IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., PFIZER PHARMACEUTICALS, LLC, PFIZER LIMITED, C.P. PHARMACEUTICALS INTERNATIONAL C.V., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, WARNER-LAMBERT COMPANY, LLC and WARNER-LAMBERT EXPORT LTD.,	)	
Plaintiffs/Counterclaim-Defendants,	)	
v.	)	Civil Action No. 07-138 (JJF)
RANBAXY LABORATORIES LIMITED, and RANBAXY INC.,	)	
Defendants/Counter-Claimants.	)	

PFIZER'S REPLY BRIEF IN SUPPORT OF ITS MOTION TO DISMISS AND FOR PARTIAL JUDGMENT ON THE PLEADINGS PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 12(c)

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I. INTRODUCTION

Ranbaxy concedes that under ordinary application of *res judicata* its First Counterclaim of Invalidity and Third Affirmative Defense to infringement relating to the '893 patent should be barred based on the final judgment entered in the prior Lipitor® Litigation. Nonetheless, Ranbaxy argues that this Court should reject normal application of the doctrine and not apply *res judicata* because (1) the Supreme Court's recent *KSR* decision allegedly alters the obviousness standard and (2) there is a purported change in facts. For the same reasons, Ranbaxy also asserts that collateral estoppel on infringement of the '893 patent does not apply. These arguments are meritless.

II. ARGUMENT

A. Res Judicata Bars Ranbaxy's Third Affirmative Defense and First Counterclaim.

The three elements of *res judicata* are indisputably satisfied here on the face of the pleadings. First, it is beyond question that the prior Lipitor® Litigation has concluded with a final judgment against Ranbaxy Laboratories Limited and Ranbaxy Pharmaceuticals, Inc. Second, Ranbaxy Laboratories Limited was a party to the prior Lipitor® Litigation, and is the defendant/counterclaimant here. Third, Ranbaxy's First Counterclaim and Third Affirmative Defense (as they are stated in the Amended Answer and Counterclaims) present the issue of the validity of the '893 patent, an issue already decided against Ranbaxy in the Lipitor® Litigation. The counterclaim and affirmative defense in this case, and the counterclaims and affirmative defense in the Lipitor® Litigation, present the identical cause of action. *See* Restatement (Second) of Judgments § 24(2) (all actions arising from the same transaction or series of transactions are regarded as constituting a single cause of action); *Gregory v. Chehi*, 843 F.2d 111, 117

(3d Cir. 1988) (for purposes of claim preclusion analysis, the term "claim" is defined "broadly in transactional terms, regardless of the number of substantive theories advanced in the multiple suits by the plaintiff") (citing Restatement (Second) of Judgments § 24 cmt. a (1982)); *Foster v. Hallco Mfg. Co.*, 947 F.2d 469, 478-79 (Fed. Cir. 1991). Further, the ANDA product involved in the current litigation (amlodipine besylate and amorphous atorvastatin calcium) unquestionably contains Ranbaxy's ANDA product from the Lipitor® Litigation (amorphous atorvastatin calcium). The previous litigation has conclusively determined that the '893 patent (and its patent term extension) is not invalid or unenforceable. Ranbaxy's attempt to relitigate the validity of the '893 patent or its term extension must therefore be rejected.

Ranbaxy does not seriously deny that *res judicata* would normally apply. Instead, it seeks to avoid application of *res judicata* on the basis of an alleged sea change in the law and an alleged significant change in facts. These arguments are meritless.

1. Ranbaxy overstates the exception from application of res judicata for changes in the law occurring after judgment is entered.

Ranbaxy relies on a single Supreme Court case to support its argument that a purported basic change in the law entitles it to avoid application of *res judicata*. The citation to *State Farm Mut. Auto. Ins. Co. v. Duel,* 324 U.S. 154 (1945) is inapposite on several grounds. First, the language is dicta. The court was not called upon to decide if *res judicata* would apply. *See id.*, 324 U.S. at 163 (Jackson, J., dissenting). It was merely speculating as to whether another suit then pending for a different license year would be barred by its judgment. Second, it was applying Wisconsin law. Third, the case arose in the arena of license law which, like tax cases, requires a new application of the law to the facts each year. The decision can not be taken as a general statement of the

law of *res judicata*.

Ranbaxy's citation to *In Re Bose* is similarly misguided. The *Bose* opinion merely determined that no change in the law had occurred, not the effect of such a change. *Id.* at 1336. Similarly, *Park Lane Hosery Co. Inc. v. Shore,* 439 U.S. 322, 326 (1979) does not involve *res judicata* but collateral estoppel and does not address change of law as a basis to avoid its application.

In the *Federated Deptartment Stores* case, the Supreme Court rejected the very argument Ranbaxy makes here.

> Nor are the *res judicata* consequences of a final, unappealed judgment on the merits altered by the fact that the judgment may have been wrong or rested on a legal principle subsequently overruled in another case. *Angel v. Bullington*, 330 U.S. 183, 187, 67 S.Ct. 657, 659, 91 L.Ed. 832 (1947); *Chicot County Drainage District v. Baxter State Bank*, 308 U.S. 371, 60 S.Ct. 317, 84 L.Ed. 329 (1940); *Wilson's Executor v. Deen,* 121 U.S. 525, 534, 7 S.Ct. 1004, 1007, 30 L.Ed. 980 (1887). As this Court explained in *Baltimore S.S. Co. v. Phillips*, 274 U.S. 316, 325, 47 S.Ct. 600, 604, 71 L.Ed. 1069 (1927), an "erroneous conclusion" reached by the court in the first suit does not deprive the defendants in the second action "of their right to rely upon the plea of *res judicata*.... A judgment merely voidable because based upon an erroneous view of the law is not open to collateral attack, but can be corrected only by a direct review and not by bringing another action upon the same cause [of action]." We have observed that "[t]he indulgence of a contrary view would result in creating elements of uncertainty and confusion and in undermining the conclusive character of judgments, consequences which it was the very purpose of the doctrine of *res judicata* to avert." *Reed v. Allen*, 286 U.S. 191, 201, 52 S.Ct. 532, 534, 76 L.Ed. 1054 (1932).

Federated Dept. Stores, Inc. v. Moitie, 452 U.S. 394, 398-99 (1981).

The Third Circuit has applied this rule of finality. *Barzin v. Selective Service Local Bd. No. 14,* 446 F.2d 1382, 1383 (3d Cir. 1971) stands for the proposition that:

> For a prior decision may serve as *res judicata* even if a contrary judicial decision on the legal issues involved intervenes between the first and second suits. *Clouatre v. Houston Fire & Casualty Co.,* 5th Cir. 1956, 229 F.2d 596; *Ripperger v. A. C. Allyn & Co.*, 2d Cir. 1940, 113 F.2d 332, *cert. denied*, 311 U.S. 695, 61 S.Ct. 136, 85 L.Ed. 450.

Ranbaxy's change of law argument is contrary to controlling law.[1]

2. A Change of Facts Does Not Generally Alter The Application of Res Judicata.

Ranbaxy misstates the law of *res judicata* in claiming that purported changes in factual circumstances preclude the application of *res judicata*. The caselaw does not support such a sweeping rule. That new facts may be discovered does not permit a party to relitigate claims already reduced to judgment.

The cases cited by Ranbaxy present application of *res judicata* in situations far from the normal. For example, *Brown v. Felsen,* 442 U.S. 127 (1979) concerns application of *res judicata* in a bankruptcy proceeding. In that case, the Supreme Court recognized that "[r]espondent's *res judicata* claim is unlike those customarily entertained by the courts." Id. at 132. Several of the other cases cited by Ranbaxy are tax cases where facts adjudicated in one year are held not to preclude a contrary adjudication for a subsequent tax year. *Commissioner v. Sunnen*, 333 U.S. 591 (1948); *Commissioner v. Thomas Flexible Coupling Co.,* 198 F.2d 350 (3d Cir. 1952). Other cases deal with administrative appeals. *In re Bose Corp., supra.* (recognizing that "exercise of caution in applying claim preclusion in an ex parte proceeding" is appropriate.); *Mayer/Berkshire Corp. v. Berkshire Fashions, Inc.,* 424 F.3d 1229, 1234 (Fed. Cir. 2005) ("[c]aution is warranted in the application of preclusion by the PTO, for the purposes of administrative trademark procedures include protecting both the consumer public and the purveyors").

These cases offer inappropriate authority to support the general rule which Ranbaxy seeks to use to avoid the prior judgment.

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[1] It should be noted that the Restatement 2d Judgments does not recognize the exception to *res judicata* urged by Ranbaxy.

The appropriate remedy for Ranbaxy, if it wished to introduce new facts, was to apply for relief from the judgment under Fed. R. Civ. P., Rule 60. If Ranbaxy truly has newly discovered evidence that the '893 patent is invalid (which it does not, *see supra* at p. 8), it should have presented that to the Court in the manner prescribed by the Federal Rules. But it should not be permitted to collaterally attack the scope of the judgment in this proceeding. In fact, Ranbaxy cannot meet the standards of Rule 60 (b) for relief from the judgment. "'Rule 60(b) provides for extraordinary relief and may only be invoked upon a showing of exceptional circumstances.'" *Color-Plus Leather Restoration System, L.L.C. v. Vincie,* 198 Fed.Appx. 165, 166 (3d Cir. 2006), *quoting Vecchione v. Wohlgemuth*, 558 F.2d 150, 159 (3d Cir. 1977) (citing *Mayberry v. Maroney*, 529 F.2d 332, 335 (3d Cir.1976)). There is no reason to permit Ranbaxy to do collaterally that which it cannot do directly. *See Selkridge v. United of Omaha Life Ins. Co.*, 360 F.3d 155, 172 (3d Cir. 2004).

3. The Claim of Patent Invalidity Is The Same Claim Previously Adjudicated.

Ranbaxy attempts to split its claims by arguing that its defense and counterclaim at issue is a different cause of action than what was at issue in the prior Lipitor® Litigation. This is incorrect. The transactional approach applies when determining what claims are barred. In the patent context, this means generally that the transaction is the specific infringement and products which are essentially the same. *Foster v. Hallco Mfg. Co., Inc.*, 947 F.2d 469, 479-80 (Fed. Cir. 1991) ("It follows that for claim preclusion to apply here, the devices in the two suits must be essentially the same.") Ranbaxy has conceded that the atorvastatin product in its original ANDA and the ANDA now at issue is the same. Any defense to infringement (including purported obviousness) that

Ranbaxy failed to raise and/or litigate previously is now barred.

4. The Supreme Court's KSR Decision Reaffirms Its Precedent On The Standard For Obviousness.

Ranbaxy's argument that *KSR* radically changes the standards for obviousness is wrong and an overstatement.

Prior to *KSR*, the Federal Circuit had employed an additional test for determining the obviousness of combining prior art references. That inquiry required the party seeking to invalidate a patent to establish "some teaching, suggestion, or motivation to combine the references." *In re Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1998). The Supreme Court addressed the "teaching, suggestion or motivation" or "TSM" test in *KSR*. The Court expressly recognized that the test "captured a helpful insight," but the Supreme Court nevertheless cautioned that "[t]he obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation." *KSR Intern. Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1941 (2007). Courts must avoid a "rigid approach" in determining whether an invention would have been obvious to a skilled artisan. *KSR*, 127 S.Ct. at 1739. Rather, an "expansive and flexible approach" must be applied, and the courts may utilize "common sense" in addressing a question of obviousness under § 103. *KSR*, 2007 WL 1237837, at *12, 15; *see also DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1367-71 (Fed. Cir. 2006) *cert. denied*, No. 06-1207, 2007 WL 682021 (June 11, 2007); *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1291 (Fed. Cir. 2006).

In *KSR*, the Supreme Court explicitly affirmed its prior holdings on obviousness:

> Neither the enactment of § 103 nor the analysis in *Graham* disturbed this Court's earlier instructions concerning the need for caution in granting a patent based on the combination of elements found in the prior art. For over a half century, the Court has held that a "patent for a combination

> which only unites old elements with no change in their respective functions ... obviously withdraws what is already known into the field of its monopoly and diminishes the resources available to skillful men." *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 152, 71 S.Ct. 127, 95 L.Ed. 162 (1950).

KSR Intern. Co. v. Teleflex Inc., 127 S.Ct. at 1739.

Moreover, KSR did not overturn all Federal Circuit precedent using the TSM test. *See McNeil-PPC, Inc. v. Perrigo Co.*, No. 05 Civ. 1321, 2007 WL 1624764, at *8 (S.D.N.Y. June 5, 2007) ("Supreme Court did suggest, however, that some Federal Circuit caselaw may have appropriately applied the broad conception of the teaching, suggestion or motivation test that the Supreme Court has endorsed.").

Thus, the argument that KSR enacted a sea change in the obviousness analysis is unavailing.

5. Ranbaxy Failed To Make And Preserve An Obviousness Defense To The '893 Patent

Ranbaxy did not make an obviousness challenge to the '893 patent at trial in the Lipitor® Litigation. It may not do so now. Even if *KSR* were found to be a major change in the law of obviousness, Ranbaxy did not preserve the right to make this challenge. To permit Ranbaxy to make such a challenge now, when it did not do so previously, would open the door for every pre-*KSR* patent case to be relitigated. Only those parties which made such an argument should be permitted to take advantage of any change in the law.

> "Where, for example, a court in deciding a case has enunciated a rule of law, the parties in a subsequent action upon a different demand are not estopped from insisting that the law is otherwise, merely because the parties are the same in both cases. But a fact, question or right distinctly adjudged in the original action cannot be disputed in a subsequent action, even though the determination was reached upon an erroneous view or by an erroneous application of the law."

Montana v. United States, 440 U.S. 147, 162 (1979), quoting *United States v. Moser*, 266

U.S. 236, 242 (1924).

Here, with respect to the '893 patent, Ranbaxy failed to raise any obviousness argument whatsoever at trial in the Lipitor® Litigation. Having failed to preserve the issue, Ranbaxy cannot take advantage of a purported change in the standard for obviousness.

6. Ranbaxy's Change of Facts Argument Fails.

Assuming that a change in the facts may be a basis to avoid *res judicata*, Ranbaxy has not established that the facts have changed sufficiently to merit such a result. Ranbaxy cannot even establish a change of facts which would meet the test of Fed. R. Civ. P. Rule 60 (b). Ranbaxy was fully aware of the relevant facts prior to trial in the Lipitor® Litigation. Ranbaxy concedes that it had the alleged prior art patent which was introduced at the Lipitor® trial and that it received the mislabeled data from CSI screen 124 in discovery. In fact, the CSI screen test data were produced to Ranbaxy on October 23, 2003, more than a full year before trial. Ranbaxy also concedes that it was aware of the mislabeling well in advance of trial. A stipulation relating to this mislabeled data was entered on September 3, 2004. [C.A. No.. 03-209, D.I. 191] The trial was not held until late November/early December. In fact, Ranbaxy was expressly told about the inadvertent mislabeling at the deposition of Francis J. Tinney, Ph.D., Esq. on July 19th, 2004, at least 114 days before trial:

> BY MR. LE MEILLEUR:
> Q. I asked: "Can you tell me if CSI data was submitted in this particular response?"
> Mr. Tinney answered: "In the comparison data sheet which is attached to Ivo Mansmann's response to the EPO, the only indication is COR test data."
> A. I'd like to clarify my answer to that question.
> Q. Okay.
> A. The comparison data sheet indicates that it's COR test in the

> upper right-hand corner, but that is erroneously mislabeled. That is CSI data.
>
> ***
>
> Q. So, Mr. Tinney, is it your testimony that no COR test data was submitted in this response, Exhibit 371?
>
> A. My testimony -- my testimony is that the data that was submitted in this response was the CSI data. There was an error in labeling it COR test data.

(Dep. of Francis J. Tinney, Ph.D., Esq., dated July 19, 2004, pp. 48-50. Attached as Exhibit "A").

Ranbaxy's argument thus condenses into an assertion that it failed to appreciate and/or act on the significance of the data until long after trial. This is not an appropriate reason to avoid the application of *res judicata*.

Even if Ranbaxy could be said to have been unaware of the relevant facts prior to trial, the remedy was to seek a new trial. New trials may be granted in the following extraordinary situations: (1) the jury's verdict is against the clear weight of the evidence, and a new trial must be granted to prevent a miscarriage of justice; (2) newly-discovered evidence later surfaces that would likely alter the outcome of the trial; (3) improper conduct by an attorney or the court unfairly influenced the verdict; or (4) the jury's verdict was facially inconsistent. *See Zarow-Smith v. N.J. Transit Rail Operations, Inc.*, 953 F.Supp. 581, 584 (D.N.J. 1997) (citations omitted). None of those unusual circumstances exist here.

Ranbaxy had a full opportunity to present an obviousness defense in the Lipitor® Litigation and elected not to do so as part of its trial strategy. Ranbaxy should not be permitted, now that its trial tactics failed, to avoid application of *res judicata*. Ranbaxy did not make appropriate attempts to bring the alleged "new evidence" (of which it had

full knowledge well before trial) to the attention of the Court in the Lipitor® Litigation.

B. Collateral Estoppel Precludes Ranbaxy's Invalidity Claims

Ranbaxy reiterates its arguments against application of *res judicata* in an attempt to defeat application of the related doctrine of collateral estoppel. Collateral estoppel bars relitigation of the issue of validity. Ranbaxy makes no argument that the atorvastatin calcium product which was the subject of the infringement in the prior Lipitor® Litigation is different from the atorvastatin calcium ingredient at issue in this litigation – indeed, it has admitted it is identical. Because the infringing product is the same or not "colorably different," Ranbaxy's attempts to defeat collateral estoppel must fail. This action is for infringement of the same patent, by the same active ingredient, with the same parties. Accordingly, collateral estoppel applies to this Court's prior determinations of the validity, enforceability and infringement of the '893 patent.

C. Public Policy Favors Repose of Litigation

Ranbaxy's reliance on the public interest in the patent system is unavailing. The Supreme Court has stated that "'[p]ublic policy dictates that there be an end of litigation; that those who have contested an issue shall be bound by the result of the contest, and that matters once tried shall be considered forever settled as between the parties.'" *Federated Dept. Stores, Inc. v. Moitie,* 452 U.S. at 401 , *quoting Baldwin v. Traveling Men's Ass'n*, 283 U.S. 522, 525 (1931). The "doctrine of *res judicata* is not a mere matter of practice or procedure inherited from a more technical time than ours. It is a rule of fundamental and substantial justice, 'of public policy and of private peace,' which should be cordially regarded and enforced by the courts...." *Hart Steel Co. v. Railroad Supply Co.*, 244 U.S. 294, 299 (1917).

The public policy of repose applies just as fully in the context of patents as it does

in other cases. *Foster v. Hallco Mfg. Co.*, 947 F.2d at 476 ("We are aware of no court which has even suggested that [*Lear, Inc. v. Adkins*, 395 U.S. 653 (1969)] abrogates the application of *res judicata* principles based on a judgment imposed by the court after full litigation."). The public policy against restricting challenges to patent validity do not override general principles of *res judicata* and collateral estoppel.

D. Ranbaxy Infringes The '893 Patent

Pfizer has moved for a judgment of infringement. Ranbaxy concedes at page 18 of its Answering Brief that it infringes the '893 patent by submission of its new ANDA. Nevertheless, Ranbaxy seeks to avoid judgment being entered on this uncontested issue, *citing Shelcore, Inc. v. Durham Industries, Inc.*, 745 F.2d 621, 628 (Fed. Cir. 1984) and *Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1580 (Fed. Cir. 1983). Neither case is apposite. While liability for infringement cannot exist in the absence of a valid and enforceable patent, infringement is capable of being determined without simultaneous inquiry into validity and enforceability. *Medtronic, Inc. v. Cardiac Pacemakers, Inc.*, 721 F.2d 1563, 1582-83 (Fed. Cir. 1983) (although an invalid claim cannot give rise to liability for infringement, the issue of infringement is capable of determination without regard to validity). As the Federal Circuit instructed in *Medtronic*, the better practice is to make the determination of infringement, even where validity is in question to avoid remand for further consideration in the event of reversal of the separate issue of validity. *Pandrol USA, LP v. Airboss Ry. Products, Inc.*, 320 F.3d 1354, 1365 (Fed. Cir. 2003); *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1540 (Fed. Cir. 1983) ("When presented with patent validity and infringement issues, trial courts should ... decide both.")

Pfizer is entitled to judgment of infringement of the '893 patent under 35 U.S.C. §

271 (e)(2).

III. CONCLUSION

For the reasons stated above, defendants/counterclaimants' Third Affirmative Defense and First Counterclaim with respect to United States Letters Patent No. 4,681,893 should be dismissed as barred under the doctrine of *res judicata*. Judgment should further be entered on Pfizer's First Claim for Relief that Ranbaxy has infringed United States Letters Patent No. 4,681,893 under 35 U.S.C. § 271(e)(2) by filing of Ranbaxy's ANDA seeking approval from the FDA to engage in the commercial manufacture, use, or sale of a product containing atorvastatin calcium as an active ingredient prior to the expiration of the patent.

RESPECTFULLY SUBMITTED,

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Exhibit A

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, WARNER-LAMBERT COMPANY, LLC, and WARNER-LAMBERT EXPORT, LTD.,

Plaintiffs,

v.

RANBAXY LABORATORIES LIMITED and RANBAXY PHARMACEUTICALS, INC.,

Defendants.

) Civil Action
) No. 03-209-JJF

Videotape 30(b)(6) deposition on Topic 24 of FRANCIS J. TINNEY, PH.D., ESQUIRE, taken pursuant to notice at the law offices of Connolly, Bove, Lodge & Hutz, LLP, The Nemours Building, 1007 North Orange Street, Ninth Floor, Wilmington, Delaware, beginning at 9:25 a.m. on Monday, July 19, 2004, before Kathleen White Palmer, Registered Professional Reporter and Notary Public.

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PAUL HASTINGS, Videographer (p.m.)

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THE VIDEOGRAPHER: This is the videotape deposition of Mr. Francis J. Tinney, Ph.D., Esquire. He's a 30(b)(6) witness on topic 24 taken by the defendant in the matter of Pfizer Incorporated, Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, Warner-Lambert Company, LLC, and Warner-Lambert Export Limited, plaintiffs, versus Ranbaxy Laboratories Limited, and Ranbaxy Pharmaceuticals Incorporated, defendants, Civil Action No. 03-209.

This is being held in the offices of Connolly Bove Lodge & Hutz, Wilmington, Delaware, on July 19th, 2004. We are going on the record at approximately 9:25 a.m.

The court reporter is Miss Kathy Palmer from the firm of Wilcox & Fetzer, Wilmington, Delaware.

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MR. BOVE: Thank you.

THE VIDEOGRAPHER: We're going off the record at 10:55 a.m.

(A recess was taken at this time.)

THE VIDEOGRAPHER: We are back on the record at 11:01 a.m.

MR. LE MEILLEUR: Mr. Bove, did you want to make a statement about privilege or --

MR. BOVE: Well, actually, why don't we pick it up in terms of your line of questioning and maybe have the last question and answer repeated for a second?

MR. LE MEILLEUR: Okay. I'll do that.

MR. BOVE: Good.

BY MR. LE MEILLEUR:

Q. I asked: "Can you tell me if CSI data was submitted in this particular response?"

Mr. Tinney answered: "In the comparison data sheet which is attached to Ivo Mansmann's response to the EPO, the only indication is COR test data."

A. I'd like to clarify my answer to that question.

Q. Okay.

A. The comparison data sheet indicates that it's COR test in the upper right-hand corner, but that is erroneously mislabeled. That is CSI data.

Q. And how do you know that?

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A. I've been informed by counsel.

Q. And when were you informed by counsel?

A. I was just informed by counsel.

Q. At the break?

A. Yes.

Q. And are you aware of any documents that support the idea that the COR test data is mislabeled and should actually be CSI test data?

MR. BOVE: I can tell you, Mr. LeMeilleur, that documents have been produced to your firm which set forth this information.

MR. LE MEILLEUR: Can you identify which documents those are?

MR. BOVE: Not sitting here right now, but we can get that -- we'll take that request under advisement.

MR. LE MEILLEUR: It would seem questions about that test data would be pertinent to this deposition. Is it possible to get that data or those documents today?

MR. BOVE: I'll check into that at another break.

BY MR. LE MEILLEUR:

Q. So, Mr. Tinney, is it your testimony that no COR test data was submitted in this response, Exhibit 371?

00050

A. My testimony -- my testimony is that the data that was submitted in this response was the CSI data. There was an error in labeling it COR test data.

Q. Who made the error?

A. I don't know.

Q. Why don't you know?

A. I was informed by counsel that there was an error and that's the only information I have.

Q. How long have you worked at Pfizer and/or Warner-Lambert?

A. In the patent department?

Q. Yes.

A. Oh, about 18 years.

Q. Since approximately what year?

A. Well, actually before that I was a research chemist at Parke-Davis. And I've worked in the patent department, I believe, since 1987.

Q. Sir, having worked there since 1987, this is the first time you've been informed that this COR test data was mislabeled?

MR. BOVE: Objection. Are you asking him now personally? Because you just asked his personal background. He's here as a 30(b)(6) witness pursuant to a category set forth by the Court and as we have qualified it at the beginning of this deposition. So --

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McNeil-PPC, Inc. v. Perrigo Co.
S.D.N.Y.,2007.
Only the Westlaw citation is currently available.
United States District Court,S.D. New York.
McNEIL-PPC, INC. et al., Plaintiffs,
v.
PERRIGO COMPANY et al., Defendants.
No. 05 Civ. 1321(WHP).

June 5, 2007.

Raymond N. Nimrod, Esq., Jenner & Block LLP, Chicago, IL, for Plaintiffs.
Steven L. Underwood, Esq., James A. Mitchell, Esq., Price, Heneveld, Cooper, DeWitt & Litton, LLP, Grand Rapids, MI, for Defendants.

OPINION AND ORDER

WILLIAM H. PAULEY III, District Judge.

***1** McNeil-PPC, Inc. ("McNeil"), Merck & Co., Inc. ("Merck") and Johnson & Johnson Merck Consumer Pharmaceuticals Co. ("Johnson & Johnson Merck") (collectively, the "Plaintiffs") bring this action pursuant to the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2), against Perrigo Company, L. Perrigo Company and Perrigo Research & Development Company (collectively, the "Defendants" or "Perrigo"). Plaintiffs accuse Perrigo of infringing U.S. Patent No. 5,817,340 (the " 340 patent") by filing Abbreviated New Drug Application ("ANDA") No. 77-355 with the United States Food and Drug Administration (the "FDA"). Defendants assert that the 340 patent is invalid and that Plaintiffs committed inequitable conduct during the patent's prosecution. This Court conducted a nine-day bench trial in February 2007. Based on the credible evidence, this Court makes the following findings of fact and conclusions of law and invalidates the 340 patent as obvious pursuant to 35 U.S.C. § 103(a).

FINDINGS OF FACT

I. *The Parties*

McNeil, an operating unit of Johnson & Johnson, is a leading pharmaceutical company that sells over-the-counter pharmaceutical products. (Trial Transcript, dated Feb. 6-28, 2007 ("Tr.") at 7.) Johnson & Johnson Merck is a joint venture company formed for the purpose of bringing Merck prescription pharmaceutical products over-the-counter. (Tr. at 7-8.) Perrigo is a leading global healthcare supplier. (Defendants' Trial Exhibit ("DX") DDD.)

II. *The 340 Patent*

The 340 patent claims a solid oral dosage of aluminum hydroxide or magnesium hydroxide (the "antacids") and famotidine. Famotidine is a bitter-tasting guanidinothiazole compound that inhibits acid secretion in the stomach by interfering with histamine receptors in the stomach lining. Aluminum hydroxide and magnesium hydroxide neutralize acid already present in the stomach. When combined in a solid oral dosage, famotidine and antacids are used to treat gastric disorders arising from acid secretion, such as acid indigestion.

McNeil filed the 340 patent application on December 1, 1992 with Edward John Roche ("Roche"), Susan Decoteau ("Decoteau") and Eleanor Freeman ("Freeman") as the named inventors. (DX L; Plaintiffs' Trial Exhibit ("PX") 1.) These inventors, along with McNeil employee John Dubek ("Dubek"), worked together on the Johnson & Johnson Merck joint venture. The team purportedly discovered that famotidine degrades when exposed to antacids in a solid dosage form, yielding a therapeutically ineffective product with unknown properties.[FN1] (PX 1 col. 1, ll. 26-30; col. 2, ll. 41-49; col. 2, ln. 61-col. 3, ln. 2.) The 340 patent teaches a method for preventing famotidine degradation.

FN1. Before the 340 patent application was filed, McNeil's famotidine supplier, Yamanouchi Pharmaceutical Co., provided McNeil with test results regarding famotidine's stability in an aqueous solution (the "Yamanouchi report"). (PX 114 at 5.) The Yamanouchi report showed that famotidine degrades in water at high and

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low pH as a result of the hydrolysis reaction. (PX 114 at 5.) McNeil did not disclose the Yamanouchi report to the Examiner.

Independent composition claim 1 of the 340 patent recites as follows:

1. A solid oral dosage form for the treatment of gastrointestinal disorders comprising a therapeutically effective amount of impermeably coated famotidine granules for the treatment of gastric disorders and pharmacologically acceptable salts thereof; and a therapeutically effective amount of aluminum hydroxide or magnesium hydroxide wherein the oral dosage form has said coated famotidine granules and the aluminum hydroxide or magnesium hydroxide in contact with each other, but separated by said impermeable coating on the famotidine granules which is impermeable to the aluminum hydroxide or magnesium hydroxide.

***2** (PX 1 col. 14, ll. 39-49.) Independent method claim 5 recites as follows:5. A method for manufacturing a solid oral dosage form comprising: a) forming granules containing famotidine for the treatment of gastric disorder; b) coating the granules with a coating impermeable to aluminum hydroxide or magnesium hydroxide to form impermeably coated famotidine granules; c) mixing a therapeutically effective amount of aluminum hydroxide or magnesium hydroxide with a therapeutically effective amount of impermeably coated famotidine granules and pharmaceutically acceptable excipients to form a compression mixture; then d) pressing the compression mixture to form a solid oral dosage form.

(PX 1 col. 15, ln. 6-col. 16, ln. 2.) The specification details several embodiments of the invention. In the preferred embodiment, granulated famotidine is coated with an impermeable material that protects the famotidine from the antacids. (PX 1 col. 9, ll. 7-12.) The specification provides for two variations on this embodiment. In Examples I and V, the coated famotidine granules and the antacids are interspersed throughout a single-layer tablet. (PX 1 col. 9, ln. 39-col. 10, ln. 60; col. 13, ln. 52-col. 14, ln. 37.) Examples II and III depict two-layer embodiments in which the coated famotidine granules comprise one layer and the antacids comprise the other layer. (PX 1 col. 10, ln. 63-col. 12, ln. 51.) The specification identifies 23 coatings that are suitable for protecting the famotidine granules. (PX 1 col. 7, ln. 52-col. 8, ln. 27.) Four of these coatings contain polyvinylpyrrolidone ("PVP").

The Patent Office repeatedly rejected McNeil's original claims, primarily on grounds of obviousness. (DX L, Paper Nos. 5, 9, 16, 20, 24, 29.) On September 18, 1997, Roche submitted a declaration to the Examiner setting forth the results of a test he conducted exposing famotidine to antacids. (DX L, Paper No. 32.) By combining 10mg of uncoated famotidine granules with 200mg of aluminum hydroxide or magnesium hydroxide in a single layer tablet, Roche observed a 25-70% degradation in the famotidine. (DX L, Paper No. 32.) When impermeably coated famotidine granules were substituted for the uncoated granules, approximately 2% degradation occurred. (DX L, Paper No. 32.) The Patent Office deemed the Roche declaration "persuasive as to unexpected results in stability over the prior art for the dosage form tested therein, i.e., coated granule solid oral dosage form containing famotidine and aluminum or magnesium hydroxide." (DX L, Paper No. 33 at 2.) The 340 patent issued on October 6, 1998. (Joint Pretrial Order, dated Jan. 25, 2007 ("JPTO") ¶ VI.A.2.)

Merck holds approved new drug application ("NDA") No. 20-958 for a single-layer tablet containing, *inter alia,* 10mg of coated famotidine and 165mg of magnesium hydroxide. (JPTO ¶ VI.A.1.) The tablets are marketed over-the-counter under the trade name Pepcid Complete. (JPTO ¶ VI.A.1.) On October 29, 2004, Perrigo filed ANDA No. 77-355 with the FDA requesting permission to market a generic version of Pepcid Complete containing, *inter alia,* 10mg of coated famotidine in one layer and 165mg of magnesium hydroxide in a separate layer. (JPTO ¶ VI.A.4, 9.) Perrigo certified that the 340 patent was invalid and would not be infringed by Perrigo's proposed tablet. (JPTO ¶ VI.A.4-5.)

III. *Litigation History*

***3** On February 3, 2005, Plaintiffs filed this action

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alleging that the ANDA willfully infringes the 340 patent and requesting attorneys' fees pursuant to 35 U.S.C. § 285. On December 2, 2005, Defendants moved for summary judgment on grounds of non-infringement and invalidity. This Court held a *Markman* hearing and oral argument concerning Defendants' motion on April 25, 2006. In a Memorandum and Order dated July 27, 2006, this Court construed the 340 patent's claims, denied Defendants' motion for summary judgment on invalidity, and awarded summary judgment to Plaintiffs on the issue of infringement. *McNeil-PPC, Inc. v. Perrigo Co.,* 443 F.Supp.2d 492 (S.D.N.Y.2006) (*"McNeil I"*). The Court's claim construction was as follows: (1) "mixing" in claim 5 was found to mean "combining two or more ingredients into one mass"; (2) "compression mixture" in claim 5 was found to mean "one mass containing two or more ingredients that are compressed into a tablet"; (3) "in contact with" in claim 1 was found to mean "a union or junction of body surfaces, a touching or meeting"; (4) "impermeable" in claims 1 and 5 was found to refer to "a coating material that does not permit the passage of aluminum hydroxide or magnesium hydroxide"; and (5) "impermeably coated famotidine granules" in claims 1 and 5 was found to refer to "famotidine granules that are coated with a material that is impermeable to the aluminum or magnesium hydroxide, using Wurster coating, rotocoating or another coating process acceptable to a person of ordinary skill in the art." [FN2] *McNeil I,* 443 F.Supp.2d at 503-512.

> FN2. The parties also disputed the meaning of "therapeutically effective amount" in claims 1 and 5. However, the construction of this term was mooted by the Court's construction of the remaining disputed terms. *McNeil I,* 443 F.Supp.2d at 509-10.

Defendants moved for reconsideration of the Court's decision granting summary judgment to Plaintiffs on infringement and requested that this Court withdraw and reserve its *Markman* determination pending trial. By Order dated January 17, 2007, the Court declined to withdraw its *Markman* rulings. *McNeil-PPC, Inc. v. Perrigo Co.,* No. 05 Civ. 1321(WHP), 2007 WL 104513 (S.D.N .Y. Jan. 17, 2007) (*"McNeil III"*). Regarding infringement, the Court noted Defendants' apparent concession at the April 25, 2006 hearing that there were no disputed issues of fact with respect to how Perrigo's tablet is constructed. Nevertheless, affording Defendants the benefit of the doubt, the Court withdrew its summary judgment determination on the issue of infringement and agreed to hear evidence on the issue at trial. *McNeil III,* 2007 WL 104513, at *1-2.

On September 20, 2006, Perrigo filed its Amended Answer and Counterclaim, alleging that the 340 patent is invalid (1) as obvious under 35 U.S.C. § 103; (2) for failure to name Dubek as an inventor under 35 U.S.C. § 102(f); (3) for failure to disclose the rotogranulation method described in U.S. Patent No. 5,260,072 (the " 072 patent") under the enablement and best mode requirements of 35 U.S.C. § 112; (4) because Plaintiffs failed to disclose the Yamanouchi report during patent prosecution; and (5) because the inclusion of PVP in the patent violates § 112's enablement requirement. Perrigo avers that all but the first of these items also constitutes inequitable conduct. On October 18, 2006, Plaintiffs moved for summary judgment on Defendants' inequitable conduct and related invalidity counterclaims and defenses. By Order dated January 12, 2007, the Court granted Plaintiffs' motion with respect to Defendants' 072 rotogranulation method enablement, Yamanouchi report and PVP-related counterclaims and defenses. *McNeil-PPC, Inc. v. Perrigo Co.,* No. 05 Civ. 1321(WHP), 2007 WL 81918, at *13 (S.D.N.Y. Jan. 12, 2007) (*"McNeil II"*). The Court denied Plaintiffs' motion with respect to Defendants' 072 rotogranulation best mode and inventorship-related counterclaims and defenses. *McNeil II,* 2007 WL 81918, at *13.

CONCLUSIONS OF LAW

I. *Obviousness*

***4** Defendants assert that the 340 patent is invalid as obvious under 35 U.S.C. § 103. This Court agrees.

A. *Legal Standard*

An issued patent is presumed valid. 35 U.S.C. § 282.

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Thus, the accused infringer bears the burden of proving invalidity by clear and convincing evidence. 35 U.S.C. § 282; *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1348 (Fed.Cir.2004); *Oakley, Inc. v. Sunglass Hut Int'l*, 316 F.3d 1331, 1339 (Fed.Cir.2003).

A patent claim is invalid if "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a); *Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1372-77 (Fed.Cir.2005); *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 716 (Fed.Cir.1991). In determining obviousness, the fact finder must consider the factors set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966):(1) the scope and content of the prior art; (2) the differences between the prior art devices and the claimed invention; (3) the level of ordinary skill in the art; [FN3] and (4) objective considerations, such as commercial success, long felt but unmet need, and unexpected results. *Graham*, 383 U.S. at 17-18; *see also KSR Int'l Co. v. Teleflex Inc.*, --- U.S. ----, 127 S.Ct. 1727, 2007 WL 1237837, at *6 (2007); *Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1371 (Fed.Cir.2000). "While the sequence of these questions might be reordered in any particular case, the factors continue to define the inquiry that controls. If a court ... conducts this analysis and concludes the claimed subject matter was obvious, the claim is invalid under § 103." *KSR*, 2007 WL 1237837, at *7.

> FN3. The Court determined in *McNeil I* that "one of skill in the art would have a Ph.D in chemistry, organic chemistry, pharmaceutics or pharmaceutical microbiology, or a B.S. or M.S. with several years of work experience in pharmaceutics or pharmaceutical microbiology, or an M.D. with several years of clinical experience in administering H_2 blockers or antacids." *McNeil I*, 443 F.Supp.2d at 503.

Until recently, the Federal Circuit had employed an additional test for determining the obviousness of combining prior art references. That inquiry required the party seeking to invalidate a patent to establish "some teaching, suggestion, or motivation to combine the references." *In re Rouffet*, 149 F.3d 1350, 1355 (Fed.Cir.1998) (citing *In re Geiger*, 815 F.2d 686, 688 (Fed.Cir.1987)); *see also ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577 (Fed.Cir.1984). The "teaching, suggestion or motivation" test was addressed by the Supreme Court in *KSR International v. Teleflex Inc.* While *KSR* recognized that the test "captured a helpful insight," the Supreme Court nevertheless cautioned that "[t]he obviousness analysis cannot be confined by a formalistic conception of the words, teaching, suggestion, and motivation." *KSR*, 2007 WL 1237837, at *14. Courts must avoid a "rigid approach" in determining whether an invention would have been obvious to a skilled artisan. *KSR*, 2007 WL 1237837, at *12. An "expansive and flexible approach" must instead be applied, and the courts may utilize "common sense" in addressing a question of obviousness under § 103. *KSR*, 2007 WL 1237837, at *12, 15; *see also DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1367-71 (Fed.Cir.2006); *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1291 (Fed.Cir.2006).

***5** "[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." *KSR*, 2007 WL 127837, at *13. "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR*, 2007 WL 1237837, at *12. However, "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR*, 2007 WL 1237837, at *14; *see also Grain Processing Corp. v. Am. Maize-Prods. Co.*, 840 F.2d 902, 907 (Fed.Cir.1988) ("In determining obviousness, the inquiry is not whether each element existed in the prior art, but whether the prior art made obvious the invention as a whole for which patentability is claimed" (citation and

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quotations omitted).). Courts should still "identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR,* 2007 WL 127837, at *14. "Any need or problem known in the field of endeavor at the time of the invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *KSR,* 2007 WL 127837, at *15. "[N]either the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103." *KSR,* 2007 WL 1237837, at *15; *see also In re Kemps,* 97 F.3d 1427, 1430 (Fed.Cir.1996) ("[T]he motivation in the prior art to combine the references does not have to be identical to that of the applicant to establish obviousness.").

Additionally, the claimed invention as a whole must be compared to the prior art as a whole, *Hybritech Inc. v. Monoclonal Antibodies, Inc.,* 802 F.2d 1367, 1383 (Fed.Cir.1986); *Hodosh v.. Block Drug Co.,* 786 F.2d 1136, 1143 n. 5 (Fed.Cir.1986), and courts must avoid aggregating pieces of prior art through hindsight which would not have been combined absent the inventors' insight, *KSR,* 2007 WL 1237837, at *16; *Graham,* 383 U.S. at 36; *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH,* 139 F.3d 877, 880 (Fed.Cir.1998). As a check against hindsight analysis, the Court must consider "secondary considerations" of nonobviousness. *Ruiz v. A.B. Chance Co.,* 234 F.3d 654, 662-63, 667 (Fed.Cir.2000); *Gambro Lundia AB v. Baxter Healthcare Corp.,* 110 F.3d 1573, 1579 (Fed.Cir.1997). These considerations include evidence of commercial success, unexpected results and long felt but unmet need. *Dann v. Johnston,* 425 U.S. 219, 230 n. 4 (1976); *Graham,* 383 U.S. at 17-18; *Syntex (U.S.A.) LLC v. Apotex, Inc.,* 407 F.3d 1371, 1378 (Fed.Cir.2005). "Evidence of secondary considerations ... are but a part of the totality of the evidence that is used to reach the ultimate conclusion of obviousness." *Richardson-Vicks Inc. v. Upjohn Co.,* 122 F.3d 1476, 1483 (Fed.Cir.1997) (quotations omitted).

B. *Scope and Content of the Prior Art*

***6** In addressing the question of obviousness, this Court must determine the scope of the prior art. The Davis patent application WO 92/00102 ("Davis") and Wolfe U.S. Patent No. 5,229,137 ("Wolfe") are prior art reciting the combination of uncoated famotidine and magnesium or aluminum hydroxide in a solid oral dosage. (DEX 4; DX F.) The Davis application was based on the purported surprising result that antacids increase the bioavailability of histamine H_2-receptor antagonists. (DEX 4 at 3.) Thus, Davis "provides the use of an orally administrable pharmaceutical composition comprising a histamine H_2-receptor antagonist and an antacid for the manufacture of a medicament for the treatment of gastric disorders." (DEX 4 at 3.) Famotidine and aluminum hydroxide and magnesium hydroxide were among the H_2-blockers and antacids, respectively, recited by Davis. (DEX 4 at 4, 13-14.) Absent from Davis is any mention of either impermeable coating for the H_2-blockers or famotidine's bitter taste. However, Davis does provide that the medicaments in the tablet formations may be "blended along with conventional tabletting aids, fillers and palatability aids," such as "flavoring agents." (DEX 4 at 7-8.)

Similarly, Wolfe claims a method of "orally administering ... together or substantially together an antacid in an amount effective to substantially neutralize gastric acid and a histamine H_2-receptor antagonist ..." (DX F col. 7, ll. 27-30.) The claim "is based upon the unexpected realization that antacids and histamine H_2-receptor antagonists can be effectively administered together or substantially together to achieve continuous relief from pain, discomfort and/or symptoms associated with episodic heartburn ..." (DX F col. 2, ll. 2-7.) The invention encompasses famotidine, aluminum hydroxide and magnesium hydroxide. (DX F col. 7, ll. 49-52.) Wolfe provides that compositions combining antacids and H_2 blockers may contain "one or more agents such as, for example, sweetening agents, flavoring agents, coloring agents and the like, in order to provide a pharmaceutically elegant and palatable preparation." (DX F col. 4, ll. 40-43.) Like Davis, Wolfe neither states that famotidine tastes bitter nor recites the coating of H_2-blocker granules.

U.S. Patent No. 5,075,114 (the " 114 patent"), which

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names Roche as the sole inventor, teaches a method for coating granulated medicaments to mask the taste of active ingredients in chewable tablets. (DX D.) Although ibuprofen is the medicament included in the preferred embodiment of the invention, the 114 specification provides details for the coating of numerous additional medications, including famotidine. (DX D col. 6, ll. 17-18; col. 7, ll. 35-42.) Example III and claims 2, 16 and 19 each identify famotidine as one type of ingredient for which taste-mask coating would be appropriate. (PX D col. 7, ll. 35-42; col. 10, ll. 37-42; col. 12, ll. 4-9, 18-23.) The coatings recited by the 114 patent are a blend of cellulose acetate, cellulose acetate butyrate and hydroxypropylcellulose (DX D col. 2, ll. 21-24), with a preferred coating weight of 7-15% of the total coated granule weight (DX D col. 7, ln. 41). The 340 patent recites the same coating materials at a similar coating weight. (PX 1 col. 7, ln. 58-col. 8, ln. 27.)

*7 The 072 patent, which lists Roche, Decoteau and Freeman as inventors, claims a method for taste-masking active ingredients by rotogranulation with a preferred particle size ranging from 5-75 microns, a binder ranging from 50-150 microns, and a carrier ranging from 5-75 microns, before application of a coating. (PX 16 col. 1, ll. 14; col. 3, ll. 1-14; col. 9, ln. 39-col. 10, ln. 10.) Famotidine is the preferred embodiment in the 072 patent and is used in the specification's examples. (PX 16 col. 3, ll. 43-47; col. 8, ln. 4-col. 9, ln. 19.) Thus, the invention "is directed to the discovery of a granulating and coating process for active medicaments which can achieve a better balance between taste masking, dissolution and rate of bioavailability when applied to irregularly shaped raw granules of compositions like famotidine than other previously known coating combinations." (PX 16 col. 2, ll. 46-52.)

Finally, European Patent Application 0,294,933 (the " 933 application") filed on April 5, 1988, is directed to "a solid pharmaceutical dosage form comprising cimetidine and an antacid and to a method for the preparation of such a dosage form." (DX M at 2 .) Cimetidine is an H_2 blocker used in the drug Tagamet. (Tr. at 30.) Chewable tablets are among the dosage forms described in the 933 specification, and the specification provides that "the pronounced bitter taste" of cimetidine may require "a coating agent." (DX M at 3.) Eudragit E 100 is the coating material employed in each of the 933 application's examples. (DX M at 3-8 .)

C. *Differences Between Claimed Invention and Prior Art*

All relevant limitations of the 340 patent-the combination of famotidine and antacids, and use of an impermeable coating-appear in the prior art. Defendants assert that a person of ordinary skill would have incorporated the teachings of the 114 and 072 patents into the composition disclosed in Davis and Wolfe in order to mask famotidine's bitter taste in the combination of famotidine and antacids. Likewise, Defendants contend that a skilled artisan would have arrived at the 340 invention by combining Davis and Wolfe with the 933 application.

The evidence adduced at trial established that famotidine has a bitter taste. (Tr. at 206, 543, 567, 608, 796, 798, 961, 1019, 1075-76.) Plaintiffs contend that the composition at issue is the combination of famotidine and antacid, not famotidine alone, and that Perrigo has failed to show that the combination product has a bitter taste. Yet the NDA Plaintiffs submitted to the FDA for Pepcid Complete states: "Taste masking of famotidine is necessary in [the combination famotidine-antacid product] due to the bitterness of the drug substance." (DX CF at JJ007695, JJ007719; Tr. at 827-29.) Internal McNeil memoranda also indicate Plaintiffs' belief that famotidine has a bitter taste in the combination product. (DX H at JJ008974.) The record evidence therefore establishes that a skilled formulator would have reason to mask the bitter taste of famotidine even with the addition of antacids.[FN4]

FN4. Relatedly, Plaintiffs assert that "famotidine does not taste especially bad." (PFF ¶ 75.) This statement is not supported by the evidence cited by Plaintiffs. First, they cite the testimony of Dr. Roland Bodmeier, who has never even tasted famotidine. (Tr. at 1564.) They also cite Dr. Metin Celik's testimony, but Celik merely testified that the majority of drugs have a

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bitter taste and that some drugs are more bitter than others. (Tr. at 1076, 1087.)

***8** In the alternative, Plaintiffs contend that other modes of taste-masking are preferable to impermeable coating. Coated granules are "much more" expensive "than simply using flavorants and sweeteners." (Tr. at 1086.) Citing to Celik's testimony, Plaintiffs assert that because of this cost disparity, a skilled formulator would resort to coating only if a bitter taste remained after the addition of flavorants and sweeteners. (Tr. at 1097.) Davis and Wolfe address the issue of the combination product's palatability and, according to Plaintiffs, teach that flavoring and sweetening agents suffice to make a palatable famotidine tablet. In addition to flavoring and sweetening agents, Plaintiffs identify the following inexpensive taste-masking options: (1) granulation alone, without the addition of an impermeable coating; (2) ion exchange resins and cyclodextrins; and (3) altering the solubility of famotidine. (Plaintiffs' Proposed Findings of Fact and Conclusions of Law, dated Mar. 19, 2007 ("PFF") ¶¶ 73-80.) Plaintiffs assert that in light of the alternatives, a person of ordinary skill would not have been motivated to use impermeable coating for taste-masking purposes.

This Court disagrees. Under *KSR,* "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR,* 2007 WL 1237837, at *12. The 340 patent does no more than combine the predictable results of Davis and Wolfe with the predictable results of the 072 and 114 patents. Of course, obviousness is not established "merely by demonstrating that each of [an invention's] elements was ... known in the prior art," because "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR,* 2007 WL 1237837, at *14; *see also Ruiz,* 234 F.3d at 665 ("[T]he notion that combination claims can be declared invalid merely upon finding similar elements in separate prior patents would necessarily destroy virtually all patents and cannot be the law under the statute, § 103" (citation and quotations omitted).). But pre-*KSR* precedent refutes Plaintiffs' theory of non-obviousness, which is that the costs of the coating process would have dissuaded a skilled formulator from combining the references. "[T]he fact that the [prior art] would not be combined by businessmen for economic reasons is not the same as saying that it could not be done because skilled persons in the art felt that there was some technological incompatibility that prevented their combination. Only the latter fact is telling on the issue of nonobviousness." *Orthopedic Equip. Co. v. United States,* 702 F.2d 1005, 1013 (Fed.Cir.1983).

KSR casts doubt on the continuing validity of Federal Circuit precedent on the issue of obviousness. The Supreme Court did suggest, however, that some Federal Circuit caselaw may have appropriately applied the broad conception of the teaching, suggestion or motivation test that the Supreme Court has endorsed. *KSR,* 2007 WL 1237837, at *16. This Court perceives no conflict between *KSR* and the portion of *Orthopedic Equipment* cited above.

***9** Even if Plaintiffs advanced a legally cognizable theory, the evidence establishes that a skilled artisan in 1991 or 1992 would have been motivated to use impermeable coating to improve the palatability of a chewable tablet comprised of coated famotidine and antacids. In an internal Johnson & Johnson Merck memorandum dated August 1, 1991, Roche discusses his progress in developing a famotidine-antacid tablet. (DX H at JJ008974.) The memorandum addresses whether an impermeable coating would be sufficient to prevent interaction between famotidine and the antacids. In the course of advocating the use of such a coating, Roche stated: "It is expected that coated Famotidine would be used in these products anyway to achieve taste masking." (DX H at JJ008974.) This admission undermines Plaintiffs' assertion that the use of an impermeable coating for taste-masking purposes would not have been obvious to a skilled formulator. Roche was a person of ordinary skill, and the additional costs associated with the coating process would not have dissuaded him from applying an impermeable taste-mask coating to the combination product.[FN5] Based on this evidence, "it appears quite feasible both economically and technologically, to combine the

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[prior art] to arrive at the claims in suit." *Orthopedic Equip.*, 705 F.2d at 1013.

> FN5. For this reason, the Court also rejects Plaintiffs' argument that even if a formulator had decided to use coated granules, he would not necessarily have selected an impermeable material for the coating. (PFF ¶ 81.) Roche clearly anticipated using an impermeable coating to mask famotidine's taste.

Plaintiffs urge this Court to ignore Roche's contemporaneous statement based on the following language in *KSR:* "The question is not whether the combination was obvious to the patentee but whether the combination was obvious to a person with ordinary skill in the art." *KSR,* 2007 WL 1237837 at *15. This argument misinterprets *KSR.* The quoted language means only that an invention may be obvious based on the combination of prior references even though the invention and the references do not address the same problem. *KSR,* 2007 WL 1237837, at *15 (holding that "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed"). The notion that contemporaneous admissions by the skilled inventor of the patent in suit must be ignored finds no support in any of the cited precedents, let alone *KSR.* "Common sense" dictates that if these admissions raise an inference of obviousness, then the patent is invalid under § 103. *KSR.* 2007 WL 1237837, at *15.

Likewise, Plaintiffs' reliance on *Winner Int'l Royalty Corp. v. Wang,* 202 F.3d 1340 (Fed.Cir.2000) is misplaced. In *Winner,* the Federal Circuit upheld the district court's rejection of the petitioner's obviousness argument, relying in part on a lack of motivation to combine the prior art. *Winner,* 202 F.3d at 1349. Assuming the holding in *Winner* survives *KSR,* it actually supports a finding of obviousness in this case. *Winner* states as follows:

The fact that the motivating benefit comes at the expense of another benefit ... should not nullify its use as a basis to modify the disclosure of one reference with the teachings of another. Instead, the benefits, both lost and gained, should be weighed against one another.

***10** *Winner,* 202 F.3d at 1349 n. 8. Roche conceded in 1991 that the "motivating benefit" of a taste-mask coating was not "nullified" by the costs of the coating process. (DX H at JJ008974.) A person of ordinary skill would appreciate the "desirability" of using coated famotidine for taste-masking purposes in the combination famotidine-antacid blend. *Winner,* 202 F.3d at 1349.

The obviousness of the 340 patent is underscored by the Pepcid Complete NDA, which states: "Taste masking of famotidine is necessary in a chewable tablet due to the bitterness of the drug substance. [The combination product] includes the use of coated famotidine granulation ..." (DX CF at JJ007695, JJ007719; *see also* Tr. at 827-28.) Impermeable coating is the *only* taste-masking process mentioned in the excerpts of the NDA that were submitted by the parties. Plaintiffs argue that the famotidine in Pepcid Complete was coated to prevent interaction with the antacids, and that any taste-masking benefit was incidental. However, it is telling that that the NDA makes no mention of Pepcid Complete's sweetening and flavoring agents in addressing famotidine's bitterness. Indeed, coated famotidine is the only taste-masking option disclosed in *any* reference that specifically identifies famotidine's bitter taste.

Prior to launching Pepcid Complete, McNeil also developed a single active ingredient famotidine tablet marketed as Pepcid AC chewable. (Tr. at 541-43.) Plaintiffs employed coated famotidine granules in this tablet for the purpose of masking the taste of famotidine. (Tr. at 543-44.) Decoteau, who was involved in the development of the famotidine tablet, conceded at trial that a coating was chosen over sweeteners and flavoring agents because "attempts to use flavorants and other materials to hide the taste of the famotidine were unsuccessful." (Tr. at 543.) Decoteau agreed with Defendants that "the coating was selected because of its superior taste masking properties over other technologies that might be available to taste mask." (Tr. at 544.) Thus, McNeil's previous efforts to use sweeteners and flavors to hide

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famotidine's bitter taste had proven unsuccessful. (Tr. at 543.) Plaintiffs argue that the bitterness of famotidine is diluted by the other ingredients in the larger famtodine-antacid combination, thereby mitigating the taste-masking problem. This Court does not credit Plaintiffs' assertion. To the contrary, the evidence indicates that Plaintiffs themselves considered impermeable coating necessary for the combination product.[FN6] (DX H at JJ008974.)

> FN6. As previously noted by this Court, both the 072 and 114 patents teach that flavoring agents can "overpower" the bitter taste of famotidine "[i]n some cases," such as within children's aspirin "where the dosage [of famotidine] is small enough." (PX 16 col. 1 ll. 52-60; DX D col. 1, ll. 49-55.) That is not the case here. The 072 patent teaches the use of 10 mg of famotidine, the same amount taught by the 340 patent. (PX 16 col. 8, ln. 62-col. 9, ln. 18; PX 1 col. 9, ln. 39-col. 10, ln. 60.)

For these reasons, a person of ordinary skill would have ample reason to combine Davis and Wolfe with the 114 and the 072 patents. It also would have been obvious to combine Davis and Wolfe with the 933 application. The 933 specification states:

With chewable [combination cimetidine/antacid] tablets, the pronounced bitter taste of cimetidine means that in practice it is necessary to provide a means of masking the bitter taste. One means of masking the bitter taste is to coat the cimetidine with a coating agent in an amount effective to mask the bitter taste but which does not significantly affect the bioavailability of the cimetidine.

***11** (DX M at p. 3, ll. 7-10.) Cimetidine, like famotidine, is an H_2 blocker. (Tr. at 30.) A skilled formulator would have understood the utility of replacing cimetidine with famotidine in the 933 invention. *See Richardson-Vicks,* 122 F.3d at 1483-84 (combination of medicaments in a single tablet found obvious when similar combinations were disclosed in the prior art).

Plaintiffs contend that Eudragit is used in the 933 patent to granulate but not to coat the cimetidine, because the examples in the specification employ Eudragit during the granulation process. (Tr. at 339-45.) However, Eudragit is listed in the 340 patent as a "suitable coating" (PX 1 col. 8, ln. 10), and McNeil itself referred to the use of Eudragit as a "coating" in describing the 933 patent to the 340 Examiner (DX L, Paper No. 18 at 000149). Plaintiffs do not dispute that Eudragit may be employed as both a granulation binder and as a coating agent. Nor do they explain why the 933 application refers to Eudragit as a "coating" if it does not teach the coating of cimetidine. Even if the 933 application's reference to Eudragit as a coating were somehow unintentional, that would not bar Eudragit's use for that purpose. A formulator could easily read the 933 application to mean what it says-namely, that Eudragit is to be used as a coating.

D. *Secondary Considerations*

Plaintiffs contend that Defendants' showing of obviousness is negated by the commercial success of Pepcid Complete and the supposedly unexpected results on which the 340 patent was based. This Court disagrees.

1. *Commercial Success*

"Commercial success is relevant [to obviousness] because the law presumes an idea would successfully have been brought to market sooner, in response to market forces, had the idea been obvious to persons skilled in the art." *Merck,* 395 F.3d at 1376. Thus, the law deems evidence of (1) commercial success, and (2) a causal relation or nexus between an invention and commercial success of a product embodying that invention, probative of whether an invention was non-obvious. *Merck,* 395 F.3d at 1376; *J.T. Eaton & Co. v. Atlantic Paste & Glue Co.,* 106 F.3d 1563, 1571 (Fed.Cir.1997); *In re Gpac Inc.,* 57 F.3d 1573, 1580 (Fed.Cir.1995); *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.,* 851 F.2d 1387, 1392 (Fed.Cir.1988). Commercial success is "usually shown by significant sales in a relevant market." *J.T. Eaton,* 106 F.3d at 1571. "[T]he secondary consideration of commercial success exists largely to provide a means for patentees to show in close cases that subject matter that appears obvious is in law

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unobvious because a high degree of commercial success permits the inference that others have tried and failed to reach a solution." *Syntex,* 407 F.3d at 1383 (citing *Merck,* 395 F.3d at 1376). Although "[i]n some cases [secondary considerations are] the most probative of obviousness ... [t]he existence of such evidence ... does not control the obviousness determination." *Richardson-Vicks,* 122 F.3d at 1483 (internal citations omitted).

***12** Pepcid Complete appears to have enjoyed some measure of commercial success. Nevertheless, Plaintiffs have failed to establish a nexus between the 340 patent and the Pepcid Complete product. First, prior the introduction of Pepcid Complete, Plaintiffs had successfully marketed the Pepcid brand through a variety of products, including Pepcid AC. (Tr. at 37-38.) The evidence introduced at trial shows that McNeil spent over $90 million per year on advertising to promote the Pepcid brand. (PX 167 at 2; Tr. at 42.) Pepcid's overall brand strength weakens the inference that Pepcid Complete's commercial success arose from incorporation of the 340 invention. *Pentec, Inc. v. Graphic Controls Corp.,* 776 F.2d 309, 316 (Fed.Cir.1985) ("Because GC was clearly the market leader well before the introduction of the [invention to the marketplace], its sales figures cannot be given controlling weight in determining the effect of commercial success in this case on the question of obviousness."); *see also Schwinn Bicycle Co. v. Goodyear Tire & Rubber Co.,* 444 F.2d 295, 300 (9th Cir.1970) (patent found obvious despite commercial success where "Schwinn [w]as a national leader in the design and manufacture of bicycles").

Second, the advertising launch for Pepcid Complete was substantial; McNeil diverted more than one third of its total Pepcid brand advertising dollars to Pepcid Complete. (DX GG.) The inference of non-obviousness arising from commercial success is weakened where the patentee's "promotional campaign contributed to the patented [product's] commercial success." *Pentec, Inc.,* 776 F.2d at 316.

Third, Plaintiffs' marketing plan involved switching users from Pepcid AC to Pepcid Complete. (DX II at 3; Tr. at 51.) The plan was successful, as Pepcid Complete cannibalized a large number of Pepcid AC sales. (Tr. at 53, 65.) Pepcid AC chewable tablets were eventually taken off the market, leaving Pepcid Complete as the only remaining chewable Pepcid product. (Tr. at 59.) This raises an inference that Pepcid Complete's success is derived at least in part from the cannibalization of Pepcid AC.

Finally, Pepcid Complete is covered by at least three patents-the 340 patent, the 5,229,137 patent, and the 5,989,588 patent. (DX BE.) This makes it difficult to attribute whatever commercial success Pepcid Complete may enjoy to any one of the three patents. For these reasons, Plaintiffs have not made a sufficient showing that Pepcid Complete's success is attributable to the patent in suit.[FN7] *See Dystar,* 464 F.3d at 1371 (patent found obvious despite commercial success); *Gpac, Inc.,* 57 F.3d at 1580-81 (same); *Pentec, Inc.,* 776 F.2d at 315-17 (same).

> FN7. For similar reasons, Plaintiffs have not established that Pepcid Complete fulfilled an unmet need in the marketplace. Plaintiffs' own marketing study prior to the launch of Pepcid Complete concluded that "the idea of a combination antacid and acid controller is not perceived to fulfill an unmet need." (DX BN.)

2. *Unexpected Results*

"Unexpected results may be sufficient to rebut a prima facie case of obviousness." *Kao Corp. v. Unilever U.S., Inc.,* 441 F.3d 963, 970 (Fed.Cir.2006); *see also In re De Blauwe,* 736 F.2d 699, 706 n. 8 (Fed.Cir.1984) ("A proper showing of unexpected results will rebut a prima facie case of obviousness."). "The basic principle behind this [rule] is straightforward-that which would have been surprising to a person of ordinary skill in a particular art would not have been obvious." *In re Mayne,* 104 F.3d 1339, 1343 (Fed.Cir.1997).

***13** Plaintiffs assert that the Roche declaration disclosed the unexpected result that famotidine degrades 25-70% when exposed to antacids in solid form. Assuming that the famotidine degradation observed by Roche was indeed unexpected-Defendants offer evidence that it was not (Defendants

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Proposed Findings of Fact, dated Mar. 19, 2007 ¶¶ 49-65)-the Roche declaration is insufficient to overcome the other evidence of obviousness in this case. *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1372 (Fed.Cir.2007) ("[W]e hold that even if Pfizer showed that amlodipine besylate exhibits unexpectedly superior results, this secondary consideration does not overcome the strong showing of obviousness in this case."). The Court notes that the patent in suit is rendered obvious for reasons entirely unrelated to the medicament's instability, and the inventor himself declared that impermeable coating would be used for taste-masking purposes regardless of whether famotidine interacted with the antacids. The invention was therefore obvious even if the level of interaction was surprising.

In sum, "[t]he unexpected results and commercial success of the claimed invention, [even if] supported by substantial evidence, do not overcome the clear and convincing evidence that the subject matter sought to be patented is obvious." *Richardson-Vicks*, 122 F.3d at 1484; *see also Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, --- F.3d ----, 2007 WL 1345333, at *5 (Fed.Cir.2007) (affirming invalidation of patent when the "district court explicitly stated in its opinion that Leapfrog had provided substantial evidence of commercial success, praise, and long-felt need, but that, given the strength of the prima facie obviousness showing, the evidence on secondary considerations was inadequate to overcome a final conclusion that claim 25 would have been obvious"). Because the 340 patent is invalid under § 103, this Court need not consider Perrigo's remaining invalidity arguments. McNeil's contention that Perrigo's ANDA infringes the 340 patent is also rendered moot by the invalidity of the patent.

VI. *Attorneys Fees*

Perrigo seeks attorneys fees under 35 U.S.C. § 285, contending that McNeil committed inequitable conduct by (1) failing to disclose the best mode of practicing the 340 patent, and (2) excluding Dubek from the 340 patent' s named inventors. For the following reasons, Perrigo's application is denied.

A. *Applicable Standards*

In "exceptional cases," the Court may award reasonable attorneys fees to the party prevailing in a patent infringement action. 35 U.S.C. § 285. To determine whether a case is exceptional, a trial court must look at the totality of the circumstances. *Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1347 (Fed.Cir.2000).

"Inequitable conduct is a ... defense to patent infringement and, either alone or in conjunction with trial conduct, may constitute the basis for an award of attorney fees under 35 U.S.C. § 285." *A.B. Chance Co. v. RTE Corp.*, 854 F.2d 1307, 1312 (Fed.Cir.1988). "Inequitable conduct occurs when a patent applicant breaches his or her duty of candor and good faith to the PTO." *Novo Nordisk Pharm., Inc. v. Bio-Technology Gen. Corp.*, 424 F.3d 1347, 1359 (Fed.Cir.2005); *see also Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1351 (Fed.Cir.2005). Inequitable conduct may include an "affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive." *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed.Cir.1995). Thus, the inequitable conduct analysis is performed in two steps: "first, a determination of whether the [conduct] meets a threshold level of materiality and intent to mislead, and second, a weighing of the materiality and intent in light of all the circumstances to determine whether the applicant's conduct is so culpable that the patent should be held unenforceable." *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1366 (Fed.Cir.2001) (internal quotations and alterations omitted).

***14** Material references may include any information that a reasonable patent examiner would find important in deciding whether the proposed claims are patentable. *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1314-16 (Fed.Cir.2006); *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1234, 1236 (Fed.Cir.2003). Information that is merely cumulative of references already before the examiner is not material. *Mentor H/S, Inc. v. Med. Device Alliance, Inc.*, 244 F.3d 1365, 1378 (Fed.Cir.2001).

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"Intent need not, and rarely can, be proven by direct evidence." *Merck & Co. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418, 1422 (Fed.Cir.1989). "Rather, in the absence of a credible explanation, intent to deceive is generally inferred from the facts and circumstances surrounding a knowing failure to disclose material information." *Bruno Indep.*, 394 F.3d at 1354 (citing *Paragon Podiatry Lab. v. KLM Lab.*, 984 F.2d 1182, 1193 (Fed.Cir.1993)). An inference of intent to deceive is based on the totality of the circumstances, including the nature of the conduct and the presence or absence of good faith. *Li Second Family L.P. v. Toshiba Corp.*, 231 F.3d 1373, 1379-80 (Fed.Cir.2000). Gross negligence alone is insufficient to establish intent. *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 876 (Fed.Cir.1988); *see also Baxter Int'l, Inc. v. McGaw. Inc.*, 149 F.3d 1321, 1329 (Fed.Cir.1998).

"As a general principle, materiality and intent are balanced-a lesser quantum of evidence of intent is necessary when the omission or misrepresentation is highly material, and vice versa." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1358 (Fed.Cir.2003); *see also Li Second Family*, 231 F.3d at 1378; *Digital Control*, 437 F.3d at 1315-16. "At the same time, however, there must be some threshold showing of intent to be balanced; [courts] will not find inequitable conduct on an evidentiary record that is completely devoid of evidence of the patentee's intent to deceive the PTO." *Amgen*, 314 F.3d at 1358. Finally, "[w]hen both materiality and deceptive intent have been established by clear and convincing evidence, decision of the ultimate issue of inequitable conduct is within the discretion of the district court." *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1331 (Fed.Cir.2004).

B. *Best Mode*

Defendants contend that the inventors of the 340 patent considered the rotogranulation method claimed in the 072 patent, i.e., using a small particle size, binder and carrier, to be the best mode for preparing coated famotidine granules. According to Defendants, McNeil committed inequitable conduct by omitting the 072 rotogranulation method from the 340 patent.

A patent's specification must "set forth the best mode contemplated by the inventor of carrying out his invention." 35 U.S.C. § 112. Thus, if an inventor has a way of practicing the invention that is better than all other ways, it must be disclosed in the patent specification. *See N. Telecom Ltd. v. Samsung Elecs. Co.*, 215 F.3d 1281, 1286 (Fed.Cir.2000). Assessing compliance with the best mode requirement requires a two-pronged factual inquiry. First, it must be determined whether the inventor had a best mode of practicing the invention when the patent application was filed. *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1064 (Fed.Cir.1998); *United States Gypsum Co. v. Nat'l Gypsum Co.*, 74 F.3d 1209, 1212 (Fed.Cir.1996). This is a subjective inquiry, which focuses on "the inventor's state of mind at the time of filing." *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 963 (Fed.Cir.2001). Second, it must be determined whether the best mode was disclosed in sufficient detail to allow a person of ordinary skill in the art to practice it. *Nobelpharma*, 141 F.3d at 1064; *United States Gypsum*, 74 F.3d at 1212. This inquiry is objective and looks to the "scope of the claimed invention and the level of skill in the art." *Eli Lilly*, 251 F.3d at 963.

***15** Perrigo has failed to show that the alleged best mode violation was material, or that Plaintiffs acted with an intent to conceal the best mode in prosecuting the 340 patent. Prior to filing the 340 patent, Plaintiffs published the 072 rotogranulation method with a variety of international patent offices. In particular, on March 4, 1992, McNeil's European Patent Office publication 0 473 431 was disclosed to the public. (PX 295.) This publication employed the same language later used in the 072 patent regarding a rotogranulation method with a small particle size, binder and carrier. (PX 295 at 1, 3-4.) Identical language is found in patent applications published by McNeil in Australia and Canada. (PX 232 at 1, 5, 8; PX 292 at 1, 5, 8.)

"[W]hether the inventor concealed [the best mode] is a function of ... how one skilled in the art would have understood his disclosure." *Chemcast Corp. v. ARCO Indus. Corp.*, 913 F.2d 923, 927 (Fed.Cir.1990). As a result, there can be no best mode violation where a person of ordinary skill would have known the

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purported best mode through the scientific literature. *Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1346 (Fed.Cir.2000). Although mere publication of a patent application in a foreign country is not necessarily sufficient to notify a person skilled in the art of the invention, *see In re Howarth*, 654 F.2d 103, 107 (C.C.P.A.1981), the evidence at trial established that during the relevant time period, scientists and attorneys routinely searched EPO publications using the databases of various abstracting services (Tr. at 167-68, 685-86, 903, 906). EPO publications were considered one of the best informational sources for technological developments. (Tr. at 167, 903.) Indeed, even Perrigo has referenced EPO publications in its patents. (PX 400 col. 1, ll. 23-32.) Perrigo's best mode allegations are weakened by the availability of the 072 rotogranulation method through the EPO and other patent offices. *Ajinomoto Co.*, 228 F.3d at 1346. That McNeil published the 072 rotogranulation method prior to filing the 340 application also undermines any inference that McNeil intentionally concealed the method from the 340 Examiner.[FN8]

> FN8. Perrigo urges this Court to consider Plaintiffs' inequitable conduct in prior litigations in assessing whether there was intent to deceive the 340 Examiner. The Court declines to do so. For the evidence to be admissible under Fed.R.Evid. 404(b), there must be a "close relation" between the prior conduct and the conduct alleged in the case at bar. *Semiconductor Energy Lab. Co. v. Samsung Elec. Co.*, 4 F.Supp.2d 477, 487 n. 16 (E.D.Va.1998); *see also Procter & Gamble Co. v. Nabisco Brands, Inc.*, 697 F.Supp. 1360, 1366 (D.Del.1988). Perrigo has failed to establish such a nexus.

This conclusion is bolstered by several features of the 340 patent. First, the purpose of using the 072 method was to achieve spherical famotidine granules to which an impermeable coating can be easily applied. Yet the 340 specification discloses a preference for spherical granules (PX 1, col. 7, ll. 38-40), and Defendants' granulation expert conceded at trial that an ordinary skilled artisan in 1991 or 1992 would have been able to create spherical famotidine granules without reference to the 072 patent (Tr. at 1220-22). It is well settled that "an inventor need only disclose information about the best mode that would not have been apparent to one of ordinary skill in the art." *Young Dental Mfg. Co. v. Q3 Special Prods., Inc.*, 112 F.3d 1137, 1144 (Fed.Cir.1997); *see also High Concrete Structures, Inc. v. New EnterStone & Lime Co.*, 377 F.3d 1379, 1383 (Fed.Cir.2004) ("The best mode requirement of § 112 is not violated by unintentional omission of information that would be readily known to persons in the field of the invention."). Although there is a suggestion in the 072 specification and elsewhere that using a carrier of 5-75 microns provides unique advantages in creating spherical granules, the evidence before this Court is inadequate to demonstrate why this is so. Second, the 340 patent did disclose rotogranulation using, *inter alia*, a confectioners sugar carrier, which has a fine particle size between 5 and 75 microns. (PX 1, col. 8, ll. 60-64; Tr. at 159.) Under these circumstances, Defendants have failed to establish the quantum of materiality and intent required to substantiate an inequitable conduct claim.

C. *Inventorship*

***16** Defendants also allege inequitable conduct based on Plaintiffs' failure to name Dubek as an inventor of the 340 patent. A patented invention may be the work of two or more joint inventors. 35 U.S.C. § 116. To qualify as a joint inventor, one must "(1) contribute in some significant manner to the conception or reduction to practice of the invention, (2) make a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention, and (3) do more than merely explain to the real inventors well-known concepts and/or the current state of the art." *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1351 (Fed.Cir.1998); *see also Acromed Corp. v. Sofamor Danek Group*, 253 F.3d 1371, 1379 (Fed.Cir.2001). "[O]ne does not qualify as a joint inventor merely by assisting the actual inventor after conception of the claimed invention." *Ethicon, Inc. v. United States Surgical Corp.*, 135 F.3d 1456, 1460 (Fed.Cir.1998). "Conception is the formation in the mind of the inventor, of a definite and permanent

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idea of the complete and operative invention, as it is hereafter to be applied in practice." *Ethicon, Inc.,* 135 F.3d at 1460 (quoting *Hybritech, Inc. v. Monoclonal Antibodies, Inc.,* 802 F.2d 1367, 1376 (Fed.Cir.1986)). "An idea is sufficiently 'definite and permanent' when 'only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation.' " *Ethicon, Inc.,* 135 F.3d at 1460 (quoting *Burroughs Wellcome Co. v. Barr Labs., Inc.,* 40 F.3d 1223, 1228 (Fed.Cir.1994)).

Plaintiffs did not commit inequitable conduct by excluding Dubek from the 340 patent's inventorship. In his trial testimony, Dubek never claimed to be an inventor of the 340 patent or to have contributed to the conception of the invention, and Defendants advance no reason to question Dubek's veracity. "When an alleged omitted co-inventor does not claim to be such, it can hardly be inequitable conduct not to identify that person to the PTO as an inventor." *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.,* 75 F.3d 1568, 1576 (Fed.Cir.1996).

Even had Dubek contributed to the conception of the patent, Defendants have failed to establish Plaintiffs' intent. Defendants speculate that Dubek was denied inventorship status because his inclusion as an author would have endangered the 340 patent application. According to Defendants, disclosing the 072 application to the 340 Examiner might have prompted the Examiner to reject the 340 patent because coating famotidine for taste-masking purposes would have been obvious to a skilled formulator. In the prosecution of a patent, a prior invention is excluded from the definition of prior art if it was authored by the inventors named in the patent application. 35 U.S.C. § 102. Thus, so long as Decoteau, Freeman and Roche authored the 340 patent, the 072 application was excluded from the prior art, and disclosure of the 072 application to the 340 Examiner was unnecessary.

***17** The record evidence does not substantiate this theory and, indeed, it is undisputed that Plaintiffs disclosed the 114 patent to the Examiner. (DX D; DX L, Paper No. 14 at 118.) The 114 patent, like the 072 patent, reveals the use of impermeable coating to mask the taste of famotidine. The evidence does not support an inference that Dubek was intentionally withheld from the 340 patent's inventorship.[FN9]

FN9. Perrigo also raises the defense that McNeil violated § 102(f) by naming Freeman as an inventor of the 340 patent. Perrigo waived this defense by asserting in the Joint Pretrial Order that the only inventorship issue to be tried was whether the patent failed "to name one of the true inventors of the subject matter claimed." (JPTO at 3.) *See Satnick v. Amtrak,* No. 03 Civ. 4896(RKE), 2005 WL 236493, at *2 (S.D.N.Y. Feb. 1, 2005) (finding an argument to be waived based on concession in the joint pretrial order).

D. *35 U.S.C. § 285*

Defendants' request for attorneys fees is predicated on the allegation that Plaintiffs' inequitable conduct renders this case "exceptional" under 35 U.S.C. § 285. Because Defendants have failed to show inequitable conduct, their request for attorneys fees is denied. However, even if Plaintiffs had committed inequitable conduct, the Court would still decline to award fees.

A Court must exercise discretion in determining whether an award of attorneys fees is warranted. *See Enzo Biochem, Inc. v. Calgene, Inc.,* 188 F.3d 1362, 1370 (Fed.Cir.1999); *see also Graco, Inc. v. Binks Mfg. Co.,* 60 F.3d 785, 794-95 (Fed.Cir.1995) ("A finding by a court that a case is exceptional is a factual determination ... whereas the decision to award fees is discretionary."). A number of factors determine whether attorneys fees are appropriate, including the "closeness of the case, tactics of counsel, the conduct of the parties and any other factors that may contribute to a fairer allocation of the burdens of litigation as between winner and loser." *J.P. Stevens Co. v. Lex Tex Ltd.,* 822 F.2d 1047, 1051 (Fed.Cir.1987) (quoting *S.C. Johnson & Son, Inc. v. Carter-Wallace, Inc.,* 781 F.2d 198, 201 (Fed.Cir.1986)). Thus, "[a]ttorney fees are not to be routinely assessed against a losing party in litigation in order to avoid penalizing a party 'for merely

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defending or prosecuting a lawsuit, and are awarded to avoid a gross injustice." *Revlon, Inc. v. Carson Prods. Co.,* 803 F.2d 676, 679 (Fed.Cir.1986) (quoting *Fleischmann Distilling Corp. v. Maier Brewing Co.,* 386 U.S. 714, 718 (1967)).

Inequitable conduct in this case could be found, hypothetically, only by a "close margin." *J.P. Stevens Co.,* 822 F.2d at 1051; *see also Elk Corp. v. GAF Bldg. Materials Corp.,* No. 94 Civ. 294, 2000 WL 265765, at *2 (N.D.Tex. Mar. 7, 2000) (denying application for fees under § 285 where "whether Elk engaged in inequitable conduct itself was "a close question"). McNeil's conduct before the Examiner was not so "egregious or lacking in good faith as to afford a basis for finding this to be an 'exceptional' case," and Plaintiffs' engaged in no litigation misconduct before this Court. *Oshkosh Truck Corp. v. Lockheed Missiles & Space Co.,* 678 F.Supp. 809, 812 (N.D.Cal.1987). Therefore, this case is not exceptional under 35 U.S.C. § 285 and an award of attorneys fees is not warranted.

CONCLUSION

Accordingly, this Court concludes that (1) the 340 patent is invalid under 35 U.S.C. § 103; and (2) this case is not exceptional under 35 U.S.C. § 285. The foregoing constitutes this Court's findings of fact and conclusions of law as required by Rule 52 of the Federal Rules of Civil Procedure. The parties are directed to submit a final judgment consistent with this Opinion and Order within seven business days.

***18** SO ORDERED.

S.D.N.Y.,2007.
McNeil-PPC, Inc. v. Perrigo Co.
Slip Copy, 2007 WL 1624764 (S.D.N.Y.)

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CERTIFICATE OF SERVICE

I hereby certify that on June 14, 2007, a true copy of the foregoing was hand delivered to the following persons and was electronically filed with the Clerk of the Court using CM/ECF which will send notification of such filing to the following and the document is available for viewing and downloading from CM/ECF:

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