IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| BOEHRINGER INGELHEIM INTERNATIONAL GMBH and BOEHRINGER INGELHEIM PHARMACEUTICAL, INC.<br><br>Plaintiffs,<br><br>v.<br><br>BARR LABORATORIES, INC.,<br><br>Defendant, | Civil Action No. 05-700 (JJF) |
| BOEHRINGER INGELHEIM INTERNATIONAL GMBH and BOEHRINGER INGELHEIM PHARMACEUTICAL, INC.<br><br>Plaintiffs,<br><br>v.<br><br>MYLAN PHARMACEUTICALS, INC.,<br><br>Defendant. | Civil Action No. 05-854 (JJF)<br><br>**REDACTED - PUBLIC VERSION** |

**PLAINTIFFS' POST-TRIAL OPENING BRIEF**

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## I. NATURE AND STAGE OF THE PROCEEDING

These cases arise from Abbreviated New Drug Applications ("ANDAs") filed by Barr Laboratories, Inc. ("Barr") and Mylan Pharmaceuticals, Inc. ("Mylan") (collectively "Defendants") seeking approval from the FDA to market generic versions of MIRAPEX® – a drug developed and sold by Plaintiffs Boehringer Ingelheim International, GmbH and Boehringer Ingelheim Pharmaceuticals, Inc. (collectively "Boehringer"). The active ingredient in both MIRAPEX® and Defendants' proposed generic products is pramipexole dihydrochloride, which Defendants admit is covered by the patent-in-suit, United States Patent No. 4,886,812 ("the '812 patent"). These cases were tried on March 11-13, 2008. This is Boehringer's opening post-trial brief.

Defendants have stipulated that by filing their ANDAs seeking approval to market generic pramipexole dihydrochloride tablets prior to the expiration of the '812 patent, they have infringed at least claim 7 of that patent. During discovery, Defendants did not contest that their proposed products also would infringe asserted claims 5, 9 and 10, but were unwilling to stipulate to infringement of those claims. At trial, Plaintiffs provided sufficient evidence to meet their burden of proving that Defendants infringe claims 5, 9 and 10, and Defendants offered no evidence to the contrary. During discovery, Defendants asserted numerous invalidity and unenforceability defenses. At trial, however, they asserted only obviousness-type double patenting.

## II. SUMMARY OF ARGUMENT

These cases present two issues for the Court. The first, whether Mylan and Barr have infringed the asserted claims of the '812 patent by filing ANDAs seeking to market generic copies of MIRAPEX®, is not seriously in question. Defendants have stipulated to infringement of claim 7 and never disputed infringement of the remaining asserted claims.

The second issue is whether the asserted compound claims are invalid for obviousness-type double patenting over the method claims of another patent, United States Patent No. 4,843,086 ("the '086 patent"). This issue was mooted when ***Boehringer filed a terminal disclaimer, at trial, disclaiming the portion of the patent term that Defendants contend Boehringer obtained as a result of the alleged double patenting***. Defendants dispute that Boehringer's terminal disclaimer is effective because it was filed after the '086 patent expired and during the '812 patent's term restoration period granted under 35 U.S.C. § 156. But Defendants point to no legal authority addressing the interplay between the statutes allowing for terminal disclaimer and extension of patent term – and certainly none that prohibits disclaimer of part of the unextended patent term and retention of the patent term extension. In the case closest to the situation at hand, the Federal Circuit held that "a patent term extension under § 156 may be applied to a patent subject to a terminal disclaimer." *Merck & Co., Inc. v. Hi-Tech Pharmacal Co., Inc.*, 482 F.3d 1317, 1324 (Fed. Cir. 2007).

Defendants' double patenting defense must fail for the following ***six independent reasons***:

- ***First***, Defendants cannot overcome the long line of cases holding that a terminal disclaimer moots an allegation of obviousness-type double patenting or the Federal Circuit's decision in *Merck* that a patentee may terminally disclaim a portion of its patent term and still retain the benefits of the FDA extension term.

- ***Second***, Defendants allege only a single fact in support of their invalidity defense: that compounds mentioned in the method claims of the '086 patent purportedly are "subgenera" of compounds claimed by the '812 patent. This fact ignores the required steps of the obviousness-type double patenting inquiry and is insufficient to meet Defendants' "heavy and

unshifting" burden of proving double patenting by clear and convincing evidence, especially where the PTO itself explicitly decided that the '086 and '812 claims were patentably distinct.

- ***Third,*** Defendants' "subgenera" theory is irrelevant to the correct test for double patenting. A genus-species relationship can only occur between claims directed to the same statutory subject matter. A method may be a subgenus of another class of methods and a compound may be a subgenus of another class of compounds, but a method claim cannot be a subgenus of a compound claim. Here, the '812 and '086 patent claims indisputably claim separate categories of statutory subject matter, and there is a specific test for determining whether such claims to "related inventions" are patentably distinct. There is no dispute that the asserted claims meet that test of distinctiveness.

- ***Fourth,*** under MPEP § 806.05(h), the special test set forth by the PTO and specifically applied by the Examiner, the '812 patent claims are patentably distinct from the '086 patent claims. Defendants have never disputed the applicability of this test or the PTO's explicit decision that under that test, the asserted claims are distinct from the '086 patent claims.

- ***Fifth***, Defendants have not rebutted any of Boehringer's evidence of secondary indicia of nonobviousness that favor a finding of no double patenting.

- ***Sixth***, under 35 U.S.C. § 121, the '086 patent cannot be used as a reference against the '812 patent.

For each of these reasons, the asserted claims of the '812 patent are valid, and Boehringer is entitled to an order that Defendants be enjoined from making, using, selling, or offering to sell their proposed products until the expiration of the '812 patent.

## III. STATEMENT OF FACTS

### A. The '812 Patent and Relevant Prosecution History

#### 1. The '947 Application Leading to the '374 Patent

Pramipexole falls within a class of compounds known as "tetrahydrobenzthiazoles." Boehringer scientists invented a number of tetrahydrobenzthiazoles, including pramipexole, in the early 1980s. FOF at ¶ 26. On December 15, 1985, Boehringer filed United States patent application No. 06/810,947 ("the '947 application") containing 15 claims covering different classes of its new tetrahydrobenzthiazole compounds (including pramipexole) as well as methods of using such compounds to treat medical conditions and methods of making such compounds. *Id.*

In the first Office Action in the '947 application, the PTO (Examiner Ceperley) imposed a ten-way restriction requirement. *Id.* at ¶ 30. The Examiner concluded that a number of the claimed compounds were patentably distinct from each other and specifically determined that the claimed compounds also were patentably distinct from the claimed methods of using those compounds. *See id.* at ¶ 30, 31. The Examiner explained that her conclusion that the claimed methods of using the described compounds were patentably distinct from the claims to the chemical compounds themselves was based, in part, on her application of the long-established test set forth in § 806.05(h) of the Manual of Patent Examining Procedure ("MPEP"):

> [I]nventions are distinct if either (1) the process for using the product as claimed can be practiced with another and materially different product, or (2) the product as claimed can be used in a materially different process of using the product. MPEP 806.05(h). In this case, the compounds could be used in each of the materially different processes as set forth in VIII-X.

*Id.* at ¶ 32. The Examiner concluded that "[b]ecause these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent

subject matter as indicated by their diverse classification, restriction for examination purposes as indicated is proper." TX 46 at BARR000277.

The Examiner divided the claims into ten patentably distinct groups. *See* FOF at ¶ 30. Groups I through V claimed different classes of tetrahydrobenzthiazoles, groups VI and VII claimed methods of preparing tetrahydrobenzthiazole compounds, and groups VIII through X claimed methods of using tetrahydrobenzthiazoles to treat specified medical conditions such as lowering blood pressure and heart rate and treating Parkinsonism, Parkinson's disease, and schizophrenia. *See id.*

The Examiner required Boehringer to elect a subset of the then-pending claims that had been determined to be distinct while permitting them to combine some of the groups:

> Applicants 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 ¶ 33. Boehringer elected claims directed to Group II, "pyrrolidinyl-substituted benzothiazoles" and methods of use to treat Parkinson's Disease and Parkinsonism. *Id.* at ¶ 34. In their Response to the Restriction Requirement, Boehringer explicitly "reserve[d] the right to prosecute claims to the unelected subject mater in divisional applications." *Id.* at ¶ 35. The elected claims ultimately issued as United States Patent No. 4,731,374 ("the '374 patent") on March 15, 1988. *Id.* at ¶ 36.

**2. The '197 Application Leading to the '086 Patent**

While the '947 application was pending, Boehringer filed Application No. 07/124,197 ("the '197 application"), as a divisional of the '947 application. *Id.* at ¶ 37. Because the '197 application was a divisional of the '947 application, Boehringer was required to file "a complete copy of the prior" '947 application. *Id.* at ¶ 38. By doing so, Boehringer ensured that there were no differences in content between the '197 and '947 applications. As a result, the '197

application initially contained the same 15 claims that were included in the original '947 application. *Id.*

The '197 application was examined by Examiner Gerstl, a different patent examiner than the one who examined the '947 application. *See id.* at ¶¶ 29, 39. In the first Office Action in the '197 application, Examiner Gerstl rejected a number of claims "under the judicially created doctrine of double patenting as being unpatentable over the prior invention as set forth in claim 1 of U.S. Patent 4731374." *Id.* at ¶ 40. Examiner Gerstl also allowed some claims, including claims 6 and 7 directed to tetrahydrobenzthiazole compounds that were not pyrrolidinyl-substituted. *See id.*

During the process of prosecuting the subject applications, Boehringer became aware of European Patent application No. 207,969 filed by scientists from Eli Lilly and also directed to tetrahydrobenzthiazoles. *See id.* at ¶ 41. The European application claimed priority to an earlier U.S. application, No. 747,748 ("the Lilly '748 application"). Boehringer decided "to bring to the attention of the Patent and Trademark Office the existence [of] U.S. Patent Application Serial No. 747,748…and its foreign equivalent" because the underlying work performed by the Lilly scientists could have "possibly interfer[ed]" with the compound claims initially pending in the '197 application. TX 99 at BARR000781.

With the Lilly '748 application in mind, Boehringer responded to Examiner Gerstl's first office action by cancelling all pending claims (the claims that had been merely copied from the original application) and adding a new set of claims. FOF at ¶ 43. The new claims were directed solely to the methods of using tetrahydrobenzthiazole compounds to treat specified medical conditions. *Id.* at ¶ 44. Boehringer specifically excluded from the claims methods of using the pyrrolidino compounds to treat Parkinson's Disease because that subject matter had been elected

already in connection with the '374 patent. *Id.* Boehringer explained that the amendment obviated the double patenting rejection, *id*. at ¶ 48, noting that the parent '947 application

> was made subject to a restriction requirement …. In view of the Applicants election to prosecute composition of matter claims directed to the invention of Group II, pyrrolidino-substituted benzthiazoles, the method claims of the '374 patent were restricted to the use of pyrrolidino-substituted compounds. Due to this restriction requirement, the '374 patent cannot be applied as a reference to support an obviousness-type double patenting rejection.

TX 286 at BARR000595.

Boehringer also explained that:

> As filed, U.S. Application Serial No. 747,748 [the Lilly application] did not contain claims corresponding to the method or process claims currently pending in the above-captioned application. There is, therefore, no possibility that the claims in the above-captioned application can or will interfere with the claims present in Serial No. 747,748, as originally filed. Further, it is not [sic] believed that the specification of that application would not support the making of such claims. It is therefore, believed that there is little possibility that claims could be added to Serial no. 747,748 which would interfere with the claims of the above-captioned application.

*Id.* at BARR000599-600. Importantly, Boehringer expressly informed Examiner Gerstl that it would seek the cancelled compound claims in a divisional application pursuant to 37 C.F.R. § 1.60. FOF at ¶ 46. Boehringer observed that this would "advance the prosecution of the above-captioned application and that issues presented by this reference [the Lilly '748 application] will be more easily dealt with in said divisional application." *Id.* Examiner Gerstl understood that method of use claims would remain in the earlier-filed application and the compound claims would be prosecuted in a later filed divisional. Not surprisingly, Examiner Gerstl did not object to the separation of these patentably distinct groups of claims or suggest that doing so would lead

to double patenting.[1] Instead, Examiner Gerstl allowed the '197 application to issue as the '086 patent and proceeded to examine the newly-filed divisional, which later issued as the '812 patent. *Id.* at ¶ 49.

**3. The '671 Application Leading to the '812 Patent**

The application that ultimately issued as the '812 patent ("the '671 application") was filed on October 12, 1988, as a divisional of the pending '197 application. *Id.* at ¶ 51. The '812 patent also was examined by Examiner Gerstl. *Id.* at ¶ 52.

As required for a divisional application, the '671 application was filed with the same 15 claims as those contained in the parent '197 and grandparent '947 applications. *Id.* at ¶ 54. Boehringer promptly filed a preliminary amendment cancelling all of the claims directed to methods of making and using tetrahydrobenzthiazoles and amending the remaining compound claims to delete all references to "pyrrolidino" compounds. *Id.* at ¶ 55. By doing so, Boehringer ensured that it would not claim subject matter previously claimed in the grandparent application or the first divisional application. Thus, Boehringer explained that the amendment was "intended to exclude from the claims subject matter already patented in U.S. Patent 4,731,374 and that pending in Serial No. 124,197 filed November 23, 1987." *Id.* at ¶ 56. At this point, the '671 application claimed a subset of the inventions originally set forth in the grandparent '947 application that did not overlap with the subsets claimed in the '374 and '086 patents. *See id.* at ¶ 60.

In the first Office Action, Examiner Gerstl rejected certain claims pending in the '671 application for obviousness-type double patenting over claims of the '374 patent. *Id.* at ¶ 61. In

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[1] Had he identified any double patenting problem between the two applications, Examiner Gerstl could have issued a provisional rejection. *See* MPEP §§ 800(I)(B), 804.02. He did not.

a May 4, 1989 interview, Boehringer and the Examiner reached agreement that in light of the preliminary amendment, the double patenting rejection would be withdrawn, given that the pending claims were not directed to "pyrrolidino" compounds and, accordingly, were "not directed to the same subject matter as those of the '374 patent." *Id.* at ¶ 63. Although plainly focused on the issue of double patenting, Examiner Gerstl never suggested that the '812 patent was double patented over the '086 patent – he proceeded consistently with the original finding that those claims were patentably distinct.

> Boehringer noted in response to the double patenting rejection that:
>
> > A restriction requirement was made during the examination of the application which matured into the '374 patent. This required that an election be made to prosecute claims directed to one of ten different inventions….***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***. Accordingly, the Patent and Trademark Office cannot now take the position that the subject matter of the present application is obvious over that claimed in the '374 patent. This being the case, a rejection for obviousness-type double patenting cannot be made.
> >
> > In view of the foregoing, it is the understanding of the undersigned attorney for Applicants that the obviousness-type double patenting rejection will be withdrawn and that no terminal disclaimer need be filed.

TX 99 at BARR000786[2]; FOF at ¶ 64. The Examiner, plainly aware of the existence of the method of use claims set forth in the '086 patent and Examiner Ceperley's holding that the method of use claims were distinct from the compound claims as well as the original restriction requirement, allowed claims 1-10, and the '812 patent issued on December 12, 1989. FOF at ¶ 65.

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[2] Emphasis is added unless otherwise noted.

**B. Boehringer's Terminal Disclaimer**

Boehringer committed substantial resources to obtain FDA approval to market pramipexole dihydrochloride in the form of MIRAPEX® tablets. On October 13, 1999, at the request of Boehringer and pursuant to 35 U.S.C. § 156, the Patent and Trademark Office extended the term of the '812 patent by 1,564 days to compensate Boehringer for the period of regulatory review undertaken by the FDA of MIRAPEX®. *See* FOF at ¶ 101. The PTO determined that, "[s]ince it appears that the requirements of the of the law have been met, this certificate extends the term of the ['812] patent for the period of 1,564 days from December 12, 2006, the original expiration date of the patent . . . with all rights pertaining thereto as provided by 35 U.S.C. § 156(b)." *Id.* Originally set to expire on December 12, 2006, the grant of the petition extended the expiration date of the '812 patent to March 25, 2011. *Id.* at ¶ 102. Defendants have never questioned the validity of this extension. *See id.* at ¶ 103. The patent term extension irrevocably attached to the patent on the day the extension was granted.

During trial and prior to the close of the evidence, Boehringer filed a terminal disclaimer with the PTO which states as follows:

> U.S. patent No. 4,886,812 ("the '812 patent") originally was set to expire on December 12, 2006. As a result of a patent term extension granted under 35 U.S.C. § 156, the term of the '812 patent was extended by 1,564 days. *See* Certificate Extending Patent Term (Exhibit A hereto). As a result, the '812 patent currently does not expire until March 25, 2011.
>
> Boehringer Ingelheim International GmbH ("Boehringer") is the owner of 100 percent of the interest of the '812 patent and U.S. Patent No. 4,843,086 ("the '086 patent"). Pursuant to 35 U.S.C. § 253 and the Federal Circuit's decision in *Merck & Co., Inc. Hi-Tech Pharmacal Co.*, 482 F.3d 1317, 1324 (Fed. Cir. 2007), that a patent term extension under § 156 may be applied to a patent subject to a terminal disclaimer, Boehringer hereby disclaims, except as provided below, only the terminal part of the statutory term of the '812 patent which would extend beyond 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 this disclaimer, the '812 patent will expire on October 8, 2010.

> This agreement runs with the '812 patent and is binding upon the grantee, its successors or assigns.

FOF at ¶ 104, TX 548 at 1.

## IV. ARGUMENT

### A. Infringement of Claim 7 is Stipulated and Infringement of Claims 5, 9 and 10 Is Undisputed

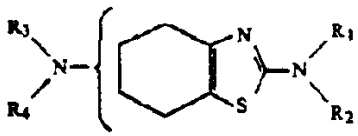
Infringement is a two-step inquiry. "First, the court determines the scope and meaning of the patent claims asserted.... [Second,] the properly construed claims are compared to the allegedly infringing device." *In re Gabapentin Patent Litig.*, 503 F.3d 1254, 1259 (Fed. Cir. 2007) (citing *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454 (Fed. Cir. 1998) (en banc)). "[C]omparison of the claim to the accused product, requires a determination that every claim limitation or its equivalent be found in the accused device." *Gabapentin*, 503 F.3d at 1259. "Those determinations are questions of fact…." *Id.* (citing *Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed. Cir. 1998)).

Boehringer bears the burden of proving infringement of one or more asserted claims by a preponderance of the evidence. *See, e.g., Warner-Lambert Co. v. Teva Pharm. USA, Inc.*, 418 F.3d 1326, 1341 (Fed. Cir. 2005). Where the accused infringers do not dispute infringement, the patentee is entitled to judgment of infringement. *See, e.g., Callicrate v. Wadsworth Mfg., Inc.*, 427 F.3d 1361, 1372 (Fed. Cir. 2005) (reversing denial of JMOL to patentee on infringement of asserted claims where defendant admitted infringement); *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1322 (Fed. Cir. 2004) (granting summary judgment of infringement where defendant did not dispute infringement).

#### 1. The Asserted Claims

At trial, Boehringer asserted infringement of claims 5, 7, 9 and 10 of the '812 patent. The asserted claims, along with unasserted claim 3, from which claim 5 depends, provide:

3. [Not asserted] A tetrahydro-benzthiazole of the formula:



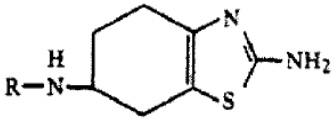
(Ia)

Wherein $R_1$ is a hydrogen atom, an alkyl group having 1 to 3 carbon atoms, an allyl, benzyl, 2-chloro-benzyl, 4-chloro-benzyl, 3,4-dichloro-benzyl or phenyl-ethyl group; $R_2$ is a hydrogen atom, a methyl or ethyl group; $R_3$ is a hydrogen atom, an alkyl group with 1 to 6 carbon atoms, an allyl, propargyl, benzyl, chlorobenzyl, phenylethyl, cyclopentyl or cyclohexyl group; and $R_3$ and $R_4$ together with the nitrogen atom between them form a piperidino, hexamethyleneimino or morpholino group; or, a pharmaceutically acceptable acid addition salt thereof.

5. A tetrahydro-benzthiazole of formula Ia, as claimed in claim 3, wherein $R_1$ and $R_2$ together with the nitrogen atom between them form an amino or allylamino group; and, $R_3$ and $R_4$ together with the nitrogen atom between them form a dimethylamino, diethylamino, N-allyl-N-(4-chloro-benzyl)-amino, n-propylamino or group."

7. 2-Amino-6-n-propylamino-4,5,6,7-tetrahydrobenzthiazole, or a pharmaceutically acceptable addition salt thereof.

9. A tetrahydrobenzthiazole of the formula



Wherein R is an alkyl group with 1 to 7 carbon atoms, a cycloalkyl group having 3 to 7 carbon atoms, an alkenyl or alkynyl group having 3 to 6 carbon atoms, an alkanoyl group having 1 to 7 carbon atoms or a phenyl alkyl or phenyl alkanoyl group having 1 to 3 carbon atoms in the alkyl moiety, wherein the phenyl nucleus may be substituted by fluorine, chlorine or bromine atoms."

10. The compound of claim 9 wherein R is an alkyl group having 1 to 7 carbon atoms.

TX 3 at claims 3, 5, 7, 9 and 10.

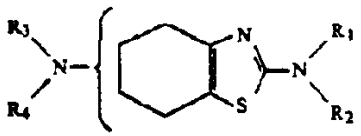
### 2. Barr and Mylan Have Admitted Infringement of Claim 7

Barr and Mylan have stipulated that "[t]he commercial manufacture, sale or use of [their accused] product[s] would infringe Claim 7 of the '812 patent. Therefore, by submitting ANDA[s]…seeking approval to engage in the commercial manufacture, use and sale of [their accused] product[s] prior to the expiration of the '812 patent, [Barr and Mylan] ha[ve] infringed claim 7 of the '812 patent." *See* FOF at ¶ 89; D.I. 190, at Ex. 1, ¶¶ 13-16.

### 3. Barr and Mylan Did Not Contest Infringement of Claims 5, 9, and 10 During Discovery or at Trial

As set forth in Boehringer's accompanying brief regarding evidentiary issues, neither Barr nor Mylan contested infringement of claims 5, 9, and 10 during discovery. *See* Mem. in Supp. re Evidentiary Issues *at passim*; FOF at ¶ 86. Nor did Barr or Mylan submit a rebuttal expert report contesting Dr. Klibanov's opinions that both Defendants had infringed those claims. FOF at ¶ 87. Nevertheless, Barr and Mylan refused to stipulate to infringement of claims 5, 9, and 10 and required that Boehringer put on evidence of infringement at trial.

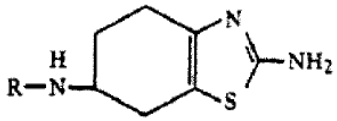
At trial, Boehringer put on ample evidence that, by filing their ANDAs, Barr and Mylan infringed claims 5, 9 and 10. It is undisputed that the active ingredient in Barr and Mylan's proposed ANDA products is pramipexole dihydrochloride. *Id.* at ¶ 78. The Court heard unrebutted testimony from Dr. Alexander Klibanov, an expert in organic and medicinal chemistry from MIT, that the pramipexole dihydrochloride in Barr and Mylan's products satisfies each element of asserted claims 5, 9, and 10. *Id.* at ¶¶ 94-98; Trial Tr. (Vol. 1), D.I. 206, at 234:18-235:3. As Dr. Klibanov explained, Defendants' pramipexole dihydrochloride products fall within claim 5 because pramipexole is a "tetrahydro-benzthiazole of formula Ia":



(Ia)

"wherein R1 and R2 together with the nitrogen atom between them form an amino… group" and "R3 and R4 together with the nitrogen atom between them form a… n-propylamino" group. *Id.* at ¶ 94. Moreover, dihydrochloride is "widely known to be a pharmaceutically acceptable salt." *Id.*

Dr. Klibanov also testified that Defendants' pramipexole dihydrochloride products fall within claims 9 and 10 of the '812 patent because pramipexole is "a tetrahydrobenzothiazole of the formula":



"wherein R is an alkyl group" having 3 carbon atoms. *Id*. at ¶¶ 96-98.

Notably, Defendants never challenged Boehringer's evidence of infringement in discovery responses, by way of any expert report, or at trial. *See id.* at ¶¶ 86-87. The Defendants' failure to proffer any evidence of noninfringement in the face of Plaintiffs' evidence that the asserted claims are infringed is sufficient basis, in and of itself, to enter judgment of infringement. As the Federal Circuit noted in *Transclean Corp. v. Bridgewood Services, Inc*., 290 F.3d 1364 (Fed. Cir. 2002):

> [The patentee] legitimately sought to discover [Defendant's] grounds for its defense of noninfringement and was entitled to a reply to its interrogatory. When [Defendant] chose not to respond before the closing of discovery other than to voice its belief that the [patent-in-suit] was invalid and unenforceable, the court was within its discretion to impose a sanction. The court found clear prejudice to

> [Patentee], as it was precluded from conducting discovery on the infringement issues.
>
> * * * * *
>
> ***[Patentee's] motion for summary judgment of infringement presented evidence sufficient to show infringement, and, in light of [Defendant's] non-response, that evidence was uncontradicted. Accordingly, we affirm the district court's grant of summary judgment of infringement*** of claims 1-4 and 12….

*Id.* at 1373-74. Similarly, in *Toro Co.*, the Federal Circuit held that the district court "properly" found Plaintiff was entitled to summary judgment of infringement "as a matter of law" where the defendant did "not dispute that the accused device is in all material respects a [patented] embodiment." 355 F.3d at 1322. *See also Jazz Photo Corp. v. International Trade Com'n*, 264 F.3d 1094, 1102 (Fed. Cir. 2001) (finding patentee's burden of showing infringement "met" where "[t]he respondents did not dispute that many or most of the claims in suit read literally on their" accused products).

**B. The Claims of the '812 Patent Are Not Invalid**

The Defendants do not contest the fact that the claims of the '812 patent comply fully with the patent statute and are enforceable. Their sole contention is that because the '812 patent, claiming chemical compounds, issued 5½ months after the '086 patent, claiming the use of therapeutically effective amounts of pharmaceuticals for the treatment of specific medical conditions, the '812 patent claims are invalid for obviousness-type double patenting.[3] Defendants contend that not only is the entirety of the statutory patent term lost as the result of the alleged double patenting, but that Boehringer should also forfeit the 1,564 days of patent term restoration granted under an entirely unrelated statute. Defendants also contend, ***with no legal authority***, that Boehringer cannot terminally disclaim the portion of the patent term that

Defendants allege constitutes an improper extension and still retain the indisputably valid additional term granted under 35 U.S.C. § 156. Defendants have many hurdles to overcome to establish that the asserted claims are invalid by clear and convincing evidence.

First, Defendants must show – in the face of a long line of cases holding that a terminal disclaimer moots an allegation of obviousness-type double-patenting – that the terminal disclaimer filed by Boehringer is ineffective. Indeed, the Defendants' argument is at odds with the Federal Circuit's decision in *Merck* holding that the term granted under the patent statute is distinct from, and unrelated to, the term granted a patentee under § 156. The Federal Circuit accordingly determined that, due to the independent and unrelated nature and purposes of these two statutory schemes, a patentee may terminally disclaim a portion of the patent term and yet obtain and retain the additional patent restoration term. Defendants claim that, although a patentee may terminally disclaim a portion of the patent term and then obtain an extension under § 156 for the terminally disclaimed patent, it is not permissible to first be granted the exact same extension and then disclaim the exact same portion of the patent term. That contention is illogical. Defendants ask the Court to penalize Plaintiffs severely because they did not first terminally disclaim the '812 patent over the '086 patent and then extend the '812 patent – ***even though the examiner who examined both applications never even suggested that the '812 patent might be double patented over the '086 patent and the result would be precisely the same: the '812 patent would expire on October 8, 2010.*** Double patenting is a defense directed to preventing unwarranted patent term extension and the law is clear that disclaimer of the alleged additional patent term cures any such issue. Boehringer disclaimed the 5½ months of

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[3] Although Boehringer only asserts infringement of claims 5, 7, 9, and 10 of the '812 patent, Barr challenges the validity of claims 3, 4, 5, 7, 9 and 10 (the "challenged claims").

which Defendants complain and now Defendants seek to change the nature of the double patenting defense to one of form based on the time of disclaimer instead of substance based on the length of the overall patent term.

Second, even if the terminal disclaimer somehow was not effective, Defendants must overcome: 1) the statutory presumption of validity; 2) the deference due to Examiner Ceperley's explicit decision, based on long standing patent office rules, that the inventions claimed in the '086 were patentably distinct from those claimed in the '812 patent; and 3) the difficulty of meeting the high burden of proving that the PTO issued a patent containing double patented claims mere months after issuing the '086 patent.

Third, Defendants must show, in the face of the PTO rules to the contrary, that their lone basis for alleging double patenting – that the compounds mentioned in the method of use claims of the '086 patent were thereafter claimed by the '812 patent – suffices to satisfy Defendants' evidentiary burden despite the fact that the claimed compounds have many materially different uses.

Fourth, Defendants must show that the test set forth in the MPEP (and actually applied in this case by Examiner Ceperley) on the precise issue presented here – whether claims to products and methods are patentably distinct – is wrong and that numerous patentees hold invalid patents because they obeyed the PTO when it ordered restrictions based on that rule. If Rule 806.05(h) is an appropriate method of ascertaining whether claims to two different statutory categories of inventions are "distinct," then Defendants' double patenting argument fails, as they failed to contend (let alone prove) that the asserted claims do not meet the criteria set forth in the PTO's test.

Fifth, Defendants must overcome the unrebutted evidence of secondary indicia of non-obviousness, which favors a finding of no double patenting.

Sixth, Defendants must show that Boehringer is not entitled to the benefit of 35 U.S.C. § 121 as a result of Examiner Ceperley's restriction requirement.

If Defendants fail to make even one of these showings, their double patenting defense fails. Defendants' burden of proof is by clear and convincing evidence, and Defendants' burden of showing double patenting is "particularly heavy." *Carman Indus., Inc. v. Wahl*, 724 F.2d 932, 940 (Fed. Cir. 1983) ("[t]here is a heavy burden of proof on one seeking to show double patenting"). That burden is heightened because the same PTO Examiner examined both the '086 and '812 patent applications and found no double patenting problem between these applications. *See American Hoist & Derrick Co. v. Sowa & Sons, Inc*., 725 F.2d 1350, 1359 (Fed. Cir. 1984); FOF at ¶¶ 39, 52; TX 99 at *passim*.

**1. Boehringer's Terminal Disclaimer Moots Any Double Patenting Issue**

**(a) The Relationship Between the '086 and '812 Patents**

The application that resulted in the '812 patent was a divisional of the application that resulted in the '086 patent. *Id.* at ¶ 51. The '086 patent issued first, on June 27, 1989. *Id.* at ¶ 50. The '812 patent issued 5½ months later, on December 12, 1989. *Id.* at ¶ 65. Under the statute in effect at the time, the expiration dates of the '812 and '086 patents also differed by 5½ months, with the '086 patent set to expire on June 27, 2006, and the '812 patent set to expire on December 12, 2006. *Id.* at ¶ 101.

On October 13, 1999, Boehringer received a 1,564-day extension of the '812 patent term pursuant to 35 U.S.C. § 156. *Id.* at ¶ 101. The extension was granted to compensate Boehringer for time taken by the FDA to review and approve pramipexole dihydrochloride for sale. *See id.* at ¶¶ 100-102; *see* 35 U.S.C. § 156 ("The term of a patent which claims a product…shall be

extended…from the original expiration date of the patent…if…the product has been subject to a regulatory review period before its commercial marketing or use."). Following the grant of this extension, the '812 patent was set to expire on March 25, 2011. FOF at ¶ 102.

**(b) Boehringer Disclaimed The Disputed Patent Term and Mooted Any Double Patenting Issue**

Defendants have never contested the validity of the 1,564-day patent term extension Boehringer received pursuant to § 156. *See* FOF at ¶ 103. Defendants' only argument is that the challenged claims of the '812 patent are obvious variants of claims of the '086 patent and, therefore, Boehringer impermissibly received an extra 5½ months of patent term by obtaining the '812 patent, beyond the 1,564 days that is not disputed.

As set forth below and at trial, Boehringer disagrees with Defendants' obviousness-type double patenting allegations. In an abundance of caution, however, Boehringer filed a terminal disclaimer with the PTO during trial, disclaiming the 5½ months of patent term Defendants contend Boehringer should not have received, and thereby changing the expiration date of the '812 patent from March 25, 2011 to October 8, 2010, the same date it would have expired had Boehringer applied the patent term extension to the '086 patent. *See id.* at ¶ 104. It bears emphasizing that during prosecution of the '812 patent, Examiner Gerstl issued a double patenting rejection, but withdrew it. *See id.* ¶ 63. Boehringer accordingly confirmed with the examiner that "no terminal disclaimer need be filed." *Id.* at ¶ 64. Had such a disclaimer been filed at the time vis-à-vis the '086 patent, the addition of the § 156 patent term extension would have resulted in precisely the same expiration date.

It is well-established that such a terminal disclaimer removes any obviousness-type double patenting issue. *See, e.g.*, *Perricone v. Medicis Pharmaceutical Corp*., 432 F.3d 1368, 1375 (Fed. Cir. 2005) ("A terminal disclaimer can indeed supplant a finding of invalidity for

double patenting."); *Ventana Med. Systems, Inc. v. Biogenex Labs., Inc*., 473 F.3d 1173, 1184 n.4 (Fed. Cir. 2006) ("[T]he filing of a terminal disclaimer … serves the statutory function of removing the rejection of double patenting…."); *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1378 (Fed. Cir. 2003) ("With nonstatutory double patenting, a terminal disclaimer may restrict the slight variation to the term of the original patent and cure the double patenting rejection."); *In re Goodman*, 11 F.3d 1046, 1052 (Fed. Cir. 1993) ("the patentee may overcome the double patenting rejection by filing a terminal disclaimer.").

Thus, when Boehringer filed its terminal disclaimer, any harm arising from the alleged obviousness-type double patenting – an allegedly unwarranted "exten[sion of] the life of patent protection" – was cured. *See Perricone*, 432 F.3d at 1372-1373. In these circumstances, Defendants' lone defense is therefore moot. *See In re Schroeder*, 1996 WL 297604, at *1 n.1 (Fed. Cir. Jun. 6, 1996) ("Claims 1-6 were also rejected under the doctrine of obviousness-type double patenting. At oral argument, counsel for the Schroeders informed this court that a terminal disclaimer had been filed which rendered this rejection moot."); *In re White*, 405 F.2d 904, 906 (C.C.P.A. 1969) ("We believe that the invention defined by the appealed claims is not the same as that defined by the patent claims; and, in view of the terminal disclaimer, the question of obviousness here is moot."); *see also Regents of Univ. of Cal. v. Dakocytomation Cal., Inc.*, 85 U.S.P.Q.2d 1929, 1934 (Fed. Cir. 2008) ("Appellants, however, had previously filed a terminal disclaimer, which cures such a double patenting rejection.").

**(c) Defendants' Theory That Boehringer's Disclaimer Was Ineffective Lacks Support and Is Contrary to *Merck & Co. v. Hi-Tech Pharmacal Co.***

Defendants do not dispute that an effective terminal disclaimer removes any double patenting issue associated with the '812 patent. Defendants contend, however, that Boehringer's terminal disclaimer is not effective. That argument is contrary to the patent statute and to the

Federal Circuit's recent decision in *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d at 1324. Defendants cite no case with facts even close to those in this case – a case where there is a patent term ***and*** a patent term extension due to time spent seeking FDA approval.

Section 253, the statutory basis for terminal disclaimers, contains no limitation on a patentee's ability to disclaim any terminal portion of his patent term. It provides simply that:

> ***any patentee or applicant may 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. The "term" referred to in the text of § 253 is the statutory patent term.

Defendants attempt to read into the statute an exception that is not there – that a terminal disclaimer cannot be effective if the disclaimed term is based on the term of an expired patent. But the statute says "any patentee" may disclaim "any terminal part of the term." *Id.* The PTO's Rule setting forth the requirements for a "terminal disclaimer…filed to obviate judicially created double patenting" rejections during prosecution also has no requirement that the underlying patent be unexpired. *See* 37 C.F.R. § 1.321(c). There is nothing to suggest that Congress or the PTO intended to impose any limits on a patentee's ability to terminally disclaim over an expired patent, as Defendants would have it.

Ignoring the applicable statute and rules, Defendants point to two cases, *In re Lonardo*, 119 F.3d 960 (Fed. Cir. 1997), and *Eli Lilly and Co. v. Barr Laboratories, Inc.*, 251 F.3d 955 (Fed. Cir. 2001). Neither of those cases involved the situation at issue here – a terminal disclaimer in the context of a patent term extension. The only case involving those two unrelated statutes is the Federal Circuit's decision in *Merck*, which makes clear that Boehringer's terminal disclaimer is effective.

In *Lonardo*, the Federal Circuit affirmed a finding by the Board of Patent Appeals and Interferences that certain claims were invalid for obviousness-type double patenting over an

expired patent. *See* 119 F.3d at 968. The Court noted in dicta that "[w]ith obviousness-type double patenting…a terminal disclaimer may overcome that basis for unpatentability, assuming that the first patent has not expired. In this case, the '762 patent over which the claims have been rejected, has expired, so a terminal disclaimer cannot cure these rejections." *Id.* at 965. Thus, *Lonardo* accordingly stands for the unremarkable proposition that where the underlying patent has expired and there is no second, independent term such as the restoration period granted under § 156, then a terminal disclaimer would be meaningless given that no patent term would remain post-disclaimer. Accordingly, *Lonardo* does not hold that there is a bar to a terminal disclaimer over an expired patent in all circumstances – even where such a disclaimer would leave a valid and unrelated statutory term.

Likewise, in *Eli Lilly*, the Federal Circuit observed in a footnote that:

> [B]ecause Lilly disclaimed the '213 patent, it cannot now terminally disclaim the '549 patent to expire at the time the '213 patent would have expired had it not been disclaimed. That is, the fact that the '213 patent has been disclaimed is of no help to Lilly, as double patenting precludes claim 7 of the '549 patent from extending beyond the termination date of the '213 patent, whether that termination date is at the end of its normal term or, as in this case, is the date it is terminated via disclaimer.

251 F.3d at 968 n.5. *Lonardo* and *Lilly* merely make the noncontroversial observation that filing a terminal disclaimer over an expired patent ***where there is no second, independent term such as an extension under § 156*** would not accomplish the patentee's goal of obtaining a currently enforceable patent – not because a terminal disclaimer could not be filed, but because if it were filed, it would not achieve that goal.

Here, by contrast, the term of the '812 patent ***was*** extended pursuant to 35 U.S.C. § 156. Thus, a terminal disclaimer of a portion of the patent term has a very real effect even though the '086 patent has expired, because the '812 patent has been extended for an additional four years based on an entirely different statute. The Defendants seek to strip Boehringer not only of the

5½ months term beyond the '086 patent – which Boehringer already has disclaimed – but also of a significant part of the four-year benefit of its § 156 extension, even though they have not attacked the propriety of that term extension.

Indeed, the Federal Circuit has rejected that very suggestion. "We hold that a patent term extension under § 156 may be applied to a patent subject to a terminal disclaimer." *Merck*, 482 F.3d at 1324. The court noted that "the language of § 156 is unambiguous and fulfills a purpose unrelated to and not in conflict with that of § 253," *id*., explaining that:

> [t]he purpose of the terminal disclaimer—to prevent extension of patent term for subject matter that would have been obvious over an earlier filed patent—remains fulfilled by virtue of the fact that the date from which any Hatch-Waxman extension is computed is the terminally disclaimed date. At the same time, the purpose of the patent term extension—to restore some of the patent term lost due to regulatory review—is also satisfied.

*Merck & Co.*, 482 F.3d at 1323. The same reasoning supports a finding that Boehringer effectively disclaimed the difference between the original expiration dates of the '086 and '812 patents while retaining its patent term extension under § 156. The Court therefore should find that Boehringer's disclaimer of the '812 patent's term beyond the 1,564 days after the term of the '086 patent is effective and moots Defendants' double patenting challenge.

**2. Even If the Court Were to Find Boehringer's Terminal Disclaimer Ineffective, There Still Is No Double Patenting**

Even if the Court were to decide that Boehringer's terminal disclaimer is not effective, Defendants have failed to satisfy their burden of showing the challenged claims are invalid for double patenting. Defendants are "required to prove double patenting by clear and convincing evidence." *Symbol Technologies, Inc. v. Opticon, Inc*., 935 F.2d 1569, 1580 (Fed. Cir. 1991). As the Federal Circuit has emphasized, that burden is a "heavy" one. *Carman Indus., Inc. v. Wahl*, 724 F.2d 932, 940 (Fed. Cir. 1983) ("[t]here is a heavy burden of proof on one seeking to show double patenting").

"Non-statutory, or 'obviousness-type,' double patenting is a judicially created doctrine adopted 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*, 432 F.3d at 1372-73. An obviousness-type double patenting analysis involves two steps: First, the court must construe the claims in the earlier patent and the later patent and determine the differences between the two patents; and second, the court must determine whether the differences in the subject matter between the two claims render the claims patentably distinct. *See, e.g., Eli Lilly and Co. v. Barr Laboratories, Inc*., 58 U.S.P.Q.2d 1869, 1878 (Fed. Cir. 2001); *Georgia-Pacific Corp. v. United States Gypsum Co*., 195 F.3d 1322, 1326 (Fed. Cir. 1999).

**(a) Defendants' Assertion that the Compounds Recited in the '086 Patent Claims Are "Sub-genera" of the Compounds Claimed in the '812 Patent Cannot Suffice as Clear and Convincing Evidence of Double Patenting**

Defendants' double patenting theory posits that because the '086 method claims mention certain tetrahydrobenzthiazoles, they anticipate the later compound claims of the '812 patent. *See* COL at ¶ 35. That argument is insufficient to satisfy their burden of establishing double patenting by clear and convincing evidence. Defendants employ a nonexistent test that ignores the differences in the respective claims, including the fact that the patents in question claim different statutory categories of invention – one directed to chemical compounds, the other to medical methods of use.

Indeed, Defendants ignore both of the required steps of the obviousness-type double patenting inquiry. *See Lilly*, 58 U.S.P.Q.2d at 1878. First, they do not even purport to "construe[] the claims in the earlier patent and the later patent and determine the differences." *Id.* On their face, the challenged '812 patent claims differ from those of the '086 patent in a

number of ways. For example, it is undisputed that the '086 claims are directed to methods of using therapeutically effective amounts of certain tetrahydrobenzthiazoles for treating Parkinson's Disease or Parkinsonism, treating schizophrenia, lowering blood pressure, and lowering heart rate. *See* FOF at ¶ 106. They do not claim compounds. *See id.* By contrast, the challenged claims of the '812 patent are directed to chemical compounds. *See id.* at ¶ 110. Several claims of the '086 patent upon which Defendants rely also recite "a therapeutically effective amount" as part of the claimed method of treatment, whereas the compound claims of the '812 patent claims contain no such limitation. *See id.* at ¶ 108. The claims of the respective patents also involve different utilities. *See id.* at ¶¶ 109, 110. These differences are material, as the '086 and '812 patents are addressed to different audiences – the '086 patent is directed to physicians, while the '812 patent is directed to medicinal chemists. *See id.* at ¶ 107. Indeed, one can practice the claims of the '812 patent without infringing any claim of the '086 patent. *See id.* at ¶¶ 114-116.

Second, Defendants make no showing that the challenged claims are patentably indistinct in light of those myriad differences. Dr. Anslyn, Defendants' lone witness on the relationship between the '086 and '812 patent claims, failed to address any of the differences between those patents' claims and offered no opinion as to the obviousness or distinctiveness of the challenged claims. *See id.* at ¶ COL at ¶ 27. He merely testified that one of ordinary skill in the art would understand that "you cannot practice the[] method claims without having the compounds" and "there is substantial overlap of the compounds described in the compound claims of the '812 patent with the compounds used in the method claims of the '086 patent, and in some cases there [sic] are actually identical." Trial Tr. (Vol. 2.) D.I. 207, at 480:20 – 481:5. These "opinions" are irrelevant to the pertinent double patenting inquiry. The record is devoid of any evidence that a

person of ordinary skill in the art would consider the '812 patent claims obvious over the '086 patent claims. *See* COL ¶ 27. Defendants adduced no evidence on this point and offer no more than attorney argument that a person of skill in the art of the '812 patent (a chemist) would have found the asserted claims obvious variants of the medical use claims of the '086 patent.[4]

Defendants cannot satisfy their burden through the mere assertion that the '086 patent claims ***mention*** compounds that are the same as, or subgenera of, the compounds claimed in the '812 patent. If Defendants were correct, an accused infringer could rest its case by alleging double patenting and identifying an element of an earlier claim that was shared by the later claim, without addressing any differences that might exist between the claims ***as a whole*** or providing any evidence that the later claim was merely an obvious variant over the earlier one. The Federal Circuit has found such an approach to be improper. *See General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1280-1281 (Fed. Cir. 1992) (reversing trial court's double patenting determination where it hinged on finding that later claimed process was directed to steps recited by single element of earlier claimed process).

Defendants' assertion "of double patenting must fail" where "[d]espite careful review of the record, this Court [will be] unable to find any evidence leading to the conclusion that the [challenged claims of the '812 patent and the '086 patent claims] are obvious relative to each

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[4] Dr. Anslyn acknowledged that he was an organic chemist, not a medical doctor. Trial Tr. (Vol. 2) (D.I. 207) at 510:24-511:4. When asked at trial about claim 29 of the '086 patent's requirements for a "therapeutically effective amount" of the recited compounds, Dr. Anslyn's could only say that "[a]s an organic chemist, I can ***read*** that and know what the authors of these applications believe were therapeutically effective amounts" and comment on how organic chemists "would interpret this sentence." *Id.* at 505:12-506-9. Because he is not a physician, Dr. Anslyn, could not "add anything other than to read the specification" of the '086 patent. *See id*. at 505:12-506:9, 511:4. His testimony highlighted the difference between claims to chemical compounds and claims to methods of use of therapeutically effective amounts of a compound. The first falls within the

other." *Rolls-Royce Ltd. v. GTE Valeron Corp.*, 228 U.S.P.Q. 489, 494 (E.D. Mich. 1985). This is especially the case here where the same PTO Examiner "was aware of both [the '086 and '812 patent] applications and allowed both." *Continuous Curve Contact Lenses, Inc. v. National Patent Development Corp.*, 214 U.S.P.Q. 86, 114 (C.D. Cal. 1982) (finding no double patenting). "This fact reinforces the presumption of validity attaching to the granting of the patent on [pramipexole dihydrochloride] and the rejection of [Defendants'] claim of double patenting." *Pfizer, Inc. v. International Rectifier Corp.*, 207 U.S.P.Q. 397, 434 (C.D. Cal. 1980); *see also Am. Hoist & Derrick Co.*, 725 F.2d at 1359 (attacker has "added burden" where no art is presented other than that which the PTO already considered).

**(b) Defendants' "Sub-Genera" Theory Is Incorrect**

Defendants also have invoked the principle that where an earlier patent claims a species of a later-claimed genus, the later claim can be invalid for obviousness-type double patenting. *See, e.g., In re Goodman*, F.3d at 1053. The species-genus principle only applies, however, when the earlier and later claims are directed to the same statutory category of patentable subject matter. See 35 U.S.C. § 101; MPEP § 806.05. This is because the four categories of subject matter enumerated in § 101 cannot be species or genera of each other. For example, a method of using a product for a particular purpose cannot be a "species" of the product itself or vice versa:

> In other words, generic claims must relate to a species of the same type of claim. Method claims and device claims are not the same species. ***Thus, if a method claim is generic, it relates to a number of species methods; a generic method claim does not relate to a number of species devices***. Or using a biological analogy, a genus of mammals may include a number of mammal species, but not a number of reptile species.

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knowledge of a chemist like Dr. Anslyn, the second falls within the knowledge of a medical doctor like Dr. Olanow.

*Michaels of Or. Co. v. Clean Gun, LLC*, 2002 U.S. Dist. LEXIS 20371, 27-28 (D. Or. 2002). *See also In re Bronson*, 168 F.2d 548, 550 (C.C.P.A. 1948) (holding that a claim for a process was not generic to an apparatus suitable for carrying out that process).

Indeed, the inapplicability of the genus-species principle to claims directed to different statutory subclasses is underscored by Defendants' allegations. Thus, Defendants do not (and cannot) allege that the method claims of the '086 patent themselves are species or subgenera of the '812 patent claims. Instead, Defendants misleadingly assert that "the compounds of the '086 Patent method claims are sub-genera of the compounds of the '812 Patent claims." TX 406 at 10. Because they are in statutorily distinct classes, however, that argument is premised on an entirely erroneous premise.

**(c) The Challenged Claims Are Patentably Distinct**

Where patent claims are directed to different categories of statutory subject matter, the PTO has adopted a specific test for determining whether the various claims are patentably distinct. That test is set forth in MPEP § 806.05, which includes a series of inquiries utilized by the PTO to determine when related inventions are "patentably distinct" over one another for purposes of assessing double patenting and the potential imposition of a restriction requirement. Among these tests is MPEP § 806.05(h):

> **806.05(h) Product and Process of Using**
>
> A product and process of using the product can be shown to be distinct inventions if either or both of the following can be shown: (A) the process of using as claimed can be practiced with another materially different product; or (B) the product as claimed can be used in a materially different process.

MPEP § 806.05(h). Because subparts (A) and (B) are expressed in the alternative, only one of these conditions need be satisfied. Here, the challenged '812 patent claims satisfy both criteria. There is no dispute the '086 patent claims identified by Defendants claim methods of treatment

for which compounds substantially different than those claimed by the '812 patent can be used. For instance, Dr. Olanow testified that levodopa, bromocriptine, and Requip® are used to treat the symptoms of Parkinson's Disease, and that these compounds are markedly different from the tetrahydrobenzthiazoles covered by the '812 patent. *See* Trial Tr. (Vol. 1), D.I. 206, at 44:3-45:16, 51:24-52:13, 53:1-54:20, Trial Tr. (Vol. 3), D.I. 208, at 688:7-689:6. Likewise, Barr's expert Dr. Mailman conceded that an entirely different class of compounds, so-called "beta blockers," have been used to treat both elevated heart rate and schizophrenia. *See* Trial Tr. (D.I. 208) at 688:7-689:6.

The second independent prong of the test set forth in MPEP § 806.05(h) also is indisputably satisfied because the products claimed by the '812 patent can be used in processes that are materially different from those claimed by the '086 patent. Applying this test, Examiner Ceperley explicitly found that "[i]n this case, the compounds could be used in each of the materially different processes as set forth in VIII-X." FOF at ¶ 32. That is, each of the compound groups could be used for the "materially different" uses of lowering blood pressure and heart rate and treating schizophrenia, Parkinson's Disease, and Parkinsonism. The Defendants have never disputed or criticized the propriety of that determination.

Additionally, Dr. Warren Olanow, an expert in the fields of medicine, neurology, and moving disorders, testified that pramipexole dihydrochloride has been approved by the FDA for treatment of Restless Legs Syndrome ("RLS"). *Id.* at ¶ 119. RLS is a potentially disabling disease that affects millions of Americans. *Id.* at ¶ 119-20. RLS is distinctly different from the conditions to which the '086 patent's method claims are directed. *See id.* at ¶ 120. It has different signs and symptoms, affects a different patient population, and has a different mechanism of action. *See id.* at ¶¶ 120-122.

Pramipexole dihydrochloride also can be used to treat depression. *Id.* at ¶ 123. "[T]here have been double blind placebo-controlled trials showing that Pramipexole is effective in depression in [the general community], even as or possibly even more effective than some of the major antidepressants like Fluoxetine [Prozac®]." Trial Tr. (Vol. 1) D.I. 206 at 79:13-80:10. Dr. Olanow explained that use of pramipexole dihydrochloride to treat depression is materially different from the uses claimed by the '086 patent. *Id.* at ¶ 118, 123. Depression affects a different demographic and has a "totally different" mechanism of action than does Parkinson's disease. FOF at ¶ 123. No person in the field looking at the '086 patent claims would reasonably think the compounds would be effective in depression. *See id.* at ¶ 125.

Physicians also prescribe pramipexole dihydrochloride for the treatment of fibromyalgia, another disabling condition characterized by aches and pains at multiple sites in the body that affects millions of people. *Id.* at ¶ 126. The use of pramipexole dihydrochloride as a treatment for fibromyalgia is again "totally different" from the methods claimed by the '086 patent claims. *Id.* at ¶ 127; Trial Tr. (Vol. 1) D.I. 206 at 89:12-21 (explaining that fibromyalgia affects a "[d]ifferent group of patient[s] [and] different symptom complex. Nothing in the proposed mechanisms would have anything to do with fibromyalgia as best I understand it.").

To satisfy the second alternative test for distinctiveness set forth in § 806.05(h), the compounds claimed by the '812 patent need only be useful for one "materially different" process. *See* MPEP § 806.05(h). The PTO explicitly found, and the Court heard ample evidence, that pramipexole can be used in at least *three* additional processes materially different from those claimed by the '086 patent – RLS, depression, and fibromyalgia. The efficacy of pramipexole to treat RLS is so well evidenced that the FDA approved labeling MIRAPEX® for

that condition. FOF at ¶ 119. Thus, the challenged claims plainly satisfy the MPEP's test for distinctiveness.

The Defendants have never addressed the test set forth in MPEP § 806.05(h) – indeed, they have studiously ignored that provision throughout this litigation. Instead, the Defendants meekly note that the MPEP is not binding, without disputing its persuasiveness, particularly given the deference afforded the PTO on such issues. Although the MPEP does not have the force of a statute, the PTO has been applying the distinctiveness tests set forth in MPEP § 806.05 for decades – and continues to use it to this day – on a subject that goes to the very heart of its charter.[5] Here, the PTO invoked the provision in concluding that the compound and method claims at issue were "distinct inventions" and in requiring Boehringer to separate them out into the applications that ultimately resulted in the '086 and '812 patents. *See* FOF at ¶ 32. Were the Court now to hold that MPEP 806.05 is inapplicable, then innumerable patentees – including Boehringer – would be unjustly punished for having obeyed the PTO.

At least two courts have relied on the applicability of a related MPEP section – 806.05(f) – in rejecting claims of double patenting. MPEP 806.05(f) sets forth a similar test for determining whether claims directed to products are patentably distinct from claims directed to processes of making those products:

> **806.05(f) Process of Making and Product Made**
>
> A process of making and a product made by the process can be shown to be distinct inventions if either or both of the following can be shown: (A) that the process *as claimed* is not an obvious process of making the product and the product as *claimed* can be used to make another materially different product; or

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[5] "The MPEP has no binding force on the courts, but it commands notice as an official interpretation of statutes and regulations with which it does not conflict. Patent attorneys and examiners commonly rely on the MPEP as a guide in procedural matters." *See Syntex (U.S.A.) Inc. v. U.S. Patent & Trademark Office*, 882 F.2d 1570, 1571 n. 3 (Fed. Cir. 1989).

> (B) that the product *as claimed* can be made by another materially different process.

MPEP § 806.05(f). The United States District Court for the District of New Jersey recently found that § 806.05(f), "which distinguishes between patents for product and process inventions," supported its conclusion "that the '063 product claims are patentably distinct from the '106 process claims." *Astellas Pharma, Inc. v. Ranbaxy Inc.*, 2007 WL 576341, *8 (D. N.J. Feb. 21, 2007) (vacated per settlement agreement between the parties). "In this case…it is generally recognized by both parties that tamsulosin can be made by processes other than those claimed by the '106 patent…." *Id.* at *6. Another district court also looked to MPEP § 806.05(f) in arriving at its conclusion that no double patenting occurred. "[T]he PTO's Manual of Patent Examining Procedure directs that process and product claims are 'distinct inventions' where 'the product as claimed can be made by another materially different process.'" *Takeda Pharmaceutical Co., Ltd. v. Dudas*, 511 F. Supp. 2d 81, 96 (D. D.C. 2007) (citing MPEP § 806.05(f)). Although no court has yet specifically considered § 806.05(h), there is no principled basis to distinguish between the two provisions.

**(d) Secondary Indicia Favor A Finding of No Double Patenting**

Although not required, Courts may also consider secondary considerations of non-obviousness, including commercial success, long felt but unsolved needs, failure of others and licensing, in evaluating a claim of obviousness-type double patenting. *See, e.g., American Cyanamid Co. v. U.S. Surgical Corp.*, 30 U.S.P.Q.2d 1561, 1569, n. 22 (D. Conn. 1992); *Mirafi, Inc. v. Murphy*, 14 U.S.P.Q.2d 1337, 1340 (W.D.N.C. 1989), rev'd on other grounds, *Mirafi, Inc. v. Murphy*, 1991 WL 10623, *3 (Fed. Cir. 1991). Here, the applicable secondary considerations – including copying, commercial success, long felt but unmet need, failure of others and licensing – weigh in favor of finding that the challenged claims of the '812 patent are not invalid.

**(1) Copying**

"The copying of an invention may constitute evidence that the invention is not an obvious one." *Vandenberg v. Dairy Equip. Co.*, 740 F.2d 1560, 1567 (Fed. Cir. 1984). Barr and Mylan both have elected to copy MIRAPEX®, a commercial embodiment of at least claims 5, 7, 9 and 10 of the '812 patent. FOF at ¶ 131. Barr has gone so far as to copy the formulation for MIRAPEX® tablets, as well as their size and shape. *Id.* That conduct is suggestive of non-obviousness. *See Vandenberg*, 740 F.2d at 1567.

**(2) Commercial success**

There is a presumption that the patented invention is commercially successful "when a patentee can demonstrate commercial success, usually shown by significant sales in a relevant market, and that the successful product is the invention disclosed and claimed in the patent." *Ecolochem, Inc. v. Southern Cal. Edison Co.*, 227 F.3d 1361, 1377 (Fed. Cir. 2000) (internal quotes omitted). As Boehringer's economics expert, Dr. Mohan Rao, explained at trial, there have been commercially significant sales of MIRAPEX® for uses other than those claimed in the '086 patent, *e.g.*, RLS, depression, fibromyalgia, and ADHD. [redacted] The sales of MIRAPEX® for uses other than those claimed in the '086 patent also generated commercially significant profits for Boehringer in 2005. *Id.* at ¶ 133.

Given Boehringer's showing, the burden shifted to the Defendants "to prove that the commercial success is instead due to other factors extraneous to the patented invention, such as advertising or superior workmanship." *J.T. Eaton & Co. v. Atlantic Paste and Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997). Defendants have made no such showing. In fact, Dr. Rao's opinions on the subject are premised exclusively on "off label" sales of MIRAPEX® for uses other than those claimed in the '086 patent, which necessarily were driven by physicians' views regarding the efficacy of pramipexole to treat those medical conditions and cannot have been influenced by any promotion or advertising. *See* FOF at ¶ 134.

**(3) Long-Felt But Unmet Need**

An invention's fulfillment of a long-felt need is further evidence of nonobviousness. *See Monarch Knitting Mach. Corp. v. Fukuhara Indus. & Trading Co., Ltd.*, 139 F.3d 877, 884 (Fed. Cir. 1998). The extensive utilization of pramipexole by physicians for off-label use in the treatment of RLS, fibromyalgia, and depression indicates that pramipexole has satisfied unmet needs associated with those medical conditions. FOF at ¶ 132. Were the needs presented by these diseases sufficiently addressed by other available therapeutic agents, there is no apparent reason why doctors would be turning to MIRAPEX® when it was not approved by the FDA or marketed prior to 2006 for any indication other than Parkinson's Disease. *See e.g., Alza v. Mylan Laboratories, Inc.*, 310 F. Supp. 2d 610, 633 (D. Vt. 2004) (finding evidence of nonobviousness where plaintiff's system for administering a continuous pain relief answered a "tremendous need" by providing an alternative to IV administration).

**(4) Licensing**

Licensing also may constitute evidence of nonobviousness. *See In re GPAC*, 57 F.3d 1573, 1580 (Fed. Cir. 1995). In 1992, the Upjohn Company paid $6 million, plus a substantial

portion of net sales of MIRAPEX®, to obtain a license to develop, manufacture, use and sell certain compounds developed by Boehringer, including pramipexole, in the United States. FOF at ¶ 135. In addition, Barr's API supplier, Amino Chemicals, acceded to the validity of the patent when it stated that it will stay out of the market until the '812 patent expires. *Id.* at ¶ 136.

**(e) Even If the Court Were To Find the '812 Patent Claims Patentably Indistinct, 35 U.S.C. § 121 Prevents the '086 patent from Being Used as a Reference**

Even if Defendants somehow could establish a double patenting issue that was not mooted by the terminal disclaimer, 35 U.S.C. § 121 prevents a finding of double patenting. The pertinent part of Section 121 reads as follows:

> If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. If the other invention is made the subject of a divisional application which complies with the requirements of section 120 of this title, it shall be entitled to the benefit of the filing date of the original application. 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. Under Section 121, a patent shall not be "used as a reference…in the courts against a divisional application" if three conditions are met.

- First, the patent being used as a reference must have "issu[ed] 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." *Id.*
- Second, the divisional application must have been "filed before the issuance of the patent on the other application." *Id.*
- Third, the divisional application must be consonant with the restriction requirement.

As set forth below, each of these requirements is satisfied.

**(1) The '086 Patent Issued On An Application Filed As A Result of a Restriction Requirement**

The '197 application that resulted in the '086 patent was filed as a result of the restriction requirement imposed during prosecution of its parent, the '947 application. "During prosecution of the '947 application, the patent examiner (Examiner Ceperley) imposed …[a ten-way] restriction requirement." *See* FOF at ¶ 30. In response, Boehringer "elected …one of the compound/composition groups—Group II, pyrrolidino substituted tetrahydro-benzthiazoles—and one of the utility groups—Group IX, a method for treating Parkinsonism—and those claims issued as the '374 application." *Id.* at ¶ 34. "Applicants reserve[d] the right to prosecute claims to the unelected subject matter in divisional applications." *Id.* at ¶ 35. Boehringer subsequently filed the '197 application as a "divisional" of the '947 application. *Id.* at ¶ 37. Thus, the first requirement under 35 U.S.C. § 121 is satisfied.

Defendants assert that Boehringer cannot benefit from Section 121 because "the '671 application that led to the '812 patent was not filed as a result of a restriction requirement." *See* TX 411 at 17-18. There is, however, no such requirement in Section 121. Rather, Section 121 only requires that the patent or application being used **as a *reference*** need be filed as a result of a restriction requirement:

> 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…***

35 U.S.C. § 121. In any event, the '671 patent application itself was filed as a result of the restriction requirement given that its claims were amended for the purpose of conforming to the restriction requirement. *See* FOF ¶¶ 55-56; *Union Carbide Corp. v. Dow Chemical Co.*, 619 F.Supp. 1036, 1060 (D. Del. 1985).

**(2) The '812 Patent Application Was Filed Before the '086 Patent Issued**

The second condition set forth in Section 121 is also satisfied. The '647 application was filed on October 12, 1988. FOF at ¶ 51. The '086 patent did not issue until eight months later, on June 27, 1989. *Id.* at ¶ 7. Therefore, the application that resulted in the '812 patent was filed before the issuance of the '086 patent.

Defendants contend that Section 121 does not apply because the '647 application resulting in the '812 patent was not filed before issuance of its ***grandparent***, the '947 application. That argument again misstates the statute. Section 121 only requires co-pendency between the '086 patent application – which is the "other application" that Defendants are attempting to use as a reference – and the '812 patent application, the "divisional application." Were Defendants' interpretation correct, Section 121 would require co-pendency between the "divisional application" and the "original application."

**(3) Consonance Was Maintained**

Finally, the claims of the '812 patent are consonant with the restriction requirement. "Consonance requires that the line of demarcation between the 'independent and distinct inventions' that prompted the restriction requirement be maintained." Gerber Garment Tech., 916 F.2d at 688. In other words, the applicant "must have limited the claims in its divisional application to the non-elected invention or inventions." Id. See also Symbol Technologies, Inc. v. Opticon, Inc., 935 F.2d 1569, 1579 (Fed. Cir. 1991) ("The corollary to this Court's statement in Gerber Garment is that new or amended claims in a divisional application are entitled to the benefit of § 121 if the claims do not cross the line of demarcation drawn around the invention elected in the restriction requirement."). Notably, the Federal Circuit has emphasized that

"[n]oncompliance with the consonance requirement is normally detected by the PTO examiner." *Gerber Garment Tech.*, 916 F.2d at 685.

The '812 patent does not claim any subject matter that was elected in either the '374 or '086 patent. As a result of the PTO's restriction requirement, Boehringer elected to prosecute pyrrolidino-substituted tetrahydrobenzthiazole compounds and compositions in the '374 patent. They subsequently filed the '197 application and amended it to claim only methods of use, and specifically excised any subject matter claimed in the '374 patent. See FOF at ¶¶ 55-56. The application that resulted in the '812 patent was amended to delete subject matter directed to methods and pyrrolidino-substituted compounds for the express purpose of "exclud[ing] from the claims subject matter already patented in U.S. Patent 4,731,374 and that [is] now pending in Serial No. 124,197." *Id.* Thus, consonance was maintained in both the '086 and '812 patents because their claims were limited to inventions that had not previously been elected.

### C. The Court Can Address Double Patenting Even If It Finds Boehringer's Terminal Disclaimer to Be Effective

At the close of trial, the Court requested that the parties address in their post-trial briefs whether the Court properly can decide the issue of double patenting even should it determine that Boehringer's terminal disclaimer is effective.

The Court is free to address both questions. According to the Supreme Court, alternative grounds for a holding do not render a decision on the issue dicta or advisory. *Woods v. Interstate Realty Co.*, 337 U.S. 535, 537, 93 L. Ed. 1524, 69 S. Ct. 1235 (1949). "Where a decision rests on two or more grounds, none can be relegated to the category of obiter dictum." *Id.* at 537; *United States v. Title Ins. & Trust Co.*, 265 U.S. 472, 486, 68 L. Ed. 1110, 44 S. Ct. 621 (1924) (Where there are two grounds, upon either of which an appellate court may rest its decision, and it adopts both, the ruling on neither is obiter, but each is the judgment of the court, and of equal

validity with the other (citation omitted); *see also In re Hession*, 49 C.C.P.A. 809, 816 (C.C.P.A. 1961) (same); *Natural Resources Defense Council v. NRC*, 216 F.3d 1180, 1189 (D.C. Cir. 2000) (same).

In the patent context, courts have repeatedly deemed it appropriate to decide alternative potential grounds for affirmance of the judgment below. *See, e.g., Pharmacia & Upjohn Co. v. Mylan Pharmaceuticals, Inc.*, 170 F.3d 1373 (Fed. Cir. 1999); *Morton Intern., Inc. v. Cardinal Chem. Co.*, 959 F.2d 948, 953 (Fed. Cir. 1992) (J. Lourie concurring). For example, the Federal Circuit found it was "proper" for a district court to grant summary judgment on the alternative grounds of noninfringement and invalidity. *Pharmacia & Upjohn Co. v. Mylan Pharmaceuticals, Inc.*, 170 F.3d 1373, 1382 (Fed. Cir. 1999). Although it may not be necessary at the Supreme Court, the "court of last resort," a judgment based on multiple grounds is favorable at both the trial court and Federal Circuit levels because it "leav[es] a complete judgment available for review by the Supreme Court." *Morton Intern.*, 959 F.2d at 953 (J. Lourie concurring). If the Court finds Boehringer's terminal disclaimer effective, a decision on the double patenting issue will provide the Federal Circuit a more complete record upon review.

**D. The Court Should Grant the Relief Provided By 35 U.S.C. § 271(e)(4)**

Barr and Mylan have filed ANDAs seeking approval of pramipexole dihydrochloride products that infringe claims 5, 7, 9 and 10 of the '812 patent. Pursuant to 35 U.S.C. § 271(e)(4)(A), the Court should issue an Order that the FDA not approve those applications until the October 8, 2010 expiration of the '812 patent, including any extension thereof. Moreover, pursuant to 35 U.S.C. § 271(e)(4)(B), Barr and Mylan should be enjoined form making, using, offering for sale, or selling their proposed pramipexole dihydrochloride products. *See* COL ¶¶ 62.

## V. CONCLUSION

The Court should enter judgment for Boehringer, and against Barr and Mylan, that the asserted claims of the '812 patent are infringed and valid, and should grant Boehringer relief under 35 U.S.C. § 271(e)(4).

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**CERTIFICATE OF SERVICE**

I, Jack Blumenfeld, hereby certify that on April 23, 2008, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF, which will send notification of such filing to the following:

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I further certify that copies of the foregoing document were also served upon the following in the manner indicated:

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