NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS PHARMA AG, and NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD., Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. Defendant.	**Hon. Dennis M. Cavanaugh** **OPINION** Civil Action No. 05-CV-1887 (DMC)

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

This matter comes before the Court upon eleven (11) motions *in limine* by Plaintiffs, Novartis International Pharmaceutical Ltd. ("NIP"), Novartis Pharmaceutical Corporation ("NPC") and Novartis Pharma, AG ("NPAG") (collectively "Plaintiffs") and twelve (12) motions *in limine* by Defendant, Teva Pharmaceutical USA, Inc., to preclude the introduction of evidence at trial of the issues of obviousness and inequitable conduct. Pursuant to Fed. R. Civ. P. 78, no oral argument was heard. After considering the submissions of the parties, the decision of this Court upon each of these motions is set forth for the reasons herein expressed separately, below.

I. BACKGROUND

The U.S. Patent No. 5,246,937 (the "'937 patent"), entitled "Purine Derivatives," was issued on September 21, 1993 to Michael R. Harnden and Richard L. Jarvest, with Beecham Group PLC as the assignee. The '937 patent claims priority to three British patent applications including GB

8423833 filed on September 20, 1984, GB 8510331 filed April 23, 1985 and GB 8520618 filed August 16, 1985. The priority date for claims 9 and 14-19 of the '937 patent is April 23, 1985. Claim 9 of the '937 patent presents the compound famciclovir, identified as 2-amino-9-(4-acetoxy-3-acetoxymethylbut-1-yl)purine. Claim 14 of the '937 patent presents a method of treating viral infections in a human or non-human animal using an effective, non-toxic amount of famciclovir. Claim 15 of the '937 patent presents a method of treating herpes virus infections in a human or non-human animal using an effective, non-toxic amount of famciclovir. Claim 16 of the '937 patent presents a method of treating herpes simplex type 1 (HSV-1) in a human or non-human animal using an effective, non-toxic amount of famciclovir. Claim 17 of the '937 patent presents a method of treating herpes simplex type 2 (HSV-2) in a human or non-human animal using an effective, non-toxic amount of famciclovir. Claim 18 of the '937 patent presents a method of treating varicella zoster in a human or non-human animal using an effective, non-toxic amount of famciclovir. Claim 19 of the '937 patent presents a pharmaceutical composition for treating viral infections which comprises famciclovir in combination with a pharmaceutically acceptable carrier.

In an Asset Sale Agreement, dated August 30, 2000, purchasers, NPAG and NPC purchased certain "Purchased Assets [as defined therein] related to Famciclovir and Penciclovir" from sellers, SmithKline Beecham PLC, SmithKline Beecham Corporation and SmithKline Beecham (Cork) Limited ("SKB").[1] Since 2001, Plaintiffs have sold an antiviral drug branded as Famvir®. The Food

[1] The standing issue as to Plaintiffs, NPC and NPAG is still in dispute. In this Court's October 21, 2009 determination of Defendant's motion to dismiss for lack of Article III standing, this Court concluded in the face of insufficient evidence, the issue of standing is to be decided before the trier of fact. For purposes of the standing issue, the trier of fact is this Court. Therefore, nothing in this opinion shall be construed to infer a disposition of the issue of standing by this Court.

and Drug Administration ("FDA") has approved Famvir® for the treatments of (1) acute herpes zoster (shingles); (2) genital herpes; (3) herpes labialis (cold sores); and (4) herpes simplex in HIV-infected patients.

The claimed compound famciclovir is a member of a class of compounds known as acyclic nucleosides. In 1977, a group from Burroughs Wellcome demonstrated that acyclovir (known by the chemical name 9-(2-hydroxyethoxymethyl)guanine), could selectively inhibit the herpes virus. Acyclovir is an acyclic nucleoside. Famciclovir is a "prodrug" - a pharmaceutical compound that does not have the desired activity (in this case, antiviral effects), but is converted in the human body into the active compound. The purpose of a prodrug is to increase the amount of active compound in the bloodstream after oral administration - that is, to increase the "absorption" or "bioavailability" of the active compound.

On December 28, 2004, pursuant to the Hatch-Waxman Act, Teva filed an Abbreviated New Drug Application ("ANDA"), seeking FDA approval to commercially manufacture a generic version of Famvir®, famciclovir tablets. On August 8, 2005, Plaintiffs brought suit against Defendant for alleged infringement of the '937 patent. The filing of an ANDA is considered a technical or "artificial" act of infringement under 35 U.S.C. § 271(e)(2) for purposes of conferring subject matter jurisdiction upon this Court. The FDA granted final approval of Teva's ANDA in August 2007. On September 25, 2007, Plaintiffs' motion for a preliminary injunction was denied by this Court, and affirmed by the Federal Circuit on June 9, 2008.

II. LEGAL STANDARD

A. Federal Rules of Evidence

"FRE 402 provides the baseline for determining the admissibility of evidence in the federal

courts." In re Nautilus Motor Tanker Co., 85 F.3d 105 (3d Cir. 1996) (citing Daubert v. Merrell Dow Pharms, 509 U.S. 579 (1993)). Fed R. Evid. 402 provides the following:

> All relevant evidence is admissible, except as otherwise provided by the Constitution of the United States, by Act of Congress, by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority.

Id. "FRE 401 defines 'relevant' evidence as evidence 'having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.'" Id. "[R]elevant [ ] evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." Fed. R. Evid. 403.

"[A] reading of the companions to Rule 403 and of the commentaries that went with them to Congress, makes it clear that what counts as Rule 403 'probative value' of an item of evidence, as distinct from its Rule 401 'relevance,' may be calculated by comparing evidentiary alternatives." Old Chief v. United States, 519 U.S. 172, 184 (1997). "The Committee Notes to Rule 401 explicitly say that a party's concession is pertinent to the court's discretion to exclude evidence on the point conceded." Id. "Such a concession, according to the Notes, will sometimes 'call for the exclusion of evidence offered to prove [the] point conceded by the opponent ….'" Id. (citing Advisory Committee's Notes on Fed. Rule Evid. 401, 28 U.S.C. App., p. 859).

B. Obviousness

"The obviousness determination turns on underlying factual inquiries involving: (1) the scope and content of prior art, (2) differences between claims and prior art, (3) the level of ordinary skill in pertinent art, and (4) secondary considerations such as commercial success and satisfaction of

a long-felt need." Proctor & Gamble Co. v. Teva Pharms., 566 F.3d 989, 994 (Fed. Cir. 2009) (citing Graham v. John Deere Co. of Kan. City, 383 U.S. 1, 17 (1966)). In discussing the question of obviousness, the Supreme Court indicated that the Graham case "set forth a broad inquiry and invited courts, where appropriate, to look at any secondary considerations that would prove instructive." Id. (citing Graham, 383 U.S. at 1). "Indeed, evidence of secondary considerations may often be the most probative and cogent evidence in the record." Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1539 (Fed. Cir. 1983). For example, "if a patent challenger makes a prima facie showing of obviousness, the owner may rebut based on "unexpected results" by demonstrating 'that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected.'" Id. (citing In re Soni, 54 F.3d 746, 750 (Fed. Cir. 1995)).

"Under the U.S. Patent Act, an invention cannot be patented if 'the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.'" Proctor & Gamble, 566 F.3d at 994 (citing 35 U.S.C. § 103(a)). "Patents are presumed to be valid." Id. (citing Kao Corp. v. Unilever United States, Inc., 441 F.3d 963, 968 (Fed. Cir. 2006)). "A party seeking to invalidate a patent based on obviousness must demonstrate 'by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.'" Id. (citing Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348, 1361 (Fed. Cir. 2007)). "Clear and convincing evidence places in the fact finder 'an abiding conviction that the truth of [the] factual contentions are highly probable.'" Id. (quoting Colorado v. New Mexico, 467 U.S. 310, 316

(1984)).

Recently, in KSR International Co. v. Teleflex Inc., the Supreme Court cautioned against (1) a rigid application of the teaching, suggestion and motivation ("TSM") test, and (2) a rigid application of using an "obvious to try" analysis when there is pressure to solve a problem with "a finite number of identified, predictable solutions. 550 U.S. 398, 418 (2007). Instead, the Court advocated a "common sense" approach in determining obviousness. Id. Specifically, the Court explained that "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining elements in the manner claimed." Id. at 1742. The Court reasoned that, "if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." Id. at 1740. Even in light of the new approach advocated by KSR, this Court must be cautious to avoid the use of hindsight when considering Defendant's obviousness argument. Thus,

> [i]n conducting an obviousness analysis, [a] factfinder should be aware . . . of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning.' This is because the genius of invention is often a combination of known elements that in hindsight seems preordained.

In re Omeprazole Patent Litig., No. MDL 1291, 2007 U.S. Dist. LEXIS 39670, at *400-01 (S.D.N.Y. May 31, 2007) (citation omitted) (quoting KSR, 398 U.S. at 420); see also Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1138 (Fed. Cir. 1985).

C. Inequitable Conduct

Patent applicants and other individuals substantively involved in the prosecution of a patent are held to the highest standards of honesty and candor. See 27 C.F.R. § 1.56(a) (2007); Molins

PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995); Norton v. Curtiss, 433 F.2d 779, 794 (C.C.P.A. 1970). Breach of the duty of candor and good faith during the patent application process can render a patent unenforceable. Molins, 48 F.3d at 1178.

To prove inequitable conduct, Defendant must show by clear and convincing evidence (1) that the patent application omitted material information or misrepresented material facts; and (2) that the applicant did so with the intention of misleading or deceiving the patent examiner. Monsanto Co. v. Bayer Bioscience N.V., 363 F.3d 1235, 1239 (Fed. Cir. 2004); Dayco Prods., Inc. v. Total Containment, Inc., 329 F.3d 1358, 1362-63 (Fed. Cir. 2003). Regarding the first prong, information is considered material if there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the patent. See Digital Control Inc. v. Charles Mach. Works, 437 F.3d 1309, 1314-16 (Fed. Cir. 2006); Dayco Prods., 329 F.3d at 1363. The Federal Circuit has explained that the issue of "materiality" does not center on whether the withheld information would have rendered the claims invalid; rather, materiality relates to whether it is a matter "within a reasonable examiner's realm of consideration." Merck & Co. v. Danbury Pharmacal, Inc., 873 F.2d 1418, 1421 (Fed. Cir. 1989). As to the second prong, the Court must have a factual basis for a finding of deceptive intent. In re Hayes Microcomputer Prods., Inc. Patent Litig., 982 F.2d 1527, 1546 (Fed. Cir. 1992); Halliburton Co. v. Schlumberger Tech. Corp., 925 F.2d 1435, 1442 (Fed. Cir. 1991). However, intent to deceive need not be proven by direct evidence. Frazier v. Roessel Cine Photo Tech. Inc., 417 F.3d 1230, 1235 (Fed. Cir. 2005). If Defendant satisfies these threshold showings, the Court must then balance the equities to determine whether the patentee has committed inequitable conduct. Monsanto, 363 F.3d at 1239.

III. DISCUSSION

A. Plaintiffs' Motions *in Limine*

Motion in limine No. 1

Pursuant to Fed. R. Evid. 402 and 403 as well Fed. R. Civ. 37(c), Plaintiffs contend that Defendant should be precluded from introducing evidence concerning the following: (1) the price differential between brand-name and generic drugs; (2) the fact that Defendant manufactures generic drugs; (3) the underlying purposes and/or incentives of the Hatch-Waxman Act; and (4) the purported role that generic drugs will play in healthcare reform efforts. Plaintiffs specifically seek to preclude the testimony of Timothy Catlett ("Mr. Catlett"), a corporate representative of Teva, for failure to comply with Fed. R. Civ. P. 26 disclosures. Defendant argues that certain background facts, including what a generic drug is and how the Hatch-Waxman Act works, are necessary to aid the jury in rendering a disposition with respect to the issues at hand. Further, Defendant contends that, in response to the Plaintiffs' background presentation permitted by this Court, Defendant is entitled to present corresponding background information through Mr. Catlett.

As an initial matter, this Court has explicitly stated and reiterates that the "Plaintiffs are permitted to offer an initial presentation relating, and limited, to the nature of the invention." The evidence proffered by Plaintiffs regarding this matter will be circumscribed in accordance with the foregoing direction. Testimony concerning generic drugs and the Hatch-Waxman Act will likely aid in the jury in understanding the context in which the case arises. Further, given that this testimony concerns background information, any prejudice arising from Defendant's failure to disclose the witness may be cured through cross-examination. Therefore, such evidence is

admissible. However, the effect of generic drugs in the recent healthcare debate is entirely irrelevant and, therefore, is precluded. Plaintiffs' motion *in limine* No.1 is **granted in part** and **denied in part.**

Motion in limine No. 2

Pursuant to Fed. R. Evid. 402 and 403, Plaintiffs move to preclude the admission into evidence of this Court's prior disposition in the preliminary injunction opinion and order, the Federal Circuit's affirmance of this Court's ruling and Novartis' request for a permanent injunction. Defendant seeks to admit the denial of Plaintiffs' request for preliminary injunction and its affirmance in order to demonstrate its prudence in launching the generic product and compliance with the Hatch-Waxman Act guidelines. Notably,

> [t]he purpose of a preliminary injunction is merely to preserve the relative positions of the parties until a trial on the merits can be held. Given this limited purpose, and given the haste that is often necessary if those positions are to be preserved, a preliminary injunction is customarily granted on the basis of procedures that are less formal and evidence that is less complete than in a trial on the merits. A party thus is not required to prove his case in full at a preliminary-injunction hearing [ ] and the findings of fact and conclusions of law made by a court granting a preliminary injunction are not binding at trial on the merits.

Univ. of Tex. v. Camenisch, 451 U.S. 390, 395 (1981) (internal citations omitted). A judicial ruling or court conclusion of law is not a matter for the jury which operates as the factfinder. Given the leniency afforded by courts at the preliminary injunction stage, the introduction of the denial of the preliminary injunction and the Federal Circuit's affirmance of that disposition creates an unduly prejudicial effect outweighing any potential probative value alleged for purposes of introduction. Bifurcation of this case for trial upon damages and/or equitable relief and trial of the underlying issues of obviousness and inequitable conduct separately renders Plaintiffs' request for a preliminary

injunction irrelevant to those issues currently before the Court for trial. Therefore, Plaintiffs' motion *in limine* No. 2 is **granted**.

Motion in limine No. 3

Motion *in limine* No. 3 is premised upon the Court's denial of Plaintiffs' request for an advisory jury with respect to the issue of inequitable conduct. However, having previously granted Plaintiffs' request, the Court deems moot Plaintiffs' motion "To Preclude Evidence And References Concerning Beecham's Alleged Inequitable Conduct In The Event The Court Denies Novartis' Request For An Advisory Jury." Therefore, Plaintiffs' motion *in limine* No. 3 is **denied.**

Motion in limine No. 4

Pursuant to Fed. R. Evid. 403 and 702 as well as Fed. R. Civ. P. 37(c), Plaintiffs move to preclude the testimony of Defendant's expert witnesses, Dr. Arthur Broom, Dr. Donald Coen and Dr. Donald F. Smee, as duplicative, unreliable and conclusory in that each witness appears to have similar expertise and the testimony sought appears to be similar. Defendant contends that Dr. Broom is a chemist with over forty years of experience in the field of antiviral drug development, and that Dr. Broom will serve as the primary technical expert on the issues of obviousness and inequitable conduct. Defendant claims that Dr. Smee is a virologist with over 25 years of experience who co-authored the "Tippie" article upon which Plaintiffs rely. Dr. Smee, Defendant asserts, will serve to aid the jury in understanding the article and to rebut arguments advanced by Novartis concerning the surprising and unexpected results based on his prior work with the prior art compound ganciclovir. Defendant agrees that Dr. Coen's testimony is responsive to Plaintiffs' arguments that famciclovir has unexpected dosing advantages, advantages in treatment of latency and advantages of treatment in post herpetic neuralgia ("PHN") associated with herpes zoster. More specifically, Dr. Coen will

testify regarding the surprising and unexpected result that famciclovir is less toxic than ganciclovir.

Pursuant to Rule 403, the Court is permitted to exclude evidence constituting an "undue delay, waste of time, or needless presentation of cumulative evidence." Further, under Rule 702, evidence that will not assist the jury may be excluded as unhelpful. However, "The Federal Rules of Evidence embody 'a strong and undeniable preference for admitting any evidence having some potential for assisting the trier of fact.'" Holbrook v. Lykes Bros. S.S. Co., 80 F.3d 777, 781 (3d Cir. 1996) (quoting DeLuca v. Merrell Dow Pharmaceuticals, Inc., 911 F.2d 941, 956 (3d Cir. 1990)). "'Rule 702, which governs the admissibility of expert testimony, specifically embraces this policy,' United States v. Velasquez, 64 F.3d 844, 849 (3d Cir. 1995), and has a liberal policy of admissibility." Id. Helpfulness to the trier of fact remains the ultimate touchstone of admissibility. Id. at 784. "Moreover, a district court is not required to preclude expert testimony simply because the proposed expert could have performed his or her analysis in a better manner." Pfizer Inc. v. Teva Pharms. USA, Inc., 461 F. Supp. 2d 271, 274 (D.N.J. 2006), aff'd in part, rev'd in part on other grounds, (citing Kannankeril v. Terminix Int'l, 128 F.3d 802, 809 (3d Cir. 1997)). Insofar as the expert testimony is restricted to the foregoing parameters, the testimony is not substantially cumulative such that it results in undue delay or waste of time. Further, this testimony is likely to aid the trier of fact. Therefore, Plaintiffs' motion on that ground is denied.

"Sheer logic" and "simple analysis" are insufficient to form an acceptable basis of an admissible expert opinion. Kolokowski v. Crown Equip. Corp., 2009 U.S. Dist. LEXIS 77474, at *34 (D.N.J. Aug. 27, 2009). Further, where it is clear an expert "employed no special skill or technique different from a layperson in forming his opinion and conclusions" such evidence may be excluded. Although Defendant concedes that Dr. Smee and Dr. Coen rely on Dr. Broom's report in

reaching a conclusion, the evidence is not conclusory on that ground alone. Additionally, so long as the experts employ a special skill or technique different from a layperson in formulating an opinion or conclusion, such evidence will not be excluded. Therefore, Plaintiffs' motion to preclude the testimony of Dr. Smee and Dr. Coen as purely conclusory is denied.[2] Accordingly, Plaintiffs' motion *in limine* No. 4 is **denied**.

Motion in limine No. 5

Pursuant to Fed. R. Evid. 402, 403 and 802, Plaintiffs move to preclude evidence and references concerning allegations that Novartis fraudulently inflated accounting goodwill and revenue projections for Famvir® on the basis of substantial prejudice, irrelevance and because the complaint constitutes inadmissible hearsay. In particular, Plaintiffs seek to exclude the complaint of a former employee, Carol Shull, asserting wrongful termination for failure to go along with profitability and sales forecast inflation. Defendant contends that the complaint is admissible in that it is being used for purposes of cross-examination and not to prove the truth of the matter asserted.

Fed. R. Evid. 801(c) defines hearsay as "a statement, other than one made by the declarant while testifying at the trial or hearing, offered in evidence to prove the truth of the matter asserted." On the one hand, "[i]f a party does not offer a statement into evidence for the purpose of establishing the statement's truth, such statement does not constitute hearsay." United States v. Daniels, 2002 U.S. App. LEXIS 21348, at *3 (3d Cir. May 24, 2002); see United States v. Reynolds, 725 F.2d 99, 101 (3d Cir. 1983). On the other hand, "[a] party can attack a witness's credibility using otherwise inadmissible evidence, but cannot pretend that inadmissible hearsay evidence is being used to

[2]However, during the course of the proceeding on the merits, if the Court concludes that the testimony of these expert witnesses is resulting in undue delay, duplication and cumulation, the right to exclude such evidence is reserved.

impeach a witness so that the jury will hear its substance." Goodman v. Penn. Turnpike Comm'n, 293 F.3d 655, 666 (3d Cir. 2002). While the complaint itself is a pleading, and, therefore, a matter of public record, the statements contained therein constitute hearsay because they are being offered to prove the truth of the matter asserted, namely that the profit and sales forecast were inflated.[3] [4] In the absence of an exclusion from or exception to the hearsay rule permitting the Court to admit these statements, the statements contained in the complaint are excluded as hearsay. Moreover, this Court finds the admission of unproved allegations unfairly prejudicial. Therefore, Plaintiffs' motion *in limine* No. 5 to exclude the complaint of Ms. Shull is **granted**.[5]

Motions in limine No. 6 and No. 7

Pursuant to Fed. R. Evid. 403 and 702, Plaintiffs move to preclude in its entirety the testimony sought to be elicited from Larry S. Nixon, Esq. ("Mr. Nixon") and, in the alternative, if his testimony is permitted, to preclude all portions pertaining to the patent applicants' purported state of mind and intent. Regarding the issue of intent, Plaintiffs cite a number of cases to support the proposition that an expert should be precluded from testifying as to intent. See Robinson v. Hartzell Propeller Inc., 326 F. Supp. 2d 631, 648 (E.D. Pa. 2004); AstraZenneca LP v. TAP Pharm Prods.,

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[3] "It was made known to Ms. Shull, early on by several people, at Novartis, that the goodwill of Famvir was under no circumstances to sustain any impairment which would cause a reduction in reported goodwill on the company's books at least until the years 2008-2010. This statement was repeated to Ms. Shull many times. . ." Ex. A. Shull Compl. ¶6.

[4] ". . . Ms. Shull was told he did not have any support. Mr. Fletcher then went on to explain that these studies were placed in the model as a way to artificially inflate the appraisal of goodwill upwards to several hundred million dollars. Ms. Shull was reminded that her top priority along with his was to ensure that the numbers were in place to keep Famvir's goodwill from impairment." Ex. A. Shull Compl. ¶11.

[5] Notably, the pre-trial order does not indicate that Defendant intends to call Ms. Shull as a witness. Therefore, this motion purely addresses the inadmissibility of the complaint.

Inc., 444 F. Supp. 2d 278, 293 (D. Del. 2006). In opposition, Defendant contends that Mr. Nixon will not opine as to the ultimate issue of whether the Beecham applicants intended to deceive the United States Patent and Trademark Office ("PTO"), but rather Mr. Nixon will offer opinions as to facts that bear on the question of whether the applicants intended to deceive the PTO. While Mr. Nixon is not precluded from testifying to objective facts underlying and perhaps, evidencing inconsistencies between copending patents, Mr. Nixon is not permitted to express an opinion with regard to the intent of the patentees in submitting such applications.

In seeking to preclude Mr. Nixon's testimony in its entirety, Plaintiffs assert that an expert's testimony is foreclosed with respect to issues of law and, in particular, the law of inequitable conduct. (Pl. Br. at 2) (citing Casper v. SMG, 389 F. Supp. 2d 618, 621 (D.N.J. 2005). Further, Plaintiffs accuse Defendant's expert of attempting to demean the PTO and suggest that any such attempt must be precluded as prejudicial and unreliable. Additionally, Plaintiffs contend that Mr. Nixon's opinion regarding the PTO amounts to speculation rather than first hand knowledge in that he has never been employed by the PTO and has never communicated with a PTO examiner who conducted the prosecution of the '937 patent. Moreover, Plaintiffs argue that Defendant's expert should not be permitted to testify with respect to the duty of candor and good faith. Also, Plaintiffs argue that Defendant's expert should not be permitted to opine as to whether prior art that had not been submitted to the PTO was material to the prosecution. Lastly, Plaintiffs argue that Mr. Nixon's testimony regarding uncontroversial aspects of PTO practices and procedures should be precluded as unnecessary.

Defendant claims that Mr. Nixon's testimony will be restricted to common PTO practices and procedures, an explanation of events occurring during the prosecution of the '937 and '445

patents and identification and discussion of events occurring during the prosecution of the '937 and '445 patents relating to possible misrepresentation and/or possible withholdings of information that would have been important to a reasonable examiner and may have occurred with intent to mislead the PTO. Further, Defendant contends that Mr. Nixon will not testify concerning the law of inequitable conduct, offer legal conclusions, attempt to demean the PTO or attempt to parrot the testimony of a technical expert. Indeed, Mr. Nixon operated in a similar capacity in the Bayer Schering Pharma AG v. Barr Labs. Inc., No. 05-cv-2308, 2008 US Dist. LEXIS 15917, at *139 (D.N.J. Mar. 3, 2008). As an attorney for 38 years, Mr. Nixon has prosecuted thousands of patents before the PTO and has testified as an expert witness in dozens of cases.

"The Federal Rules of Evidence permit relevant opinion testimony by a qualified expert if the court deems it helpful to the factfinder." Mars Inc. v. Coin Acceptors, 1996 U.S. Dist. LEXIS 21514, at *2 (D.N.J. July 27, 1996). Fed. R. Evid. 702 provides the following:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

In civil cases, the court acknowledged, the rules even permit "expert opinion testimony 'that embraces an ultimate issue to be decided by the trier of fact." Id. at *3.[6]

In a recent bench trial, the Court determined "that expert testimony that extends beyond

[6]Notably, the court acknowledged that "there is some evidence that in patent cases courts relax the rule that expert witnesses cannot testify about the state of the law, or the application of law to a specific factual controversy." Id; see, Beckman Instruments, Inc. v. LKB Produkter AB, 892 F.2d 1547(Fed. Cir. 1989).

factual presentation and approximates will not help the Court, but will indeed hinder, as non-evidential testimony prolongs what is already anticipated to be a lengthy bench trial." Pfizer Inc. v. Teva Pharms. USA, Inc., 2006 U.S. Dist. LEXIS 77966, at *6 (D.N.J. Oct. 26, 2006), aff'd in part, rev'd in part on other grounds, 518 F.3d 1353 (Fed. Cir. 2008). "Indeed, the Court of Appeals for the Third Circuit has explicitly held that 'it is not permissible for a witness to testify as to the governing law,' United States v. Leo, 941 F.2d 181, 196 (3d Cir. 1991), or as to legal conclusions." Id. In that case, an expert, registered as a patent attorney with nearly forty years of experience in the field of patent law, was permitted to testify concerning patent practices and procedures, "factual information regarding the prosecution history of the applications that issued as the patents-in-suit" and his opinion regarding unexpected results. Id. at *7-8.

Pursuant to Fed. R. Evid. 703, this Court concludes that "the facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert," and concludes, therefore, the personal knowledge requirement imposed by Plaintiffs is misplaced. Mr. Nixon will be permitted to testify with respect to the PTO practices and procedures. Additionally, while Mr. Nixon will be permitted to testify with respect to the underlying facts regarding the prosecution of the '445 and '937 patent applications, his testimony will not be permitted to address the mental states of the patentees. Mr. Nixon will not be precluded from testifying as to the existence of the duties of good faith and candor or the underlying criteria comprising the measure for compliance with these duties. However, Mr. Nixon is not permitted to draw inferences from the underlying facts or opine with respect to the intent of such parties in presenting these applications. In that regard, Mr. Nixon will not be permitted to express an opinion concerning whether the absence of material alleged to exist as part of the prior art constitutes

inequitable conduct. Plaintiffs' motion *in limine* No. 6 is **granted** and Plaintiffs' motion *in limine* No. 7 is **denied**.

Motion in Limine Number 8

Pursuant to Federal Rules of Evidence 402, 403, 404 and 802, Plaintiffs move to preclude evidence of prior and/or collateral litigation, specifically a lawsuit between "Beecham and the University of Amsterdam ("UA")" and between "Burroughs Wellcome ("BW") and Beecham." Plaintiffs contend that these other suits are irrelevant and inadmissible as prior "bad acts," the admission of which would cause undue delay and serve only to confuse the jury. Defendants contend that the prior and/or collateral litigations are relevant to establishing that Plaintiffs copied the lead compound utilized in famciclovir.

This Court concludes that the prior and/or collateral litigations are likely to result in unfair prejudice, confusion and undue delay will result. Therefore, evidence concerning these prior and/or collateral litigation matters is precluded. Plaintiffs' motion *in limine* No. 8 is **granted**

Motion in limine No. 9

Pursuant to Fed. R. Evid. 402 and 403, Plaintiffs contend that the testimony of Keith B. Leffler, Ph.D., ("Dr. Leffler") should be limited because in attempting to rebut the alleged commercial success of Famvir®, the expert impermissibly injects a profitability requirement into the standard defining commercial success. Plaintiffs' seek to exclude Dr. Leffler's testimony that profit is reflective of commercial success. Defendant seeks to produce as evidence countering commercial success Dr. Leffler's testimony that the profits of Famvir® do not exceed the cost of the drug development.

"Commercial success is 'usually shown by significant sales in a relevant market.'" Daiichi Sankyo Co. v. Mylan Pharms., 2009 U.S. Dist. LEXIS 67978, at *63-64 (D.N.J. July 30, 2009) (quoting Ecolochem, Inc. v. Southern Cal. Edison Co., 227 F.3d 1361, 1377 (Fed. Cir. 2000) ("We have further held that a presumption arises 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.'"). "However, evidence showing sale of a large number of goods supposedly embodying the claimed invention does not necessarily demonstrate non-obviousness." Daiichi, 2009 U.S. Dist. LEXIS at *64. "The success must be due to the claimed features of the invention, rather than factors such as advertising, superior workmanship, or other features within the commercialized technology." Id. Upon a showing of a nexus between commercial success and the patented invention, the burden shifts to the Defendant to demonstrate that commercial success is the product of "other factors extraneous to the patented invention." Ecolochem, 227 F.3d at 1377. At least one court in the District of New Jersey is willing to entertain an argument that profit is relevant to commercial success. Daiichi, 2009 U.S. Dist. LEXIS at *69 ("Finally, Mylan contends that olmesartan medoxomil cannot be considered a commercial success because Daiichi Sankyo did not earn a profit from the sale of Benicar products"). "So long as the expert's testimony rests upon 'good grounds', it should be tested by the adversary process -- competing expert testimony and active cross-examination -- rather than excluded from juror's scrutiny for fear that they will not grasp its complexities or [satisfactorily] weigh its inadequacies." In re TMI Litig., 193 F.3d 613, 692 (3d Cir. 1999).

Evidence concerning profits is not irrelevant. Although profits may not traditionally be

considered reflective of commercial success, the weight of expert testimony to that effect is a matter for the jury. Plaintiffs' motion *in limine* No. 9 is **denied**.

Motion in limine No. 10

Plaintiffs move to preclude all evidence and references concerning allegedly inappropriate promotional activities for Famvir®. Specifically, Plaintiffs move to exclude letters by the FDA, Division of Drug Marketing Advertising and Communication ("DDMAC") and correspondence between SKB and Pharmaceutical Advertising Advisory Board ("PAAB"), an agency of the Canadian government that oversees advertisements, that Plaintiff contends was received more than ten years ago suggesting that SKB sales representatives may have employed aggressive and/or inappropriate tactics. Plaintiffs contend that the correspondence is irrelevant, that the prejudicial effect outweighs the probative value and the documents constitute inadmissible hearsay. Further, Plaintiffs allege that the letters concern draft promotional materials never released to the public. Defendant argues that the letters are relevant to commercial success and evidence thereof is admissible under the public records as an exception to the hearsay rule. In particular, Defendant contends that whether Novartis is marketing its product based on overstated or misleading claims is directly relevant to the question of nexus and that if commercial success is the product of marketing, then such a nexus is entirely absent.

Fed. R. Evid. 803(8) defines the "public records and reports" which are not excludable, as follows:

> Records, reports, statements, or data compilations, in any form, of public offices or agencies, setting forth (A) the activities of the office or agency, or (B) matters observed pursuant to duty imposed by law as to which matters there was a duty to report, . . . or (C) in civil actions and proceedings and against the Government in criminal cases, factual findings resulting from an investigation made pursuant to

> authority granted by law, unless the sources of information or other circumstances indicate lack of trustworthiness.

Beech Aircraft Corp. v. Rainey, 488 U.S. 153, 161 (1988). "Rule 803(8)(c) plainly includes findings in investigatory proceedings, accusatory or otherwise [where] [t]here is nothing in the record casting any doubt upon the thoroughness of the investigation." In re Japanese Elec. Prods. Antitrust Litig., 723 F.2d 238, 273 (3d Cir. 1983), rev'd on other grounds, 475 U.S. 574 (1986).

The FDA is a regulatory agency. The DDMAC conducts surveillance of marketing and advertisements and in the course of surveillance, appears to extend letters memorializing the findings and conclusions of the individual regulatory review officers monitoring the case. Indeed, contrary to Plaintiffs assertion that these letters are not final, at least with respect to the letter, either received on or dated, June 12, 1996, extended to SKB by Russell Fleicher, a Regulatory Review Officer for DDMAC, conclusions and findings are advanced with respect to promotional activities for the marketing of Famvir®. Therefore, such records will not be excluded as inadmissible hearsay.

Contrary to Plaintiffs' assertion that there has been no public dissemination of the promotional measures called into question by the DDMAC, it appears that the alleged false and misleading representations were promulgated at an American Academy of Physician Assistant conference in New York as underscored in the foregoing letter by Mr. Fleicher. Therefore, Plaintiffs' motion *in limine* No. 10 is **denied**.

Motion in limine No. 11

Plaintiffs move to preclude all evidence and references concerning allegations that SKB or Plaintiffs improperly delayed the release of clinical data on Famvir® to Anna Wald, M.D. One article in particular, authored by Dr. Wald and published in September, 2006, comparing vacyclovir (brand

name Valtrex®) with famciclovir and concluding that vacyclovir performs better than famciclovir, is sought to be excluded. The other articles identified as DXT 50 and DXT 59, a 2006 newspaper article and 2006 editorial claiming that the release of data to Dr. Wald was improperly delayed, although referenced, are not identified by title and are not discussed in detail. Defendant contends that the article by Dr. Wald directly rebuts Plaintiffs' argument that famciclovir resulted in unexpected advantages over vacyclovir and acyclovir. Further, even if the articles are excluded as inadmissible hearsay, nonetheless, the expert testimony of Dr. Broom in reliance on and pertaining to such articles is admissible.

In terms of the newspaper article and editorial (DTX 59 and 60) alleging that the release of clinical data to Dr. Wald was impermissibly delayed, the Court concludes that such accusations are irrelevant and the prejudicial effect outweighs the probative value of the material. Therefore, with respect to these articles, Plaintiffs' motion is granted.

Insofar as the Wald article is being offered to prove the truth of the matter asserted, namely, that vacyclovir is better than famciclovir, such evidence is inadmissible. However, assuming, without concluding, that Plaintiffs advance an argument to the effect that a surprising and unexpected result of famciclovir is its superiority over vacyclovir, introduction of the evidence for the purpose of impeachment under those circumstances is permissible.

Further, "Rule 703, which provides that expert opinions based on otherwise inadmissible hearsay are to be admitted only if the facts or data relied upon are of a type reasonably relied upon by experts in the particular field in forming opinions." In re TMI Litig., 193 F.3d 613, 664 (3d Cir. 1999). So long as articles documenting scientific studies are reasonably relied upon by experts in the field, an expert is permitted to opine with respect to otherwise inadmissible hearsay. Therefore,

Plaintiffs' motion *in limine* No. 11 is **granted in part** and **denied in part**.

B. Defendant's Motions *in Limine*

Motion in limine No. 1

Pursuant to Fed. R. Evid. 403, Defendant moves to exclude the evidence or argument regarding the alleged "failure of others" to synthesize famciclovir occurring after April 23, 1985, the agreed upon priority date for the '937 patent claim addressing the compound famciclovir, as irrelevant, prejudicial and confusing to the jury. In particular, Defendant seeks to exclude references to Dr. Smee's deposition testimony and arguments suggesting that Dr. Smee admitted that Syntex sought to develop prodrugs of penciclovir. In opposition, Plaintiffs contend that the evidence to be presented consists of printed publications including, patents, patent applications, notebooks produced by third parties, scientific articles and the testimony of Dr. Smee, a former Syntax employee.

"The obviousness inquiry [ ] correctly include[s] review of the evidence offered on the objective indicia of nonobviousness, [ ], [including] the failure of others to develop the claimed invention." Symbol Technologies, Inc. v. Opticon, Inc., 935 F.2d 1569, 1579 (Fed. Cir. 1991) (internal citations omitted). "Nonobviousness is suggested by the failure of others to 'find a solution to the problem which the patent[s] in question purport[] to solve[;] [s]uch evidence shows indirectly the presence of a significant defect [in the prior art], while serving as a simulated laboratory test of the obviousness of the solution to a skilled artisan.'" Id. Scientific literature may be a source utilized to evidence the secondary consideration of the failure of others. See Eli Lilly & Co. v. Zenith Goldline Pharms., 364 F. Supp. 2d 820, 832 (S.D. Ind. 2005).

This Court concludes that to the extent Plaintiffs seek to introduce the deposition testimony of Dr. Smee, as memorialized in deposition pages 126-129, such testimony is excluded. Dr. Smee

clearly indicates that he has no knowledge as to Dr. Martin's thought process, never discussed the material contained in the notebook in question with Dr. Martin and when pressed, did offer a qualified answer on the basis of speculation. However, to the extent that Plaintiffs can present evidence in the form of failed patents, patent applications, notebooks by third parties and/or scientific articles evidencing a failure to obtain the solution that the patent in question solves, it is admissible. Therefore, Defendant's motion *in limine* No. 1 is **granted in part** and **denied in part**.

Motion in limine No. 2

Pursuant to Fed. R. Evid. 402 and 403, Defendant moves to preclude evidence and argument relating to the alleged toxicity of 6-deoxy acyclovir discovered after the priority date of the '937 patent, April 23, 1985. Defendant contends that the drug company, Burroughs Wellcome, published data and articles concerning this compound in 1984, describing acyclovir as a "non-toxic" prodrug "well-tolerated" by patients, and that the toxicity concerns did not even come to light until 1992. Further, given that the drug Purifoy and similar references concerning the alleged toxicity of 6-deoxy acyclovir arose after the alleged priority date, they cannot constitute prior art. Plaintiffs contend that the later evidence concerning toxicity demonstrates the unpredictability in the prior art and therefore, is admissible. Further, Plaintiffs assert their claim of unpredictability in the art evidences a "failure of others" to discover the claimed invention. In Church & Dwight Co. v. Abbott Labs., the court recognizes that "the real meaning of 'prior art' in legal theory - it is knowledge that is available, including what would be obvious from it, at a given time, to a person of ordinary skill in the art." 545 F. Supp. 2d 447, 452 (D.N.J. 2008) (citing Kimberly-Clark Corp. v. Johnson & Johnson, 745 F.2d 1437, 1453 (Fed. Cir. 1984). "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference,

or would be led in a direction divergent from the path that was taken by the applicant." In re Gurley, 27 F.3d 551, 553 (Fed. Cir. 1994). "The degree of teaching away will of course depend on the particular facts; in general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." Id. A reference qualifies as prior art if it is published before the priority date. See 35 U.S.C. § 103.

"[T]he Supreme Court stated that when an obvious modification 'leads to the anticipated success,' the invention is likely the product of ordinary skill and is obvious." Daiichi, 2009 U.S. Dist, at *54 (quoting KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 402 (2007)). "[O]bviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonable probability of success." Id. (quoting Pfizer, 480 F.3d at 1364). "In determining whether the subject matter of a patent claim is obvious, [ ], subject matter can be proved obvious by noting that there existed at the time of the invention a known problem for which there was an obvious solution encompassed by the patent's claims." Id. at 419-20.

Defendant correctly asserts that obviousness is measured as of the priority date of the invention. Therefore, prior art references as well as evidence of unpredictability must pre-date the priority date of the invention. Plaintiffs are misguided in asserting that the previously undiscovered toxicity consequences support a failure of others to discover the drug or evidence of unpredictability of the prior art at the time of the priority date of the patented invention. Toxicity in fact was not recognized as a problem to be solved at the time. Therefore, in terms of unpredictability and prior art, Defendant's motion *in limine* No. 2 is **granted**.

Motion in limine No. 3

Pursuant to Fed. R. Evid. 402 and. 403, Defendant moves to preclude evidence regarding statistics of the alleged difficulties in obtaining FDA approval for a pharmaceutical drug on the basis of irrelevance and the likelihood of confusion and unfair prejudice of the jury. Plaintiffs contend that in seeking to exclude paragraphs 108-124 of Plaintiffs contested facts, Defendant not only incorrectly seeks to preclude evidence concerning FDA statistics, but also seeks to preclude evidence concerning the following: "(1) how pharmaceutical companies typically identify lead compounds; (2) how, after a lead compound is selected drugs are designed; (3) how drugs are tested and subjected to clinical trials; and (4) how drugs obtain the FDA's approval." Neither the common practice of pharmaceutical companies nor the procedure necessary for FDA approval can be considered irrelevant to the factual underpinnings required to demonstrate obviousness or non-obviousness. Such evidence is likely to aid the jury concerning the relevant issues and, therefore, is not precluded. Accordingly, Defendant's motion *in limine* No. 3 is **denied**.

Motion in limine No. 4

Pursuant to Federal Rules of Evidence 401, 402 and 403, Defendant moves to preclude the alleged "dosing advantage" of famciclovir over other pharmaceutical drugs, such as acyclovir and vacyclovir. Plaintiffs contend that Defendant's argument to preclude a claim of unexpected "dosing advantages" is misguided and that the Court should entertain such an argument in that findings of fact and conclusions of law made during the preliminary injunction phase are not binding during a trial on the merits. To be clear, although a court is permitted during a trial on the merits to depart from an earlier finding at the preliminary injunction phase, a court is by no means required to discard earlier findings of fact and conclusions of law. See Univ. of Tex, 451 U.S. at 395. At the preliminary

injunction phase of this matter, this Court found the Novartis studies pertaining to dosing advantage unpersuasive "because it does not do a head-to-head comparison of the various treatments" and further, such advantage "flows from the inherent properties of penciclovir," rather than modifications made to famciclovir. Novartis Pharms. Corp. v. Teva Pharms. USA, Inc., 2007 U.S. Dist. LEXIS 65792, at * 25 (D.N.J. Sept. 6, 2007). Plaintiffs are correct in asserting that, when present, secondary considerations must be considered in determining obviousness. Ruiz v. A.B. Chance Co., 234 F.3d 654, 667 (Fed. Cir. 2000). However, in the instant matter, this Court has previously determined that a dosing advantage has not been established through the studies presented before this Court. Therefore, in the interest of avoiding confusion to the jury, to the extent that Plaintiffs seek to introduce evidence supporting a dosing advantage through studies this Court has previously found unavailing, such studies, in isolation, are precluded. However, to the extent that Plaintiffs can establish a dosing advantage by means other than, or in combination with these studies in isolation, such evidence is not precluded. Therefore, Defendant's motion to preclude Plaintiffs from introducing evidence with respect to the dosing advantage of famciclovir is **granted in part** and **denied in part**.

Motion in limine No. 5

Defendant requests that the Court preclude the admission of evidence concerning Defendant's stipulation of infringement premised on a finding of patent validity.[7] In support of this argument, Defendant contends the stipulation of infringement is neither relevant to the issue of obviousness nor

[7]"For purposes of this litigation only, Teva stipulates that its Famciclovir Tablets would infringe the Asserted Claims of the '937 patent, if there is a final judgment that these claims are valid and enforceable." (Stipulation).

to the issue of enforceability. Further, Defendant contends that admission of the stipulation evidence is prejudicial in that it will mislead and confuse the jury. Lastly, Defendant suggests that contrary to its efforts to act in good faith, the admission into evidence of the stipulation permits the Plaintiffs to impute Defendant with the label of a "bad actor" despite the fact that Defendant is merely acting in compliance with the Hatch-Waxman Act. Plaintiffs contend that Defendant's stipulation of infringement is relevant and, therefore, admissible. Plaintiffs argue that admission of the stipulation of infringement and copying are necessarily dependent upon one another.

Plaintiffs are misguided. The secondary consideration of copying may be proven even in the absence of a stipulation of infringement. Therefore, the Court finds Plaintiffs contention that the admission of one automatically requires the admission of the other unavailing. The issue of copying will be discussed below as it is asserted pursuant to a separate motion *in limine*.

"The Committee Notes to Rule 401 explicitly say that a party's concession is pertinent to the court's discretion to exclude evidence on the point conceded." Old Chief, 519 U.S. at 184. "Such a concession, according to the Notes, will sometimes 'call for the exclusion of evidence offered to prove [the] point conceded by the opponent ….'" Id. (citing Advisory Committee's Notes on Fed. Rule Evid. 401, 28 U.S.C. App., p. 859). Although the stipulation of infringement may be relevant, the probative value of the admission of such evidence is substantially outweighed by the prejudicial effect that it will have on the jury impaneled for this matter. The admission of such evidence will only serve to mislead and confuse the jury; and, therefore, Defendant's motion *in limine* No. 5 to preclude the introduction of the stipulation of infringement is **granted**.

Motion in limine No. 6

Defendant seeks to preclude evidence concerning the issue of standing in this matter, asserting

that standing is a matter of law to be decided by the Court. DBB Techs. L.L.C. v. MLB Advanced Media, L.P., 517 F.3d 1284, 1291-92 (Fed. Cir. 2008). Further, in the event that the Court decides to conduct a preliminary hearing regarding the issue of standing, Defendant claims pursuant to Fed. R. Civ. P. 37(c)(1) that the testimony of three witnesses, Ms. Watson, Mr. Wipfli and Mr. Dembiec, should be excluded by reason of Plaintiffs' failure to identify these witnesses in discovery as required by Fed. R. Civ. P. 26(a)(1). Plaintiffs' contend that the Court instruction that the issue of standing will be resolved by the trier of fact in this matter renders Defendant's desire to preclude certain witnesses and to preclude admission of this issue to the jury is moot. Plaintiffs also are willing to dispose of this issue following the trial on the merits.

To be clear, either a judge or a jury may serve as trier of fact. See Johnson v. Tennis, 549 F.3d 296, 299 (3d Cir. 2009). Pursuant to this Court's letter, dated November 4, 2009, the Court will serve as the trier of fact for purposes of resolving the standing issue as a threshold matter. See Miller v. Rite Aid Corp., 334 F.3d 335, 341, n.2 (3d Cir. 2003); Steel Co. V. Cotozens for a Better Env't, 523 U.S. 83, 94-95 (1998). Defendant raised the issue of standing in a formal motion to dismiss two of the named Plaintiffs, NPC and NPAG on August 10, 2009. Thereafter, Defendant raised an objection at the pre-trial hearing to three foregoing witnesses listed as irrelevant to an issue which must be resolved as a matter of law. However, in this Court's October 21, 2009 opinion, the Court concluded that underlying material facts are in dispute and will be resolved before the trier of fact. Defendant now asserts that Plaintiffs' failure to produce these witnesses in accordance with Fed. R. Civ. P. 26 renders their testimony inadmissible.

However, the underlying issue concerns the existence of oral implied exclusive licenses. At this time, in the absence of direct documentary evidence, it appears that the only way to establish the

existence or non-existence of the alleged oral implied exclusive licenses is through testimony. Given the Defendant's request for expedient resolution of this matter and the necessity of testimonial witnesses, a preliminary evidentiary hearing will be conducted intermittent to the conclusion of the Plaintiffs' introductory evidence and the commencement of the Defendant's case-in-chief. The foregoing witnesses will not be excluded because the probative value of such testimony outweighs the prejudicial effect under these circumstances. Further, Defendant will have the opportunity to cure any perceived prejudice through cross-examination. Therefore, Defendant's motion *in limine* No. 6 is **granted in part** and **denied in part**.

Motion in limine No. 7

Pursuant to Fed. R. Civ. P. 26(a), (e) and Fed. R. Civ. P. 37(c)(1), Defendant moves to preclude Plaintiffs from introducing evidence concerning alleged commercial success of Famvir®. Defendant's motion seeks to exclude evidence of actual or projected sales or market share after 2006. Defendant alleges Plaintiffs made an affirmative representation up to and until their pre-trial submissions, including the deposition of Suzanne C. Lemieux ("Ms. Lemieux"), a Novartis corporate representative, interrogatories identifying annual sales exceeding 150 million dollars from the period of 2002 to 2005 and the alleged absence of expert reports concerning commercial success following 2006. As of the conclusion of 2006, Plaintiffs contend that the market sales of Famvir® were directly affected by the launch of Defendant's generic famciclovir and as a consequence, Plaintiffs do not intend to rely on any actual sales following the conclusion of 2006, but will put forth evidence demonstrating projected sales following 2006.

Indeed, the interjection of Plaintiffs' attorney restricts the scope of Ms. Lemieux's testimony to the end of 2006, although it appeared she understood her testimonial obligation to cover the period

of time from the moment of launch to the present. The attorney's commentary reads as follows: "[t]he facts upon which Novartis relies for commercial success are essentially set forth in the expert report -- the expert reports. And those speak of the end of 2006. So that - that's the scope." The interrogatories underscore a period of successful sales, but do not explicitly limit the scope of commercial success to the period identified. Further, Plaintiffs indicate that they do not seek to introduce evidence of actual commercial sales following 2006, but rather the projected commercial sales for that period. Additionally, the expert report of Daniel C. Smith, Ph.D. ("Dr. Smith") forecasts expected sales from the period of 2007 through 2011. In the collective, the Court does not interpret the Plaintiffs conduct as precluding a presentation of evidence concerning projected sales or necessarily limiting commercial success evidence to a defined period before the conclusion of 2006. However, in accordance with Plaintiffs representation in this motion limiting evidence concerning actual sales to the period prior to, and including the year of 2006, Plaintiffs will not be permitted to present evidence inconsistent therewith. To the extent Defendant's motion speaks to projected commercial sales, Defendant's motion *in limine* No. 7 is **denied**.

Motion in limine No. 8

Pursuant to Fed. R. Civ. P. 26(a), (e) and Fed. R. Civ. P. 37(c)(1), Defendant moves to preclude evidence concerning the alleged "unexpected advantage" that famciclovir treats post-herpetic neuralgia ("PHN") on the basis that Plaintiffs failed to disclose, either in its contention interrogatories or expert reports, that it intended to assert such a claim. Further, Defendant contends such evidence is irrelevant and its admission constitutes unfair prejudice. Specifically, Defendant contends that the only unexpected advantages identified by Plaintiffs in response to contention interrogatories include bioavailability, lower toxicity, dosing advantages and treatment of latent herpes infections. Further,

Defendant claims that Plaintiffs incorporation by reference of the Expert Rebuttal Report of Paul Bartlett and the Preliminary Injunction Declarations of Paul Bartlett and Richard Jarvest is insufficient to place Defendant on notice of the claimed unexpected PHN advantage of Famvir®.

Plaintiffs contend that Defendant was on notice by virtue of the incorporation by reference of the Famvir® label in response to the interrogatory request regarding secondary considerations of the drug. Alternatively, Plaintiffs assert that the expert report advanced by Dr. Smith clearly identifies the advantage of Famvir® in reducing the effect and duration of PHN.

Defendant is correct in asserting that the purpose of contention interrogatories is to "narrow and define the issues for trial beyond what may be ascertained from the parties'" thus, avoiding "surprise and undue prejudice." Daiichi, 2005 U.S. Dist. LEXIS 26059, at *12. Fed. R. Civ. P. 26(a)(2)(A) requires disclosure of expert witnesses accompanied by an report containing "a complete statement of all the opinions the witness will express and the basis and reasons for them." Sanofi-Aventis v. Barr Labs., 598 F. Supp. 2d 632, 635 (D.N.J. 2009) (citing Fed. R. Civ. P. 26(a)(2)(B)(I)). "The reason for requiring expert reports is the "elimination of unfair surprise to the opposing party and the conservation of resources." Id. (citing Reed v. Binder, 165 F.R.D. 424, 429 (D.N.J. 1996). Given the recitation of PHN benefits in Dr. Smith's expert report, the Court concludes Defendant was on notice that Plaintiffs were likely to raise an argument concerning the unexpected advantage of Famvir® with regard to PHN. Therefore, Defendant's motion *in limine* No. 8 is **denied**.

Motion in limine No. 9

Defendant moves to preclude the introduction of evidence concerning the United States Patent No.4,942,166 (''166 patent") as untimely and prejudicial. Defendant argues that the '166 patent, an

8-page document, should be excluded because Plaintiffs never submitted information with regard to this patent in response to an interrogatory No. 19 requesting information as to why certain prior art references were not disclosed to the PTO. Defendant contends that the first time Plaintiffs disclosed their intention to rely on the '166 patent in support of their good faith defense was upon submission of trial exhibits on August 31, 2009.

Plaintiffs contend that Defendant was on notice of its "good faith" defense to the issue of inequitable conduct and further that a copy of the '166 patent was produced to Defendant during discovery. Additionally, Plaintiffs contend that interrogatory No. 19 merely required Plaintiffs to disclose why the particular references cited in that question were not disclosed to the PTO. Even if there is a Rule 26 violation, evidence is not subject to exclusion under Rule 37(c)(1) if there is substantial justification for the violation or if the violation is harmless. ABB Air Preheater, Inc. v. Regenerative Envtl. Equip. Co., 167 F.R.D. 668, 671 (D.N.J. 1996). Exclusion pursuant to the Fed. R. Civ. P. 37(c)(1) is governed by several factors, including: (1) the prejudice to the opposing party; (2) the ability of the party to cure the prejudice; (3) the extent to which permitting the use of the evidence would disrupt the orderly and efficient trial of the case, and (4) bad faith or willfulness. Meyers v. Pennypack Woods Home Ownership Ass'n, 559 F.2d 894, 904-04 (3d Cir. 1977).

Given that Defendant was on notice of Plaintiffs intent to assert a "good faith" defense in response to allegations of inequitable conduct and in doing so, intended to present evidence of other patents before the PTO, the admission of an 8-page public document appears harmless in this instance. Any prejudice that may arise from an unrelated patent serving as evidence of good faith can be cured by cross-examination. Trial will not be disrupted by admission of the '166 patent. In disclosing this patent as a trial exhibit, and in previously producing it for Defendant's inspection in

discovery, if Plaintiffs did so, does not evidence bad faith or willfulness. Accordingly, Defendant's motion *in limine* No. 9 is **denied**.

Motion in limine No. 10

Defendant moves to preclude argument and evidence that penciclovir was not the single best, only or clear lead compound as irrelevant, prejudicial and likely to result in jury confusion. Citing KSR, Defendant claims that Plaintiffs recognition of penciclovir as one of 25 acyclic nucleosides shown to have antiviral activity demonstrates that penciclovir was not the best, only or clear choice as lead compound in the prior art is not relevant and should be excluded. KSR recognized the following:

> Where there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

550 U.S. at 421. Plaintiffs contend that the burden lies with Defendant to establish that a person of ordinary skill in the art would have been motivated to choose penciclovir as a lead compound. See Proctor & Gamble, 556 F.3d at 994.

The Court concludes that the finite number of acyclic nucleosides in the prior art does not preclude evidence suggesting that penciclovir was not the optimal lead compound. Indeed, whether penciclovir is the best, only or clear lead compound appears to fall under the purview of the factual inquiry concerning the scope and content of the prior art to be presented before the jury in this matter. Id. Therefore, Defendant's motion *in limine* No. 10 is **denied**.

Motion in limine No. 11

Defendant moves before this Court to preclude evidence of copying by Defendant as irrelevant and prejudicial pursuant to the Hatch-Waxman Act. Plaintiffs contend that Defendant's motion "invites this Court to commit reversible error." Plaintiffs assert that both the Federal Circuit and the United States District Courts for the District of New Jersey routinely consider evidence of copying. See Ortho-McNeil Pharm, Inc. v. Mylan Labs., Inc., 520 F.3d 1358, 1365 (Fed. Cir. 2008); Daiichi, 2009 U.S. Dist. LEXIS 67978 (D.N.J. July 30, 2009).

"The Hatch-Waxman Act strikes a balance between the sometimes-competing policy interests of inducing pioneering research and development of new drugs and enabling production of low-cost, generic copies of those drugs." Eli Lilly & Co. v. Teva Pharms. United States, Inc., 557 F.3d 1346, 1348 (Fed. Cir. 2009). With the advent of the Hatch-Waxman Act, the copying rationale in the context of an ANDA application has been recognized as weak, but not irrelevant. Pfizer Inc. v. Teva, 2006 U.S. Dist. LEXIS 77967, at *5 (D.N.J. Oct. 26, 2006). In the foregoing case, the court recognized that "more than the mere fact of copying by an accused infringer is needed to make that action significant to a determination of the obviousness issue." Id. (quoting Cable Electric Prods. Inc v. Genmark, Inc., 770 F.2d 1015, 1028 (Fed. Cir. 1985)). However, in admitting the evidence of copying pursuant to a *motion in limine*, the court acknowledged that "the fact that this case arises under the Hatch-Waxman Act does not render the evidence entirely irrelevant." Id. Therefore, evidence of copying will not be excluded as irrelevant.

Inherent in the Hatch-Waxman Act is an element of copying. 21 U.S.C. § 355(j). The new drug must be the bioequivalent of the listed drug. Id. This Court does not recognize an outcome determinative stipulation of infringement as synonymous with allegations of copying that arise

pursuant to the filing of an ANDA. The filing of an ANDA is considered an act of artificial infringement for purposes of conferring jurisdiction upon the court. In the event that Defendant had filed an ANDA without stipulating to infringement, it would be necessary to address liability on the question of infringement as well. Here, upon a determination of non-obviousness, the Defendant has stipulated to infringement. Therefore, while evidence of copying is not precluded, the parties are reminded that the stipulation of infringement is prohibited. Moreover, the prejudicial effect of the introduction into evidence of a stipulation of infringement is clearly distinguishable from any prejudicial effect that may arise as a consequence of allegations of copying. Accordingly, Defendant's motion *in limine* No. 11 is **denied**.

Motion in limine No. 12

Defendant seeks to preclude evidence concerning the experimentation by Beecham with compounds other than famciclovir or penciclovir as irrelevant to the issue of obviousness and prejudicial and likely to confuse the jury. Defendant claims that whether the invention is the product of toil, experimentation or a flash of genius is not relevant to the obviousness inquiry. Graham, 383 U.S. at 17 n.8. Defendant does not seek to exclude evidence regarding efforts by inventors to solve the problem to which the '937 patent is directed. Plaintiffs contend that an inventor's own unsuccessful attempts to arrive at the claimed invention are relevant to the question of obviousness.

In Pfizer Inc. v. Teva Pharms. USA, Inc., the court determined reliance on a similar proposition, in seeking to exclude evidence of the inventor's efforts to arrive at the invention, was misguided. 2006 U.S. Dist. LEXIS 74849, at *2 (D.N.J. Oct. 13, 2006). The court recognized that "35 U.S.C. 103(a) provides that '[p]atentability shall not be negatived by the manner in which the invention was made.'" Id. The court also indicated that prior to the enactment of that provision,

"courts often required applicants to establish that the invention was the result of a 'flash of genius.'" Therefore, the provision was enacted with the purpose of expanding the circumstances under which patents could be obtained. "It expands the realm of patentable inventions[;] [i]t does not render all information regarding the manner in which the invention was made irrelevant."

Therefore, this Court concludes that Plaintiffs are permitted to present evidence with respect to the efforts put forth by the inventors to arrive at the contemplated invention. The time and resources expended in attempting fruitlessly to arrive at the contemplated invention is not beyond the purview of the jury. Defendant's motion *in limine* No. 12 is **denied**.

IV. CONCLUSION

In accordance with the foregoing the Plaintiffs' motions *in limine* Nos. 2, 5, 6 and 8 are **granted**, Nos. 3, 4, 7, 9 and 10 are **denied** and Nos. 1 and 11 is **granted in part** and **denied in part**; and further, Defendant's motions *in limine* Nos. 2 and 5 are **granted**, Nos. 3, 7, 8, 9, 10, 11 and 12 are **denied**, and Nos. 1, 4 and 6 are **granted in part** and **denied in part**. An appropriate Order accompanies this Opinion.

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

Date: November 5, 2009

Orig.: Clerk
cc: Counsel of Record
The Honorable Mark Falk, U.S.M.J.
File