UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MERCK & CO., INC., and MSD TECHNOLOGY L.P., *Plaintiffs*, v. **MEDIPLAN HEALTH CONSULTING, INC., d/b/a RXNORTH.COM,** *Defendant.*	**Civil Action No. 05-CIV-3650 (DC) (FM) ECF Case**

(CAPTIONS CONTINUED)

REPLY BRIEF IN SUPPORT OF JOINT MOTION FOR PARTIAL SUMMARY ADJUDICATION ON PATENT REMEDIES AND IN OPPPOSITION TO RULE 56(F) CROSS MOTION

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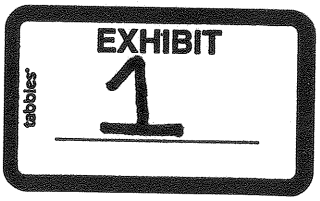

MERCK & CO., INC., and MSD TECHNOLOGY L.P., *Plaintiffs*, v. **NORTH PHARMACY, INC., and PPI PIVOTAL PARTNERS INC., d/b/a CANADAPHARMACY.COM,** *Defendants.*	**Civil Action No. 05-CIV-3696 (DC) (FM) ECF Case**
MERCK & CO., INC., and MSD TECHNOLOGY L.P., *Plaintiffs*, v. **UNIVERSAL DRUG STORE LTD., d/b/a UNIVERSALDRUGSTORE.COM,** *Defendant.*	**Civil Action No. 05-CIV-3698 (DC) (FM) ECF Case**
MERCK & CO., INC., and MSD TECHNOLOGY L.P., *Plaintiffs*, v. **CANADA DRUGS.COM PARTNERSHIP and KRIS THORKELSON, d/b/a CANADADRUGS.COM,** *Defendants.*	**Civil Action No. 05-CIV-3699 (DC) (FM) ECF Case**
	(CAPTIONS CONTINUED)

MERCK & CO., INC., and MSD TECHNOLOGY L.P., *Plaintiffs,* v. **MEDCENTER CANADA INC.,** *Defendant.*	**Civil Action No. 05-CIV-3700 (DC) (FM) ECF Case**
MERCK & CO., INC., and MSD TECHNOLOGY L.P., *Plaintiffs,* v. **TOTAL CARE PHARMACY LTD. and DAVE ROBERTSON, d/b/a CROSSBORDERPHARMACY.COM,** *Defendants.*	**Civil Action No. 05-CIV-3701 (DC) (FM) ECF Case**

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Merck's attempts to be excused from the requirements of Section 287(a) are contrary to the express language and purpose of the statute, and must be rejected. There are no material facts in dispute as to marking or actual notice. The Defendants are entitled as a matter of law to partial summary judgment on damages.[1]

I. An Orange Book Listing Is Not "Actual Notice Of Infringement"

In response to requests for admissions, Merck stated that it never marked its physical ZOCOR products or product packaging. Merck also admitted that it had never provided "actual notice of infringement" to Defendants before filing suit. *See, e.g.*, Ex. A to Defendant's Opening Br. at Response No. 4 ("Plaintiffs admit that they first provided actual notice to defendants of their allegations of infringement of the '784 patent on April 11, 2005."). Merck now takes a contrary position and offers a novel argument that the Orange Book listing itself constitutes "actual notice of infringement."[2] It does not.

Merck is attempting to rewrite Section 287(a). The statute provides that without proper marking, no past damages can be recovered unless "the infringer was notified of the infringement and continued to infringe thereafter." 35 U.S.C. § 287(a). There is no exception for pharmaceuticals—just like any other product, they must be marked.

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[1] Merck admitted to all of the material facts through its responses to requests for admission. Defendants complied with Local Rule 56.1 by attaching those responses as Exhibits A and B to their opening brief. Merck has since made equivalent admissions in Case Nos. 05-3650, 05-3696, 05-3698, and further clarified that it had not distributed copies of the Orange Book with packages of Zocor. *See* Exhibit A hereto.

[2] Merck had previously contended instead that the Orange Book listings constituted "marking." *See, e.g.*, Ex. A to Opening Br. at Response No. 3. It has abandoned this position.

Merck identifies no case law or statutory authority supporting its contrary argument.[3] Merck's public policy theory—that the Orange Book listing should constructively satisfy Section 287(a)—is squarely contradicted by the text of the marking statute. A Court's analysis "begins with the language of the statute," *Bailey v. United States*, 516 U.S. 137, 144 (1995), since "the function of the courts is to determine the intent of the legislature, not to rewrite the statute based on our notions of appropriate policy." *BankAmerica Corp. v. United States*, 462 U.S. 122, 140 (1983).

Section 287(a) of the Patent Act long predates the recent Hatch-Waxman amendments. The marking and actual notice requirements were first enacted in 1870 and have remained essentially unchanged for more than a century. *See generally Wine R.R. Appliance Co. v. Enterprise R.R. Equipment Co.*, 297 U.S. 387, 528-29 (1936); *Nike, Inc. v. Wal-Mart Stores, Inc.*, 138 F.3d 1437, 1443-45 (Fed. Cir. 1998).

Nothing in the Hatch-Waxman Act of 1984 indicates Congressional intent to upset this longstanding requirement in the context of patents on drugs. Those amendments modified the Food, Drug and Cosmetic Act to streamline the regulatory approval process for pharmaceuticals. The Orange Book provides a different type of notice in a different context, for the regulatory approval of generic drugs. Nothing in those amendments purported to modify Section 287(a) or otherwise weaken the marking requirement for pharmaceuticals.

Had Congress wanted to modify the marking requirement for pharmaceuticals, it could easily have done so at that time. Its inaction evinces a Congressional intent *not* to allow an Orange Book listing to function as a substitute for marking or notice. *See Olmsted v. Pruco Life*

[3] The Hatch-Waxman Act was passed over twenty-one years ago. Defendants have found no decision which even raises the argument made by Merck here.

Ins. Co. of New Jersey, 283 F.3d 429, 433 (2d Cir. 2002) (Congress' explicit provision of a private right to enforce one Section of a statute suggests that omission of explicit right to enforce other sections was intentional).

Merck argues that an Orange Book listing should be constructively treated as "actual notice of infringement" because a drug manufacturer could look up a drug in the Orange Book and determine whether it was patented before filing an abbreviated new drug application. But this rationale makes no sense here. The Defendants are not drug manufacturers, and they are not seeking FDA approval.[4]

Even if Defendants had known about this particular Orange Book listing or the existence of the patent, that knowledge would be irrelevant. Neither "general knowledge in the marketplace" about a patent nor "accepted practice in [an] industry" is a substitute for actual notice of infringement. *See Stryker Corp. v. Intermedics Orthopedics*, 891 F. Supp. 751, 829 (E.D.N.Y. 1995), *aff'd*, 96 F.3d 1409 (Fed. Cir. 1996); *Lemelson v. Fisher Price Corp.*, 545 F. Supp. 973, 976 (S.D.N.Y. 1982). Even a defendant's specific knowledge about a patent does not eliminate the need for proper notice:

> Evidence of [defendant's] state of mind, *i.e.* that [defendant] knew of the patent and had the soundest possible reason to believe [that it may be infringing], is irrelevant. ... The statutory requirement of "notice" is unambiguous. There can be no recovery for the period before the defendant is expressly notified by the patentee that it is infringing a particular patent.

Int'l Nickel Co. v. Ford Motor Co., 166 F. Supp. 551, 567 (S.D.N.Y. 1958); *see also Amsted Indus. v. Buckeye Steel Castings Co.*, 24 F.3d 178, 187 (Fed. Cir. 1994) (holding that actual

[4] Merck's argument that Defendants should have obtained such FDA approval is not only wrong, it is completely beside the point. Because the Defendants provide pharmaceuticals in Canada, no FDA approval is necessary. Merck is not asserting any causes of action to enforce the FDCA, nor could it. *See, e.g., In re. Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d 781, 788 (3d Cir. 1999) ("It is well settled... that the FDCA creates no private right of action.").

notice was required even though defendant had "known about the [asserted] patent for ten years and ultimately decided to copy it after numerous unsuccessful attempts to design around it").

Just as the Orange Book listing does not *constructively* satisfy the statute, it does not meet the alternative requirement of *actual* notice. Actual notice of infringement requires an affirmative communication "of a specific charge of infringement by a specific accused product or device." *Amsted*, 24 F.3d at 187.

First of all, Merck did not provide "actual notice" of any sort before filing suit. Actual notice requires an express communication from the plaintiff to the *specific* individual defendant. *See Amsted*, 24 F.3d at 187; *Int'l Nickel*, 166 F. Supp. at 567. *Generalized* notice in a government publication like the Orange Book is no substitute.

Secondly, Merck did not provide actual notice "of infringement." It is not enough for a plaintiff merely to give notice that it owns certain patent rights. *See Gart v. Logitech, Inc.*, 254 F.3d 1334, 1345 (Fed. Cir. 2001) ("Mere notice of the patent's existence or ownership is not notice of the infringement, and as such would be insufficient to comply with Section 287(a)."); *see also AT&T Corp.*, 290 F. Supp. 2d 409, 412-418 (S.D.N.Y. 2003) (holding that letters and other statements informing defendant about its patents did not constitute actual notice). Rather, the plaintiff must provide the defendant with a specific accusation of infringement and the factual basis for those allegations. *See Amsted*, 24 F.3d at 187.

The alleged "notice" here is inadequate. The relevant Orange Book listing reads in full:

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATES	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATES
SIMVASTATIN; ZOCOR					
019766 001	4444784	Dec 23, 2005	U-59	I-390	Apr 16, 2006
	4444784*PED	Jun 23, 2006	U-59	I-350	Oct 18, 2005
				PED	April 18, 2006

FDA Orange Book, 2005 Annual Edition, at 983 (available at http://www.fda.gov/cder/ob/docs/preface/eclink.htm). This listing simply indicates Merck's opinion that simvastatin is covered by the '784 patent. In other words, at most it provides "notice of the patent's existence or ownership," not a specific charge of infringement directed to an individual recipient. *Gart*, 254 F.3d at 1345. An Orange Book listing by itself does not constitute a threat of litigation because a patentee might ultimately decide not to bring suit. *See Teva Pharm., Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1333 (Fed. Cir. 2005) (the mere listing of a patent in the Orange Book "should not be construed as a blanket threat to potential infringers" of litigation). Moreover, this listing does not provide any factual details "of the infringement," such as specific allegations that Defendants' sales of simvastatin products in Canada would somehow infringe the patent. Absent any "specific charge of infringement by a specific accused product or device," this listing fails as actual notice. *Amsted*, 24 F.3d at 187.

The actual notice requirement is intended to give defendants advance warning of prospective litigation before significant damages will begin to accrue. The Defendants here had no reason to anticipate this suit.[5] Merck filed suit without so much as a courtesy letter to Defendants. Because Merck neither marked its patented products nor provided advance notice to the individual defendants before filing suit, it cannot collect pre-suit damages.

[5] Dispensing of drugs in Canada could not infringe any United States patents. The Patent Act specifically limits liability to infringement that occurs "within the United States." 35 U.S.C. § 271(a). *See, e.g., Pellegrini v. Analog Devices, Inc.*, 375 F.3d 1113, 1117 (Fed. Cir. 2004) ("the U.S. patent laws 'do not, and were not intended to, operate beyond the limits of the United States'") (quoting *Brown v. Duchesne*, 60 U.S. (19 How.) 183, 195 (1857)); *accord NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1313 (Fed. Cir. 2005).

II. Merck Cannot "Opt Out" of the Marking Requirement

A. An "election" of claims would have no effect on damages

Merck cannot exempt itself from the limitation on damages by simply "electing" not to assert any product claims. Notably, Merck admits that its product claims have been put in issue by its pleadings already of record. Merck's brief states:

> " ... the factual allegations asserted by Merck ***support a claim for direct infringement of product claims*** covering the simvastatin compound ..." Opposition Br. at 14-15 (emphasis added).

Both the product claims and the method claims involve the same chemical compound, simvastatin. Indeed, Merck admits that the primary reason for pursuing its desired "election" strategy would be to circumvent the marking requirement to obtain pre-suit damages that would otherwise be precluded. *See* Opposition Br. at 21. Yet Merck is still trying to have it both ways. In each of the six separate complaints, Merck specifically alleged that defendants had infringed the patent through their "sales" and "offers for sales" of infringing "products." *See, e.g.*, Complaint in Civ. No. 05-3650, ¶ 22.

Merck contends that these were just generalized averments of infringement, and that it had not yet identified any particular theory. Merck is mistaken. The complaints speak for themselves, and they could not be any more specific about their theory of liability. Merck has not even alleged any other factual basis for infringement. Merck is only now attempting to recant its prior allegations in order to avoid the marking requirement.[6]

Merck may not circumvent the marking requirement simply by manipulating its pleadings. Merck sold a patented product for years that it never marked. This case is therefore

[6] Amendment of the pleadings to specifically allege infringement of the method claims would be futile since defendants neither practice the patented method nor induce or contribute to such infringement by anyone else.

controlled by *American Medical Systems*. *See Am. Med. Sys. v. Med. Eng'g Corp.*, 6 F.3d 1523, 1538-39 (Fed. Cir. 1993) ("Where the patent contains both apparatus and method claims, however, to the extent there is a tangible item to mark by which notice of the asserted claims can be given, a party is obliged to do so if it intends to avail itself of the [marking] provision of Section 287(a)."). Merck attempts to limit this holding to cases where the plaintiff has asserted both the method and product claims during litigation. But the holding itself makes no such distinction.

Hanson v. Alpine Valley Ski Area, Inc., 718 F.2d 1075 (Fed. Cir. 1983), relied on almost exclusively by Merck, does not conflict with *American Medical Systems*. In *Hanson*, the Federal Circuit emphasized that its decision was "a narrow one" that was essentially limited to the unusual procedural posture and facts of that case. *Id.* at 1083. According to the district court opinion, there was genuine doubt about whether the products sold by Hanson's licensees even fell within the claims of the patent. *See Hanson*, 1977 U.S. Dist. LEXIS 15855 at *3 ("The [machines sold by the licensee] use a different method for subdividing the water than is disclosed in the Hanson patent but otherwise uses the basic Hanson method"). Moreover, the product claims in particular were considerably narrower than the method claims. There was no indication that the plaintiff (an individual inventor) was deliberately manipulating his theory of infringement to avoid the marking requirement. Rather, the product claims were not legitimately relevant to the lawsuit.

A recent article compared *Hanson* and *American Medical Systems* and found no conflict between them. *See* Susan Perng Pan, *The InterSection Between Damages Recovery Under the Patent Marking Statute and Prosecution Practice*, 24 ABA IPL Newsletter 1, 19, at 19-20 (Fall 2005) (attached as Exhibit B). As the author noted, the product claims in *Hanson* were quite

narrow, and were essentially directed to different inventions than the method claims. Because the unmarked products apparently were not even within the scope of the product claims, there was no duty to mark them. *See id.* at 20 ("It is reasonable to infer that the patent holder in *Hanson* was permitted to recover for prefiling damages without marking because he was not deemed to have sold the patented apparatus of [the product claim].").

In contrast, *American Medical Systems* and its progeny all involved situations in which the method claims were closely related to the product claims. *See* Pan at 20 ("Unlike the case in *Hanson*, where there were more readily apparent differences between the method and apparatus claims, the claims in *American Medical* appear to be of essentially coextensive scope."); *see also Devices for Med., Inc. v. Boehl*, 822 F.2d 1062, 1066 (Fed. Cir. 1987) (holding that marking requirement applied and barred damages where "the claimed method is the use of the product"). Because the plaintiff had admittedly sold unmarked products within the scope of the product claims, it did not matter whether it was asserting product claims, method claims or both during the litigation.

Not a single published district court opinion has recognized the purported distinction that Merck relies upon.[7] *See generally Mosel Vitelic Corp. v. Micron Tech., Inc.*, Civ. No. 98-449, 2000 WL 1728351, *2 (D. Del. Feb. 25, 2000) ("As the *American Medical Systems* court has made clear, regardless of whether a plaintiff is asserting method claims, apparatus claims, or both, that party must properly mark its products in order to obtain the benefits of the constructive

[7] *Compare Soverain Software LLC v. Amazon.com, Inc.*, 383 F. Supp. 2d 904, 909 (E.D. Tex. 2005) (product and method claims), *and Loral Fairchild Corp. v. Victor Co.*, 906 F. Supp. 813, 816-17 (E.D.N.Y. 1995) (same), *with Philips Electronics North America Corp. v. Contec Corp.*, 312 F. Supp. 2d 649, 651-52 (D. Del. 2004) (method claims only), *and Halliburton Services. v. Smith International, Inc.*, 317 F. Supp. 2d 719, 725 (E.D. Tex. 2004) (same).

notice provisions set forth in Section 287."). In each such published opinion, the dispositive factor instead was whether the plaintiff had sold an unmarked, patented product. If so, *American Medical Systems* controlled and past damages were precluded. These opinions have applied this rule consistently regardless of which claims the plaintiff was asserting.

Merck's argument is also contrary to the plain language of the marking statute. The statute by its terms requires the patentee to mark "any patented article" or forfeit damages. 35 U.S.C. § 287(a). It addresses the commercial article being sold, not the claims, and so does not make or suggest any distinction based on the particular claims being asserted in a litigation.

Courts have recognized an implied exception to the marking requirement when a patent contains *only* method claims, because abstract methods cannot have a physical embodiment as "patented articles." When a patent also has product claims, however, there is no predicate for this exception. Consequently, the proper consideration is whether the patent "contains" any product claims that can be represented as a tangible article. *See Am. Med. Sys.*, 6 F.3d at 1538 ("Where the patent *contains* both apparatus and method claims, however, to the extent that there is a tangible item to mark by which notice of the asserted method can be given, a party is obliged to do so[.]") (emphasis added); *see also Loral Fairchild Corp. v. Victor Co.*, 906 F. Supp. 813, 816-17 (E.D.N.Y. 1995) (Rader, Fed. Cir. J., sitting by designation) ("*American Medical* clarifies that a patentee must mark a product covered by a patent with both method and product claims."). If the patent has product claims and tangible articles are actually sold to the public, they must be marked.

Merck's own counsel has eloquently defended this interpretation. In the *Coca-Cola* case cited by Merck, defendant PepsiCo was represented by the firm of Fitzpatrick, Cella. They

argued persuasively that plaintiff Coca-Cola was attempting to "distort the law" through its misplaced reliance on *Hanson*:

> In *Hanson*, the Federal Circuit noted that patent marking was not necessary because the claims of the patent were directed to "[t]he method of forming, distributing and depositing snow upon a surface" (718 F.2d at 1083). ... Neither *Hanson* nor *Bandag* had a "tangible item to mark" with the patent number to provide notice that its asserted method claims were infringed. ... But where, as here, there is something "tangible" to mark... notice is required....
>
> Coca-Cola's theory is that a patentee with claims in the same patent directed to a method *and* an apparatus manufactured under the method can avoid the marking and actual notice requirements of § 287 by selectively asserting only method claims against an accused infringer. That theory would defeat the express purpose of § 287 and flies in the face of the decision in *American Medical.*

Reply Br. for Defendants at 5-7, *Coca-Cola Co. v. PepsiCo. Inc.*, Civ. No. 1:02-2887 (N.D. Ga. Apr. 13, 2004) (attached as Exhibit C). The district court held to the contrary in an unpublished opinion (not available even on LEXIS or Westlaw) that expressly disagreed with the better-reasoned authority. It is questionable whether this isolated decision has precedential value even in the Northern District of Georgia; it is neither persuasive nor precedential here.

The marking requirement is not optional. Merck admits that it sold a "patented article" for years that it never marked. It cannot escape the marking requirement by choosing at some later date (even just prior to trial, as it contends[8]) which claims to assert.

B. The Court need not await further discovery

Merck alleges that it needs further discovery before it can decide which claims to assert. However, Merck has not explained how the defenses already of record could even in theory apply any differently to product or method claims, despite its burden to do so. *Ruotolo v.*

[8] If Merck's "election" theory were to be given any credence at all—it should not be—it would be manifestly unfair for such an election to be delayed until after the close of discovery, as Merck wishes. That would impose the full burden of pre-suit damages discovery on defendants, for no legitimate purpose.

Department of Justice, 53 F.3d 4, 11 (2d Cir. 1995) (movant for continuance must file affidavit that explains *(inter alia)* the information requested, and how genuine issue of material fact will be created by it); *see also Byrd v. United States EPA*, 174 F.3d 239, 248 n.8 (D.C.Cir. 1999) (conclusory statements insufficient); *Carpenter v. Federal Nat'l Mortg. Ass'n*, 174 F.3d 231, 237 (D.C.Cir. 1999) (same), *cert. denied*, 528 U.S. 876, 120 S.Ct. 184, 145 L.Ed.2d 155 (1999).

If the Court agrees with Defendants and holds that *American Medical Systems* controls, Merck's election theory would be irrelevant: Merck would be precluded from past damages no matter what amendments it makes to its pleadings or which claims it asserts at trial. The Court may therefore grant this motion in its entirety without any need to await Merck's "election". Such a decision would limit the scope and burden of damages discovery, preventing Merck from pursuing blind alleys to Defendants' prejudice.

Even if the Court were to agree with Merck that such an election of claims might affect damages, the Court should nevertheless hold that Merck's past damages are precluded unless it affirmatively decides to abandon the product claims. The Court could also eliminate the need for unnecessary damages discovery by setting a reasonable date by which Merck would be required to make such a choice. Consequently, regardless of how the Court decides this issue, there is no need for the Court to stay its decision.

III. There is No Dispute as to Future Damages

In its opposition brief, Merck admits that it is not entitled to damages for acts of infringement after the patent expires on December 23, 2005. That is, it cannot recover any traditional measure of patent damages, like lost profits or a reasonable royalty, based on sales by Defendants that occur after that date. Merck also agrees that no injunctive relief will be available after the patent expires.

Merck instead advances an unusual theory of damages based on "accelerated market entry" ("AME"), under which Merck would allegedly claim damages for a loss of market share based on infringement that occurred *before* the patent expired. But even this theory assumes that Defendants would lawfully be entitled to begin sales of the accused products starting December 24, 2005.

Defendants take no position at this time on whether such an AME theory is supportable. However, they do agree that such damages do not constitute the type of post-expiration damages contemplated by the underlying motion. The Court may grant Defendants' motion for partial summary judgment with the proviso that the ruling neither affects Merck's ability to pursue its AME theory, nor limits Defendants' ability to contest it in due course.

IV. Conclusion

For the forgoing reasons and the reasons in the opening brief, the Court should grant Defendants' motion for partial summary judgment on pre-suit and prospective remedies for patent infringement, and deny Merck's cross-motion under Rule 56(f) for a continuance.

Dated: December 5, 2005

Respectfully submitted,

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The undersigned hereby certifies that a true copy of the foregoing:

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