

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., :  
MYLAN PHARMACEUTICALS, INC., :  
 :  
Defendants. :

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**MEMORANDUM OPINION**  
**ON EVIDENTIARY RULINGS**

July 15, 2008  
Wilmington, Delaware

Farnan, District Judge



During the course of the bench trial in the above-captioned action, the Court reserved judgment on several evidentiary objections raised by the parties. The parties have briefed their respective positions, and this Memorandum Opinion constitutes the Court's rulings with regard to the pending evidentiary matters.

#### **I. PLAINTIFFS' POST-TRIAL EVIDENTIARY OBJECTIONS**

Plaintiffs raise two evidentiary matters post-trial. Specifically, Plaintiffs request the Court to preclude Defendants from contesting infringement with respect to claims 5, 9 and 10 of United States Patent No. 4,886,812 (the "'812 patent") and preclude Defendants from relying upon any argument other than the "sub-genera" argument disclosed in the Notice Letter sent by Defendant Barr Laboratories, Inc. ("Barr") to Plaintiffs. Plaintiffs contend that Defendants did not timely disclose their infringement and invalidity contentions in response to Interrogatories propounded by Plaintiffs, and instead, waited until the filing of the Pretrial Order to raise these issues. Plaintiffs contend that Defendants' conduct violates the duty to supplement discovery responses set forth in Fed. R. Civ. P. 26(e)(1) and warrants evidentiary sanctions under Fed. R. Civ. P. 37 in the form of the exclusion of any evidence supporting the undisclosed contentions.

In response, Defendants contend that they are not required to disclose every detail of their defense, but only to provide

fair notice to Plaintiffs of the facts upon which Defendants rely for their double patenting defense. Defendants contend that Plaintiffs were on notice of their double patenting defense in advance of the Pretrial Order through (1) Barr's Notice Letter, which Defendants contend is not limited to a sub-genera theory; (2) Barr's interrogatory response, which Defendants contend is broader than a reference to the Notice letter and includes a reference to its expert reports; (3) Barr's expert reports and (4) various pleadings submitted to the Court. With respect to infringement, Defendants contend that Plaintiffs bear the burden of proof on infringement, and therefore, Defendants were not required to prove or raise evidence of noninfringement.

Rule 26(e)(1) provides:

A party who has made a disclosure under Rule 26(a)--or who has responded to an interrogatory, request for production, or request for admission--must supplement or correct its disclosure or response:

(A) in a timely manner if the party learns that in some material respect the disclosure or response is incomplete or incorrect, and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing; or

(B) as ordered by the court.

Courts consider four factors in determining whether a party has breached its duty to amend a discovery response under Rule 26(e)(2): (1) whether there was a prior response; (2) whether the response became materially incorrect or incomplete; (3)

whether the party knew that the response was incomplete; and (4) whether the corrective information was otherwise made known to the other party through the discovery process or in writing.

Tritek Technologies, Inc. v. United States, 63 Fed. Cl. 740, 746-47 (Ct. Cl. 2005).

Violations of Rule 26(e) are addressed by Rule 37(c)(1) which provides, in pertinent part:

If a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless.

In determining whether a failure to disclose is harmless courts consider such factors as: (1) the importance of the information withheld; (2) the prejudice or surprise to the party against whom the evidence is offered; (3) the likelihood of disruption of the trial; (4) the possibility of curing the prejudice; (5) the explanation for the failure to disclose; and (6) the presence of bad faith or willfulness in not disclosing the evidence (the "Pennypack factors"). See Konstantopoulous v. Westvaco Corp., 1112 F.3d 710, 719 (3d Cir. 1997) (citing Meyers v. Pennypack Woods Home Ownership Ass'n, 559 F.2d 894, 904-905 (3d Cir. 1977)).

In this case, the Court concludes that Defendants provided sufficient notice to Boehringer to comply with their Rule 26(e) obligations, and in any event, Boehringer has not demonstrated

the exclusion of evidence is warranted. Boehringer's Notice Letter referenced its expert reports, and the Court finds those reports sufficient to place Boehringer on specific notice of Defendants' contentions regarding their double patenting defense. Moreover, other documents filed in this case reveal Defendants' contentions, including Barr's Interrogatory responses which discuss Defendants' position vis-à-vis the application of Section 121 in this case and Defendants' Answer Brief to a Motion To Strike Barr's Expert Report which points out that Dr. Anslyn raised factual analyses that relate directly to Defendants' double patenting defense. These documents were filed before the close of discovery, and the nature of the questions raised by Plaintiffs during the depositions of Defendants' expert witnesses leads the Court to conclude that Plaintiffs were on notice of Defendants' contentions.

With respect to their infringement defense, the Court understood Defendants' position not to be a denial, but rather to require Plaintiffs to establish their burden of proof on infringement. In this regard, the Court has found that Plaintiffs offered sufficient evidence of Defendants' infringement by Dr. Klibanov's testimony.

Because Plaintiffs were able to examine Defendants' witnesses on the theories and contentions advanced by Defendants, and present their own witnesses on the issues both during

discovery and at trial, the Court concludes that Plaintiffs were not unduly prejudiced by Defendants' conduct. Additionally, Plaintiffs have not demonstrated that Defendants acted in bad faith. Accordingly, the Court will overrule Plaintiffs' objection seeking to preclude Defendants from contesting infringement or advancing certain arguments regarding nonstatutory double patenting.

## II. DEFENDANTS' POST-TRIAL EVIDENTIARY OBJECTIONS

Defendants raise three post-trial evidentiary objections. Specifically, Defendants object to the admission of evidence concerning objective indicia of nonobviousness on the basis that such evidence is irrelevant, and therefore, should be excluded. Defendants also contend that Dr. Olanow's testimony comparing the methods of using compounds claimed in the '086 patent with the alleged new uses of pramipexole should be excluded on the grounds that this testimony exceeded the scope of Dr. Olanow's expert report. In addition, Defendants contend that the Court should exclude from evidence the terminal disclaimer filed by Plaintiffs on the grounds that Plaintiffs failed to raise this defense to invalidity in the Pretrial Order.

### A. Objective Indicia Of Nonobviousness

As the Court discussed in its Memorandum Opinion on invalidity, the Court of Appeals for the Federal Circuit has

neither required nor expressly precluded consideration of secondary indicia of nonobviousness in a nonstatutory double patenting analysis. Geneva Pharms., Inc. v. Glaxosmithkline PLC, 349 F.3d 1373, 1378, n.1 (Fed. Cir. 2003). The Court further concluded that such evidence is not irrelevant and may be considered in the Court's discretion. Boehringer Ingelheim Intern. GMBH v. Barr Laboratories, Inc., --- F. Supp. 2d ----, 2008 WL 2553237, \*16 (D. Del. June 26, 2008). Accordingly, the Court will overrule Defendants' objection seeking the exclusion of evidence concerning secondary indicia of nonobviousness.

B. Dr. Olanow's Testimony

Defendants contend that they did not have notice that Dr. Olanow would be discussing the differences between the use of pramipexole to treat the medical conditions referenced in the '086 patent and the alleged use of pramipexole to treat conditions like restless leg syndrome ("RLS"), depression, or fibromyalgia, or its alleged use as a neuroprotector. Defendants contend that this violation of Rule 26 requires the exclusion of his testimony on the undisclosed issues under the Pennypack factors.

The Court has reviewed the expert report submitted by Dr. Olanow and concludes that it was sufficient to provide Defendants with notice of the testimony at issue. See D.I. 225, Exh. A at ¶¶ 15, 16, 28-30, 39, 45, 48. Dr. Olanow discussed Parkinson's

disease and the manner in which pramipexole works in the treatment of that disease. Id. at ¶¶ 17-20, 23. He then went on to explain how pramipexole works as a neuroprotector and in the treatment of RLS, fibromyalgia and depression. Id. at ¶¶ 28-30, 32-48. Dr. Olanow compared these alleged "new" uses of pramipexole to the uses for pramipexole described in the '086 patent. Id. at ¶¶ 39, 45, 48. The Court finds Dr. Olanow's trial testimony to be consistent with the opinions contained in his expert report and to be a permissible synthesis of and/or elaboration on those opinions. See e.g., Forest Labs, Inc. v. Ivax Pharms., Inc., 237 F.R.D. 106, 113 (D. Del. 2006). Accordingly, the Court will overrule Defendants' objection to Dr. Olanow's testimony.

C. The Terminal Disclaimer

Defendants contend that the Court should exclude from evidence Plaintiffs' terminal disclaimer, because it was not disclosed in the Pretrial Order. Defendants contend that Plaintiffs cannot demonstrate that an amendment of the Pretrial Order is warranted. In the alternative, Defendants contend that the terminal disclaimer should be excluded because it was introduced after the close of evidence, and Plaintiffs cannot demonstrate that the evidenced should be reopened.

Although Plaintiffs' terminal disclaimer was not filed pretrial, the Pretrial Order outlined the legal issues relevant



to any potential filing of a terminal disclaimer. Once the terminal disclaimer was filed, it became part of the prosecution history of the '812 patent, and therefore, the Court concludes that it is an admissible supplementation of an already identified trial exhibit.

In its Memorandum Opinion on invalidity, the Court expressed concern over the timeliness of the terminal disclaimer, but declined to base its decision on the issue of timeliness.

Boehringer, --- F. Supp. 2d at ---, 2008 WL 2553237 at \*8, n.8.

In the circumstances of this case, the Court concludes that the issue of timeliness is more appropriately addressed in the context of the disclaimer's effectiveness, rather than its admissibility. Accordingly, the Court will overrule Defendants' objection to the admission into evidence of the terminal disclaimer.

#### **CONCLUSION**

For the reasons discussed, the Court will overrule the post-trial evidentiary objections lodged by both Plaintiffs and Defendants.

An appropriate Order will be entered.

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**ORDER**

At Wilmington, this 15 day of July 2008, for the reasons  
set forth in the Memorandum Opinion issued this date;

IT IS HEREBY ORDERED that:

1. Plaintiffs' post-trial evidentiary objections are  
**OVERRULED**.

2. Defendants' post-trial evidentiary objections are  
**OVERRULED**.

  
UNITED STATES DISTRICT JUDGE