NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PFIZER INC., PHARMACIA & UPJOHN COMPANY, and PFIZER HEALTH AB,

Plaintiffs,

v.

IVAX PHARMACEUTICALS, INC.,

Defendant.

IVAX PHARMACEUTICALS, INC., and TEVA PHARMACEUTICALS USA, INC.,

Counterclaim-Plaintiffs,

v.

PFIZER INC., PHARMACIA & UPJOHN COMPANY, and PFIZER HEALTH AB,

Counterclaim-Defendants.

Hon. Dennis M. Cavanaugh

OPINION

Civil Action No. 07-CV-00174 (DMC)

DENNIS M. CAVANAUGH, U.S.D.J.:

This matter comes before the Court upon motions *in limine* by Plaintiffs Pfizer Inc., Pharmacia & Upjohn Company, and Pfizer Health AB (collectively "Plaintiffs") and Defendants IVAX Pharmaceuticals, Inc. ("IVAX") and Teva Pharmaceuticals USA, Inc. ("Teva") (collectively "Defendants"). Pursuant to Fed. R. Civ. P. 78, no oral argument was heard. After carefully considering the submissions of the parties, and based upon the following, it is the finding of the

Court that Plaintiffs' *in limine* motions to limit the testimony of Defendants' expert Dr. Keith B. Leffler, and to preclude Defendants from offering evidence concerning fesoterodine are **granted**; Plaintiffs' motion to limit the testimony of Defendants' expert Dr. Gary D. Glick is **granted in part and denied in part**; Defendants' *in limine* motions to exclude evidence relating to tolterodine, to exclude evidence regarding the purported "selectivity" of claims 4 and 6 of United States Patent No. 5,382,600 (the "'600 Patent"), to limit the testimony of Plaintiffs' expert witnesses Dr. Anton J. Hopfinger and Dr. Mathew D. Krasowski, and to preclude testimony related to unexpected results, are **denied**. The order in which evidence shall be presented at trial is as follows: Plaintiffs shall briefly present background information regarding the invention-at-issue; Defendants shall present their case-in-chief; Plaintiffs shall present their case in response; and Defendants shall be given an opportunity to present rebuttal evidence.

I. BACKGROUND[1]

This case concerns the enforceability of Plaintiffs' patent (the "'600 Patent") which was issued on January 17, 1995. Pfizer and its subsidiaries are pharmaceutical companies that develop and market drug products. Teva is also a pharmaceutical company that develops and markets drug products. In 2007, Teva acquired IVAX, a pharmaceutical company that produces generic versions of drug products. Pfizer instituted the underlying litigation claiming patent infringement under the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2)(A), on January 11, 2007. IVAX's parent company, Teva, became a party to this suit as a Counterclaim Plaintiff on February 7, 2007. On March 30, 2007, Pfizer joined Teva as a Counterclaim Defendant by filing its Reply and Counterclaim to the

[1] The facts set forth in this Opinion are taken from the record established by the parties' numerous submissions.

Answer and Counterclaims of IVAX and Teva.

A. The '600 Patent

The '600 Patent names six inventors: Nils A. Jonsson, Bengt A. Sparf, Lemit Mikiver, Pinchas Moses, Lisbeth Nilvebrant and Gunilla Glas. The inventors assigned the patent application to Kabi Vitrum AB ("Kabi"). Kabi and the six inventors are the '600 Patent applicants ("Applicants"). The Applicants filed an application for what became the '600 patent in December 1991.[2]

The '600 Patent claims various diphenylpropylamines and alleges that these compounds have favorable anticholinergic activity. Anticholinergic properties serve to reduce the effects of acetylcholine in the central and peripheral nervous systems such as: emptying of the bladder, production of saliva, slowing of heart rate, and contraction of intestinal smooth muscle. Claim 1 of the '600 Patent claims a broad class of 3,3-diphenylpropylamines. Claim 4 of the '600 patent claims eleven specific 3,3-diphenylpropylamines. Claim 6 of the '600 Patent claims the 3,3-diphenylpropylamines of Claim 1 with (+) isomers. *Tolterodine tartrate,* or tolterodine, is one of the 3,3-diphenylpropylamine compounds claimed in the '600 patent. Tolterodine subsequently became the compound used in Pfizer's Detrol® line of urinary incontinence products.

The United States Patent and Trademark Office ("PTO") twice rejected the '600 Patent application for obviousness. The Applicants disclosed several prior art references, including United States Patent No. 3,446,901 (the "Jones '901 Patent"), which the examiner found "generically

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[2] During the prosecution of the '600 Patent, the USPTO changed the patent application number several times, the last of which was 5,382,600. For the purposes of this Opinion, the '600 Patent and all predecessor application numbers which resulted in the '600 Patent shall be referred to uniformly as the '600 Patent.

teaches the present compounds and specifically discloses the dimethylamino lower homolog."

In a third action, the PTO rejected all but two of the pending compound claims. The examiner allowed what would become Claims 4 and 6 of the '600 Patent. The Applicants responded to the PTO's determination in the third action by amending their application to claim compounds with at least four carbon atoms in the amine group (rather than three) in an attempt to distinguish the prior art compounds of the Jones '901 Patent. The Applicants stated that "the compounds of the present invention contain at least four carbon atoms on the amine, which provides considerably increased anticholinergic effect." The Applicants further amended their application to include representations of "unexpected results," which distinguish the claimed compounds from the prior art.[3]

In the PTO's fourth action, the examiner stated that the grounds for the prior rejections were not overcome because the showing of unexpected results was not in declaration form as required by 17 C.F.R. § 1.132. The examiner stated that certain claims would be allowed upon the filing of a declaration attesting to unexpected results. The Applicants submitted a supplemental response enclosing a declaration by one of the inventors, Dr. Lisbeth Nilvebrant, Ph.D (the "Nilvebrant Declaration"). In the declaration, Dr. Nilvebrant represented that "comparative tests" "established that [claimed] compounds (A) and (B) that were tested are approximately six to seven times better than the [closest] compound" disclosed in the Jones '901 Patent "with respect to anticholinergic activity." Based on the Applicants' showing of unexpected results, the examiner allowed the '600

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[3] Courts have found "unexpected results" when a compound has been tested and displays a "superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected." In re Soni, 54 F.3d 746, 750 (Fed. Cir. 1995). A patentee may use evidence of unexpected results to rebut a prima facie finding of obviousness. Id.

Patent to issue.

B. The Infringement

At the present time Pfizer owns the '600 Patent, which claims various chemical compounds, including tolterodine, the active ingredient in Pfizer's Detrol® brand prescription medication. Detrol® is a prescription medication used to treat symptoms related to overactive bladder. IVAX submitted an Abbreviated New Drug Application ("ANDA"), now designated as ANDA 77-006, to the Food and Drug Administration ("FDA") seeking permission to market a generic form of tolterodine pursuant to 21 U.S.C. § 355(j). On January 10, 2007, IVAX amended its ANDA to seek approval to manufacture and sell tolterodine prior to the expiration of the '600 Patent in 2012. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), IVAX submitted a certification which stated that the '600 Patent is invalid, unenforceable, or will not be infringed by IVAX's manufacture, use, or sale of tolterodine. In January 2007, IVAX notified Pfizer that it had submitted an ANDA regarding tolterodine. IVAX concedes that it has infringed claims 4 and 6 of the '600 Patent but asserts that the patent is invalid due to obviousness.

II. DISCUSSION

Plaintiffs move (i) to limit the testimony of Defendants' expert Dr. Keith B. Leffler, (ii) to limit the testimony of Defendants' expert Dr. Gary D. Glick, and (iii) to preclude Defendants from offering evidence concerning fesoterodine. Defendants move (i) to exclude evidence of the purported selectivity of claims 4 and 6, (ii) to exclude evidence relating to tolterodine, (iii) to limit the testimony of Plaintiffs' experts, Dr. Anton J. Hopfinger and Dr. Matthew D. Krasowski, and (iv) to exclude evidence of "unexpected results." Defendants have also filed a motion asking the Court to confirm the order in which evidence will be presented at trial.

A. Plaintiffs' *In Limine* Motions

i. Plaintiffs' *In Limine* Motion to Limit the Testimony of Dr. Keith B. Leffler

Plaintiffs have filed an *in limine* motion requesting that the Court limit the testimony of Dr. Keith B. Leffler, Ph.D pursuant to Fed. R. Civ. P. 26. Plaintiffs move to preclude Dr. Leffler from testifying about, referring to, or relying upon certain documents that Defendants provided to Plaintiffs after Dr. Leffler submitted his expert report on September 1, 2006. Plaintiffs deposed Dr. Leffler on the contents of his report on November 11, 2006, and expert discovery closed on April 7, 2008. Defendants produced new documents on April 6, 2009, which Defendants claim Dr. Leffler may have relied upon when he drafted his expert report. Defendants produced additional documents on July 2, 2009, indicating by letter that they intended to use these documents in connection with the proposed trial testimony of Dr. Leffler.

In support of their position, Plaintiffs allege that Dr. Leffler's testimony must not address the new information pursuant to Fed. R. Civ. P. 26(a)(2)(B). Fed. R. Civ. P. 26(a)(2)(B) requires that an expert's "report [] contain...a complete statement of all opinions the witness will express and the basis and reason for them." Plaintiffs allege that Defendants have neither submitted an amended report, to which Plaintiffs would have objected as untimely, nor have Defendants explained how the untimely documents fit into Dr. Leffler's original report. Plaintiffs assert that if the Court allows Dr. Leffler to rely on these documents, the scope of Dr. Leffler's expert opinion would be impermissibly expanded.

Defendants assert that because the documents did not yet exist at the close of expert discovery, they were unable to produce the documents as part of Dr. Leffler's initial submission. Defendants argue that under Fed. R. Civ. P. 26(e)(2) any additions or changes to the information

contained in an expert report or given during an expert's deposition "must be disclosed by the time the party's pre-trial disclosures under 26(a)(3) are due." Defendants argue that by submitting the documents on April 6, and July 2, 2009, they met the deadline for pre-trial disclosures. Defendants further argue that Dr. Leffler's supplementation of the materials he relied upon is proper because inclusion of these new documents does not expand the scope of his previously offered opinions. Defendants rely on Engers v. AT&T, No. 98-CV-3660, 2005 U.S. Dist. LEXIS 41682, at *2-3 (D.N.J. Sept. 8, 2005) in which the Court denied a motion to exclude supplemental expert declarations filed after the close of expert discovery because "the opinions proffered merely expound upon–and only briefly–opinions included in his original report." Defendants argue that the supplemental information about which Dr. Leffler intends to testify will simply augment Dr. Leffler's previously expressed opinion that sales of the Detrol® product was the result of Pfizer's marketing efforts.

Plaintiffs counter that Dr. Leffler has already testified that the opinions in his report are limited to the period between 1998-2006, and that he was particularly interested in the "first few years of sales" of Detrol®, which was launched in 1998.

Plaintiffs would be prejudiced if Dr. Leffler was allowed to testify regarding the new information because Plaintiffs were unable to depose Dr. Leffler regarding this evidence. Further, the new information pertains to sales during the 2007-2008 period, and would expand the scope of Dr. Leffler's testimony. Accordingly, Plaintiffs' motion *in limine* is **granted** and Dr. Leffler's testimony must be limited to information included in his original report.

ii. Plaintiffs' *In Limine* Motion to Limit the Testimony of Dr. Gary D. Glick

Plaintiffs request that the Court limit the testimony of Defendants' expert Dr. Gary D. Glick,

Ph.D. pursuant to Fed. R. Civ. P. 26 and 37. Plaintiffs seek to prohibit Dr. Glick from testifying about: (1) the approved indications for, or other known uses of Bilagol®, as a commercialized drug; (2) P. Janssen, Diphenylpropylamines in SYNTHETIC ANALGESICS (Pergamon Press 1960), as it concerns stereoisomers; (3) the properties and/or relative therapeutic advantages of the compounds comprising claims 4 and 6 of the patent-in-suit, including tolterodine, other than as disclosed in Table 1 of the patent-in-suit; (4) the sales, marketing, advertising, or promotion of tolterodine; (5) the publication bearing Bates numbers IVAX064099-103; (6) the medical conditions of overactive bladder or urinary incontinence; and (7) the "closest prior art" to the compounds claimed in the patent-in-suit, to the extent Dr. Glick identifies any compound other than that contained in the '901 Patent (i.e., the "Jones Compound").

Plaintiffs argue that Dr. Glick submitted three expert reports in this case, and none of these reports referenced items 1 through 6 above. Dr. Glick was not deposed on any of these subjects. Dr. Glick did not supplement or amend his reports to include items 1 through 6, and he did not indicate during his deposition that he had changes to his expert opinion. Regarding item 7, Plaintiffs argue that Dr. Glick should only be permitted to testify within the parameters of his reports regarding the closest prior art. Specifically, Plaintiffs assert that in his deposition and reports Dr. Glick only referenced the Jones Compound and should, therefore, be prohibited from identifying any other compound as the closest prior art.

Defendants respond that Dr. Glick should be permitted to present testimony on items 1, 2, 3 and 5.[4] Regarding item 1, Defendants assert that Dr. Glick extensively discussed the Janssen

[4] Dr. Glick will not offer testimony as to items 4 and 6 and the Court, therefore, need not address Plaintiffs' motion to preclude testimony on these subjects.

Reference in his report, including a section of the Janssen Reference that concerned Bilagol®. Accordingly, Defendants argue, Plaintiffs were clearly aware of the drug's relevance to the Janssen Reference, and thus additional data regarding Bilagol® should be deemed admissible.

As to item 2, Defendants again observe that Dr. Glick relied heavily on the Janssen Reference in preparing sections of his report. Further, in other sections of his report, he explicitly suggested that the (+) isomers contained in the patent claims-in-issue were obvious. Defendants argue that, in light of the multiple citations to the Janssen Reference and the discussion of (+) isomers, Dr. Glick should be permitted to rely on all of the Janssen Reference's teachings related to stereoisomers, even if the teachings were not explicitly referred to in his report.

Regarding item 3, Defendants argue that Dr. Glick should be permitted to testify regarding the properties and claimed therapeutic advantages of the compounds claimed in the patent-in-suit.[5] Defendants assert that such testimony is necessary to respond to Plaintiffs' contention that the claimed compounds display increased selectivity.

As to item 5, Defendants assert that the publication merely bolsters the previously presented opinion of Dr. Glick without modifying or enlarging the scope of his testimony, and is thus admissible.

Finally, as to item 7, Defendants dispute the notion that Dr. Glick explicitly identified the Jones Compound as the closest prior art. Defendants, instead, assert that the Jones Compound was identified simply because Plaintiffs only questioned Dr. Glick regarding compounds claimed in the

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[5] As Defendants concede, Dr. Glick will not testify in Defendants' case-in-chief as to the properties and alleged therapeutic advantages of the claimed compounds. Dr. Glick will be permitted to offer his opinion regard unexpected results in response to Plaintiffs' presentation of such evidence. As explained in Section II.B.4., below, Plaintiffs will be given the opportunity to present evidence regarding unexpected results.

Jones Patent during his deposition. Defendants argue that Dr. Glick should, accordingly, not be limited in his identification of the closest prior art.

Fed. R. Civ P. 26(a)(2)(B) requires that an expert's "report [] contain...a complete statement of all opinions the witness will express and the basis and reason for them." The "duty to supplement extends both to information included in the report and to information given during expert's deposition." Fed. R. Civ. P. 26(e). An expert "is not allowed to use [new] information...to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless," under Fed. R. Civ. P. 37(c)(1). Dr. Glick has neither supplemented nor amended any of his three expert reports to include discussions of items 1, 2 or 5 identified by Plaintiffs. Plaintiffs have not had the opportunity to depose Dr. Glick regarding these items, and he will not be permitted to present testimony regarding these items at trial.

Although not addressed in his original expert report, Dr. Glick will be permitted to provide rebuttal testimony pertaining to item 3. The parties' discussion of the Janssen Compound as a potential "closest prior art" was a relatively late development in the course of this litigation, and Dr. Glick should not be prevented from offering testimony to respond to Plaintiffs' "secondary considerations" argument in support of nonobviousness.[6] Finally, as to item 7, Dr. Glick's identification of the Jones Compound as the closest prior art was his response to a question regarding the closest prior art within the '901 patent. Dr. Glick's expert reports, however, discuss both the Jones and Janssen Patents, and Dr. Glick will be permitted to opine as to the overall closest prior art.

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[6] In Plaintiffs' response to Defendants' case-in-chief, they will present evidence pertaining to "secondary considerations" of nonobviousness. One such consideration, as noted above, are any "unexpected results" discovered when comparing the properties of the claimed compound to the closest prior art.

Plaintiffs' motion is **granted** as to items 1, 2 and 5, and **denied** as to items 3 and 7.

iii. Plaintiffs' *In Limine* Motion to Exclude Evidence Concerning Fesoterodine

Plaintiffs have moved to exclude evidence related to the drug fesoterodine pursuant to Fed. R. Civ. P. 26 and 37 and Fed. R. Evid. 402. Fesoterodine is a recently launched urinary incontinence drug that is not covered by the claims of the patent-at-issue. Defendants wish to offer evidence of Pfizer's advertizing plans for fesoterodine to support their argument that tolterodine was not truly a "commercial success" and was instead only successful as a result of effective marketing.

In a similar case involving the same parties the Honorable Mark Falk, U.S.M.J. held that Defendants should not be allowed to seek discovery of documents regarding fesoterodine. Pfizer Inc. v. Teva Pharms. USA, Inc., No. 08-1331, 2009 WL 1587893, at *1 (D.N.J. June 4, 2009). In that case, which concerns the patent-at-issue, Teva moved to compel discovery related to fesoterodine over Pfizer's relevance objections. There, Judge Falk rejected Teva's argument that Pfizer's internal strategy for the launch of fesoterodine was relevant to the commercial success of tolterodine. The Court rejected the argument and noted that fesoterodine was a new product and its marketing could not have impacted the commercial success of tolterodine as tolterodine entered the market many years prior to fesoterodine. The same argument applies in this case. There is no nexus between fesoterodine and the commercial success of tolterodine during the relevant time period. Accordingly, Plaintiffs' motion is **granted** and Defendants are precluded from offering evidence pertaining to fesoterodine at trial.

B. Defendants' *In Limine* Motions

i. Defendants' Motion *In Limine* to Exclude Evidence of Purported "Selectivity" of the Claimed Compounds

Defendants ask the Court to preclude Plaintiffs from presenting evidence regarding the "selectivity" of the compounds contained in claims 4 and 6 of the '600 Patent.

Plaintiffs assert that the claimed compounds are particularly effective in treating overactive bladder because they are more selective than prior anticholinergic compounds. Plaintiffs contend that this increased selectivity constitutes an unexpected result, and thus contributes to a finding that the claimed compounds are not obvious.

Defendants argue that "selectivity" was not provided for in claims 4 and 6 of the '600 Patent, and therefore evidence of the compounds' selectivity over prior art is irrelevant. Defendants also argue that the fact that the inventors sought to achieve increased selectivity is inapposite, as a patent's claims must be interpreted objectively. Next, Defendants argue that Plaintiffs' assertion that the compounds provided for in claims 4 and 6 exhibit unexpected results is unsupported because Plaintiffs cannot prove that they compared the claimed compounds to the closest prior art.[7] Lastly, Defendants argue that confusion from the admission of evidence of purported selectivity would outweigh any conceivable probative value because Plaintiffs have not provided a coherent definition of the term "selective."

Plaintiffs respond that although the term selectivity is not included in the disputed claims, selectivity is the fundamental property of the claimed compounds and is inseparable from the

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[7] The "unexpected results" analysis contemplates a comparison between a compound and the closest prior art. Kao Corp. v. Unilever United States, Inc., 441 F.3d 963, 970 (Fed. Cir. 2006).

compounds for the purposes of an obviousness analysis under 35 U.S.C. § 103. Plaintiffs explain that the Court will be unable to conduct a meaningful obviousness analysis if selectivity, the central property of the claimed compounds, is not a part of the consideration. Plaintiffs argue that there is no danger of unfair prejudice or confusion should the Court allow the admission of evidence concerning selectivity.

Given that the Court's ultimate determination will be premised upon the obviousness analysis–which must consider the key properties of the claimed compounds–testimony regarding selectivity is vital to the Court's inquiry. Sanofi-Synthelabo, Inc. v. Apotex, Inc., 550 F.3d 1075, 1086 (Fed. Cir. 2008); In re Sullivan, 498 F.3d 1345, 1353 (Fed. Cir. 2007). Evidence regarding the selectivity of claims 4 and 6 of the '600 Patent will properly be presented at trial, and Defendants' motion is **denied**.

ii. Defendants' Motion *In Limine* to Exclude Evidence Relating to Tolterodine.

Defendants move to prevent Plaintiffs from presenting evidence at trial concerning tolterodine, including evidence pertaining to Plaintiffs' commercial products Detrol®, Detrusitol®, Detrol® LA, and Detrusitol® XL. Defendants argue that tolterodine is not relevant because the issue before the Court is the obviousness of two other compounds contained within claims 4 and 6 of the '600 Patent, not tolterodine. Defendants recognize that they are only required to show that one of the compounds within claims 4 and 6 are obvious to successfully challenge the validity of the '600 Patent. Defendants further note that their obviousness defense is directed at one compound covered by claim 4 and one compound covered by claim 6, neither of which is tolterodine. Accordingly, Defendants assert that evidence related to the commercial success of tolterodine irrelevant.

Plaintiffs respond that the commercial success of a compound covered by a patent claim–even

a compound other than the one being challenged by the Defendant–is relevant in assessing whether the challenged compound is commercially successful.

The Court finds that Defendants' motion is without merit. The Court will permit Plaintiff to present evidence regarding the commercial success of Detrol® to assist in the obviousness inquiry. A party is permitted to show evidence of the commercial success of a particular embodiment of the challenged claim(s) even where the commercialized embodiment is not the particular compound being challenged on obviousness grounds. Applied Materials, Inc. v. Adv. Semiconductor Materials Am., Inc., 98 F.3d 1563, 1570 (Fed. Circ. 1996); Pfizer Inc. v. IVAX Pharms., Inc., No. 07-0174, 2008 WL 5188838, at *11 (D.N.J. December 10, 2008). The fact that Defendants are challenging a claimed compound that was not ultimately commercialized is inapposite. Accordingly, Defendants' motion is **denied**.

iii. Defendants' Motion *In Limine* to Limit the Testimony of Plaintiffs' Expert Witnesses

Defendants seek to restrict Plaintiffs from offering the expert opinions of Dr. Anton J. Hopfinger, Ph.D. and Dr. Mathew D. Krasowski, M.D., Ph.D. regarding the meaning of claims 4 and 6. Defendants argue that Plaintiffs' experts will incorrectly rewrite claims 4 and 6 by adding limitations to the specifications of the claims. Defendants argue that the probative value of Dr. Hopfinger's and Dr. Krasowski's opinions is substantially outweighed by the likelihood of prejudice and confusion that will result from admission of the testimony.

Plaintiffs oppose Defendants' motion, arguing that Defendants' *in limine* motion raises a claim construction issue when there is no such issue before the Court. Plaintiffs argue that their witnesses will offer expert testimony as to the pharmacological and chemical properties of the claimed

compounds and that those properties are inseparable from the compounds for the purposes of the Court's obviousness analysis.

Expert witnesses, by virtue of said designation, are allowed to offer their opinion on subjects within their expertise. Fed. R. Evid. 702. The issues raised by Defendants do not provide grounds to limit Plaintiffs' expert testimony. The properties of the claimed compounds are critical to the Court's obviousness determination, and Dr. Hopfinger and Dr. Krasowski will testify regarding such properties. Defendants' suggestion that the witnesses will attempt to "rewrite" the claims of the patent-in-issue is purely speculative. Defendants' motion to limit the testimony of Plaintiffs' witnesses is **denied**.

iv. Defendants' *In Limine* Motion to Preclude Testimony Relating to Unexpected Results

Defendants move to strike certain facts in paragraphs 30-31 and 91-96 of Plaintiffs' Statement of Contested Facts and preclude testimony regarding unexpected results because Defendants allege that they were not provided with this information during discovery, specifically in response to Interrogatory 12 served on July 12, 2004. Defendants rely on Fed. R. Civ. P. 26(e)(1) and Fed. R. Civ. P. 37(c)(1) which provides that "if a party fails to provide information...the party is not allowed to use that information...at trial, unless the failure was substantially justified or harmless." Defendants allege that Plaintiffs did not state their contention of unexpected results during discovery when explicitly asked in Interrogatory 12 and did not serve a supplemental response identifying unexpected results until the last day of discovery. Defendants argue that they will be prejudiced if this evidence is allowed to be heard at trial because they did not have an opportunity to conduct discovery, prepare a response, or engage experts to consider this evidence.

Plaintiffs argue that the facts in paragraphs 30-31 and 91-96 relating to unexpected results should not be excluded because Plaintiffs provided these facts immediately upon request and their admission will not prejudice the Defendants. Plaintiffs allege that they initially did not note unexpected results in response to Interrogatory 12 because they and Defendants were relying on the Jones Compound as the closest prior art at that point in the litigation. Plaintiffs explain that Defendants brought the Janssen Compound into the discourse as the closest prior art in Defendants' Statement of Contested Facts, on July 10, 2009. In response to Defendants' Statement of Contested Facts, Plaintiffs noted that the compounds identified in the patent-in-issue were unexpectedly superior to the Janssen Compound. Plaintiffs argue that allowing this evidence will not prejudice the Defendants because documents containing the inventors' data that shows the inferiority of the Janssen Compound were provided to Defendants in 2004. The data was in a two-page chart and a laboratory notebook produced in 2004. The chart was repeatedly referenced during discovery, and the notebook was marked as an exhibit during the deposition of the '600 patent inventors. Further, the chart and notebook were reviewed and expressly relied upon by Defendants' expert Dr. Glick in his 2005 expert report.

Defendants have been in possession of Plaintiffs' data regarding unexpected results for over four years; in fact, the data was relied upon by Defendants' own expert who will testify at trial. Accordingly, the Defendants' motion *in limine* is **denied**.

v. Defendants' Motion Concerning the Order in Which Evidence will be Presented at Trial

Defendants move to have the Court declare the order in which evidence shall be presented at trial. Defendants request that they be allowed to present their case first after which Plaintiffs

present responsive evidence, followed by Defendants' rebuttal evidence.

Plaintiffs agree to the order sought by Defendants with the caveat that Plaintiffs would like an opportunity to present a brief background of the invention at issue by calling one or two fact witnesses.

Defendants argue that allowing Plaintiffs to present background evidence would be inefficient because it is only relevant to determine whether there are secondary considerations that rebut Defendants' evidence of obviousness. Defendants cite cases from other Circuits where it was determined that the party with the burden of proof has the right to open and close the argument. See Anheuser-Bush, Inc. V. John Labatt Ltd., 89 F.3d 1339, 1344 (8th Cir. 1996); Martin v. Chesebrough-Pond's, Inc., 614 F.2d 498, 501 (5th Cir. 1980). Defendants also cite a Federal Circuit case in which it was noted that allowing the patentee "to 'go first' with testimony on validity....result[s] in cluttered records, irrelevant detours, undue burdens on the judicial process, and unnecessary work for the trial court." Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1570-71 (Fed. Cir. 1986). Defendants argue that allowing Plaintiffs to present first would be unfair and prejudicial.

Plaintiffs argue that hearing background information first would be helpful to the Court, and that any information provided would be relevant to the obviousness determination. To support this proposition, Plaintiffs cite Merck Sharp & Dohme Pharms. SRL v. Teva Pharms. USA, Inc., No. 07-1596 (D.N.J. Nov. 5, 2008) where the Court allowed the patentee to provide background information on the invention at the commencement of trial. Plaintiffs argue that it would not be unfair or prejudicial to Defendants to allow Plaintiffs to briefly present background information because Plaintiffs would not present the sum and substance of their secondary

considerations of nonobviousness arguments, nor would it provide duplicative information in rebuttal.

The Federal Rules of Evidence permit courts to "exercise reasonable control over the mode and order of interrogating witnesses and presenting evidence so as to make the interrogation and presentation effective for the ascertainment of truth." Fed. R. Evid. 611(a). In this instance, the Court will permit Plaintiff to briefly present background information pertaining to the invention-at-issue. Defendants, as the party with the burden of proof, shall then present their case-in-chief, followed by Plaintiffs' response, and the trial will conclude with Defendants' rebuttal evidence.

III. CONCLUSION

For the reasons stated, it is the finding of the Court that Plaintiffs' *in limine* motions to limit the testimony of Defendants' expert Dr. Keith B. Leffler, and to preclude Defendants from offering evidence concerning fesoterodine are **granted**; Plaintiffs' motion to limit the testimony of Defendants' expert Dr. Gary D. Glick is **granted in part and denied in part**; Defendants' motions to exclude evidence relating to tolterodine, to exclude evidence regarding the purported "selectivity" of claims 4 and 6 of the '600 Patent, to limit the testimony of Plaintiffs' expert witnesses Dr. Anton J. Hopfinger and Dr. Mathew D. Krasowski, and to preclude testimony related to unexpected results, are **denied**. The order in which evidence is to be presented at trial shall be as follows: Plaintiffs shall briefly present background information regarding the invention at issue; Defendants shall present their case-in-chief; Plaintiffs shall present their case-in-response; and Defendants will then present rebuttal evidence.

Dennis M. Cavanaugh, U.S.D.J.

Date: September 8, 2009
Orig.: Clerk
cc: All Counsel of Record
Hon. Mark Falk, U.S.M.J.
File