disclosure of usefulness did not constitute separate inventions, but an essential part of a single invention.

In re Byck, 48 F.2d 665, 666-67 (CCPA 1931) (emphasis added) ; In re Christmann, 128 F.2d 596, 600 (CCPA 1942) (same). This approach to double patenting was adopted by the Federal Circuit in the Geneva-Pfizer line of cases. See Geneva, 349 F.3d at 1386; Pfizer 518 at 1363 n.8. In Geneva, the Federal Circuit concluded that two sets of claims were not patentably distinct where the earlier claims were directed to a compound and the earlier patent disclosed a utility for the compound, and the later claims claimed that utility as a method of using the compound. In concluding that a compound and a previously disclosed method of using the compound constitutes a single invention for which only one patent may be granted, the Federal Circuit observed that it "does not consider the [compound] claim in a vacuum, as a simple compound, without considering the compound's disclosed utility." 349 F.3d at 1385. The Federal Circuit adhered to this approach in Pfizer when it considered nonstatutory double patenting in the context of a later patent claiming a method of using a composition with an earlier patent claiming the composition itself. In Pfizer, the Federal Circuit

stated, "[W]e agree with the district court that the [later] patent merely claims a particular use described in the [earlier] patent of the claimed compositions of the [earlier] patent. The asserted claims of the [later] patent are therefore not patentably distinct over the claims of the [earlier] patent." 518 F.3d at 1363.

Boehringer contends that this line of cases is distinguishable from the circumstances here because those cases were limited to compounds having a single utility, but pramipexole has multiple utilities. The Court agrees that both Geneva and Pfizer involved single utility compounds; however, the Court does not read the rationale of Geneva and Pfizer to be limited to that circumstance. Indeed, case law from the CCPA suggests that this distinction is irrelevant:

> The claims in the instant case are not directed to any particular use although . . . appellants rely in part upon the new use to justify their contention for allowance of the new claims. Unquestionably, under the stated circumstances the allowance of the appellants' claims would be an extension of the appellants' monopoly not warranted by law. If they were to obtain a patent including the instant claims, they would presumptively be given a monopoly for seventeen years on the exclusive use of the compound for any purpose.

Christmann, 128 F.2d at 599-600 (emphasis added). In the Court's view, allowing Boehringer to secure a new patent on a compound which was itself specifically identified in the earlier method claims of the '086 patent is precisely the type of monopolistic conduct the doctrine of nonstatutory double patenting was

designed to prevent. Patent protection is designed to reward true innovation, and the Court cannot conclude that the alleged "new" uses of tetrahydrobenzthiazoles are sufficient to support their separate patentability where, as here, those same compounds were precisely claimed as the compounds to be used in the methods described in the '086 patent.

Boehringer also urges the Court to consider secondary indicia of nonobviousness in its double patenting analysis, which Boehringer contends weigh in favor of the validity of the '812 patent. Courts have disagreed on whether it is appropriate to consider secondary indicia of nonobviousness in the context of nonstatutory double patenting.[12] On this issue, the Federal Circuit has held that "[o]bviousness requires inquiry into objective criteria suggesting non-obviousness, but nonstatutory double patenting does not." 349 F.3d at 1378, n.1. While the Court understands this statement to indicate that secondary indicia of nonobviousness are not required to be considered in

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[12] Compare Applera Corp. v. MJ Research Inc., 363 F. Supp. 2d 261, 264 (D. Conn. 2005) ("In addition, the double patenting inquiry does not include an examination of the motivation to modify the prior art, nor does it involve inquiry into objective criteria suggesting non-obviousness.") with Eli Lilly and Co. v. Zenith Goldline Pharms., Inc., 364 F. Supp. 2d 820, 911 (S.D. Ind. 2005) ("[T]he factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103 are employed when making an obvious-type double patenting analysis," including "objective indicia of nonobviousness.") (citations omitted) (emphasis added).

the nonstatutory double patenting inquiry, the Court does not read this statement to suggest that secondary indicia of nonobviousness are irrelevant. Rather, the Court believes there is discretion to be applied between the idea of maintaining the focus on what is claimed rather than what is disclosed, while simultaneously considering factors beyond the scope of the claim language like secondary indicia of nonobviousness. To the extent that secondary indicia of nonobviousness should be considered by the Court, the Court concludes that, in the context of this case, those factors presented by Boehringer are insufficient to overcome the nonstatutory double patenting issue presented here. Richardson-Vicks Inc. v. Upjohn Co., 122 F.3d 1476, 1483 (Fed. Cir. 1997); see also Agrizap, Inc. v. Woodstream Corp., 2008 WL 819757, *6 (Fed. Cir. 2008) (holding that objective evidence of nonobviousness, including commercial success, copying and satisfaction of long-felt need, could not overcome "such a strong prima facie case of obviousness"). The evidence in this case offered as secondary considerations of nonobviousness is mixed and unpersuasive, and as such, it neither fully supports nor fully negates obviousness, to the extent that such evidence should even be considered for purposes of nonstatutory double-patenting.[13] Accordingly, the Court declines to place any

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[13] For example, Boehringer's expert, Dr. Olanow testified that pramipexole had several unexpected properties, specifically, its use for the treatment of RLS, fibromyalgia, depression and as

significant weight on the secondary considerations of nonobviousness in this case.

In sum, the Court concludes that the '812 patent which claims tetrahydrobenzthiazoles is obvious in light of the '086 patent, which claims methods of using tetrahydrobenzthiazoles for the treatment of certain illnesses. Accordingly, the Court concludes that Defendants have established by clear and convincing evidence that the '812 patent is invalid on the grounds of nonstatutory double patenting.

CONCLUSION

For the reasons discussed, the Court concludes that Boehringer has demonstrated by a preponderance of the evidence that Defendants' ANDA products infringe the asserted claims of the '812 patent. However, the Court concludes that Defendants have established by clear and convincing evidence that the '812 patent is invalid on the grounds of nonstatutory double patenting. Because an invalid patent cannot be infringed, the

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a neuroprotector. Tr. (Vol. 1), D.I. 206 at 69:14-115:15. However, on cross-examination, Dr. Olanow conceded that the use of dopamine agonists, which includes pramipexole, had been suggested by others for the treatment of RLS. Id. at 169:172:13; 182:2-183:1. Further, Dr. Olanow acknowledged that while there are studies showing that pramipexole has positive effects on conditions like depression and fibromyalgia, those studies have not definitely proven that pramipexole is an effective treatment for these conditions and there is still an unmet need insofar as treatment for these conditions is concerned. Id. at 120:13-8, 122:18-22, 124:16-125:3, 125:22-126:9, 145:14-20, 158:10-15, 160:20-161:8.

Court will enter judgment in favor of Defendants on both issues. Accordingly, Defendants shall submit a proposed form of Final Judgment Order within ten (10) days of the date of the Court's Memorandum Opinion and accompanying Order.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOEHRINGER INGELHEIM INTERNATIONAL GMBH and BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,	:	
Plaintiffs,	:	
v.	:	Civil Action No. 05-700-JJF
	:	**CONSOLIDATED**
BARR LABORATORIES, INC. and MYLAN PHARMACEUTICALS, INC.,	:	
Defendants.	:	

O R D E R

At Wilmington, this 26 day of June 2008, for the reasons set forth in the Memorandum Opinion issued this date;

IT IS HEREBY ORDERED that:

1. Claims 3, 4, 5, 7, 9 and 10 of U.S. Patent No. 4,886,812 are invalid on the grounds of nonstatutory double patenting.

2. Defendants shall submit with notice to Plaintiffs a proposed Final Judgment Order **within ten (10) days** of the date of this Order.

Joseph J. Farnan, Jr.
UNITED STATES DISTRICT JUDGE