

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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|------------------------------|---|-----------------------------|
| 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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 Attorneys for Defendant, Mylan Pharmaceuticals, Inc.

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.

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 Preparation 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

