Abbott Labs. v. Sandoz, Inc.

United States District Court for the Northern District of Illinois, Eastern Division

May 24, 2010, Decided; May 24, 2010, Filed

No. 05 C 5373

Reporter
743 F. Supp. 2d 762 *; 2010 U.S. Dist. LEXIS 109114 **

ABBOTT LABORATORIES, ABBOTT LABORATORIES, INC., and ABBOTT PHARMACEUTICAULS PR LTD, Plaintiffs, v. SANDOZ, INC., Defendant.

Prior History: *Abbott Labs. v. Sandoz, Inc., 2010 U.S. Dist. LEXIS 46985 (N.D. Ill., May 12, 2010)*

Case Summary

Overview

Because a patent holder's expert in an infringement case specifically relied upon settlement agreements in calculating reasonable royalties, the defense could present the agreements in accordance with *Fed. R. Evid. 705* when discussing the basis for the expert's calculations; *Fed. R. Evid. 403*, *408* did not require exclusion of the agreements. Invalidity defenses that were not disclosed in supplemental responses as required by *Fed. R. Civ. P. 26(e)(2)* were subject to exclusion under *Fed. R. Civ. P. 37(c)(1)* to the extent that inadequate notice was prejudicial to the patent holder.

Outcome

The court granted some motions in limine and denied others.

LexisNexis® Headnotes

Evidence > Relevance > Exclusion of Relevant Evidence > Confusion, Prejudice & Waste of Time

Patent Law > ... > Damages > Patentholder Losses > Reasonable Royalties

Evidence > Admissibility > Statements as Evidence > Compromise & Settlement Negotiations

HN1 **Exclusion of Relevant Evidence, Confusion, Prejudice & Waste of Time**

Even though a patent holder's license agreements with third parties are permissible and relevant considerations in a reasonable royalty calculation, courts frequently exclude such agreements under *Fed. R. Evid. 408*. Evidence of settlement agreement royalties is generally excluded for two primary reasons. First, *Rule 408* aims to promote settlements, and accordingly, admitting these agreements could chill parties' willingness to engage in settlement negotiations. Second, because many considerations contribute to settlement agreements, such agreements are not very reliable guides for determining the value of a reasonable royalty. Admitting evidence of settlement agreements with third parties would invite a mini-trial on similarities and differences

in the facts regarding the same claims against other defendants to determine the value of the claim in the case at hand. In addition, given the marginal relevance of the settlement agreements, their probative value is outweighed by the danger of unfair prejudice under *Fed. R. Evid. 403*.

Evidence > Admissibility > Statements as Evidence > Compromise & Settlement Negotiations

Patent Law > ... > Damages > Patentholder Losses > Reasonable Royalties

Evidence > ... > Testimony > Expert Witnesses > General Overview

HN2 Statements as Evidence, Compromise & Settlement Negotiations

Despite the precedent supporting the exclusion of settlement agreements, where the plaintiff's expert has specifically relied upon settlement agreements in a reasonable royalty calculation in a patent infringement case, the defendant can present those agreements to rebut the expert's testimony. *Fed. R. Evid. 705* imposes upon the opposing party the onus of eliciting the bases of an expert witness' opinion on cross-examination. To the extent that the defendants can show that the plaintiff's expert relied in any way on the settlement agreements in question in reaching his conclusions about a reasonable royalty in such a case, the defendants are entitled to present those settlement agreements and to show in what way they form an appropriate or inappropriate basis for the plaintiff's expert's calculations. However, other authority holds that a court is not required to allow otherwise inadmissible settlement agreements into evidence simply because one party's expert relies on them in reaching a reasonable royalty. Based on the important policy considerations underlying *Fed. R. Evid. 408*, a court may opt to exclude the licenses altogether rather than admitting discussion of settlement negotiations.

Patent Law > ... > Defenses > Patent Invalidity > General Overview

HN3 Defenses, Patent Invalidity

Patent claims do not stand and fall together; rather the court considers invalidity on a claim-by-claim basis. *35 U.S.C.S. § 282*.

Civil Procedure > ... > Methods of Discovery > Interrogatories > General Overview

Patent Law > Nonobviousness > Elements & Tests > Prior Art

Civil Procedure > Discovery & Disclosure > Discovery > Misconduct During Discovery

HN4 Methods of Discovery, Interrogatories

The extreme sanction of exclusion is not warranted under *Fed. R. Civ. P. 37(c)* where the defendant's failure to include prior-art references in its interrogatory response was harmless because the plaintiff still had a full opportunity to inquire into the defendant's expert's opinion at his deposition.

Evidence > Relevance > Exclusion of Relevant Evidence > Confusion, Prejudice & Waste of Time

Patent Law > Nonobviousness > Elements & Tests > Ordinary Skill Standard

Evidence > Relevance > Relevant Evidence

HN5 Exclusion of Relevant Evidence, Confusion, Prejudice & Waste of Time

Evidence of a manufacturer's alleged anticompetitive strategy is not relevant to the issue of obviousness. Although courts may look to secondary considerations helpful to the obviousness inquiry, such considerations must be objective. Because the court's obviousness inquiry depends on the perspective of a person having ordinary skill in the art, a manufacturer's subjective motivations for developing a product are not relevant. The case law instructs courts to weigh secondary considerations such as market pressure; however, courts are to consider the market pressure, faced by an objective person of ordinary skill, to solve a particular problem. A manufacturer's subjective experience of the market pressure to extend the life of its patent does not fall within the secondary considerations contemplated. Even if such evidence is marginally relevant, because of its peripheral significance to the obviousness determination and potential to prejudice the jury against the manufacturer's, its probative value is substantially outweighed by the danger of unfair prejudice under *Fed. R. Evid. 403*.

Patent Law > ... > Defenses > Inequitable Conduct > General Overview

HN6 Defenses, Inequitable Conduct

Courts retain discretion to determine how inequitable conduct issues will be handled at trial.

Civil Procedure > Discovery & Disclosure > Disclosure > Mandatory Disclosures

Patent Law > ... > Defenses > Patent Invalidity > Notice

HN7 Disclosure, Mandatory Disclosures

The case law does not reveal a hard-and-fast rule requiring the exclusion of patent invalidity defenses that were not disclosed during discovery. Rather, courts consider whether to exclude such undisclosed defenses and arguments on a case-by-case basis, depending on whether the plaintiff would suffer prejudice if these defenses or arguments were introduced. Thus, the key question in resolving a motion in limine is whether the plaintiff had sufficient notice of the intended defenses such that it would not be prejudiced by their introduction at trial.

Civil Procedure > Discovery & Disclosure > Disclosure > Mandatory Disclosures

Patent Law > ... > Defenses > Patent Invalidity > Notice

Civil Procedure > ... > Methods of Discovery > Interrogatories > Purpose & Use of Interrogatories

HN8 Disclosure, Mandatory Disclosures

Courts have excluded undisclosed patent invalidity defenses after rejecting arguments that notice of the defense in expert reports compensated for the defendants' failure to disclose the defense by supplementing interrogatory responses as required by *Fed. R. Civ. P. 26(e)(2)*.

Civil Procedure > Judgments > Preclusion of Judgments > Law of the Case

HN9 **Preclusion of Judgments, Law of the Case**

Under the law of the case doctrine, a ruling by a trial court, in an earlier stage of the case, is binding on subsequent stages of the case.

Civil Procedure > Discovery & Disclosure > Discovery > Misconduct During Discovery

HN10 **Discovery, Misconduct During Discovery**

Courts have discretion—which they often exercise—to preclude parties from presenting arguments or evidence that they have not properly disclosed during the course of discovery. *Fed. R. Civ. P. 37(c)(1)*. However, there is no hard-and-fast rule requiring courts to exclude undisclosed arguments or evidence. Rather, courts decide whether to exclude such arguments or evidence on a case-by-case basis, depending on whether the plaintiff would suffer prejudice if these defenses or arguments were introduced.

Patent Law > ... > Defenses > Inequitable Conduct > Effect of Inequitable Conduct
Business & Corporate Compliance > ... > Defenses > Inequitable Conduct > Effect of Inequitable Conduct

HN11 **Inequitable Conduct, Effect of Inequitable Conduct**

Inequitable conduct associated with the prosecution of a later patent does not affect the enforceability of an earlier patent.

Civil Procedure > Pretrial Matters > Motions in Limine > General Overview

HN12 **Pretrial Matters, Motions in Limine**

A genuine factual dispute cannot be resolved through a motion in limine.

Evidence > Relevance > Exclusion of Relevant Evidence > Confusion, Prejudice & Waste of Time

Patent Law > Infringement Actions > General Overview

HN13 **Exclusion of Relevant Evidence, Confusion, Prejudice & Waste of Time**

Many courts have considered a generic drug's labeling, when derived from the brand-name product's, as evidence of the generic drug's characteristics. These courts have often done so over the generic producer's objection that it was simply required by law to duplicate the innovator's labeling.

Evidence > ... > Testimony > Expert Witnesses > General Overview

Evidence > Weight & Sufficiency

HN14 **Testimony, Expert Witnesses**

Counsel's help preparing an expert report is relevant to the weight of the expert's testimony. Similarly, counsel's potential impact on the substance of expert testimony is relevant to the weight and credibility of that testimony.

Evidence > Admissibility > Expert Witnesses > Daubert Standard

Evidence > Admissibility > Expert Witnesses

HN15 **Expert Witnesses, Daubert Standard**

Fed. R. Evid. 702 permits expert testimony if: (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case. *Rule 702* ensures that when expert witnesses testify in court, they adhere to the same standards of intellectual rigor that are demanded in their professional work. Expert witnesses need not perform hands-on testing to meet this objective; they may do so simply through the review of experimental, statistical, or other scientific data generated by others in the field.

Counsel: **[**1]** For Abbott Laboratories, Plaintiff: R. Mark McCareins, LEAD ATTORNEY, Winston & Strawn LLP, Chicago, IL; Andrea Weiss Jeffries, Munger, Tolles & Olson, Los Angeles, CA; Andrew Winston Song, Munger, Tolles & Olson LLP, Los Angeles, CA; Genevieve A. Cox, Jennifer L. Polse, Munger, Tolles & Olson LLP, San Francisco, CA; Jeffrey Ira Weinberger, Ted G Dane, Munger, Tolles & Olson, LLP, Los Angeles, CA; Michael Alan Flomenhoft, Todd Jay Ehlman, Winston & Strawn LLP, Chicago, IL.

For Abbott Laboratories, Inc., Abbott Pharmaceuticals PR Ltd., Plaintiffs: Michael Alan Flomenhoft, Winston & Strawn LLP, Chicago, IL.

For Sandoz, Inc., Defendant: Keith D. Parr, LEAD ATTORNEY, David B Abramowitz, James T Peterka, Kevin Michael Nelson, Myoka Kim Goodin, Scott B. Feder, Locke Lord Bissell & Liddell LLP, Chicago, IL; Alan B Clement, PRO HAC VICE, Locke Lord Bissell & Liddell, LLP, New York, NY.

For Sandoz, Inc., Counter Claimant: Keith D. Parr, Myoka Kim Goodin, LEAD ATTORNEYS, Locke Lord Bissell & Liddell LLP, Chicago, IL; Alan B Clement, PRO HAC VICE, Locke Lord Bissell & Liddell, LLP, New York, NY.

For Abbott Laboratories, Counter Defendant: Andrew Winston Song, Munger, Tolles & Olson LLP, Los Angeles, **[**2]** CA; Jennifer L. Polse, Munger, Tolles & Olson LLP, San Francisco, CA; Jeffrey Ira Weinberger, Ted G Dane, Munger, Tolles & Olson, LLP, Los Angeles, CA; Michael Alan Flomenhoft, Winston & Strawn LLP, Chicago, IL.

For Sandoz, Inc., Counter Claimant: Keith D. Parr, LEAD ATTORNEY, David B Abramowitz, James T Peterka, Kevin Michael Nelson, Myoka Kim Goodin, Scott B. Feder, Locke Lord Bissell & Liddell LLP, Chicago, IL; Alan B Clement, PRO HAC VICE, Locke Lord Bissell & Liddell, LLP, New York, NY.

For Abbott Laboratories, Inc., Abbott Pharmaceuticals PR Ltd., Counter Defendants: Michael Alan Flomenhoft, Winston & Strawn LLP, Chicago, IL.

For Abbott Laboratories, Counter Defendant: R. Mark McCareins, LEAD ATTORNEY, Winston & Strawn LLP, Chicago, IL; Andrea Weiss Jeffries, Munger, Tolles & Olson, Los Angeles, CA; Andrew Winston Song, Munger, Tolles & Olson LLP, Los Angeles, CA; Genevieve A. Cox, Jennifer L. Polse, Munger, Tolles & Olson LLP, San Francisco, CA; Jeffrey Ira Weinberger, Ted G Dane, Munger, Tolles & Olson, LLP, Los Angeles, CA; Michael Alan Flomenhoft, Todd Jay Ehlman, Winston & Strawn LLP, Chicago, IL.

Judges: David H. Coar, United States District Judge.

Opinion by: David H. Coar

Opinion

[*765] ORDER

Presently before **[**3]** this Court are motions *in limine* filed by Plaintiffs, Abbott Laboratories, Abbott Laboratories, Inc., and Abbott Pharmaceuticals PR LTD (collectively "Abbott" or "Plaintiff"), as well as motions *in limine* filed by Defendant, Sandoz, Inc. ("Sandoz" or "Defendant"). Subject to the explanations below, Plaintiff Abbott's motions *in limine* [478], [479], [483], and [484] are GRANTED, Plaintiff Abbott's motions *in limine* [477], [480], [482], [486], [492], are DENIED, and Plaintiff Abbott's motions *in limine* [481], [485], and [489] are DENIED IN PART and GRANTED IN PART. Defendant Sandoz's motions *in limine* [468], [473], and [474] are GRANTED, and Defendant Sandoz's motions *in limine* [469], [470], [471], [472], [475], and [476] are DENIED.

[*766] A. PLAINTIFF ABBOTT'S MOTIONS IN LIMINE

1. To preclude Sandoz from offering evidence or relying upon settlement agreement royalties. [Dkt. 492.]

Abbott entered into three settlement agreements (with Teva, Andrx, and Ranbaxy) involving the patents at issue in this case. As a term of these settlements, Abbott agreed to allow Teva, Andrx, and Ranbaxy to sell their generic versions of Biaxin XL on a royalty-free basis. Abbott argues that, under *Federal Rules of Evidence 402*, **[**4]** *403*, and *408*, the Court should prevent Sandoz from introducing the royalty rates to which Abbott agreed in those settlements. First, royalty rates from these settlements should be excluded under *Rule 408* to further the important policy of promoting settlements. Second, the royalty rates are irrelevant under *Rule 402*; because amounts paid in prior settlement agreements are based on many factors in addition to the value of use of a patented product, such amounts are not probative of the amount a patentee should be awarded following a finding of infringement. For the same reason, the potentially marginal relevance of this evidence is outweighed by the danger of unfair prejudice and potential to distract the jury under *Rule 403*. Finally, introducing this evidence would invite a mini-trial on the similarities or differences between the facts of this case and the cases against Andrx, Teva, or Ranbaxy, and Abbott's reasons for settling those cases. (Abbott argues, for example, that one key difference between the instant case and the settled cases is that Sandoz chose to launch its product at risk, decreasing the likelihood that Abbott would offer Sandoz the same exclusivity it offered Andrx, **[**5]** Teva, and Ranbaxy.)

In response, Sandoz argues that, because Abbott's damages expert put Abbott's settlement agreements in issue, Sandoz is entitled to rely upon those agreements to rebut the expert's testimony. During his deposition, Abbott's expert stated that he considered the zero-percent royalty rate agreements when he conducted the "book of wisdom" analysis underlying his reasonable royalty calculation. Sandoz argues that because *Federal Rule of Evidence 705* imposes upon the defendant the burden of showing on cross-examination the basis for the plaintiff's expert's testimony, Sandoz is entitled to use the settlement agreements at issue to rebut the expert's testimony. *Century Wrecker Corp. v. E.R. Buske Mfg. Co., No. C 95-4050, 898 F. Supp. 1334, 1995 U.S. Dist. LEXIS 14136 (N.D. Iowa Sept. 25, 1995)*. In addition, Sandoz argues that the settlement agreements are relevant evidence of Abbott's perceived value of the patents-in-suit, and there is no hard-and-fast rule that royalty

rates in settlement agreements may not be relied upon to determine a reasonable royalty rate in a patent infringement case.

On April 26, 2010, Sandoz submitted *ResQnet.co, Inc. v. Lasna, Inc., 594 F.3d 860, 2010 WL 396157 (Fed. Cir. 2010)*, **[**6]** as supplemental authority in further support of its opposition to this motion. In response, Abbott argues that this case is inapposite because it does not address the admissibility of licenses that are specifically part of settlement agreements. Abbott also submitted supplemental authority in support of its motion: *Insight Technology Inc. v. SureFire LLC, No. 04-CV-74-JD, 2009 U.S. Dist. LEXIS 97183, 2009 WL 3242554 (D.N.H. 2009)* (holding evidence of other settlement agreements inadmissible at trial to prove the value of a reasonable royalty); *Uniloc USA, Inc. v. Microsoft Corp., 632 F. Supp. 2d 147, 159 (D.R.I. 2009)* (excluding licenses entered into as part of settlements in other cases because they are not probative of a reasonable royalty and "whatever relevance the evidence could have as to reasonable royalty is substantially outweighed by the unfair prejudice . . . **[*767]** and juror confusion that would likely result from these collateral issues"); *Cornell Univ. v. Hewlett-Packard Co., No. 01-CV-1974, 2008 U.S. Dist. LEXIS 41833, 2008 WL 2223122, at *1 (N.D.N.Y. May 21, 2008)* (federal circuit judge sitting by designation excluded under *Rules 402* and *408* testimony on the amounts the patentee had offered to license a third party in settlement **[**7]** negotiations).

Abbott's motion will be DENIED. This determination would be easy if the question merely involved whether to admit evidence of license agreements contained in Abbott's settlements with Andrx, Teva, and Ranbaxy. It is clear that these license agreements would be inadmissible under *Fed. R. Evid. 408* and the wealth of cases excluding evidence of settlement agreements offered to establish reasonable royalty rates in the context of patent infringement. However, the fact that Abbott's expert relied on the license agreements at issue separates this case from the precedent and supports the admission of these agreements under *Century Wrecker Corp. v. E.R. Buske Mfg. Co., No. C 95-4050, 898 F. Supp. 1334, 1995 U.S. Dist. LEXIS 14136 (N.D. Iowa Sept. 25, 1995)*.

HN1 Even though a patent holder's license agreements with third parties are permissible and relevant considerations in a reasonable royalty calculation, courts frequently exclude such agreements under *Fed. R. Evid. 408*. *PharmaStem Therapeutics, Inc. v. Viacell, Inc. et. al., No. C.A. 02-148 (GMS), 2003 U.S. Dist. LEXIS 27869, at *6 (D. Del. Oct. 7, 2003)*; *Century Wrecker, 898 F.Supp. at 1340*. Evidence of settlement agreement royalties is generally **[**8]** excluded for two primary reasons. First, *Rule 408* aims to promote settlements, and accordingly, admitting these agreements could chill parties' willingness to engage in settlement negotiations. *Vardon Golf Co., Inc. v. BBMG Golf Ltd., 156 F.R.D. 641, 652 (N.D. Ill. 1994)*; *PharmaStem, 2003 U.S. Dist. LEXIS 27869, at *10*. Second, because many considerations contribute to settlement agreements, such agreements are not very reliable guides for determining the value of a reasonable royalty. *Uniloc USA, Inc. v. Microsoft Corp., 632 F. Supp. 2d 147, 159 (D.R.I. 2009)*; *Vardon Golf Co., 156 F.R.D. at 651*. Admitting evidence of settlement agreements with third parties would "invite a 'mini-trial' on similarities and differences in the facts regarding the 'same' claims against other defendants" to determine the value of the claim in the case at hand. *Pioneer Hi-Bred Intern., Inc. v. Ottawa Plant Food, Inc., 219 F.R.D. 135, 145 (N.D. Iowa 2003)*. In addition, given the marginal relevance of the settlement agreements, their probative value is outweighed by the danger of unfair prejudice under *Rule 403*. *Id. at 144-45*; *see*

also Uniloc USA, Inc., 632 F. Supp. 2d at 159.

Despite the plethora of cases **[**9]** and supplemental authority submitted by the parties, the two most relevant cases are Century Wrecker Corp. v. E.R. Buske Mfg. Co., No. C 95-4050, 898 F. Supp. 1334, 1995 U.S. Dist. LEXIS 14136 (N.D. Iowa Sept. 25, 1995) and PharmaStem Therapeutics, Inc. v. Viacell, Inc. et. al., No. C.A. 02-148 (GMS), 2003 U.S. Dist. LEXIS 27869 (D. Del. Oct. 7, 2003). These are the only two cases that deal with the admissibility of settlement agreements in patent infringement cases *when the defendant's expert has relied on such agreements in his reasonable royalty calculation.* **HN2** After noting the precedent supporting the exclusion of settlement agreements, the court in *Century Wrecker* held that, because the plaintiff's expert specifically relied upon settlement agreements in his reasonable royalty calculation, the defendant could present those agreements to rebut the expert's **[*768]** testimony. Century Wrecker, 898 F.Supp. at 1341. The court explained that "Federal Rule of Evidence 705 imposes upon the opposing party the onus of eliciting the bases of an expert witness' opinion on cross-examination" and went on to admit the evidence at issue, holding:

> To the extent that defendants can show [plaintiff's expert] relied in any way **[**10]** on the settlement agreements in question in reaching his conclusions about a reasonable royalty in this case, defendants are entitled to present those settlement agreements and to show in what way they form an appropriate or inappropriate basis for [plaintiff's expert's] calculations.

Id. Addressing essentially the same facts, the court in *PharmaStem* noted that it was not bound by *Century Wrecker* and held that it was "not required to allow otherwise inadmissible settlement agreements into evidence simply because one party's expert relies on them in reaching a reasonable royalty." PharmaStem, 2003 U.S. Dist. LEXIS 27869, at *9. Citing the important policy considerations underlying Rule 408, the court opted to exclude the licenses altogether rather than admitting discussion of settlement negotiations. Id. at *9-10.

This precedent presents the Court with two clear alternatives: (1) deny Abbott's motion under *Century Wrecker* or (2) grant Abbott's motion *and* preclude Abbott's expert from relying on the license agreements as part of his reasonable royalty calculation. As neither party suggests option (2), I will simply deny Abbott's motion under Century Wrecker.

2. To limit the use of deposition **[**11]** testimony. [Dkt. 483.]

a. Witnesses who are available and were not corporate designees or officers, directors, or managing agents of Abbott when deposed.

Abbott argues that, under Fed. R. Civ. P. 32, the Court should preclude Sandoz from offering the depositions of witnesses who are available to testify live and were not corporate officers, directors, managing agents, or 30(b)(6) designees of Abbott when deposed. Abbott contends that the Court should exclude the use of deposition testimony, for purposes other than impeachment, of the following witnesses:

- George Aynilian
- Karen Devcich
- Bernard Donner
- Ho-Wah Hui*
- James Lancaster
- Nelly Milman

• Gerard Notario

• Carol Olson

• Robert Palmer

• Nicholas Poulos

• Chetan Pujara

• Susan Semla*

• Victor Thomas*

Sandoz responds that it listed these witnesses as "[witnesses who will be called by deposition" instead of testifying live to promote the order and efficient operation of the trial. Sandoz hopes to reach an agreement with Abbott regarding its ability to call the above witnesses by deposition. However, if this is not possible, Sandoz requests leave to amend its witness list to include those individuals listed above as "witnesses who may be called" **[**12]** at trial. [1]

[*769] If the parties do not reach agreement, I will GRANT Abbott's motion to limit the use of these witnesses' deposition testimony to impeachment only (assuming that they are available to testify), and I will GRANT Sandoz's request to amend its list of witnesses who may be called.

b. Witnesses who will testify live at trial.

Abbott argues that the Court should not allow Sandoz "unfettered use" of the depositions of witnesses who will testify live and who were not officers, directors, managing agents, or corporate designees of Abbott when deposed. Also, Abbott argues that the depositions of former Abbott employees and expert witnesses should be excluded for the additional reason that it is hearsay. [2] Abbott argues, finally, that under *Fed. R. Civ. P. 32*, Sandoz should be precluded from using Linda Gustavson's deposition testimony of Sept. 9, 2005, Dec. 1, 2005, and Dec. 2, 2005 because, on those occasions, Gustavson testified as a mere employee **[**13]** of Abbott, not as a corporate designee under *Rule 30(b)(6)*.

Sandoz responds that it intends only to use the depositions at issue for impeachment, or if the witnesses become unavailable. Additionally, although not entirely relevant to Abbott's motion, Sandoz correctly notes that, under *Rule 32(a)(3)*, it may use the deposition testimony of Abbott's 30(b)(6) witnesses for any purpose.

I will GRANT Abbott's motion. As the parties apparently agree, the depositions at issue may be used only for impeachment, in the case that a witness becomes unavailable, or to the extent that *Rule 30(b)(6)* is applicable.

3. To preclude Sandoz from offering evidence or argument relating to invalidity theories not disclosed in discovery. [Dkt. 485.]

I will address this motion in three parts, separately considering Abbott's motion to exclude (a) defenses based on the '571 publication; (b) defenses based on the '667 motion; and (c) defenses and prior art that Abbott **[**14]** did not disclose during discovery.

a. Defenses based on the '571 publication

Abbott argues that the Court rejected Sandoz's anticipation and obviousness defenses based on

[1] Sandoz notes that the witnesses designated by a "*" above are already on the parties' lists of witnesses to be called at trial, and Sandoz intends only to use their deposition testimony for impeachment, or if those witnesses become unavailable.

[2] In addition to the witnesses listed in *subsection (a)*, these witnesses include: Jeffrey Bauer, Walter Chambliss, Hartmut Derendorf, Siyawosh Moghaddam, Marcello Pagano, Gordon Rausser, Stanley Davis, Ronald Sawchuk, Michael Wagner, and Daniel Weiner.

the '571 publication, and an issue decided by the court cannot be relitigated in the same case. Specifically, Abbott notes Sandoz's intention to use the '571 patent as a basis for anticipation and obviousness defenses to claim 6 of the '718 patent and claim 2 of the '616 patent. Abbott argues that, even though these defenses were not directly at issue in Abbott's summary judgment motion, the Court's summary judgment decision precludes Sandoz from introducing them at trial. Abbott explains that each claim at issue improves one of the product's side effects, and such improvements are tied to the different pharmacokinetic ("PK") characteristics of the extended release composition. Abbott argues that, because the Court found at summary judgment that the '571 patent failed to disclose the PK characteristics that produce side effect improvements, that same deficiency should preclude Sandoz from relying on the '571 patent to show the invalidity of claim 6 of the '718 patent or claim 2 of the '616 patent.

Sandoz responds that, **[**15]** because these particular invalidity defenses were not at **[*770]** issue at summary judgment, Sandoz should be allowed to present them at trial. Sandoz points out that Abbott moved for summary judgment with respect to the validity and enforceability of claims 1, 2, and 4 of the '718 patent—not claim 6 of the '718 patent or claim 2 of the '616 patent. Sandoz argues that the Court must reject Abbott's attempt to extend the Court's summary judgment ruling (that the '571 publication did not render claims 1, 2, or 4 of the '718 patent invalid) to claim 6 of the '718 patent or claim 2 of the '616 patent. Sandoz also specifically rejects Abbott's assertion that side effect improvements are tied to the PK characteristics of the extended-release composition. In fact, Sandoz argues that neither claim 6 of the '718 patent nor claim 2 of the '616 patent require any PK characteristics at all. It follows, according to Sandoz, that the Court's ruling that the '571 patent failed to disclose any PK characteristics does not preclude Sandoz's invalidity defenses to claim 6 of the '718 patent and claim 2 of the '616 patent. Finally, Sandoz argues that invalidity challenges to a patent must be considered on a claim-by-claim **[**16]** basis.

Abbott's motion to preclude Sandoz from offering invalidity defenses to claim 6 of the '718 patent and claim 2 of the '616 patent based on the '571 patent is DENIED. First, at summary judgment, the Court considered the validity of only claims 1, 2, and 4 of the '718 patent. Second, Abbott has not conclusively demonstrated that the Court's holding with respect to claims 1, 2, and 4 of the '718 patent is broad enough to cover claim 6 of the '718 patent and claim 2 of the '616 patent. This is especially true in light of the well-established law that ***HN3*** patent claims do not stand and fall together; rather the court considers invalidity on a claim-by-claim basis. *See* 35 U.S.C. § 282; *Amazon v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1351 (Fed. Cir. 2001)* ("infringement and validity analyses must be performed on a claim-by-claim basis").

b. Defenses based on the '667 publication

Abbott argues that Sandoz should be precluded from basing an anticipation or obviousness defense on the '667 publication. When Abbott moved for summary judgment on obviousness and anticipation with regard to the '667 publication, Sandoz never attempted to defend its reliance on the '667 publication, leading Abbott **[**17]** to note in its reply that Sandoz had waived any claim that summary judgment should not be entered as to the '667 publication. The Court did not mention the '667 publication in its summary judgment opinion. Abbott submits that it is well-established that if a party

does not present arguments for why summary judgment should be denied, those arguments are deemed waived.

Sandoz does not respond directly to this argument; it states only that the Court never adjudicated Sandoz's defenses against claims that are devoid of PK limitations, including claim 6 of the '718 patent, which Sandoz argues is invalid based in part on the '571 publication and the '667 patent.

This motion is GRANTED with respect to Sandoz's invalidity defense to claims 1, 2, or 4 of the '718 based on the '667 publication and DENIED with respect to Sandoz's invalidity defense based on the '667 publication to claims not adjudicated at summary judgment—e.g., claim 6 of the '718 patent and claim 2 of the '616 patent.

c. Defenses and prior art that Sandoz did not disclose during discovery

Abbott argues that Sandoz's failure to disclose its reliance on certain defenses and prior art during discovery precludes Sandoz from relying **[**18]** on those defenses or prior art at trial. Specifically, Abbott asserts that Sandoz did not disclose its intention **[*771]** to rely on enablement or written-description defenses to the '718 or '616 patents, and Sandoz failed to reference the '803 patent or Welling-1983 article as prior art supporting Sandoz's obviousness and anticipation defenses to the '718 and '616 patents. Abbott argues that, under *Fed. R. Civ. P. 37(c)(1)*, if a party fails to meet the discovery obligations required by *Rules 26(a)* or *(e)*, the party may not introduce the material it failed to disclose at trial. (Abbott again argues for the exclusion of Sandoz's enablement and written-description defenses in its Motion *in Limine* #6.)

Sandoz argues that it should be permitted to rely on the defenses and prior art at issue because, even though they were not disclosed formally in response to interrogatories, they were disclosed in other ways. For example, Dr. Chambliss referenced the '803 patent and Welling-1983 article when opining on the invalidity of claim 6 of the'718 and claim 2 of the '616 patent. Sandoz notes that Abbott had the opportunity to question Dr. Chambliss about his reliance on these references and did so at his **[**19]** deposition. In addition, Sandoz contends that its enablement and written-description defenses were disclosed in "numerous forms" including expert reports, deposition testimony, and Sandoz's preliminary injunction briefs. Sandoz argues that Abbott is not prejudiced because its awareness of these defenses and prior art references afforded Abbott the opportunity to investigate them. Sandoz likens this case to *DataQuill Ltd. v. Handspring, Inc.*, in which the court held that ***HN4*** "the extreme sanction of exclusion is not warranted under *Rule 37(c)*" where the defendant's failure to include prior-art references in its interrogatory response was harmless because the plaintiff still had "a full opportunity to inquire into [defendant's expert's] opinion at his deposition." *No. 01 C 4635, 2003 U.S. Dist. LEXIS 27659, 2003 WL 25696445, at *1 (N.D. Ill. Dec. 19, 2003)*.

Abbott's motion is DENIED with respect to the '803 patent and Welling-1983 article for Sandoz's reasons. Even though Sandoz did not disclose these prior art references in response to interrogatories, because Sandoz has established that Abbott was aware of these prior art references, and had a fair opportunity to investigate them during the course of discovery, they **[**20]** should not be excluded. However, Sandoz should be limited to relying on this prior art only as related to claim 6 of the '718 patent and claim 2 of the '616 patent. In Abbott's

Motion *in Limine* #6, Abbott indicates, and Sandoz does not refute, that Dr. Chambliss did not opine that any of the claims other than claim 6 of the '718 patent and claim 2 of the '616 patent were invalid based on the '571 publication in combination with other references. (*See* Abbott Mot. *in Limine* #6 at 2; Sandoz Resp. to Abbott Mot. *in Limine* #3 at 6.)

Abbott's motion is GRANTED with respect to Sandoz's undisclosed enablement and written-description defenses for the reasons detailed in the analysis of Abbott's Motion *in Limine* #6 below.

4. To preclude Sandoz from introducing evidence regarding anti-generic or anti-competitive strategies. [Dkt. 484.]

I will address this motion in two parts, separately considering Sandoz's motion to preclude (a) evidence of Abbott's alleged anti-generic or anti-competitive strategy, and (b) invocation of terms such as "monopoly," "milking strategy," and "milking the brand."

a. Evidence of Abbott's alleged anti-generic/anti-competitive strategy

Abbott argues that evidence of its alleged **[**21]** anti-generic or anti-competitive strategy (e.g., internal memoranda suggesting that it developed the '718 patent in part to extend its clarithromycin monopoly) **[*772]** should be excluded as irrelevant, prejudicial, and misleading. With respect to the infringement and invalidity issues, Abbott argues that its subjective intent is irrelevant and therefore inadmissible under *Fed. R. Evid. 401* and *402*. For the proposition that the obviousness inquiry does not depend on inventors' subjective motivations, Abbott cites *Life Techs., Inc. v. Clontech Labs, Inc., 224 F.3d 1320, 1325 (Fed. Cir. 2000)*, *Graham v. John Deere Co., 383 U.S. 1, 17, 86 S. Ct. 684, 15 L. Ed. 2d 545 (1966)*, and *KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 127 S.Ct. 1727, 1742, 167 L. Ed. 2d 705 (2007)*. With respect to the issue of damages, Abbott suggests that, while Sandoz may properly offer evidence regarding demand for Biaxin XL, Abbott's marketing expenditures, and the existence of acceptable non-infringing alternatives, evidence regarding Abbott's "anti-generic" or "anti- competitive" intent bear no relevance to the calculation of lost profits or a reasonable royalty. Abbott further argues that, even if relevant, evidence of an alleged anti-generic or anticompetitive strategy should be **[**22]** excluded because, under *Fed. R. Evid. 403*, the probative value (which is marginal) is substantially outweighed by the danger of unfair prejudice and confusion as to the central issues of patent infringement and validity.

Sandoz responds that this evidence is relevant to its showing of obviousness and the issue of damages, and even if the evidence is prejudicial, the danger of unfair prejudice is not substantial enough to outweigh the probative value of the evidence. With respect to the obviousness issue, Sandoz argues that *Graham* and *KSR* teach that courts may look at any secondary considerations that would prove instructive of the obviousness inquiry, including market pressure. Sandoz argues that Abbott's internal documents and memoranda, which capture its understanding of the market pressures threatening Abbott's business at the time, are probative of the obviousness determination. With respect to the issue of damages, Sandoz points out that Abbott's internal documents and memoranda discuss the demand for clarithromycin and the extended-release formulation and argues that a lost profits analysis under *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc., 575 F.2d 1152, 1156 (6th Cir. 1978)* **[**23]** must take into account the demand for the patented product. According to

Sandoz, Abbott's interest in "extend[ing] the life of clarithromycin and keep[ing its] various product lines protected from generic competition" (Abbott Mot. *in Limine* #4, Ex. A) shows that Abbott believed that the generic clarithromycin products would constitute "acceptable noninfringing substitutes." Sandoz argues that this evidence is relevant to show the availability of acceptable noninfringing substitutes, or Abbott's belief as to the availability of these substitutes under *Panduit* factor two. Further, Sandoz contends that evidence relating to Abbott's marketing strategies is relevant to the reasonable royalty analysis under *Georgia-Pacific Corp. v. U.S. Plywood Corp., 318 F.Supp. 1116, 1120 (S.D.N.Y. 1970)*. Sandoz adds that this evidence was considered by both Abbott's and Sandoz's damages experts as part of their reasonable royalty analyses and should not be excluded at trial.

This motion is GRANTED. ***HN5*** Evidence of Abbott's alleged anti-generic or anticompetitive strategy is not relevant to the issue of obviousness. Although, under *KSR*, courts may look to "secondary considerations" helpful to the obviousness **[**24]** inquiry, such considerations must be "objective." *KSR, 550 U.S. at 406*. Because the court's obviousness inquiry depends on the perspective of a "person having ordinary skill in the art," *id.*, Abbott's subjective motivations for developing Biaxin XL are not relevant. **[*773]** Sandoz correctly states that *KSR* instructs courts to weigh "secondary considerations" such as market pressure; however, contrary to Sandoz's interpretation, *KSR* directs courts to consider the market pressure, faced by an objective person of ordinary skill, to solve a particular problem. *Id. at 421*. Abbott's subjective experience of the market pressure to extend the life of its patent does not fall within the "secondary considerations" contemplated by the court in *KSR*. Even if such evidence is marginally relevant, because of its peripheral significance to the obviousness determination and potential to prejudice the jury against Abbott, its probative value is substantially outweighed by the danger of unfair prejudice under *Rule 403*.

Additionally, to conduct a lost profits analysis under *Panduit* or a reasonable royalty analysis under *Georgia-Pacific*, Sandoz may offer evidence regarding demand for Biaxin XL, Abbott's marketing **[**25]** expenditures, and the existence of acceptable non-infringing alternatives; however evidence of Abbott's alleged anti-generic or anti-competitive strategy is not relevant to the damages consideration.

b. Invocation of terms such as "monopoly," "milking strategy," & "milking the brand"

Abbott argues that terms such as "monopoly," "milking strategy," and "milking the brand" are not relevant, and invocation of such terms would unfairly prejudice Abbott under *Rule 403* by suggesting that Abbott's enforcement of patent rights is unfair or unlawful and improperly inviting the jury to view Abbott in a negative light.

Sandoz responds that these terms are not unfairly prejudicial. First, the term "monopoly" appropriately describes the patentee's legal right to exclusion, and the jury would understand that this right is the reward for the patentee's effort. Second, the terms "milking the brand" and "milking strategy" derive from Abbott's internal documents, and because they are the names of Abbott's strategy, excising the phrases would destroy the context of the evidence.

This motion is GRANTED for the reasons articulated by Abbott.

5. To preclude Sandoz's presentation of

inequitable conduct evidence **[**26]** to the jury. [Dkt. 477.]

Abbott argues that Sandoz has already agreed that the inequitable conduct issue, because it is wholly equitable in nature, should be decided by the Court outside of the presence of the jury. Recognizing that ***HN6*** courts retain discretion to determine how inequitable conduct issues will be handled at trial, Abbott argues that the Court is justified in separating the presentation of the evidence on these issues in cases such as this one, where claims of inequitable conduct and infringement are distinct. Lastly, Abbott argues that presenting evidence of inequitable conduct to the jury risks unfairly prejudicing the jury against Abbott and causing confusion in an already complicated patent case.

Sandoz responds that this Court already decided against bifurcating the issue of inequitable conduct from the other issues during the 3/27/08 hearing on the matter. First, Sandoz's evidence of inequitable conduct also relates to issues that will be decided by the jury such as noninfringement, invalidity, and the credibility of witnesses, and Sandoz will suffer prejudice if it is unable to present this evidence to the jury. Second, Abbott has not stated specifically what prejudice **[**27]** it might suffer if Sandoz is allowed to present the jury with evidence relating to both inequitable conduct and other issues, and any possible prejudice may be cured with a limiting instruction or cautionary warning to the **[*774]** jury. Finally, Sandoz adds that addressing all issues in a single case will promote convenience and judicial economy, especially because all of the witnesses testifying about inequitable conduct will also testify on other issues before the jury.

This motion will be DENIED. Inequitable conduct issue will be intertwined with the other issues in the trial. *(See* Sandoz Resp. to Abbott Mot. *in Limine* #5, Ex. 1, 03/27/08 Hearing Transcript at 2-3.)

6. To preclude Sandoz from offering invalidity evidence or argument not disclosed in its expert reports. [Dkt. 478.]

Abbott moves to exclude the following invalidity evidence or argument that Sandoz failed to disclose in its expert reports but apparently intends to introduce at trial: [3]

• Claims 1, 2, 4, 10, 11, or 13 of the '718 patent are invalid on grounds of obviousness in light of the '571 patent in combination with other references;

• A written-description defense to the '616 or '718 patent; and

• An enablement defense to the '616 or '718 patent.

In addition to arguing that none of these defenses were addressed by Sandoz's expert on invalidity, Dr. Chambliss, Abbott points out, in Motion *in Limine* #3, that Sandoz never disclosed written-description or enablement defenses in either its initial or amended invalidity contentions, or in response to Abbott's interrogatories requesting that Sandoz identify all of its invalidity and unenforceability arguments. (*See* Abbott Mot. *in Limine* #3, Exs. 4, 5, &6.)

Abbott argues that Sandoz should not be able to introduce evidence or argument relating to these invalidity theories because direct testimony of experts must be limited to the matters disclosed

---

[3] Sandoz's proposed jury instruction on invalidity defenses provides: "Sandoz contends that claims 1, 4, and 6 of the '718 patent and claim 2 of the '616 are each invalid for anticipation and/or obviousness. Sandoz must prove by clear and convincing **[**28]** evidence that each claim is invalid. Sandoz also contends that the asserted claims are invalid for failure to meet the written description and enablement requirements." (Sandoz Proposed Instr. 4.1.)

in their reports. *See, e.g., Funai Elec. Co. v. Daewoo Elec. Corp., No. C 04-1830 CRB, 2007 U.S. Dist. LEXIS 29782, 2007 WL 1089702, at *1 (N.D. Cal. Apr. 11, 2007)*. **[**29]** Abbott cites several cases in which courts precluded defendants from introducing particular invalidity theories that were not disclosed during discovery. *See Transclean Corp. v. Bridgewood Servs., Inc., 290 F.3d 1364, 1374 (Fed. Cir. 2002)*; *Bridgestone Sports Co., Ltd. v. Acushnet Co., No. CIVA 05-132 JJF, 2007 U.S. Dist. LEXIS 11370, 2007 WL 521894, at *4-5 (D. Del. Feb. 15, 2007)*; *Astrazeneca AB v. Mutual Pharm. Co., 278 F.Supp.2d 491, 508 (E.D. Pa. 2003)*; *Heidelberg Harris, Inc. v. Mitsubishi Heavy Ind., Ltd., No. 95 C0673, 1996 U.S. Dist. LEXIS 17362, 1996 WL 680243 at *8-10 (N.D. Ill. Nov. 21, 1996)*. Abbott argues that, even if Sandoz were allowed to present these new invalidity defenses, because Sandoz cannot present expert testimony on its previously undisclosed defenses, it will be unable to support these defenses. As authority for this argument, Abbott cites a number of cases in which courts rejected invalidity defenses where defendants could not offer any expert testimony in support of those defenses. *See Ry-Lock Co. v. Sears, Roebuck & Co., 227 F.2d 615, 616-18 (9th Cir. 1955)*; *Oxford Gene Tech. Ltd. v. Mergen Ltd., 345 F.Supp.2d 444, 451 (D. Del. 2004)*; *Johns Hopkins Univ. v. CellPro, 978 F.Supp. 184, 189 (D. Del. 1997)*; *United States Surgical Corp. v. Hosp. Prods. Int'l **[*775]** Party Ltd., 701 F.Supp. 314, 338-39 (D. Conn. 1988)*. **[**30]** Finally, Abbott contends that its arguments for precluding Sandoz's invalidity defenses also support the exclusion of Sandoz's obviousness defense to claims 1, 2, 4, 10, 11, and 13 of the '718 patent.

Sandoz responds that Abbott's motion should be denied because Abbott has been made aware of the invalidity arguments at issue through: (1) the expert reports and declarations of Dr. Chambliss (Sandoz's expert); (2) Dr. Chambliss's deposition testimony; (3) Sandoz's preliminary injunction opposition and appeal briefs; and (4) the deposition testimony of Dr. Davis (Abbott's expert). Sandoz cites *Se-Kure Controls, Inc. v. Vanguard Prods. Group, Inc.* for the proposition that expert testimony on an issue should not be excluded where "the information was made known to the other side in the context of the case itself." *No. 02-3767, 2007 U.S. Dist. LEXIS 17228, 2007 WL 781253, at *6 (N.D. Ill. Mar. 7, 2007)*.

Sandoz's arguments for the admission of its enablement and written-description defenses center on its contention that, under Dr. Davis's construction of certain claim terms, including the term "pharmaceutically acceptable polymer," Abbott's patent claims are invalid on enablement and/or written-description grounds. Sandoz **[**31]** lists a number of ways in which it believes Abbott has been apprised of these defenses during the course of this litigation. Here are a few examples of Sandoz's arguments:

• Dr. Chambliss laid the foundation for Sandoz's enablement and written-description defenses when he stated, in response to Dr. Davis's contention that the "pharmaceutically acceptable polymer" does not need to be the ingredient responsible for extending release, that "a person of ordinary skill in the art would understand that Abbott did not describe or invent an extended-release composition in which the 'pharmaceutically acceptable polymer' does not extend release." (Sandoz Resp. to Abbott Mot. *in Limine* #6, Ex. 1, 3/2/07 Chambliss Rpt. at P 12.)

• Dr. Chambliss showed that Dr. Davis's proposed construction raises written-description concerns when he opined that Dr. Davis's proposed construction is "divorced from the patent specification and seek[s] to re-write the specification to cover any extended release

clarithromycin composition containing a polymer." (Sandoz Resp. to Abbott Mot. *in Limine* #6, Ex. 2, 3/22/07 Chambliss Rebuttal Rpt. P 25.)

• Dr. Chambliss suggested that Dr. Davis's broad construction may raise **[**32]** enablement issues when he stated that "Abbott's inventors did not describe their compositions to encompass the range of compositions that Dr. Davis envisions in his report." *(Id.)*

• In Sandoz's preliminary injunction briefs both before this Court and the Federal Circuit, Sandoz argued: "Abbott's patent is presumed to be enabled across the full scope of its claims. *Teva, 452 F.3d at 1350*. Thus, Abbott cannot be heard to argue that a composition falling

In addition to citing these examples, Sandoz argues that the Court's summary judgment opinion "created a framework where enablement and written description are at issue in this case." (Sandoz Resp. to Abbott Mot. *in Limine* #6 at 5.) Sandoz notes that, at summary judgment, the Court stated that a person of ordinary skill in the art would not have had a reasonable expectation that the '571 compositions would satisfy the '718 patent's PK requirements. *See Abbott Labs. v. Sandoz Inc., 529 F.Supp.2d 893, 915-18 (N.D. Ill. 2007)*. According to Sandoz, if this means that the PK properties are not inherent in Abbott's **[*776]** patented compositions, then the claims are not enabled to their full extent.

Finally, with respect to the obviousness **[**33]** arguments at issue in this motion, Sandoz denies that it intends to argue that claims 2, 10, 11, or 13 of the '718 patent are invalid and contends that the rest of its obviousness arguments have been disclosed in reports and declarations of its experts. Sandoz argues that Abbott suggests that it is not familiar with the difference between prior art that discloses and/or renders obvious the claimed compositions and prior art that demonstrates the knowledge and skill of one of ordinary skill in the art at the time of the invention. Sandoz points out that the law presumes that the person of ordinary skill in the art is aware of all prior art and argues that its experts provided detailed opinions on the application of prior art, and the knowledge of those skilled in the art, to the obviousness issues in this case. Sandoz broadly cites Abbott Mot. *in Limine* #6, Ex. 1, 3/2/07 Chambliss Rpt. at PP 5-6, 61-62, 66-67, 57-123.

Abbott's motion will be GRANTED. I will address separately (a) the enablement and written-description defenses, and (b) the argument that claims 1, 2, 4, 10, 11, or 13 are invalid due to obviousness.

a. Enablement and written description defenses

It is undisputed that Sandoz **[**34]** did not disclose these invalidity defenses during discovery— in its invalidity contentions, in its amended invalidity contentions, in response to Abbott's interrogatories requesting that Sandoz disclose its invalidity defenses, or in any supplemental responses provided during the course of discovery. That said, ***HN7*** the case law cited by Abbott does not reveal a hard-and-fast rule requiring the exclusion of invalidity defenses that were not disclosed during discovery. Rather, courts consider whether to exclude such undisclosed defenses and arguments on a case-by-case basis, depending on whether the plaintiff would suffer prejudice if these defenses or arguments were introduced. *See Transclean Corp., 290 F.3d at 1374*; *Bridgestone Sports Co., Ltd., 2007 U.S. Dist. LEXIS 11370, 2007 WL 521894, at *4-5*; *Astrazeneca AB, 278 F.Supp.2d at 508*; *Heidelberg Harris, Inc., 1996 U.S. Dist. LEXIS 17362, 1996 WL 680243 at *7-10*. Thus, the key question in

resolving this motion *in limine* is whether, as Sandoz contends, Abbott had sufficient notice of its intended enablement and written-description defenses such that it would not be prejudiced by their introduction at trial.

Although not entirely clear, Sandoz seems to argue that Dr. Davis's construction of claim **[**35]** terms provide a foundation for enablement and written-description defenses. Sandoz cites several excerpts of Dr. Chambliss's reports and deposition testimony that it believes provided Abbott notice that it may raise these defenses. One thing is certain about all of these excerpts: none actually uses the terms "enablement" or "written-description" or addresses these defenses directly. Looking closely at the excerpts cited by Sandoz, it is possible that they offer implicit support for Sandoz's defenses. For example, Sandoz's intended enablement and written-description defenses may be implicated by Dr. Chambliss's statements that Dr. Davis's construction is "divorced from the patent specification and seek[s] to re-write the specification to cover any extended release clarithromycin composition containing a polymer," (Sandoz Resp. to Abbott Mot. *in Limine* #6, Ex. 2, 3/22/07 Chambliss Rebuttal Rpt. P 25,) and that "Abbott's inventors did not describe their compositions to encompass the range of compositions that Dr. Davis envisions in his report" (*id.*).

Sandoz's briefs during preliminary injunction proceedings do not invoke the defenses at issue any more directly. In the **[*777]** briefs presented **[**36]** to both this Court and the Federal Circuit, Sandoz argued, "Abbott's patent is presumed to be enabled across the full scope of its claims. *Teva, 452 F.3d at 1350*. Thus, Abbott cannot be heard to argue that a composition falling squarely within the subject matter claimed in claim 1 would somehow not inherently exhibit the same claimed DFL and bioavailability properties." (Sandoz Resp. to Abbott Mot. *in Limine* #6, Ex. 6, 2/1/07 PI Opp. Br. at 7-8; Ex. 7, 7/2/07 PI Appeal Br. at 47-48.) It is not clear why Sandoz contends that this excerpt would have apprised Abbott of its intent to assert an enablement defense, when Sandoz stated directly that Abbott's patent is presumed to be enabled.

The single case Sandoz cites in support of its argument that the Court should permit its written-description and enablement defenses is *Se-Kure Controls, Inc. v. Vanguard Prods. Group, Inc. No. 02-3767, 2007 U.S. Dist. LEXIS 17228, 2007 WL 781253 (N.D. Ill. Mar. 7, 2007)*. In that case, the court declined to preclude the declarations by two witnesses who the defendants had not explicitly disclosed as witnesses they intended to rely on under *Rules 26(a)(1)(A)* and *26(e)*. *Id. at *6*. The court held that the plaintiff was undoubtedly aware **[**37]** that the defendants might rely on these two witnesses as both provided clearly relevant declarations during discovery. *Id.* Here, alleged notice of Sandoz's defenses—essentially through inferences drawn from Dr. Chambliss's testimony—is far more subtle. It is even more subtle than the level of notice courts have deemed insufficient to prevent the exclusion of undisclosed evidence. *See, e.g., Heidelberg Harris, Inc., 1996 U.S. Dist. LEXIS 17362, 1996 WL 680243 at *7-10* ***HN8*** (excluding undisclosed defense after rejecting argument that notice of defense in expert reports compensated for defendants' failure to disclose defense by supplementing interrogatory responses as required by *Rule 26(e)(2)*). Under the facts of this case, Sandoz's purported notice to Abbott of its enablement and written-description defenses is too subtle to compensate for its failure to disclose these defenses during discovery. Moreover, as Abbott argues, Sandoz has not provided any indication that it has evidence to

support these defenses at trial. *See* *Ry-Lock Co. v. Sears, Roebuck & Co., 227 F.2d 615, 616-18 (9th Cir. 1955)* (reversing district court's finding of invalidity where defendant failed to support its invalidity claims with expert testimony); **[**38]** *United States Surgical Corp. v. Hosp. Prods. Int'l Party Ltd., 701 F.Supp. 314, 338-39 (D. Conn. 1988)* (rejecting defendant's enablement defense where "[t]he only testimony cited by the defendant to support [this defense] is the testimony of . . . plaintiff's expert"). Sandoz should therefore be precluded from introducing enablement and written-description defenses at trial.

b. Obviousness defense to claims 1, 2, 4, 10, 11, and 13 of the '718 patent

Abbott's motion to preclude Sandoz from arguing that claims 1, 2, 4, 10, 11, are 13 of the '718 patent are invalid on grounds of obviousness in light of the '571 patent in combination with other references will be GRANTED. Sandoz denies that it intends to argue that claims 2, 10, 11, and 13 are invalid, leaving only claims 1 and 4 at issue. With respect to these claims, Sandoz does not point to any specific place where its obviousness defenses to claims 1 or 4 have been disclosed, citing only broadly to Dr. Chambliss's expert report.

7. To preclude Sandoz from offering evidence or argument regarding alleged benefits of generic drugs. [Dkt. 479.]

Abbott argues that such evidence should be excluded under *Federal Rules of Evidence 402* and *403* **[**39]** because it is irrelevant to the issues in the case, and it would **[*778]** unfairly prejudice Abbott, distract the jury, and cause confusion. Abbott expresses concern, specifically, that evidence regarding the benefits of generic drugs would conjure negative stereotypes of branded pharmaceutical companies and appeal to the popular concern about the perceived role of such companies in contributing to the rising cost of healthcare.

Sandoz responds that Abbott improperly seeks a broad, wholesale exclusion, without identifying specific evidence, even though evidence regarding the competition between branded and generic drug companies, and the reduced cost of generic versus branded pharmaceuticals, is relevant to the issue of damages (whether calculated using a lost profits analysis under *Panduit* or a reasonable-royalty analysis under *Georgia-Pacific*).

This motion will be GRANTED. Although Abbott does not seek to exclude specific pieces of evidence, the Court will exclude as irrelevant and prejudicial any evidence or argument regarding the general benefits of generic drugs over branded drugs. However, as Abbott concedes, the Court should (and will) admit evidence regarding the difference in cost between **[**40]** the drugs at issue because such evidence is relevant to damages. To the extent that competition between Abbott and generic brands sheds light on the issue of damages, this evidence will be admitted as well. Abbott may propose a limiting instruction as to the use of this type of evidence on the issue of damages.

8. To preclude Sandoz from offering inequitable conduct evidence or argument regarding (a) matters decided on summary judgment, (b) untimely and irrelevant inequitable conduct theories, and (c) the '407 patent. [Dkt. 489.]

Abbott argues that, with respect to Sandoz's defense that the '718 and'616 patents are unenforceable due to inequitable conduct, a significant portion of the evidence that Sandoz intends to present should be barred based on prior rulings by this Court, the untimeliness of

disclosure, and/or the inadmissibility of evidence. Sandoz responds that this evidence is admissible because it demonstrates that Abbott has engaged in a pattern of making false statements to, and withholding information from, the PTO during prosecution of the patents-in-suit, and from this pattern, the Court may infer an intent to deceive. Sandoz also claims that Abbott was sufficiently aware **[**41]** of the inequitable conduct defenses at issue, and moreover, because inequitable conduct is a bench issue, Abbott has not established any prejudice or harm warranting exclusion of Sandoz's inequitable conduct theories.

I will address this motion in three parts, separately considering Abbott's arguments for the exclusion of inequitable conduct evidence regarding (a) matters decided on summary judgment, (b) untimely and irrelevant inequitable conduct theories, and (c) the '407 patent.

a. Matters decided at summary judgment

Abbott argues that, at summary judgment, the Court resolved several issues related to inequitable conduct in Abbott's favor; accordingly, under the law-of-the-case doctrine, Sandoz may not re-introduce these issues at trial. *See, e.g.,* *South Beach Beverage Co. v. Rush Beverage Co., Inc., 2004 U.S. Dist. LEXIS 2477, 2004 WL 416358, at *2 (N.D. Ill. Feb. 20, 2004)* ***HN9*** ("Under the law of the case doctrine, a ruling by a trial court, in an earlier stage of the case, is binding on subsequent stages of the case."). According to Abbott, the issues resolved at summary judgment include:

• *The Gustavson declaration*—summary judgment in favor of Abbott on the issue of whether Abbott engaged in inequitable conduct **[**42]** when it submitted Dr. Linda **[*779]** Gustavson's declaration in support of the '718 patent prosecution

• *Biaxin XL and incidence rates*—summary judgment in favor of Abbott on the issue of whether Abbott engaged in inequitable conduct by withholding material labeling data from the PTO

Sandoz responds that the summary judgment ruling does not preclude Sandoz from using evidence of Abbott's conduct in connection with the Gustavson declaration and Biaxin XL label to show intent to deceive. Sandoz asserts that the Court did not even reach the issue of intent to deceive because it granted summary judgment to Abbott based on the Court's determination that the Gustavson declaration and the taste perversion incidence rates in the label were not material. Sandoz argues further that the law-of-the-case doctrine does not apply because the Court only granted summary judgment that these individual incidents do not constitute inequitable conduct; the Court did not, however, consider whether this evidence, taken in combination with additional evidence of material misrepresentations and omissions, demonstrates an intent to deceive. Finally, Sandoz argues that the Court is free to revisit its rulings on whether **[**43]** each instance constituted inequitable conduct because, under *Fed. R. Civ. P. 54(b)*, "any order or decision, however designated, that adjudicates fewer than all the claims . . . does not end the action as to any of the claims . . . and may be revised at any time before the entry of a judgment adjudicating all the claims . . ." [4]

Abbott's motion to preclude Sandoz from

[4] Sandoz also cites Judge Gajarsa's dissent in the Federal Circuit's preliminary injunction ruling, which stated that there are at least questions of fact on the issue of whether Abbott's submission of false statements in Gustavson's Rule 132 declaration amounts to inequitable conduct by itself. *Abbott Labs. v. Sandoz, Inc., 544 F.3d 1341, 1379-80 (Fed. Cir. 2008)* (Gajarsa, J., dissenting).

introducing evidence related to the Court's summary judgment findings on inequitable conduct is DENIED. Contrary to Sandoz's last argument, the Court need not revisit its summary judgment rulings. However, Sandoz persuasively argues that the particular incidents addressed at summary judgment, even if they do not constitute inequitable conduct independently, may demonstrate an intent to deceive when combined with other evidence. Federal **[**44]** Circuit precedent permits the evidence at issue to be offered in this context. *See* *Refac Intern., Ltd v. Lotus Dev. Corp., 81 F.3d 1576, 1582 (Fed. Cir. 1996)* (omissions in certain affidavits, while not themselves constituting inequitable conduct, heighted the effect of another material omission in a related affidavit and supported a finding of intent to deceive); *see also eSpeed, Inc. v. BrokerTec USA, LLC, 480 F.3d 1129, 1138 (Fed. Cir. 2007)* ("Intent to deceive may be 'inferred from the facts and circumstances surrounding the applicant's overall conduct.'") (quoting *Impax Labs. v. Aventis Pharms., 468 F.3d 1366, 1375 (Fed. Cir. 2006)*).

b. Inequitable conduct theories that Abbott alleges were improperly disclosed

Abbott argues that Sandoz improperly proposed findings of fact and conclusions of law relating to its inequitable conduct defense that included three new theories of inequitable conduct that Sandoz had not previously disclosed in its interrogatory responses, invalidity contentions, or other pleadings. Abbott argues that Sandoz should be precluded from presenting these inequitable conduct theories at trial because Sandoz flouted its Rule 26 discovery obligations by failing **[**45]** to timely disclose any of these theories in response to Abbott's interrogatory requesting the basis of Sandoz's unenforceability **[*780]** defense. Sandoz argues that, even though it did not formally disclose these theories, Abbott had sufficient notice of the theories such that they should not be excluded. Abbott moves to exclude the following theories:

• A claim that Abbott's non-disclosure of Study W98-268/DMR 95 to the Patent Office constituted inequitable conduct with regard to Claim 4 of the '718 patent;

• A claim of inequitable conduct relating to the '407 patent based on Gustavson's interview with the examiner during the prosecution of the patent; and

• A claim of inequitable conduct against the '718 patent based on the submission of a Rule 132 declaration from Gustavson during the prosecution of the '407 patent

Sandoz asserts that its arguments concerning the materiality of Study W98-268 to claim 1 of the '718 patent gave Abbott adequate notice of Sandoz's argument with respect to claim 4. Moreover, given the questions Sandoz posed to Abbott's experts about the results of the W98-268 study, Abbott cannot claim that it was unaware that Sandoz would argue that the W98-268 study was material **[**46]** to claim 4. Sandoz also asserts that it has repeatedly argued that Abbott's failure to disclose the W98-268 study to the PTO constitutes inequitable conduct because the results contradict statements made in the '718 and'616 patents specification that were meant to distinguish the inventive composition from the prior art. Because these statements were meant to support patentability of the extended-release compositions as a whole—not just one claim— information that contradicts them would be material to all claims. Sandoz argues that, for this reason, Abbott's argument that Sandoz should be precluded from alleging inequitable conduct related to claim 4 based on the W98-268

study is without merit. [5] Additionally, Sandoz claims that Abbott was aware of the inequitable conduct arguments concerning Gustavson's actions during the prosecution of the '407 patent based on the questions posed to Gustavson during her 30(b)(6) deposition and to Nick Poulos, the prosecuting attorney for the '407 patent, during his deposition.

With respect to Sandoz's claim that Abbott's non-disclosure of Study W98-268/DMR 95 to the Patent Office constituted inequitable conduct with regard to Claim 4 of the '718 patent, the motion is DENIED. The same considerations addressed in Abbott's Motion *in Limine* #6 apply here. It is undisputed that Sandoz never disclosed this particular inequitable conduct defense in either its initial or amended invalidity contentions, or in response to Abbott's interrogatories. Abbott correctly notes that ***HN10*** courts have discretion—which they often exercise—to preclude parties from presenting arguments or evidence that they have not properly disclosed during the course of discovery. [6] However, **[**48]** **[*781]** there is no hard-and-fast rule requiring courts to exclude undisclosed arguments or evidence. Rather, courts decide whether to exclude such arguments or evidence on a case-by-case basis, depending on whether the plaintiff would suffer prejudice if these defenses or arguments were introduced. *See* *Transclean Corp., 290 F.3d at 1374*; *Bridgestone Sports Co., Ltd., 2007 U.S. Dist. LEXIS 11370, 2007 WL 521894, at *4-5*; *Astrazeneca AB, 278 F.Supp.2d at 508*; *Heidelberg Harris, Inc., 1996 U.S. Dist. LEXIS 17362, 1996 WL 680243 at *7-10*. Here, Sandoz argues persuasively (as summarized above) that Abbott had adequate notice of Sandoz's Study W98-268/DMR 95 argument such that it would not be prejudiced by the admission of this argument at trial. Because the notice provided to Abbott throughout the course of litigation compensates for Sandoz's failure to disclose this defense during discovery, Sandoz may introduce this defense at trial.

c. Inequitable conduct issues regarding the '407 patent

Abbott argues that Sandoz's inequitable conduct theories that relate to the '407 patent should be excluded because the '407 patent is no longer part of this case, and the evidence Sandoz seeks to introduce is not admissible in connection with any issue relating to the '718 and '616 patents. According to Abbott, Sandoz contends that evidence of inequitable conduct related to the '407 patent is admissible as evidence of inequitable conduct related to the '718 and '616 patents because it shows a pattern of intent to deceive. In response, Abbott argues that Sandoz never properly disclosed such a theory during discovery, and this theory is without legal basis

---

[5] Sandoz makes one additional technical argument:

> Abbott's argument that it was unaware of Sandoz's theory with respect to claim 4 is also undermined by the fact that the C_{max} **[**47]** of the prior-art MR composition is a component of the DFL of that composition, and thus the information material to claim 1 was derived from the information material to claim 4. . . . Accordingly, Sandoz's arguments concerning the DFL results of study W98-268 necessarily involve the C_{max} results of that study as well, and Abbott cannot seriously claim that it did not know that Sandoz would assert that those C_{max} results were material to claim 4 of the '718 patent.

(Sandoz Resp. to Abbott Mot. *in Limine* #8 at 7-8.)

[6] *See* *Fed. R. Civ. P. 37(c)(1)* ("If a party fails to provide information or identify a witness as required by *Rule 26(a)* or *(e)*, the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at trial, unless the failure was substantially justified or is harmless."); *See also* ***[**49]*** *See* *Transclean Corp. v. Bridgewood Servs., Inc., 290 F.3d 1364, 1374 (Fed. Cir. 2002)*; *Bridgestone Sports Co., Ltd. v. Acushnet Co., No. CIVA 05-132 JJF, 2007 U.S. Dist. LEXIS 11370, 2007 WL 521894, at *4-5 (D. Del. Feb. 15, 2007)*; *Astrazeneca AB v. Mutual Pharm. Co., 278 F.Supp.2d 491, 508 (E.D. Pa. 2003)*; *Heidelberg Harris, Inc. v. Mitsubishi Heavy Ind., Ltd., No. 95 C0673, 1996 U.S. Dist. LEXIS 17362, 1996 WL 680243 at *8-10 (N.D. Ill. Nov. 21, 1996)*.

because an inequitable conduct challenge must be directed to the patent or patents **[**50]** alleged to be infringed, not '407, which is no longer part of this case. *Pharmacia Corp. v. Par Pharm. Inc., 417 F.3d 1369, 1375 (Fed. Cir. 2005)*. Abbott also notes that, by seeking to introduce evidence regarding the '407 prosecution, Sandoz seeks to challenge the enforceability of the '718 and '616 patents based on conduct that took place two years after the '718 patent was issued and two years after the filing of the '616 application.

Sandoz responds that the Stipulated Order that dismissed the claims and counterclaims related to the '407 patent does not preclude Sandoz from offering evidence related to the '407 patent "that otherwise would be admissible at trial of the remaining claims." Sandoz argues that evidence concerning Abbott's inequitable conduct during prosecution of the '407 patent is admissible because it reveals a pattern of behavior demonstrating Abbott's overall deceptive intent during prosecution of the '718, '616, and '407 patents. *Refac Int'l., Ltd. V. Lotus Dev. Corp., 81 F.3d 1576 (Fed. Cir. 1996)*.

This motion is GRANTED. Federal Circuit precedent makes clear that ***HN11*** inequitable conduct associated with the prosecution of a later patent does not affect the enforceability **[**51]** of an earlier patent. *See Pharmacia Corp. v. Par Pharm. Inc., 417 F.3d 1369, 1375 (Fed. Cir. 2005)* (inequitable conduct in the prosecution of a later patent did not infect the enforceability of a prior patent); *see also Lannett Co. Inc. v. KV Pharmaceuticals, No. 08-338 JJF, 2008 U.S. Dist. LEXIS 94898, 2008 WL 4974579, at *3 (D. Del. Nov. 21, 2008)* ("Inequitable conduct cannot be imputed to the earlier prosecuted [patents] based upon alleged conduct relating to later prosecuted patents."). [7] For that reason, Sandoz is precluded from introducing evidence **[*782]** or argument as to inequitable conduct in the prosecution of the '407 and '718 patents.

9. To preclude Dr. Pagano from offering evidence or opinions regarding Dr. Weiner's rebuttal and supplemental expert reports that are contrary to or not included in his deposition testimony. [Dkt. 486.]

Abbott moves broadly to preclude Dr. Pagano, Sandoz's expert, from offering any evidence or opinions responsive to Dr. Weiner's rebuttal or supplemental exert reports that Sandoz has not previously disclosed. There is no indication that Dr. Pagano in fact plans to testify to undisclosed matters. However, Abbott's concern that he may do so apparently stems from Dr. Pagano's deposition testimony that he did not thoroughly review Dr. Weiner's rebuttal or supplemental reports, and Sandoz's subsequent assertion that it reserved the right to respond to these reports. Abbott bases its motion to exclude any undisclosed expert testimony by Dr. Pagano on *Rule 26(a)*, **[**53]** which requires complete disclosure of expert opinions, and *Rule 37(c)(1)*, which precludes a party from presenting expert testimony it did not disclose under *Rule 26*, unless the party can show that its *Rule 26* violation was either justified or harmless.

In response, Sandoz argues that Abbott's broad

[7] Under some circumstances, inequitable conduct during the prosecution of a parent patent can undermine the enforceability of a descendant patent. *See Cordis Corp. v. Boston Scientific Corp. 188 Fed.Appx. 984, 988-89 (Fed. Cir. 2006)*; *Bone Care Intern., LLC v. Pentech Pharmaceuticals, Inc., No. 08-CV-1083, 2010 U.S. Dist. LEXIS 39984, 2010 WL 1655455, at *3 (N.D. Ill. Apr. 23, 2010)* ("the Federal Circuit has held that inequitable conduct in the prosecution of a patent infects a later-issued related patent only where there is an 'immediate and necessary relation' between the inequitable conduct and the enforcement **[**52]** of the patent-in-suit"). The '407 patent is not a parent patent and was, in fact, filed after both patents-in-suit. Nor does Sandoz assert the existence of an "immediate and necessary relation" between the alleged inequitable conduct concerning the during the prosecution of the '407 patent and the enforcement of the patents-in-suit.

motion, which does not seek to exclude any specific testimony or evidence, is improper. Further, Sandoz contends that, "[i]n the unlikely event that Dr. Pagano's opinions at trial somehow exceed the scope of subject matter that Abbott has notice of, the court can address this if Abbott raises an objection at trial." (Sandoz Resp. to Abbott Mot. *in Limine* #9 at 1.)

This motion is DENIED. Specific objections to Dr. Pagano's testimony can be addressed at trial, although it is clear that any such testimony must be confined to his previously disclosed report and testimony.

10. To preclude Sandoz's experts from testifying regarding claim construction at trial. [Dkt. 480.]

Abbott moves to preclude Sandoz's experts from testifying about claim construction, arguing that claim construction is a matter of law for the court, not the jury, to decide. *See Markman v. Westview Instruments, Inc., 52 F.3d 967, 978-79 (Fed. Cir. 1995)* **[**54]** (en banc), *aff'd*, *517 U.S. 370, 116 S. Ct. 1384, 134 L. Ed. 2d 577*; *see also NTP, Inc. v. Research in Motion, Ltd., 418 F.3d 1282, 1305 n.8 (Fed. Cir. 2005).*

Sandoz contests Abbott's motion, arguing that it may be necessary for both parties' experts to testify about the claim language so that the jury can understand that language. Sandoz cites no legal basis for this proposition. Instead, Sandoz argues that, in light of *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., 521 F.3d 1351 (Fed. Cir. 2008)*, the Court should revisit its prior claim construction. Sandoz's arguments in this vein do not directly address Abbott's motion *in limine.*

[*783] This motion is DENIED. Sandoz may not present evidence or argument that the Court's claim construction, as stated in the final jury instruction, is incorrect. However, Sandoz may present evidence during trial that informs the Court what the final construction should be.

11. To preclude certain testimony from Dr. Walter Chambliss. [Dkt. 481.]

Abbott seeks the exclusion of testimony by Sandoz's expert, Dr. Walter Chambliss, on three subjects: (a) alleged differences between the way in which Sandoz's formulation and the formulations of the patents-in-suit function to extend release; (b) the **[**55]** development and licensing of Sandoz's formulation; and (c) Abbott's understanding of Sandoz's formulation as a result of its licensing discussions with Madison Life Sciences employees. I will address (a) separately from (b) and (c).

a. Alleged differences between how Abbott's and Sandoz's products extend release

Abbott argues that Dr. Chambliss's testimony comparing the ways in which Sandoz's and Abbott's formulations operate to extend release is irrelevant. Abbott explains that it plans to pursue a literal infringement claim rather than invoking the doctrine of equivalents, which provides that a product may infringe, if not literally, by performing "substantially the same function in substantially the same way with substantially the same result" as the claim limitation. *AquaTex Inds., Inc. v. Techniche Solutions, 479 F.3d 1320, 1326 (Fed. Cir. 2007)*. Abbott points out that the Court has construed the term "pharmaceutically acceptable polymer" to mean a polymer that is pharmaceutically acceptable and that "extends drug release into the bloodstream either alone or in conjunction with other such polymers or other components, and is capable of forming a gel or a matrix to extend drug release **[**56]** into the bloodstream." *Abbott Labs v. Sandoz, Inc., 529 F.Supp.2d 893, 910-911 (N.D. Ill. 2007)*. Based on Abbott's contention that Sandoz's formulation literally contains this claim limitation, Abbott argues that the only question

for the jury is whether Sandoz's formulation contains a pharmaceutically acceptable polymer capable of extending release by forming a matrix or gel. Therefore, Abbott argues, the way in which Sandoz's formulation extends release is irrelevant and risks confusing the jury about what exactly Abbott has to prove.

Sandoz argues, in response, that the testimony at issue is relevant to Abbott's literal infringement claim (rather than merely to a theory of infringement under the doctrine of equivalents). As Sandoz points out, the Court stated at summary judgment that "the defining feature of any pharmaceutically acceptable polymer is its capability to extend release into the bloodstream." *Abbott Labs, 529 F.Supp.2d at 909-10*. According to Sandoz, its expert must be able to offer testimony that addresses whether the polymer in Sandoz's product actually functions to extend release. Sandoz intends to argue that its polymers are not the release-extending agent in its **[**57]** formulation and seeks to offer testimony supporting this position.

This motion is DENIED. Because Dr. Chambliss's testimony directly addresses whether Sandoz's product includes a substance that meets the definition of a "pharmaceutically acceptable polymer," it is relevant to Sandoz's defense to Abbott's literal infringement claim

b. & c. The development and licensing of Sandoz's formulation and Abbott's understanding of Sandoz's formulation as a result of licensing discussions with Madison Life Sciences employees

Abbott argues that Dr. Chambliss should not be permitted to testify about **[*784]** the events surrounding the development and licensing of Sandoz's formulation because he lacks personal knowledge about these matters, and his opinions derive only from the same documents and testimony that will be before the jury. Similarly, Abbott argues that Dr. Chambliss lacks personal knowledge for his opinion that employees at Abbott concluded that there was no release-extending polymer in Sandoz's formulation.

Sandoz responds that, under *Fed. R. Evid. 703*, Dr. Chambliss was entitled to rely on evidence, whether or not admissible, if it is "of a type reasonably relied upon by experts in the particular **[**58]** field in forming opinions or inferences upon the subject." Sandoz contends that it is permissible for an expert pharmaceutical formulator to rely on studies or data from other formulators. Sandoz also asserts that Dr. Chambliss does not intend to summarize the development of Sandoz's formulation, but rather plans to explain the documents that formed the basis for this opinion. With respect to Dr. Chambliss's proposed testimony that Abbott employees concluded that there was no release-extending polymer in Sandoz's formulation, Sandoz claims that the documents underlying this testimony cannot be understood by a lay jury. Dr. Chambliss therefore intends to explain the technical meaning of certain terms in these documents.

Part of Sandoz's response to Abbott's motion misses the mark. In opposing Abbott's motion to preclude Dr. Chambliss from testifying about the development and licensing of Sandoz's formulation, Sandoz argues that, under *Fed. R. Evid. 703*, an expert may base his opinion on otherwise inadmissible evidence. However, Abbott does not argue that evidence relating to the development and licensing of Sandoz's formulation is inadmissible; rather, Abbott argues that it is inappropriate **[**59]** for Sandoz's expert to usurp the jury's function by interpreting this evidence. Since Sandoz does not explain why an expert is helpful to interpret documents regarding the development and licensing of

Sandoz's product, Dr. Chambliss's testimony on these matters will be precluded, and Abbott's motion will be GRANTED in this respect.

Abbott's motion to preclude Dr. Chambliss from offering expert testimony that there was no release-extending polymer in Sandoz's formulation will be DENIED. As Sandoz argues, Dr. Chambliss's opinion derives from documents that may not be understood by a lay jury. (*See* Abbott Mot. *in Limine* #11, Ex. 2 at P 32.) It is therefore appropriate for Dr. Chambliss to use his expertise to interpret the technical language in these documents.

12. To preclude Sandoz from offering evidence or argument of advice of counsel or legal opinions regarding noninfringement, invalidity, or nonenforceability. [Dkt. 482.]

Abbott seeks specifically to exclude testimony from Sandoz's witnesses, Jeffrey Bauer and Nirmal Mulye, regarding legal opinions on whether Sandoz's product infringes Abbott's product. Abbott seeks the exclusion of this testimony under *Rules 402* and *403*. Abbott argues **[**60]** that this evidence is irrelevant and prejudicial because it pertains only to willful infringement, which is no longer a claim in this case. Moreover, Abbott contends, Sandoz should be precluded from referring to these opinions since it did not disclose them in discovery.

Sandoz responds that it does not intend to introduce this evidence on the issue of willful infringement. Rather, Sandoz contends that this testimony is relevant to determining the reasonable royalty in this case. When applying the *Georgia-Pacific* factors to opine on the reasonable royalty, **[*785]** Abbott's expert, Dr. Wagner, considered the rates paid by Sandoz for use of other patents comparable to the patents-in-suit. Specifically, Dr. Wagner opined that the rate Sandoz was willing to pay to license its own extended-release clarithromycin product weighs in favor of increasing the reasonable royalty in this case. (Sandoz Resp. to Abbott Mot. *in Limine* #12, Ex. 1 at 22, 36.) Sandoz intends to challenge Dr. Wagner's reliance on this comparison with testimony that Sandoz believed it had "freedom to operate" with respect to its product when it agreed to the rate at issue. Sandoz notes that the testimony will extend no further **[**61]** than this point; Sandoz will not present evidence concerning the substance or conclusions of any opinion obtained by counsel. Also, Sandoz points out that this particular challenge to Dr. Wagner's reasonable royalty calculation arose both in its damages expert's report and during Bauer's deposition. (*Id.* Ex. 2 at 40, Ex. 3 at 51:11-19; 56:15-22.)

This motion is DENIED. While the cases cited by Abbott preclude testimony on legal opinions related to patents in the absence of a willful infringement claim, none of these cases address the relevance of such testimony for Sandoz's intended objective. *See, e.g.*, *Advanced Cardiovascular Sys. v. Medtronic, 265 F.3d 1294, 1309 (Fed. Cir. 2001)*; *Symbol Tech. v. Metrologic Instruments, Inc., 771 F.Supp. 1390, 1404-05 (D.N.J. 1991)*. Sandoz intends only to present this evidence for the purpose of rebutting the reasonable royalty opinion submitted by Abbott's expert. Confined to the limited purpose articulated by Sandoz, this testimony is relevant, and its probative value substantially outweighs any danger of unfair prejudice. *Fed. R. Evid. 403*. Abbott may propose a limiting instruction to cabin the jury's consideration of this evidence.

B. DEFENDANT [**62] SANDOZ'S MOTIONS IN LIMINE

1. To exclude argument or suggestion to the jury that Sandoz was required to give Abbott notice prior to launch. [Dkt. 468.]

Sandoz moves to exclude argument that Sandoz was required to give Abbott notice before commencing sales of its extended-release clarithromycin product. Sandoz contends that this argument should be excluded under *Rules 401*, *402*, and *403* because it is not relevant to any issue in this case and would unfairly prejudice the jury against Sandoz.

This motion is unopposed.

Sandoz's motion is GRANTED.

2. To exclude any argument or testimony that a person of ordinary skill in the art would not view azithromycin and clarithromycin as interchangeable. [Dkt. 469.]

Sandoz contends that any argument or testimony that a person of ordinary skill in the art would not view azithromycin and clarithromycin as interchangeable would confuse and mislead the jury and should therefore be excluded under *Rule 403*. Sandoz argues that this is so because the Federal Circuit, in *Abbott Labs. v. Andrx Pharm., Inc.*, found that:

> Because the '190 patent explicitly discloses only clarithromycin controlled release compositions, yet claims azithromycin compositions, we conclude **[**63]** that Abbott has represented to the U.S. Patent and Trademark Office ("PTO") that the differences between clarithromycin and azithromycin were such that azithromycin could be substituted into a controlled release clarithromycin composition by a person of ordinary skill in the art without undue experimentation.

[*786] *452 F.3d 1331, 1341 (Fed. Cir. 2006)*. According to Sandoz, because the Federal Circuit held that clarithromycin and azithromycin are interchangeable in a controlled-release formulation, any argument or testimony to the contrary would confuse the jury.

In response, Abbott argues that an appellate court's rulings in a preliminary injunction appeal do not establish the law of the case for the purposes of a subsequent trial. *See Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. U.S. Dep't of Agric., 499 F.3d 1108, 1114 (9th Cir. 2007)*; *Hunter v. Atchison, Topeka & Santa Fe Ry. Co., 188 F.2d 294, 298-99 (7th Cir. 1951)*. Consistent with this principle, this Court noted in the preliminary injunction opinion in this case that it was not bound by the Federal Circuit's *Teva* decision, as "the Federal Circuit did not have the benefit of certain evidence demonstrating that the **[**64]** '190 patent did not in fact disclose compositions with substantially bioequivalent PK properties as the PK properties of claim 1 of the '718 patent." *Abbott Labs. v. Sandoz, Inc., 500 F.Supp.2d 807, 840 (N.D. Ill. 2007)*. Abbott also points out that, in its more recent summary judgment opinion, this Court held that "there is a disputed genuine issue of material fact with regard to the interchangeability of azithromycin and clarithromycin . . ." *Abbott Labs. v. Sandoz, Inc., 529 F.Supp.2d 893, 917 (N.D. Ill. 2007)*. Finally, Abbott argues that the key obviousness inquiry in this case is not whether the '190 patent treats clarithromycin and azithromycin interchangeably for purposes of its "control release" formulations, but more specifically, whether clarithromycin and azithromycin are interchangeable in order to make a formulation *with a specific PK profile*, as claimed in Abbott's '718 patent.

This motion is DENIED. As Abbott notes, this Court held at summary judgment that there is a genuine issue of material fact as to the interchangeability of azitrhomycin and clarithromycin. Clearly, ***HN12*** a genuine factual dispute cannot be resolved through a motion *in*

limine.

3. To exclude evidence of the **[**65]** Court's preliminary injunction and product recall order. [Dkt. 470.]

Sandoz moves to exclude evidence of the Court's preliminary injunction and product recall order under *Rules 402* and *403*. Sandoz argues that the preliminary determination as to the likelihood of success of Abbott's patent infringement claim is irrelevant to the jury's ultimate determination of that claim. *See Univ. of Texas v. Camenisch, 451 U.S. 390, 101 S. Ct. 1830, 68 L. Ed. 2d 175 (1981)*. Sandoz argues that, even if relevant, this evidence should be excluded under *Rule 403* because it would unfairly prejudice Sandoz and confuse the jury.

Abbott responds that this evidence is relevant to the scope and amount of damages. Abbott argues that the jury must be apprised of the injunction and recall order to understand why Sandoz's sales were relatively limited, despite the dramatic effect of generic entry upon the market for a brand-name drug, why Sandoz stopped selling its product after four months, and why Sandoz recalled its product. Abbott expresses concern that, without this evidence, the jury may fill in the blanks with inferences adverse to Abbott. With respect to the recall, in particular, Abbott notes that Sandoz has made the recall an issue because **[**66]** it seeks to deduct all recalled sales from Abbott's alleged damages. Abbott argues that, because the parties' experts disagree as to how to calculate the value of the recalled products, the jury will have to be informed of the fact of the recall order and the order's details so they can properly assess the **[*787]** damages. [8] Abbott contends that any potential prejudice inflicted by this evidence could be cured with a jury instruction. Alternatively, Abbott requests that if the Court grants Sandoz's motion, it also preclude Sandoz from introducing evidence of the Court's TRO opinion or order.

This motion is DENIED. Evidence of the Court's preliminary injunction and product recall order are directly relevant to the issue of damages. Any potential prejudice caused by this evidence can be neutralized with an appropriate jury instruction. **[**67]** Sandoz may propose such an instruction.

4. To exclude argument and evidence relating to international patent application WO 2005/053650 A1 ("the '650 application") [Dkt. 471.]

Sandoz moves to exclude evidence relating to the '650 application under *Rule 403*, claiming that the '650 application is not relevant to whether the '422 publication, alone or together with the '190 patent, renders the'718 patent obvious, and evidence relating to the '650 patent will only confuse the jury.

By way of background, Sandoz intends to present an obviousness defense that the '422 application, alone or together with the '190 patent, would have taught a person of ordinary skill in the art how to make the '718 patent, including its specific PK profile. As the Court stated in its preliminary injunction decision, "[t]o succeed on its obvious[ness] claim, Sandoz must produce evidence indicating that the PK limitations were disclosed in the prior art or were at the very least inherent to the structural limitations of the prior art compositions." *Sandoz, 500 F.Supp.2d at 840*. Because both parties concede that neither the '422 publication nor the '190 patent expressly

[8] For example, Abbott argues that the fact that the Court's order extended to tablets sold to wholesalers and retailers (but not individual patients) is relevant to the jury's evaluation of whether Abbott's expert's valuation, which is based on the common practices of such wholesalers and retailers, is more accurate than the weighted average method used by Sandoz's expert.

discloses the particular PK limitations, the **[**68]** key question is whether the PK profile claimed by the '718 patent is inherent in the structural limitations of the '422 publication. Abbott intends to rely on the '650 application to refute Sandoz's position that the formulations in the '422 publication inherently possess the same PK profile of the '718 patent. According to Abbott, the '650 application reveals that the formulations in the '422 application actually failed to exhibit the most basic PK parameters required by claims 1 and 4 of the '718 patent: bioavailablity substantially equivalent to that of an immediate release formulation.

Sandoz argues that the '650 application should be excluded as irrelevant because it was not published until 2005, and thus it has no bearing on what a person of ordinary skill in the art would have known or reasonably expected in 1997, when the '718 patent was issued. Sandoz argues that the '650 application addressed many formulations, and Abbott cannot show precisely which formulations of the '422 publication allegedly "failed" bioequivalency. Sandoz concludes that evidence relating to the '650 patent is therefore irrelevant and would serve only to confuse the jury.

Abbott rejects Sandoz's reliance **[**69]** on the fact that the '650 application does not specifically identify the formulations on which Sandoz bases its obviousness defense as failing bioequivalency. According to Abbott, Sandoz ignores that it holds the burden of showing by clear and convincing evidence that formulations taught in the '422 application inherently exhibit elements **[*788]** of the '718 patent claims. Abbott contends that, given Sandoz's burden, the important point is that *Sandoz* cannot identify which, if any, of the '422 formulations achieved adequate bioavailability. Additionally, Abbott points out that this Court has already recognized the relevance of the '650 application in its preliminary injunction opinion. *See Sandoz, 500 F.Supp.2d at 841*. Finally, according to Abbott, the fact that the '650 application is not prior art has no bearing on its relevance since Abbott does not rely on the '650 application as prior art.

This motion is DENIED. Sandoz has not demonstrated that evidence relating to the '650 application is irrelevant or risks confusing the jury. If the '650 application demonstrates that the formulations in the '422 publication do not actually exhibit the PK limitations required by the '718 patent, that evidence **[**70]** would be directly relevant to Sandoz's obviousness defense. This is especially so given that, to succeed on its obviousness defense, Sandoz must prove that the PK limitations of the '718 patent were "at the very least inherent to the structural limitations" in the '422 publication. *Sandoz, 500 F.Supp.2d at 840*.

5. To exclude the statements made in Sandoz's labeling as evidence to support any argument of infringement. [Dkt. 472.]

Sandoz argues that allowing Abbott to introduce statements from Sandoz's product's labeling would mislead the jury and confuse the issues; therefore this evidence should be excluded under *Rule 403*. As background, Sandoz explains that an applicant submitting an abbreviated new drug application ("ANDA") to the FDA must show that the generic drug's proposed labeling is the same as the brand-name drug's labeling. *See 21 U.S.C. § 355(j)(2)(A)(v)*. Sandoz explains that, due to this requirement, the labeling for its product is nearly identical to Abbott's Biaxin XL labeling. [9] Further, statements in Sandoz's labeling pertaining to its product's effects were lifted directly from Biaxin XL's labeling, and Sandoz never conducted studies that confirmed the

[9] Sandoz writes "Biaxin," but I presume Sandoz means "Biaxin XL."

veracity of these **[**71]** statements as applied to its own product. [10] Sandoz argues that, if these statements were admitted at trial, "it would mislead the jury into thinking that the statements describe Sandoz's extended-release product when they do not." (Sandoz Mot. *in Limine* Dkt. #472 at 5.)

Abbott argues **[**72]** that the statements in Sandoz's labeling constitute highly probative evidence of infringement that is not substantially outweighed by a danger of unfair prejudice. *See Fed. R. Evid. 403*. Abbott argues that the accuracy of statements in the ANDA may be presumed since inaccuracy is grounds for an application's disapproval. *21 U.S.C. § 355(j)(4)(J)* & *(K)*; *Dr. Reddy's Labs., Inc. v. Thompson, 302 F.Supp.2d 340, 354-55 (D.N.J. 2003)*. Abbott also points out that in both its preliminary injunction and summary **[*789]** judgment opinions, this Court has already relied on the labeling statements at issue. Next, Abbott rejects Sandoz's contention that Sandoz was "required by law" to include these statements, arguing that Sandoz voluntarily chose to submit an ANDA relying on Abbott's labeling, rather than submitting a New Drug Application ("NDA"), which would have required Sandoz to conduct its own studies. Also, a generic company can seek to modify the innovator's product label if it believes the statements are inaccurate with respect to its product, and once an ANDA is approved, a generic producer has the same duty to update warnings as the innovator. *21 C.F.R. § 314.94(a)(8)(iv) (2009)*; *§ 314.70*; *§ 314.71*; **[**73]** *Abbott Labs v. TorPharm, Inc., 300 F.3d 1367, 1374 (Fed. Cir. 2002)*; *Foster v. Am. Home Prods. Corp., 29 F.3d 165, 169 (4th Cir. 1994)*; *Laisure-Radke v. Par. Pharm., Inc., No. C03-365RSM, 2006 U.S. Dist. LEXIS 57158, 2006 WL 901657, at *4-5 (W.D. Wash. Mar. 29, 2006)*. Recognizing these considerations, courts have allowed portions of an ANDA applicant's label, even when copied from the brand-name drug's label, to serve as evidence of the characteristics of the applicant's product. *See, e.g., TorPharm, 300 F.3d at 1374*; *Foster, 29 F.3d at 169-70*. Abbott argues that, given this case law, the statements in Sandoz's labeling should be admitted. Finally, Abbott rejects Sandoz's argument that the jury may be confused into thinking that these statements describe testing done on Sandoz's own product; Abbott suggests that the simple way to avoid such confusion is for Sandoz to introduce evidence that it did not perform the studies referenced in its product's label.

This motion is DENIED. Sandoz has not demonstrated that the danger of unfair prejudice or confusion substantially outweighs the probative value of the statements in Sandoz's labeling. As Abbott argues, ***HN13*** many courts have considered a generic drug's labeling, when **[**74]** derived from the brand-name product's, as evidence of the generic drug's characteristics. These courts have often done so over the generic producer's objection that it was simply "required by law" to duplicate the innovator's labeling. Sandoz offers no authority or explanation distinguishing these cases from the instant case.

6. To exclude any argument or suggestion that the Pharma Medica study was not conducted in accordance with Canadian regulations. [Dkt. 473.]

[10] Sandoz lists several examples of these statements: (1) "[i]n the acute exacerbation of chronic bronchitis and acute maxillary sinusitis studies," patients taking the extended-release formulation "reported significantly less severe gastrointestinal symptoms compared to patients taking the immediate-release formulation (Def. Mot. Ex. 2, PTX0521 at SANDOZ000725); (2) patients taking the extended-release product "had significantly fewer premature discontinuations for drug-related gastrointestinal or abnormal taste adverse events" compared to patients taking the immediate-release product (*id.*); (3) "relative to an equal total daily dose of immediate-release clarithromycin tablets, clarithromycin extended-release tablets provide lower and steady-state peak plasma concentrations but equivalent 24-hour AUC's" (*id.* Ex. 2, PTX0521 at SANDOZ000706).

Sandoz argues that *Rules 401*, *402*, and *403* require the Court to exclude any argument or suggestion that the Pharma Medica study was not conducted in accordance with Canadian regulations. Sandoz argues that, as a matter of incontrovertible fact, the Pharma Medica study *did* comply with Canadian regulations. Additionally, Sandoz argues that the proper vehicle for argument on this topic is expert testimony, yet Abbott has provided no related expert opinion. Finally, Sandoz contends that any argument that the Pharma Medica study did not comply with Canadian regulations would unfairly prejudice Sandoz by providing an improper basis to discount the study.

This motion is unopposed.

Sandoz's motion is GRANTED.

7. To exclude any argument **[**75]** or testimony that storage conditions of clarithromycin products used in the Pharma Medica study affected the study's results. [Dkt. 474.]

Sandoz argues that *Rules 401*, *402*, and *403* require the exclusion of any argument or testimony that storage conditions of clarithromycin products used in the Pharma Medica study affected the study's results. According to Sandoz, such evidence would be irrelevant and unfairly prejudicial **[*790]** because there is no evidence that: (1) the product samples were ever stored at extreme temperatures; (2) the storage conditions of the samples could have affected the study's results; or (3) any of the samples were opened prior to being tested.

This motion is unopposed.

Sandoz's motion is GRANTED.

8. To exclude any argument and evidence concerning Locke Lord Bissell & Lidell LLP's sponsorship of the Pharma Medica study and/or selection of study parameters. [Dkt. 475.]

Sandoz moves to exclude, under *Rules 401*, *402*, and *403*, argument and evidence pertaining to Locke Lord Bissell & Liddell's ("LLBL") sponsorship of the Pharma Medica study or selection of study parameters. By way of background, Sandoz explains that LLBL engaged Pharma Medica to perform a study comparing Sandoz's **[**76]** product to Abbott's immediate-release Biaxin. Sandoz argues that, in considering the Pharma Medica study, the only relevant aspect of the study design is the study parameters, not who chose those parameters or why. Further, Sandoz contends that evidence of LLBL's sponsorship of the Pharma Medica study or selection of parameters would provide the jury with an improper basis to discount the credibility and results of the study and must therefore be excluded under *Rule 403*. Sandoz argues that the jury's assessment of the Pharma Medica study must be based only on the scientific evidence itself. Sandoz specifically seeks to exclude argument and evidence concerning the fact that LLBL sponsored the Pharma Medica study or was involved with the selection of study parameters, including exclusion of PTX0053-61, PTX0085-97, PTX0099-101, PTX0105, PTX0109-10, PTX0366, PTX0382, and the testimony of Scott B. Feder.

The crux of Abbott's criticism of the Pharma Medica study is that Sandoz's counsel allegedly defied the advice of the clinical study professionals and adopted an asymmetrical feeding regimen to produce results that support Sandoz's defense. Abbott argues that evidence of counsel's sponsorship **[**77]** and participation in the Pharma Medica study is clearly relevant and is crucial to the weight assigned to the study. To support this proposition, Abbott cites a number of cases in which courts excluded surveys that were designed by counsel. *See, e.g.,*

Hodgdon Powder Co., Inc. v. Alliant Techsys, Inc., 512 F.Supp.2d 1178, 1181 (D. Kan. 2007); *Muha v. Encore Receivable Mgmt., Inc., 516 F.Supp.2d 959, 963-64 (E.D. Wis. 2007)*; *U.S. v. Southern Indiana Gas and Elec. Co., 258 F. Supp. 2d 884 (S.D. Ind. 2003)*. Abbott relies most on the court's decision in *Southern Indiana Gas* to exclude a census where the consultants and lawyers had collaborated extensively in designing and conducting the census. Abbott contends that, under *Southern Indiana Gas*, the proper question should not be whether Sandoz's lawyers' involvement is fair game for attack at trial, but whether the study should even be admissible at all. Abbott concludes that, where counsel's sponsorship or involvement in studies affects their design, counsel's involvement is always relevant to the credibility, potential bias, and reliability of those studies. To support this contention, Abbott cites several cases in which an attorney's help **[**78]** preparing an expert report was deemed relevant to the weight of the expert's testimony. *See Elm Grove Coal Co. v. Director, Office of Workers Compensation Prog., 480 F.3d 278, 301 n.23 (4th Cir. 2007)*; *Keystone Mfg. Co., Inc. v. Jaccard Corp., 394 F.Supp.2d 543, 568 (W.D.N.Y. 2005)*. Finally, Abbott points out that none of the cases on which Sandoz relies addresses the relevance of attorney involvement in **[*791]** studies commissioned for use as evidence in litigation.

This motion is DENIED, but not entirely for the reasons stated by Abbott. The first set of cases Abbott cites are inapposite, as both the nature and extent of attorney involvement are distinguishable from the instant case. In addition to dealing with surveys rather than the type of medical study at issue here, the cases Abbott cites involve much more extensive participation by the attorneys than is alleged here. For example, in *Southern Indiana Gas*, the case on which Abbott places the greatest emphasis, the court excluded census data where the census was flawed for several reasons, including the lawyers' extensive participation in designing and administering the census and reviewing the census data. The court noted that, while **[**79]** some level of participation by attorneys in designing a survey actually may be preferable rather than objectionable, the "concern in the instant case is the *degree* of attorney involvement by SIGECO's lawyers, and SIGECO's lawyers' participation in carrying out the survey." *Southern Indiana Gas, 258 F. Supp. 2d at 894* (emphasis in original). The court rejected the defendant's argument that the survey's reliability goes to its weight rather than its admissibility. Instead, the court concluded that, because the census's "infirmities are substantial and fundamental, rendering the Census inherently untrustworthy," it should be excluded altogether. *Id. at 895*.

The alleged flaws in the Pharma Medica study are not nearly this extreme. Abbott does not allege that Sandoz's attorneys were as deeply involved in the study as the attorneys who designed and helped administer the census in *Southern Indiana Gas*. Abbott contends that Sandoz's attorneys sponsored the study, communicated with Pharma Medica about the study, and helped select the study's parameters. Abbott does not explain how this type of involvement is comparable to actually writing survey questions and administering the survey. Rather, **[**80]** the alleged degree of attorney participation here is more akin to the attorneys' involvement in the second set of cases Abbott cites. These cases held that ***HN14*** counsel's help preparing an expert report was relevant to the weight of the expert's testimony. *See Elm Grove Coal Co., 480 F.3d at 301 n.23*; *Keystone Mfg. Co., 394 F.Supp.2d at 568*. Similarly, counsel's potential impact on the substance of expert testimony here is relevant to the weight and credibility of that testimony. Sandoz has not cited any relevant authority explaining why its sponsorship of the Pharma Medica study and

participation in selecting the study's parameters are irrelevant or improper grounds for challenging the study's results. Accordingly, the motion is denied.

9. To exclude the expert testimony of Dr. Stanley S. Davis. [Dkt. 476.]

Sandoz moves to exclude the testimony of Dr. Stanley Davis, arguing that his testimony is neither reliable nor relevant as required by *Fed. R. Evid. 702*. Sandoz moves to exclude this testimony on five specific grounds:

(1) Dr. Davis's construction of "pharmaceutically acceptable polymer" as requiring a "matrix" violates the law on claim construction and is therefore unreliable and irrelevant. **[**81]** Specifically, because Dr. Davis's construction would exclude a disclosed embodiment (a suspension, which is not a matrix formulation), it is contrary to the law of claim construction. In addition, Dr. Davis's construction contradicts the intrinsic evidence of the patent specification and therefore cannot support a jury verdict of infringement.

[*792] (2) Dr. Davis's opinion that a "matrix" as opposed to the claimed "pharmaceutically acceptable polymer" extends release of the claimed composition is unreliable because it is contrary to the intrinsic teaching in the patent, contradicts his previous sworn testimony, and is merely an untested hypothesis. Moreover, Dr. Davis's testimony is unreliable because he has improperly extrapolated, from a basic scientific premise, an unsupported conclusion that the patent claims do not require that the "pharmaceutically acceptable polymer" extend release.

(3) Dr. Davis did not test Sandoz's product and admitted that he cannot determine which component of Sandoz's product functions to extend release of clarithromycin. Sandoz argues that, where an expert's opinions "clearly lend themselves to testing and substantiation by the scientific method," it is appropriate **[**82]** for a court to exclude opinion evidence if the expert has not performed tests. *Cummins v. Lyle Indus., 93 F.3d 362, 369 (7th Cir. 1996)*.

(4) Dr. Davis presupposed, without any testing, that Sandoz's product is a matrix, and that the matrix is responsible for extending release of clarithromycin.

(5) The scientific references Dr. Davis relies on to show that maltodextrin or SMCC extend release are irrelevant because they do not discuss formulations that contain clarithromycin or any other erythromycin derivative.

On these five grounds, Sandoz moves to exclude any testimony or evidence from Dr. Davis, including the following trial exhibits: PTX0156-58, PTX0189, PTX0192-94, PTX0196-201, PTX0208, PTX0222, PTX0224-26, PTX0265, PTX0267-68, PTX0271, PTX0273-74, PTX0276-77, PTX0282-83, PTX0302-03, and PTX0310.

Abbott responds that none of the grounds identified by Sandoz justify precluding Dr. Davis from testifying. Below are Abbott's responses to each of Sandoz's grounds for exclusion:

(1) Abbott argues that Sandoz's request that the Court exclude Dr. Davis's construction of "pharmaceutically acceptable polymer" is misplaced. Abbott does not intend to offer this type of opinion from Dr. Davis since **[**83]** claim construction is an issue of law, which the Court has already resolved. [11] Dr.

---

[11] The Court construed the term "pharmaceutically acceptable polymer" to mean a polymer that is pharmaceutically acceptable and that "extends drug release into the bloodstream either alone or in conjunction with other such polymers or other components, and is capable of forming a gel or a matrix to extend drug release into the

Davis plans to testify as to why, under the Court's construction of the term "pharmaceutically acceptable polymer," Sandoz's product meets this claim limitation, including the matrix requirement.

(2) With respect to Sandoz's second ground for excluding Dr. Davis's testimony, Abbott argues that Sandoz misinterprets Dr. Davis's opinion. Dr. Davis has not opined that a "matrix," as opposed to the claimed "pharmaceutically acceptable polymer," extends release. Rather, Dr. Davis will testify that the "pharmaceutically acceptable polymer" controls release, and it does so by forming part of a matrix drug delivery system. Abbott argues that this opinion is **[**84]** consistent with the Court's claim construction, and any contention that it is not can be addressed on cross-examination.

[*793] (3) & (4) Addressing Sandoz's third and fourth grounds, which both relate to Dr. Davis's failure to personally conduct testing, Abbott argues that neither *Rule 702* nor *Daubert* require that Dr. Davis conduct hands-on testing to support his opinions. See *Cummins, 93 F.3d at 369* (hands-on testing is not an "absolute prerequisite to the admission of expert testimony. *Rule 702* is designed to ensure that, when expert witnesses testify in court, they adhere to the same standards of intellectual rigor that are demanded in their professional work."). Abbott contends that Dr. Davis based his opinion on scientific literature as well as the experiments and published patent application of Niral Mulye, the developer of Sandoz's formulation. Abbott also points out that Sandoz does not hold its expert, Dr. Chambliss to the same standard it seeks to impose on Abbott, as Dr. Chambliss conducted no testing to support his various opinions. Next, Abbott argues that Dr. Davis's opinions conform to the standards and practices of scientists in his field, who determine the likely role of **[**85]** excipients in a given formulation based on the literature and their general understanding, without conducting any testing. For example, Sandoz did no testing to confirm the function of the excipients in its

(5) Finally, Abbott contends that Sandoz's argument that Dr. Davis's scientific references are irrelevant because they do not involve clarithromycin is hypocritical. Abbott points out that Sandoz presses this argument despite the fact that: (1) its own expert relies on literature that does not involve clarithromycin, and (2) Sandoz argues that a person of ordinary skill in the art, looking at non-clarithromycin references such as the '571, '667, and '422 publications, would find it obvious to make the clarithromycin composition in the patents-in-suit. According to Abbott, Sandoz seeks to exclude references on which Dr. Davis relies to rebut *Dr. Chambliss's* testimony involving non-clarithromycin formulations. More generally, that maltodextrin or other excipients have been described in scientific literature as extending release (whether or not in connection with clarithromycin) is relevant to Dr. Davis's opinion that such excipients may perform this role in Sandoz's formulation.

In **[**86]** addition to contesting the five grounds for Sandoz's motion to exclude Dr. Chambliss's testimony, Abbott argues that the scope of preclusion Sandoz seeks goes far beyond the issues upon which it bases its motion. (Abbott Resp. to Sandoz Mot. *in Limine* #476 at 9) (listing examples of references that have no bearing on the infringement issues upon which Sandoz bases its motion).

This motion is DENIED for the reasons stated by Abbott. ***HN15*** *Federal Rule of Evidence 702*

bloodstream." *Abbott Labs. v. Sandoz, Inc., 529 F.Supp.2d 893, 911 (N.D. Ill. 2007)*, *aff'd*, *544 F.3d 1341, 1359-60 (Fed. Cir. 2008)*.

permits expert testimony if:

> (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702; *see also Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993)*. *Rule 702* ensures that "when expert witnesses testify in court, they adhere to the same standards of intellectual rigor that are demanded in their professional work." *Cummins v. Lyle Indus., 93 F.3d 362, 369 (7th Cir. 1996)*. Expert witnesses need not perform "hands-on testing" to meet this objective; they may do so simply "through the review of experimental, statistical, or other **[*794]** scientific data generated **[**87]** by others in the field." *Id.*; *see also Clark v. Takata Corp., 192 F.3d 750, 758 (7th Cir. 1999)* ("Either 'hands-on testing' or 'review of experimental, statistical, or other scientific data generated by others in the field' may suffice as a reasonable methodology upon which to base an opinion.") (quoting *Cummins, 93 F.3d at 369*); *Gaskin v. Sharp Electronics Corp., No. 2:05-CV-303, 2007 U.S. Dist. LEXIS 65532, 2007 WL 2572397, at *6 (N.D. Ind. Aug. 31, 2007)*("The key inquiry is, whether testing is done or not, whether the expert is testifying with the 'same standards of intellectual rigor that are demanded in their professional work.'") (quoting *Cummins, 93 F.3d at 369*).

None of the grounds offered by Sandoz demonstrate that Dr. Davis's expert testimony is improper under *Fed. R. Evid. 702* and *Daubert*. Sandoz's first ground for exclusion is misplaced, as Abbott does not intend to offer Dr. Davis's testimony on claim construction, which is a matter of law that has been resolved by the Court. Additionally, even though Dr. Davis did not personally conduct testing to support his opinions, his reliance on scientific literature, and testing performed by the developer of Sandoz's product, meets the "same standards of intellectual **[**88]** rigor" demanded by the field of pharmaceutical formulation. *Cummins, 93 F.3d at 369*. Moreover, Abbott shows that Sandoz's criticisms of Dr. Davis—for failing to perform hands-on testing and relying on references that do not involve clarithromycin—apply equally to its own expert, Dr. Chambliss. Ultimately, none of Sandoz's arguments support the exclusion of Dr. Davis's testimony. This testimony will be admitted, and Sandoz will be permitted to address the issues raised in this motion through its cross-examination of Dr. Davis at trial.

CONCLUSION

For the reasons stated above, Plaintiff Abbott's motions *in limine* [478], [479], [483], and [484] are GRANTED, Plaintiff Abbott's motions *in limine* [477], [480], [482], [486], [492], are DENIED, and Plaintiff Abbott's motions *in limine* [481], [485], and [489] are DENIED IN PART and GRANTED IN PART. Defendant Sandoz's motions *in limine* [468], [473], and [474] are GRANTED, and Defendant Sandoz's motions *in limine* [469], [470], [471], [472], [475], and [476] are DENIED.

Dated: May 24, 2010

/s/ David H. Coar

David H. Coar

United States District Judge

End of Document