REDACTED VERSION – PUBLICLY FILED

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICAL COMPANY, LTD., a Japanese Corporation, and TAP PHARMACEUTICAL PRODUCTS, INC., a Delaware Corporation, Plaintiffs and Counterclaim-Defendants,	Civil Action No. 06-33-SLR
vs.	Highly Confidential – Outside Attorneys Eyes Only Subject to Protective Order
TEVA PHARMACEUTICALS USA, INC., a Delaware corporation, and TEVA PHARMACEUTICAL INDUSTRIES LTD., an Israeli Corporation, Defendants and Counterclaim-Plaintiffs.	

TEVA PHARMACEUTICALS USA, INC.'S AND TEVA PHARMACEUTICAL INDUSTRIES LTD.'S MOTION FOR LEAVE TO AMEND ANSWER, DEFENSES, AND COUNTERCLAIMS TO ASSERT INEQUITABLE CONDUCT AND MEMORANDUM IN SUPPORT THEREOF

Teva respectfully moves to amend its Answer to add affirmative defenses and declaratory judgment counterclaims of unenforceability as to U.S. Patent No. 4,628,098 based on inequitable conduct committed by Takeda before the United States Patent and Trademark Office ("PTO") during (1) the prosecution of the application that resulted in the '098 patent and (2) Takeda's improper petition for a patent term extension for the '098 patent. Takeda and TAP have agreed to Teva's proposed amendments on the first ground but oppose the second ground.

Recent production and translation of Takeda's Japanese documents and the testimony provided by Takeda's witnesses during recent depositions in Japan demonstrate that Takeda materially misrepresented the efficacy of the alleged invention in relation to prior art compounds, such as omeprazole, to convince the PTO of patentability. Recent discovery further shows that

Takeda failed to disclose efficacy test data, or reports thereof, that contradicted the data represented to the PTO as a basis for patentability.

The recent discovery also demonstrates that, even after issuance of the '098 patent, Takeda continued to test the efficacy of the claimed invention and continued to receive results that directly contradicted to the data represented to the PTO during prosecution. Although Takeda was aware that the data it presented to the PTO in the '098 patent was contradicted by other data and results that showed that the claimed invention was not superior to prior art compounds, Takeda nevertheless improperly pursued and obtained a patent term extension on the '098 patent of 1,381 days. Without that extension, the '098 patent would have expired on July 29, 2005 and would not be a part of this litigation.

Teva recognizes that it moves this Court to amend beyond the time to amend set forth in the Scheduling Order. Teva, however, promptly has moved forward with the filing of this motion after it discovered the facts necessary to plead its inequitable conduct defenses and counterclaims with particularity, as required by Fed. R. Civ. P. 9(b). It took a number of months to gather these facts given the large volume of Japanese documents produced by Takeda that needed to be translated and the need to schedule two rounds of depositions of Takeda witnesses in Japan after the translation was substantially complete. This case remains in fact discovery, and expert discovery has yet to commence. In short, Takeda will suffer no procedural prejudice as a result of this amendment, and the case schedule will not be delayed.

Teva further notes that it does not proceed with this motion lightly and seriously considers inequitable conduct claims before alleging such defenses and counterclaims. Teva respectfully submits that amendment is warranted here based on compelling evidence of inequitable conduct. The Federal Circuit has affirmed findings of inequitable conduct on

grounds similar to the facts that have come to light in this case. *See Cargill, Inc. v. Canbra Foods, Ltd.*, __ F.3d __, No. 2006-1265, 1302, 2007 WL 466248 (Fed. Cir. Feb. 14, 2007).

A copy of Teva's proposed First Amended Answer containing Teva's proposed new defenses and counterclaims is attached as Exhibit A to this motion, and a black-line copy of the same pointing out Teva's proposed new defenses and counterclaims is attached as Exhibit B.

I. NATURE AND STAGE OF THE CASE

On January 17, 2006, Plaintiffs filed this action alleging that Teva USA's filing of its Abbreviated New Drug Application ("ANDA") No. 77-255 with the United States Food & Drug Administration ("FDA") constructively infringed five Takeda patents, including the '098 patent. *See* Compl. ¶¶ 19-49. The '098 patent (attached hereto as Ex. C) claims a class of substituted benzimidazole compounds, including lansoprazole (Prevacid®), which are useful in the treatment of ulcers. Teva USA timely answered the Complaint on February 6, 2006, denying infringement and asserting affirmative defenses and counterclaims of non-infringement and invalidity. On June 13, 2006, Plaintiffs filed an agreed-to Amended Complaint adding Teva Ltd. as a party and accusing it of infringing the same five patents. Teva USA and Teva Ltd. timely answered the Amended Complaint on June 29, 2006, again denying infringement and asserting affirmative defenses and counterclaims of non-infringement and invalidity.

On January 24, 2007, the Court approved a stipulation dismissing three of the five asserted patents with prejudice. The remaining patents-in-suit are the '098 patent and U.S. Patent No. 5,045,321.

The Court entered a stipulated Scheduling Order setting November 15, 2006 as the date by which to file motions to amend the pleadings. The Scheduling Order also scheduled fact

discovery to complete on April 12, 2007, expert discovery to complete on July 31, 2007, and trial to begin on October 29, 2007.

Takeda produced over 600,000 pages of documentation between July 2006 and December 2006, with a large portion of the documents being produced after the Court's November 15 deadline for the parties to amend the pleadings. More than 200,000 pages of the documents produced by Takeda, a Japanese corporation, were written in Japanese. Teva diligently reviewed the documents with translators and ordered translation of pertinent documents. The process of reviewing and translating Japanese documents was extensive, time consuming, and was not completed by Teva until March 16, 2007. The review of Takeda's Japanese documents has provided substantial factual bases for Teva's inequitable conduct allegations.

The Japanese documents were, in turn, used to support the deposition of Takeda witnesses in Japan during the weeks of January 29-February 2, 2007 and February 26-March 2, 2007. Takeda insisted that the depositions of those witnesses take place in Japan. Given the difficulty of traveling to Japan, and the practical reality that each deponent would only be deposed once, the parties agreed in October 2006 to schedule the depositions after substantial time to review the produced documents.[1] The parties therefore set the depositions well after the November 15, 2006 deadline to amend the pleadings. Testimony provided by Takeda's witnesses during those depositions additionally forms the basis for Teva's inequitable conduct claims.

[1] Because Takeda continued to produce Japanese language documents as late as December 2006, many still were not translated even as of the date of the depositions in Japan.

Teva filed this motion promptly after having developed the facts necessary to plead its inequitable conduct defenses and counterclaims with particularity, as required by Rule 9 of the Federal Rules of Civil Procedure. At the November 15, 2006 deadline to amended the pleadings without leave, with approximately five months left in fact discovery, Teva did not yet have a basis to plead its inequitable conduct claims with particularity.

II. STATEMENT OF FACTS

Discovery by Teva in pursuit of its invalidity defenses and counterclaims has revealed facts showing that the '098 patent was procured through material misrepresentations and failure to disclose information that a reasonable examiner would find material to patentability with the intent to deceive the PTO rendering the '098 patent unenforceable. Subsequent to issuance of the patent, Takeda continued to misrepresent and deceive the Patent Office in its petition for a Patent Term Extension pursuant to 35 U.S.C. § 156.

A. Takeda's Documents And Witnesses Demonstrate That The '098 Patent Was Procured Through Incomplete Disclosure And Inequitable Conduct.

The January and February depositions of Takeda witnesses made clear that Takeda developed the claimed invention through a synthesis and testing program that saw Takeda's synthesis group make known substitutions to prior art anti-ulcer compounds that Takeda's testing group test would test for efficacy in fighting ulcers. (*See, e.g.*, Nohara Tr. at 23:20-24:17, attached hereto as Ex. D; Maki Tr. at 35:18-36:8 and 38:23-39:9, attached hereto as Ex. E.) Upon synthesis and testing of the alleged inventive compounds, Takeda applied for patent protection in Japan and subsequently the United States.

To advocate patentability in the U.S. patent application, Takeda represented to the PTO that prior art compounds' "gastric mucous membrane protecting action is insufficient, thus being hardly considered satisfactory as anti-ulcer agents." (*See* '098 patent, Col. 1, ln. 14-16.) To

further convince the PTO of patentability, Takeda submitted conclusory data alleging superior efficacy of the claimed invention over certain prior art compounds. Takeda summarized the results of this unidentified test data in the table located in Column 6 of the '098 patent. (*See id.* at Col. 6, ln. 5-23.) Takeda further asserted that the claimed invention exhibits superior anti-ulcer activity over prior art compounds -- up to and exceeding 20 times more effective than the well-known prior art anti-ulcer drug omeprazole. (*See id.* at Col. 6, ln. 30-32.)

After reviewing Takeda's Japanese documents, including monthly status reports and test data, and taking the deposition of Takeda's witnesses, Teva uncovered that Takeda chose not to disclose to the PTO contradictory efficacy data indicating that the alleged invention was not superior to prior art compounds and certainly not 20 times superior to competitive anti-ulcer prior art compounds. (*See, e.g.,* portion of translated version of Central Research Institute Monthly Report (December 1984) at Takeda 40989 stating, [redacted], entire report attached hereto as Ex. F; *see also* Maki Tr. at 62:17-63:12 and 100:25-102:7, attached hereto as Ex. E, and Satoh Tr. at 92:6-15, attached hereto as Ex. G.)

Having chosen to assert efficacy data as a basis for patentability, any efficacy data that was not cumulative of and that refuted or was inconsistent with the submitted data became highly material to patentability under 37 C.F.R. § 1.56, and Takeda had a duty to disclose it. Such information would have been considered important by a reasonable examiner in deciding whether or not to allow the application to issue as a patent.

B. The Evidence Further Demonstrates That The Subsequent Patent Term Extension on the '098 Patent is Unenforceable.

The '098 patent issued on December 9, 1986. On July 6, 1995, Takeda applied for a patent term extension pursuant to 35 U.S.C. § 156. On January 6, 1997, the PTO awarded Takeda a patent term extension of 1,381 days extending the term of the patent to May 10, 2009. Without that patent term extension, the '098 patent would be expired and would not be part of this action.

At the time it sought the patent term extension, Takeda knew that the '098 patent was invalid in light of prior art and unenforceable due to its inequitable conduct before the PTO. Moreover, Takeda continued to test the efficacy of the claimed invention against prior art compounds after issuance of the '098 patent. The results of those efficacy tests further confirmed to Takeda that the claimed invention was not superior to the prior art compounds. (*See, e.g.*, portion of translated version of Research and Development Head Office Monthly Report (August 1991) at Takeda 452242 stating [redacted] entire report attached hereto as Ex. H.)

Despite knowing that it misrepresented the efficacy data and that it failed to disclose material efficacy test results, Takeda sought a patent term extension on the '098 patent. Takeda's failures to disclose its misrepresentations or the contradictory efficacy test results to the PTO, both during and after prosecution, were material to Takeda's entitlement to the extension under 37 C.F.R. § 1.765 because there is a substantial likelihood the PTO would have considered such adverse information important in considering whether to grant the extension.

III. LAW AND ARGUMENT

Rule 15(a) provides that leave to amend "shall be freely given when justice so requires." Fed. R. Civ. P. 15(a).[2] The factors to consider in weighing a motion for leave to amend are well-settled: (1) whether the amendment has been unduly delayed; (2) whether the amendment is brought for some improper purpose; (3) whether the amendment would unfairly prejudice the non-moving party; and (4) whether the amendment is futile. *See Foman v. Davis,* 371 U.S. 178, 182 (1962); *Enzo Life Scis., Inc. v. Digene Corp.,* 270 F. Supp. 2d 484, 487 (D. Del. 2003) (granting motion to assert inequitable conduct defense); *Symbol Tech., Inc. v. Proxim Inc.*, 2003 WL 1905637, *1 (D. Del. 2003) (Robinson, C.J.) (granting motion to assert inequitable conduct defense). Here, all four factors unequivocally support granting leave.

A. Teva's Proposed Amendment Is Timely.

Teva's amendment is timely because Teva could not have pled these unenforceability defenses and counterclaims earlier in the case. Inequitable conduct and other unenforceability claims and defenses fall within the scope of Federal Rule of Civil Procedure 9(b), and therefore, must be pled with particularity. *See Ferguson Beauregard/Logic Controls, Div, of Dover Res., Inc. v. Mega Sys., LLC,* 350 F.3d 1327, 1344 (Fed. Cir. 2003) ("[I]nequitable conduct, while a broader concept than fraud, must be pled with particularity."). Teva filed this motion promptly after it was able to ascertain the information needed to satisfy those particularity requirements. To ascertain that information, Takeda had to undertake the considerable efforts required to translate pertinent Japanese documents containing the relevant efficacy data and then travel to Japan for the depositions of the named inventors of the '098 patent and other Takeda witnesses

[2] Teva files this motion pursuant to F.R.C.P. 15(a), but Teva respectfully submits that the facts set forth herein would also satisfy the "good cause" standard set forth in F.R.C.P. 16(b).

to confirm the importance of that data. Given the complicated process of translating Japanese documents and scheduling depositions in Japan, Teva has not unduly delayed bringing these inequitable conduct defenses and counterclaims.

B. Teva's Proposed Amendment Is Brought in Good Faith.

Teva's amendment is not brought for any improper purpose. As explained below in subsection D, Teva's amendment is entirely consistent with the law of inequitable conduct. Teva's good faith in seeking leave to amend its Answer is demonstrated further by the fact that it waited to obtain evidence, such that it could plead unenforceability with particularity, rather than asserting the claims at the outset of the case based on only partial information. Having properly waited until discovery confirmed the unenforceability claims were available, Teva now should be permitted to proceed.

C. Plaintiffs Will Not Be Unduly Prejudiced By Teva's Proposed Amendments.

Teva's amendment to add the proposed new unenforceability defenses and counterclaims will not unfairly prejudice Plaintiffs in conducting subsequent discovery or presenting a defense. Discovery on the additional defenses and counterclaims would cover the same or similar ground to Teva's existing invalidity defenses and counterclaims. In any event, the evidence regarding Teva's allegations *comes from Plaintiff's own documents and witnesses.*

The addition of Teva's proposed defenses and counterclaims will not delay the pre-trial schedule or the start of trial. As discussed above, Teva does not believe Plaintiffs will require any fact discovery on these issues. Further, there are still two months until opening expert reports are due, more than four months until the close of expert discovery, and more than seven months until the start of trial.

D. Teva's Proposed Amendment Is Not Futile.

Finally, Teva's proposed amendments are far from futile. To establish that its proposed amendments are not futile, Teva need only show at this stage that its unenforceability allegations "state a claim upon which relief could be granted." *Alvin v. Suzuki*, 227 F.3d 107, 121 (3d Cir. 2000). Thus, the proposed amendment would only be futile if the unenforceability defenses and counterclaims Teva seeks to add would not survive a Rule 12(b)(6) motion to dismiss. *See id.* at 122. Teva, as discussed below, respectfully submits that its allegations would survive such a motion.

1. Takeda's Inequitable Conduct During Prosecution of the '098 Patent

Patent applicants "are required to prosecute patent applications 'with candor, good faith, and honesty.'" *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1233 (Fed. Cir. 2003) (quoting *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995)); *see also* 37 C.F.R. § 1.56. "A breach of this duty can take several forms: affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false information." *See Bristol-Myers*, 326 F.3d at 1233.

To establish inequitable conduct due to the failure to disclose material information or the submission of false information, Teva must prove that: (1) the information is material; (2) the knowledge of this information and its materiality is chargeable to the patent applicant; and (3) the applicant's submission of false information or its failure to disclose this information resulted from an intent to mislead the PTO. *See Ferring v. Barr*, 437 F.3d 1181, 1186-87 (Fed. Cir. 2006); *Elk Corp. of Dallas v. GAF Bldg. Materials Corp.*, 168 F.3d 28, 30 (Fed. Cir. 1999).

Information is deemed material if "there is a substantial likelihood that a reasonable examiner would have considered the material important in deciding whether to allow the

application to issue as a patent." *See Elk Corp.*, 168 F.3d at 31. The Federal Circuit recently held that a "reasonable examiner would certainly want to consider test data that is directly related to an important issue of patentability, along with the applicant's interpretation of that data." *Cargill*, 2007 WL 466248 at *5 (emphasis added). A patentee's decision to withhold its own non-cumulative, contradictory test data when the patentee asserted similar data as a basis for patentability impermissibly prevents the examiner from considering material information. *Id.*; see *also Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc.*, 176 Fed. Appx. 117, 122 (Fed. Cir. 2006) (Unpublished opinion).

In this case, Takeda asserted efficacy of the claimed invention in support of patentability. Takeda failed, however, to disclose data that contradicted Takeda's conclusory claims of superior efficacy over prior art compounds, including the successful prior art compound omeprazole. Takeda's actions constitute both a material misrepresentation of the facts and an omission of material information. *See Cargill*, 2007 WL 466248 at *4-5 (Fed. Cir. Feb. 14, 2007); *Aventis*, 176 Fed. Appx. at 120 (finding that "an omission that would have revealed that the difference in half-lives was actually much smaller was material to patentability.").

With respect to intent, the Federal Circuit has made it clear that "intent may be inferred where a patent applicant knew, or should have known, that withheld information would be material to the PTO's consideration of the patent application." *Cargill*, 2007 WL 466248 at *5 (quoting *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.* 120 F.3d 1253, 1256 (Fed. Cir. 1997)). Intent can be inferred in this situation from the high materiality of the efficacy data known to the inventors of the '098 patent and their staff, which data was produced from Takeda's own files, as well as Takeda's motivation to obtain a patent on the alleged invention.

2. Takeda's Improper Patent Term Extension on the '098 Patent

"In applying for a patent term extension, the patentee has a duty of candor and good faith towards the PTO and must disclose any 'material information adverse to a determination of entitlement to the extension sought.'" *Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 457 F.3d 1284, 1290 (Fed. Cir. 2006) (quoting 37 C.F.R. 1.765(a)). Information is considered material "where there is a substantial likelihood that the [PTO] ... would consider it important in determinations to be made in the patent term extension proceeding." *Id.*

Patent term extensions have not been the subject of much litigation to date, and Teva is not aware of any Federal Circuit adverse to Teva's proposed amendment. At the district court level in *Pfizer*, the defendant argued that the failure of a patentee to disclose statements affecting the scope of the patent claims during the application for an extension rendered the extension invalid. *Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 405 F. Supp. 2d 495, 511-12 (D. Del. 2005). The Federal Circuit subsequently upheld the district court's ruling that the omitted information was not material but left open the issue of whether the extension would have been invalidated if the information had been material. 457 F.3d at 1291. This suggests that at least one panel at the Federal Circuit believes that there is a duty to disclose material information regarding the existence of valid, enforceable patent coverage over a drug in connection with requests for a patent term extension as a result of the FDA's approval to market that drug, a duty which Teva contends was violated here.

Such a result is entirely consistent with 37 C.F.R.§ 1.765, which states "No patent will be determined eligible for extension and no extension will be issued if it is determined that fraud on the [Patent and Trademark] Office or the Secretary [of Health and Human Services or the Secretary of Agriculture] was practiced or attempted or the duty of disclosure was violated

through bad faith or gross negligence in connection with the patent term extension proceeding." The District of Delaware addressed a similar issue in the context of a motion to dismiss in *United Sweetener USA, Inc. v. Nutrasweet Co.*, 760 F. Supp. 400 (D. Del. 1991) (declining to hold a patent term extension unenforceable)[3], but that case was resolved before appeal and long prior to Federal Circuit's *Pfizer* decision. It is therefore not binding precedent on this Court.

In this case, Takeda applied for the extension on the '098 patent knowing that it had misrepresented the efficacy of the claimed invention by providing selective efficacy data to the PTO in support of patentability and failing to submit contradictory data. Takeda therefore was aware that the '098 patent was invalid and/or unenforceable. Certainly, the PTO would have considered a patentee's knowledge that its patent was invalid or unenforceable to be important to the decision to award a patent term extension. If the '098 patent is invalid or unenforceable, then Takeda would not have patent coverage on the FDA-approved form of lansoprazole, and a patent term extension would not be warranted under 35 U.S.C. § 156. Thus, unlike *Pfizer*, the omitted information is material, and Takeda violated its duty of candor and good faith in seeking the patent term extension without disclosing the data. As a result, the Court is empowered to hold Takeda's patent term extension on the '098 patent unenforceable.

IV. CONCLUSION

For the foregoing reasons, Teva respectfully submits that its Motion For Leave to Amend its Answer, Defenses, and Counterclaims should be granted.

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[3] The Pfizer and United Sweetener courts are inconsistent in stating whether an improper patent term extension should be held invalid or unenforceable. The burden of proof is the same regardless of the term used. Teva uses the term unenforceable because Takeda's actions involved inequitable conduct before the PTO.

Submitted this 23rd day of March, 2007.

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TAKEDA PHARMACEUTICAL COMPANY, LTD., a Japanese Corporation, and TAP PHARMACEUTICAL PRODUCTS, INC., a Delaware Corporation, Plaintiffs and Counterclaim-Defendants, vs. TEVA PHARMACEUTICALS USA, INC., a Delaware corporation, and TEVA PHARMACEUTICAL INDUSTRIES LTD., an Israeli Corporation, Defendants and Counterclaim-Plaintiffs.	C. A. No. 06-33-SLR

ORDER

AND NOW, this _____ day of _____, 2007, the Defendants/Counterclaim-Plaintiffs Teva Pharmaceuticals USA, Inc.'s and Teva Pharmaceutical Industries Ltd.'s having presented a Motion for Leave to Amend Answer, Defenses, and Counterclaims to Assert Inequitable Conduct;

IT IS ORDERED that Defendants/Counterclaim-Plaintiffs Teva Pharmaceuticals USA, Inc.'s and Teva Pharmaceutical Industries Ltd.'s Motion for Leave to Amend Answer, Defenses, and Counterclaims to Assert Inequitable Conduct is GRANTED.

Sue L. Robinson
United States District Judge

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TAKEDA PHARMACEUTICAL COMPANY, LTD., a Japanese Corporation, and TAP PHARMACEUTICAL PRODUCTS, INC., a Delaware Corporation, Plaintiffs and Counterclaim-Defendants,	
vs.	Civil Action No. 06-33-SLR
TEVA PHARMACEUTICALS USA, INC., a Delaware corporation, and TEVA PHARMACEUTICAL INDUSTRIES LTD., an Israeli Corporation, Defendants and Counterclaim-Plaintiffs.	

LOCAL RULE 7.1.1 DISCLOSURE

I, Karen E. Keller, Esquire, hereby certify pursuant to Local Rule 7.1.1, that counsel for Defendants contacted both Plaintiffs concerning Defendants' motion for leave to amend their Answer to add affirmative defenses and declaratory judgment counterclaims of unenforceability based on inequitable conduct committed by Takeda before the United States Patent and Trademark Office during (1) the prosecution of the application that resulted in the '098 patent and (2) Takeda's petition for a patent term extension for the '098 patent.

Plaintiffs have agreed to Defendants' proposed amendments to add the first ground but oppose Defendants' proposed amendment to add the second ground.

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DATED: March 23, 2007

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CERTIFICATE OF SERVICE

I, Karen E. Keller, Esquire, hereby certify that on March 23, 2007, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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I further certify that on March 23, 2007, I caused a copy of the foregoing document to be served by e-mail and hand delivery on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

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CERTIFICATE OF SERVICE

I, Karen L. Pascale, Esquire, hereby certify that on April 4, 2007, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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I further certify that on April 4, 2007, I caused a copy of the foregoing document to be served by e-mail and hand delivery on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

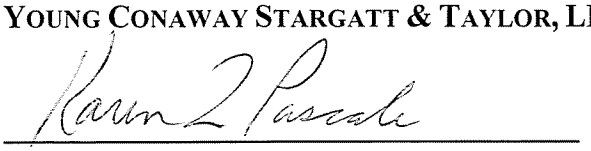
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