Exhibit C

Merck's Memorandum in Opposition to Defendants' Joint Motion for Partial Summary Judgment on Patent Remedies… (Doc. No. 23)

***Merck & Co., Inc. v. Mediplan Health Consulting, Inc.*, 1:05-cv-03650-DC**

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

MERCK & CO., INC. and MSD TECHNOLOGY, L.P., Plaintiffs, v. MEDIPLAN HEALTH CONSULTING, INC. d/b/a RXNORTH.COM, Defendants.	Civil Action No. 05 CV 3650 Electronically Filed Case Judge: Hon. Denny Chin Magistrate Judge: Hon. Frank Maas
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 CV 3696 Electronically Filed Case Judge: Hon. Denny Chin Magistrate Judge: Hon. Frank Maas
MERCK & CO., INC. and MSD TECHNOLOGY, L.P., Plaintiffs, v. UNIVERSAL DRUG STORE LTD. d/b/a UNIVERSAL DRUGSTORE.COM, Defendant.	Civil Action No. 05 CV 3698 Electronically Filed Case Judge: Hon. Denny Chin Magistrate Judge: Hon. Frank Maas

(CAPTIONS CONTINUED)

MERCK'S MEMORANDUM IN OPPOSITION TO DEFENDANTS' JOINT MOTION FOR PARTIAL SUMMARY JUDGMENT ON PATENT REMEDIES, AND IN SUPPORT OF MERCK'S ALTERNATIVE RULE 56(f) CROSS MOTION FOR A CONTINUANCE OF DEFENDANTS' JOINT MOTION

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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 CV 3699 Electronically Filed Case Judge: Hon. Denny Chin Magistrate Judge: Hon. Frank Maas
MERCK & CO., INC. and MSD TECHNOLOGY, L.P., Plaintiffs, v. MEDCENTER CANADA, INC., Defendant.	Civil Action No. 05 CV 3700 Electronically Filed Case Magistrate Judge: Hon. Frank Maas
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 CV 3701 Electronically Filed Case Judge : Hon. Denny Chin Magistrate Judge: Hon. Frank Maas

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INTRODUCTION

Plaintiffs Merck & Co., Inc. and MSD Technology L.P. (collectively "Merck") submit this Memorandum in Opposition to Defendants' Joint Motion for Partial Summary Judgment on Patent Remedies,[1/] and in Support of Merck's Alternative Rule 56(f) Cross Motion for a Continuance of Defendants' Joint Motion.

Merck's Rule 56(f) cross motion is being submitted with Merck's opposition to defendants' joint motion. As explained below, the Court need only consider the Rule 56(f) application if defendants' joint partial summary judgment motion is not denied by this Court.

As alleged in the complaint, defendants in all six of these cases are operating Canadian-based Internet pharmacies, selling prescription drug products, including simvastatin, to customers in the United States. Defendants cannot seriously dispute that they promote their products in the United States, offer them for sale to customers in the U.S., and that the products they sell have not been approved for sale in the United States by the Food and Drug Administration ("FDA"). See accompanying declaration of Peter Shapiro ("Shapiro Decl.") Tabs 1-6.

In their joint motion, defendants seek to (1) limit Merck's past damages for patent infringement on grounds of alleged failure to comply with the patent marking statute, and (2) to terminate any patent infringement damages as of the day the patent expires.[2/] As explained below, the joint motion should be denied, or at least deferred under Rule 56(f) because:

1/ Defendants have not submitted a statement of material facts as to which they contend there is no genuine issue to be tried, as required by Local Rule 56.1. Hence, Merck is unable to provide its response required by the same rule. According to this rule, the movant's failure to submit such a statement may constitute grounds for denial of a motion for summary judgment.

2/ Defendants' joint motion is limited to issues concerning patent remedies under Title 35 of the U.S. Code. The motion is not directed to remedies for any of Merck's other claims in this case, including trademark and unfair competition causes of action.

As for past damages:

(1) under the circumstances here, Merck's listing of the patent in suit in the Orange Book satisfies the patent notice requirements; and

(2) should Merck elect to assert only the method of use claim of the patent in suit, there will be no patent marking requirement. Merck submits that this motion should be denied on this basis, or at the very least, that the motion be continued under Rule 56(f) pending discovery required before Merck reasonably can make this election.

As for post-patent expiration damages, Merck is entitled to accelerated market entry damages, namely, damages based on the illegal head start defendants gained by entering the market during the life of the patent, which results in a benefit after the patent expires. Merck believes that defendants' motion should be denied on this basis. However, should this Court believe that a more complete record is required, this motion should be continued while relevant discovery concerning accelerated market entry damages proceeds.

ARGUMENT

I.

Defendants' Motion To Limit Past Damages Should Be Denied, Or At Least Deferred

A. Under The Circumstances Here, The Orange Book Listing Of The Patent In Suit Satisfies Patent Notice Requirements

1. The Orange Book Satisfies the Notice Requirements of 35 U.S.C. § 287(a)

Merck's contention that the Orange Book provides adequate notice under 35 U.S.C. § 287(a) to preserve its claim for past patent infringement damages, is based on the statutory and regulatory scheme under which the Orange Book was created.

The Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act, became law in 1984. It was enacted to allow for FDA approval of generic drugs through a faster and less expensive process than for innovator drugs. In order to achieve this goal, the Hatch-Waxman Act includes several trade offs between the interests of the generic drug manufacturers and the innovator companies whose FDA approved pioneer drugs are subject to patent protection. See 59 Federal Register 50338, Abbreviated New Drug Application Regulations; Patent Exclusivity Provisions at 2.

First, Hatch-Waxman allows generic drug companies to begin development work even while the innovator product is still patent protected. See 35 U.S.C. § 271 (e)(1). Such development activities had constituted patent infringement under prior law, since "use" of a patented product or method ordinarily constitutes infringement. See Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc., 733 F.2d 858 (Fed. Cir. 1984).

Second, under Hatch-Waxman, generic manufacturers are not required to submit the extensive drug safety and efficacy data to obtain FDA approval that is required of a pioneer drug applicant in its New Drug Application ("NDA"). Rather, generic drug applicants may instead file Abbreviated New Drug Applications ("ANDAs") that rely on the innovator's NDA data, without the innovator's permission and without paying any compensation for the collection and use of that data. See 21 U.S.C. § 355(j)(2)(A). Under this procedure, generic applicants avoid the enormous expenditure of time and money involved in obtaining the necessary safety and efficacy data to obtain drug approval.

Also, under the Hatch-Waxman scheme, there are specific and defined processes that a generic company must follow to obtain FDA approval where a patent protects the innovator's product the generic company wishes to copy. Three of these processes apply where

the ANDA filer does not challenge the patent, while the fourth process, commonly called the Paragraph IV certification process, applies when the generic drug maker claims either that the patent is invalid or would not be infringed. See 21 U.S.C. § 355 (j)(2)(A)(vii).

Under this process, in return for reliance on the costly and time-consuming work done by the innovator drug company, Hatch-Waxman mandates that generic applicants must include a certification (known as a paragraph IV certification) stating that each patent covering the drug or its use is either invalid or will not be infringed by sale of the product for which approval is sought. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). If such a certification is made, the generic manufacturer also must notify the patent holder who then has forty-five days to initiate an action for patent infringement. 21 U.S.C. § 355(j)(2)(B); 21 U.S.C. § 355(j)(5)(B)(iii). Although the generic product is not yet on the market (since it has not been approved by the FDA), the law makes the filing of the ANDA an act of infringement upon which suit may be filed in federal court, thereby allowing the generic company's future conduct to be adjudicated. See 35 U.S.C. § 271(e)(2); Organon, Inc. v. Teva Pharmaceuticals, Inc., 244 F. Supp. 2d 370, 374 (D.N.J. 2002). If the patent holder elects to sue, there is an automatic 30-month stay during which the FDA may not approve the generic company's ANDA, while the patent litigation proceeds. 21 U.S.C. § 355(j)(5)(B)(iii).

It is in the context of this important statutory and regulatory scheme that the Orange Book came into being. The official name of the Orange Book is the "Approved Drug Products with Therapeutic Equivalence Evaluations"[3/] because, by its own description, it identifies (1) drug products that have been approved by the FDA, (2) therapeutic equivalence evaluations for multi-source prescription drug products, and (3) patent information concerning

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3/ The Orange Book is available on-line at http://www.fda.gov/cder/ob/default.htm.

the listed drugs (Orange Book Preface to Twenty Fifth Edition at v-vi). The Orange Book is published by the FDA under mandate of the Hatch-Waxman Act in furtherance of, inter alia, that statute's defined processes for ANDA filers seeking approval to market patent protected, FDA approved drug products. See id. at vi. Also in furtherance of these processes, all innovator companies that submit NDAs to the FDA for new drugs are required by law to also submit information concerning each patent that claims a drug or method of using a drug that is the subject of the NDA. 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53. This information is published in the Orange Book where ANDA filers must look when seeking FDA approval for generic copies of FDA approved drugs to comply with the Paragraph IV certification procedure described above, as well as the three processes involved where no patent challenge is made. Clearly, this statutory scheme is the mechanism by which a generic company which seeks to legally replicate an FDA approved drug gets notice that filing an ANDA for the drug will be an act of infringement if the drug is listed as covered by a patent.

Thus, as the Court of Appeals for the Federal Circuit has recognized, the purpose of the Orange Book listings is to implement Hatch-Waxman's attempt to provide "a streamlined mechanism for identifying and resolving patent issues related to the proposed generic products" and to "facilitate judicial resolution of the question whether the generic drug would infringe a pertinent patent." Apotex, Inc. v. Thompson, 347 F.3d 1335, 1338-39 (Fed. Cir. 2003).

Imitative prescription drugs subject to patent protection cannot be FDA approved for sale in this country without following the Hatch-Waxman scheme. Hence, patent listings in the Orange Book which are required of the innovator companies serve as clear and specific notice of what patents will be infringed by imitative products for which FDA approval is sought.

In this case, all of the defendants are knowingly selling simvastatin products covered by Merck's patent in suit, without FDA approval in violation of various U.S. laws, and in circumvention of the Hatch-Waxman statutory and regulatory requirements. Yet, these defendants nonetheless seek to benefit from the provisions of 35 U.S.C. § 287(a), and to avoid damage liability on grounds that the alleged technical requirements of the marking statute have not been met here. Merck submits that neither the marking statute, nor any decisions construing it require that result, which effectively would reward defendants for violating U.S. FDA laws. In other words, had the defendants complied with U.S. law, they would have had to file a paragraph IV certification before selling any drugs into the U.S. during the '784 patent term, which would have given Merck a 45 day window to file suit. Defendants, in that case, would not have been selling infringing products and the issue of damages and patent marking would never have arisen. Defendants therefore are only in the position to even make their motion because they intentionally violated FDA rules and statutes and ignored the legally mandated notice of patent protection for drugs in the Orange Book.

It is highly significant here that the patent marking statute was drafted long before Hatch-Waxman was enacted in 1984. Thus, the marking statute should not be read to refute that, in the unique prescription drug arena, the Orange Book fully serves the purpose of notifying potential infringers that imitative drug products will infringe the listed patents. Nor does it negate that in this area, patent marking ordinarily would not be contemplated since products imitative of those protected by patent could not gain FDA approval – or be legally marketed in this country – absent compliance with the statutory scheme, including the patent certification process.

Defendants' arguments to the contrary rest upon cases which do not address the circumstances present here. For example, defendants rely upon decisions to the effect that generalized warnings of patent infringement, such as in press releases and advertisements, or patent markings that appear on literature associated with the patented product do not satisfy section 287(a) (Defendants' Brief at 5-7). Of course, however, none of the cases defendants cite were decided in the context of the Hatch-Waxman statutory scheme, much less involved infringing activities that circumvented that scheme and violated U.S. FDA laws.

Morever, the Orange Book is not limited to mere generalized information or warnings, and thus is not at all analogous to the press release and advertisements that were involved in the cases upon which defendants rely. Rather, the Orange Book provides direct and specific notice to an audience that is required by statute to seek out and heed that notice that imitative drug products will infringe the patents listed therein. Thus, contrary to defendants' contentions, the Orange Book does, in fact, serve as a vehicle in which the patentee "communicate[s] a specific accusation of infringement to the alleged infringer". Defendants' Brief at 4, citing AT & T Corp. v. Microsoft Corp., 290 F. Supp. 2d 409, 412 (S.D.N.Y. 2003).[4/]

[4/] Defendants misplace reliance upon Teva Pharm., Inc. v. Pfizer, Inc., 395 F.3d 1324, 1333 (Fed. Cir. 2005). The issue in Teva was limited to whether there was an explicit threat or action creating a reasonable apprehension of suit, so as to establish an actual controversy between the parties, and support declaratory judgment jurisdiction. Of course, whether suit has been threatened is an entirely different issue from whether the Orange Book provides notice that copies of FDA approved drugs will infringe listed patents.

Nor, as defendants contend, has Merck admitted that it did not provide actual notice of infringement in any form to defendants before filing suit. Fairly read, Merck's response to Request to Admit No. 4 (Exhibit A to defendants' brief) acknowledged only that Merck's first communication sent directly by it to defendants occurred when suit was filed.

In addition, defendants' reliance upon the policy behind the marking statute is misplaced. Defendants argue that the purpose of marking "is to encourage the patentee to give notice to the public of the patent." Defendants' Brief at 2-3, citing American Medical Systems, Inc. v. Medical Engineering Co., 6 F.3d 1523, 1537 (Fed. Cir. 1993). Other decisions also have recognized that the purpose of the marking statute is to prevent innocent infringement (see Toro Company v. McCulloch Corp., 898 F. Supp. 679, 684 (D. Minn. 1995)), and to provide a ready means to discern whether an article is patented. See Bonito Boats Inc. v. Thunder Craft Boats Inc., 489 U.S. 141, 162 (1989).

In fact, defendants' arguments fail to consider that (a) the patent marking statute long pre-dates the Hatch Waxman notice of the Orange Book, and (b) all of the policies and purposes of the marking statute are fully satisfied by the Orange Book in the area of prescription drugs. The Orange Book not only encourages but requires the patentee to give notice of the patent; it prevents the possibility of innocent infringement since purveyors of generic drugs must consult the Orange Book to properly pursue an ANDA, and the Orange Book provides a ready (and, again, required) means to ascertain whether FDA approved drug products are patented. And defendants do not contend that they were unaware of Merck's U.S. patent in suit – clearly, their decisions to ship, or have shipped, simvastatin products into the U.S. were made with full knowledge that FDA laws would be violated, and that those products are patent protected here. Defendants do not dispute that they were aware of the '784 patent from the Orange Book, and in the case of most of the defendants, have effectively acknowledged on their websites that their products are not FDA approved (see Shapiro Decl. Tabs 1-5).

Under all of these circumstances, Merck submits that patent listing in the Orange Book satisfies the notice requirements of section 287(a), and that it is entitled to damages from the inception of defendants' infringing activities.

2. Alternatively, This Court Need Not Yet Decide the "Orange Book Issue"

As explained below, under controlling law, if Merck elects to pursue its infringement claims only with respect to the method of use claim of the patent in suit, there will be no marking requirement in this case, and no limitation to Merck's ability to recover damages for the period prior to filing of the complaints. For this reason, Merck has asked this Court to deny or defer decision on this motion pending further discovery, so that Merck can make an informed decision whether to make this election. Should this Court agree to do so, it need not yet consider the "Orange Book issue" presented by this case, since that issue will be mooted if Merck ultimately proceeds only on the basis of the method of use claim, and the marking requirement is excused as a result.

B. There Is No Limitation On Past Damages For Infringement of the '784 Method Claim

1. Hanson Is Controlling Federal Circuit Precedent

The Federal Circuit has clearly defined the law governing when method of use claims may be subject to 35 U.S.C. § 287(a), the patent marking statute. The only issue in dispute here is whether section 287(a) will apply to limit damages for infringement of a patent that contains both method and apparatus (or compound) claims, but where only the method claims are asserted. Only one Federal Circuit case, Hanson v. Alpine Valley Ski Area, Inc., 718 F.2d 1075 (Fed. Cir. 1983), has directly addressed that issue, holding that under these facts the

asserted method claim will not be subject to the section 287(a) marking requirements, and that case is binding precedent for this court. See Hanson, 718 F.2d at 1082-83.

In the Hanson case, the Federal Circuit held that section 287(a) did not apply to limit damages where only the method claims were asserted from a patent which contained both apparatus claims for a machine to make snow using a specific process, and method claims for making the snow:

> Alpine contends that Hanson is precluded from recovering for the infringing use, prior to the filing of the complaint . . . because Hanson did not prove that [its licensee] had marked the machines it sold [embodying the invention], as 35 U.S.C. § 287 (1976) allegedly required. . . .The magistrate rejected the contention on two grounds: . . . (2) the patent is a process patent, to which section 287 does not apply. We agree [with the second ground] . . . Alpine states that the Hanson patent also includes apparatus claims. The only claims that were found infringed in this case, however, were claims 1, 2, and 6 of the Hanson patent, which are drawn to 'the method of forming, distributing and depositing snow upon a surface'...

Hanson, 718 F.2d at 1082-83 (emphasis added). Thus, although the patent in Hanson contained both method and apparatus claims "for making snow used in winter sports," the three claims asserted at trial, 1, 2, and 6, were all method claims. Id. at 1076; Hanson v. Alpine Valley Ski Area, Inc., Civ. No. 3260, 1977 U.S. Dist. LEXIS 15855, at *2 (E.D. Mich. May 17, 1977) ("This cause was tried by the Court without a jury to determine . . . whether defendant Alpine Ski Valley Area, Inc., had infringed Claims No. 1, 2, or 6 [the method claims] of said patent.").

Defendants incorrectly assert that Hanson, which is the only Federal Circuit case to directly address the issue before this court, is no longer good law and has been superceded by the more recent decision in American Medical Systems, Inc. v. Medical Engineering Corp., 6 F.3d 1523 (Fed Cir. 1993). However, far from superceding Hanson, American Medical Systems dealt with a different, and settled issue, that is, whether method and apparatus claims are both

subject to the marking statute when both types of claims in the same patent are asserted in the same lawsuit. The American Medical Systems Court specifically recognized earlier Federal Circuit precedent created by Hanson and its progeny (id. at 1538), and then carefully limited its holding to be in accord with the earlier Hanson decision:

> [i]n this case, both apparatus and method claims of the '765 patent were asserted and there was a physical device produced by the claimed method that was capable of being marked. Therefore, we conclude that AMS was required to mark its product pursuant to section 287(a) in order to recover damages. . . ."

Id. at 1539 (emphasis added).[5/]

Likewise, two of the district court cases upon which defendants rely are limited to the same issue addressed in American Medical Systems, namely, where both apparatus and method claims were asserted in the lawsuit. Soverain Software LLC v. Amazon.com, Inc., 383 F. Supp.2d 904, 906, 909 (E.D. Tex. 2005) ("in this case [plaintiff] alleges that [defendant] infringes three patents [it] acquired . . . . All of the patents-in-suit contain both method and apparatus claims");[6/] Loral Fairchild Corp. v. Victor Co., 906 F. Supp. 813, 816 (E.D.N.Y. 1995) ("In this case, however, the '485 patent contains both product and method claims . . . Loral asserts infringement of both the product and method claims against [the defendants].").

[5/] Even if this Court disagrees with Merck and finds that the holding in American Medical Systems conflicts with the holding in Hanson, this Court is still bound to follow the Hanson decision since it was decided first, and since American Medical Systems was not an *en banc* decision and does not expressly overrule the earlier decision in Hanson. See UMC Elecs. Co. v. United States, 816 F.2d 647, 652 n.6 (Fed. Cir. 1987) ("[a] panel of this court is bound by prior precedential decisions unless and until overturned *en banc*.")

[6/] Although it is unclear from the decision cited by defendants whether both method and apparatus claims were asserted in Soverain, another decision from the District Court in that action indicates that both types of claims were, in fact, asserted. Soverain Software LLC v. Amazon.com, Inc., No. 6:04-CV-14, 2005 U.S. Dist. LEXIS 20280, at *2 (E.D. Tex. Aug. 8, 2005).

Defendants also cite to three district court cases that found patent marking requirements applicable where only the method claims were asserted from a patent with both method and apparatus claims. These cases, however, are wrongly decided, and Merck submits they should be given no persuasive weight since all failed to follow, or even acknowledge prevailing Federal Circuit precedent in the Hanson case. See Philips Electronic N. Am. Corp v. Contec Corp., 312 F. Supp.2d 649, 651-52 (D. Del. 2004); Halliburton Servs. v. Smith Int'l, Inc., 317 F. Supp.2d 719, 725 (E.D. Tex. 2004)[7]; Mosel Vitelic Corp v. Micron Tech., Inc., Civ. No. 98-449, 2000 WL 1728351, at *2 (D. Del. Feb. 25, 2000).

Instead, the Court should give persuasive weight to another district court decision that addressed this issue because, in that decision, the court carefully analyzed Hanson and American Medical Systems together. In Coca-Cola v. Pepsico, Inc. et al., No. 1:02-CV-2887-RWS, slip op., at 88-90 (N.D. Ga. Sept. 29, 2004) (see Shapiro Decl. Tab 11), the District Judge addressed exactly the same arguments raised here and found that Hanson is controlling law – hence, the marking statute did not apply to limit damages where only method claims were asserted from a patent with both method and apparatus claims. This is the only district court case of which Merck is aware to decide the legal issue in dispute here, and that explicitly recognized Federal Circuit precedent in the Hanson decision. Defendant Pepsico, like the defendants here, argued that "the Federal Circuit's more recent decision in American Medical Systems, Inc. supercedes the rule announced in [Hanson and Bandag]." Id. at 88. The court rejected this argument and ruled that:

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[7] The Haliburton case also erroneously cites to two district court decisions as support for its position on the applicability of section 287(a) to method claims. Id. at 725. However, these decisions have nothing to do with patent marking issues. See Honeywell Int'l, Inc. v. Hamilton Sundstrand Corp., 166 F. Supp.2d 1008 (D. Del. 2001); Mosel Vitelic Corp. v. Micron Tech., Inc., 162 F. Supp.2d 307 (D. Del. 2000).

> After careful examination of the relevant decisions, the Court cannot accept Defendants' reading of American Medical Systems, Inc. The language of the opinion Defendants rely on in support of their argument is "Where the patent contains both notice [sic] apparatus and method claims, however, to the extent that there is a tangible item to mark by which notice of the asserted method claims can be given, a party is obligated to do so if it intends to avail itself of the constructive notice provisions of section 287(a)." American Medical Sys. Inc., 6 F.3d at 1583-39. Read out of context, that statement could well be understood to overrule the holding of Hanson relied upon by Coca-Cola. A close reading of the opinion, however, illustrates that the American Medical Systems, Inc. Court left Hanson undisturbed.
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> First, the Federal Circuit began its discussion of § 287 in American Medical Systems, Inc. by emphasizing that its prior decisions had recognized that "in . . . Hanson, a distinction was made between cases in which only method claims are asserted to have been infringed and in cases where a patentee alleges infringement of both the apparatus and method claims of the same patent." See 6 F.3d at 1538. Moreover, in applying the above-quoted "rule" to the case before it, the Federal Circuit again emphasized that "[i]n this case, both the apparatus and method claims of the . . . patent were asserted . . . ." Id. at 1539. Nowhere in American Medical Systems, Inc. did the Federal Circuit expressly overrule Hanson, and indeed, cited Hanson both there and in a subsequent decision with approval for the proposition now relied upon by Coca-Cola.

Id. at 89-90.

Thus, Hanson, which has consistently been recognized by subsequent Federal Circuit decisions, is the law and should be followed by this Court. See, e.g., Devices for Medicine, Inc. v. Boehl, 822 F.2d 1062, 1066 (Fed. Cir. 1987) ("In Bandag, and in Hanson this court specifically noted a distinction between cases in which only method claims are asserted to have been infringed and cases like the present case, where [Plaintiff] alleged infringement of all its apparatus and method claims."); State Contracting and Eng'g Corp. v Condotte Am., Inc., 346 F.3d 1057, 1074 (Fed. Cir. 2003) (citing Hanson as "upholding decision that section 287 did not

apply when only process claims were found infringed and the patent contained apparatus claims").[8/]

2. Merck Has Not Elected To Assert The Product Claims Of The Patent In Suit

In an effort to avoid the rule of Hanson, defendants argue that Merck already has elected to assert the product claims of the patents in suit. In fact, the complaints in these cases assert only that defendants alleged activities infringe U.S. Patent No. 4,444,784 under 35 U.S.C. § 271,[9/] without specifying particular patent claims, as permitted under the notice pleading requirements that apply here (see, e.g. complaint in Civ. No. 05-3650, ¶22). Thus, Merck, by its pleadings has not elected which patent claims it will pursue.

Defendants also argue that Merck already has implicitly asserted its product claims because the complaints make the factual allegation that defendants offer to sell and sell their simvastatin "products" in the United States. Again, however, nowhere in the complaint does Merck specify which claims it is asserting or that it is asserting any product claims. While the factual allegations asserted by Merck support a claim for direct infringement of product

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8/ As a final attempt to avoid the precedent in Hanson, defendants argue that marking is required here because, unlike Hanson, the method of use claims of Merck's patent in suit cover a method of using the same compound specified in the product claims. Hanson, however, draws no such distinction, and this Court should not either.

9/ 35 U.S.C. § 271 states: "(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent. (b) Whoever actively induces infringement of a patent shall be liable as an infringer. (c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer."

claims covering the simvastatin compound, the same factual assertions, namely offering to sell and selling simvastatin in the United States, also support claims for inducement and contributory infringement of Merck's method of use claim (e.g. patent claim 11)[10/], since defendants sales of simvastatin to U.S. patients induce those patients to infringe that claim by using the drug. Simply put, Merck has broadly plead infringement under section 271 and then gone on to describe factual allegations that support various legal claims under that section. But contrary to defendants' argument, Merck has not committed itself to asserting any one legal argument under section 271, or any one specific claim or type of patent claim. And, as explained below in Point III, Merck requires fact discovery of defendants before it reasonably can elect which patent claims to pursue.

II.

Defendants' Motion To Limit Post Patent Damages Should Be Denied, Or At Least Deferred

Defendants argue that Merck can obtain no damages for any activities beyond the December 23, 2005 expiration of the patent in suit, and seek summary adjudication excluding damages accruing after that date. This contention is incorrect, and defendants' request to limit post patent damages should be denied.

As more fully explained in the accompanying declaration of Merck's damages expert, Mr. Raymond S. Sims ("Sims Decl."), Merck will prove in this case that it is entitled to accelerated market entry ("AME") damages (sometimes called "accelerated reentry" damages) , based on the illegal head start that defendants gained by entering the market with their infringing

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[10/] A copy of the patent in suit is attached as Exhibit A in each of the complaints in these actions.

products before the patent expired. AME refers to the plaintiffs' lost profits as a result of the infringer's pre-patent expiration presence in the market. Ordinarily, the patentee's competitors enter the market after patent expiration with zero share of the market. An infringer, however, begins with some level of market share and a head start due to prior infringement. These benefits to the infringer after the patent expires result in losses to the patentee that are not included in traditional patent damages, which are measured only during the patent term (see Sims Decl. ¶¶ 6-12). As Mr. Sims has detailed, this theory of damages is squarely applicable to this case (see Sims Decl. ¶¶ 6-15).

There are a number of decisions that have considered this measure of damages in patent cases and have recognized the applicability of this approach. For example, in Bic Leisure Products Inc. v. Windsurfing International, Inc., 687 F. Supp. 134, 138 (S.D.N.Y. 1988), the Court explained the rational of AME damages, noting that the plaintiff in Bic sought

> compensation for future losses it claims it will incur because BIC will reenter the market at a level accelerated by its earlier infringement. By the very nature of the argument, WSI in these two damages theories proposes only to be made whole for past violations of BIC, and thus the theories are consistent with the purpose of 35 U.S.C. § 284 of awarding damages approximating what "the patent holder would have made had the infringer not infringed."

See THK America Inc. v. NSK Ltd., 917 F. Supp. 563, 575 (N.D. Ill. 1996) (AME "theory of damages is well recognized by the courts [and] is not seriously contested by NSK"); Amsted Industries, Inc. v. National Castings Inc., No. 88 C 0924, 1990 U.S. Dist. LEXIS 8553 at *57 (N.D. Ill. July 11, 1990) (Amsted entitled to "accelerated reentry" damages because infringer "gained a foothold in the market for center plates which it would not otherwise have enjoyed had it waited until the patent expired to begin its sales"); TP Orthodontics Inc. v. Professional Positions Inc., Case No. 72-C-697, 1990 U.S. Dist. LEXIS 15219 at *33 (E.D. Wisc. June 9,

1990) (partial summary judgment denied since plaintiff "should not be precluded from amplifying [the] evidence at trial and using the accelerated reentry approach as a lens through which to view damages"). Compare Grain Processing Corp. v. American Maize Products Co., 185 F. 3d 1341, 1350 (Fed. Cir. 1999) (noting that courts have given patentees significant latitude to measure lost profits for foreseeable economic effects of infringement, citing Bic Leisure Products, 877 F. Supp. at 137-38, as permitting recovery for AME by the infringer); Calloway Golf Co. v. Dunlop Slazenger Group Americas Inc., Civ. Act. No. 01-669-KAJ, 2003 U.S. Dist. LEXIS 25625 at *7 (D. Del. May 21, 2003) (allowing expert in trade secret case to testify on plaintiff's entitlement to accelerated market entry damages); Bayer AG v. Housey Pharm. Inc., 228 F. Supp. 2d 473 (D. Del. 2002), citing Amsted, 1990 U.S. Dist. LEXIS 8553 at *20 (recognizing in a patent misuse context that "[a]ccelerated reentry damages . . . are not the equivalent of a royalty which [impermissibly] extends beyond the expiration of the patent").

Examples of decisions where AME damages have been awarded in patent cases are Amsted Indus. Inc. v. Nat'l Castings Inc., No. 88 C 0924, 1990 U.S. Dist. LEXIS 16657 at *16 (N.D. Ill. Dec. 7, 1990) (jury award of an additional $64,135 made to plaintiff "to compensate for [defendants'] accelerated re-entry into the market . . ."); and Coyle v. Sega of America, CV 90-2323 RJK (C.D. Cal., April 10, 1992) (jury awarded reasonable royalty damages of $21 million for accelerated market entry) (See Tab 12 to Shapiro declaration – the completed general verdict form in this case).

Thus, because AME damages are appropriate to this case and accepted by the courts, Merck submits that defendants motion for partial summary judgment precluding post patent expiration damages should be denied.

III

Alternatively, Merck Is Entitled To Continuance Of This Motion Under Rule 56(f) While Relevant Discovery Proceeds

Merck submits that it has demonstrated in its opposition to defendants' joint motion that (1) past damages are fully recoverable given the Orange Book listing of the patent-in-suit and, alternatively, will be fully recoverable should Merck elect to assert only the method claim in the patent in suit; and (2) post-patent expiration AME damages are appropriate here.

As explained below, with respect to Merck's election of which patent claims to assert, any such election would be premature at this early stage of discovery in this case where neither document production by defendants nor any depositions have occurred, nor have contention interrogatories been served. Thus, it is appropriate for this Court to deny or defer decision on this aspect of defendants' motion until further discovery has been taken, allowing Merck reasonably to make this election.

As for post-patent AME damages, Merck submits that the record is fully sufficient to support denial of this aspect of defendants' motion. However, should this Court believe that a further factual showing is required to support the viability of such a damage claim, Merck respectfully requests deferral of the motion since discovery in this case is in its very early stages and, as a result, there has been no discovery yet relating to Merck's AME damages claim.

A. Rule 56(f) Discourages Premature Summary Adjudications

Rule 56(f) of the Federal Rules of Civil Procedure[11/] provides nonmovants with protection from being "'railroaded' by premature summary judgment motions." Opryland USA, Inc. v. Great Am. Music Show, Inc., 970 F.2d 847, 852 (Fed. Cir. 1992), citing Celotex Corp. v. Catrett, 477 U.S. 317, 326 (1986); Miller v. Wolpoff & Abramson L.L.P., 321 F.3d 292, 304 (2d Cir. 2003).

The law is clear: summary judgment should not be granted until the party opposing the motion has had an adequate opportunity to conduct the necessary discovery and gather its supporting materials. Id. at 303; Hellstrom v. U.S. Dept. of Veterans Affairs, 201 F.3d 94, 97 (2d. Cir. 2000). The nonmoving party's ability to respond to summary judgment motions is dependent on the progress made during discovery. See Miller, 321 F.3d at 303-04; Meloff v. New York Life Insurance Co., 51 F.3d 372, 375 (2d Cir. 1995).

Not surprisingly, there is a "high fatality rate of summary judgment dispositions at a time before the facts have been fully developed." Snook v. Trust Co. of Georgia Bank of Savannah, N.A., 859 F.2d 865, 870 (11th Cir. 1988) (citation omitted). Indeed, "[s]ummary judgment should not, therefore, ordinarily be granted before discovery has been completed." Id. (citation omitted); See Miller, 321 F.3d at 303. Here, as detailed below, summary judgment is premature because no discovery concerning the subject matter relevant to these motions has occurred. See Meloff, 51 F.3d at 375.

11/ Rule 56(f) provides: "Should it appear from the affidavits of a party opposing the motion that the party cannot for reasons stated present by affidavit facts essential to justify the party's opposition, the court may refuse the application for judgment or may order a continuance to permit affidavits to be obtained or depositions to be taken or discovery to be had or may make such other order as is just."

Finally, where information concerning the facts to be discovered is solely in the possession of the movant, "a motion for continuance of a motion for summary judgment for purposes of discovery should [then] ordinarily be granted almost as a matter of course." Contractors Ass'n of E. Pa., Inc. v. City of Philadelphia, 945 F.2d 1260, 1263, 1267 (3d. Cir. 1991) (citation omitted). See Vivid Technologies, Inc. v. American Science & Engineering, Inc., 200 F.3d 795, 809 (Fed. Cir. 1999). As discussed below, the evidence most pertinent to the Court's decisions on these motions is solely in defendants' possession or control.

1. Discovery Is In Its Early Stages

These cases were commenced in April 2005. At the first Court conference in this case on June 27 of this year (a premotion conference concerning defendants' now pending motions to dismiss trademark and unfair competition claims), this Court directed that discovery of patent issues should proceed. Immediately thereafter, Merck initiated a Rule 26(f) conference between the parties, held in late July. During and after that conference, the parties negotiated a proposed scheduling order which was submitted in early August to the Court for approval. Pursuant to the proposed order, the parties in all six cases have exchanged initial disclosures, served document requests and provided written responses to those requests, and in some cases have served and responded to interrogatories and requests for admissions. The parties have negotiated and agreed to the provisions of protective orders, which will be executed and submitted to the Court shortly. Merck's production of documents in all six of these cases is ongoing on a rolling basis. Defendants have yet to produce any documents to Merck, contending that it is first necessary to resolve certain issues that Merck has raised concerning their written responses to document requests -- a position that can only be intended to delay discovery since

there are many categories of documents which defendants have agreed to produce and as to which there is no dispute. See Shapiro Decl. ¶¶ 2, 4-9, Tabs 7, 8.

Because document production is incomplete (and in the case of defendants, has not yet begun), there have been no depositions taken in any of these cases. Also, pursuant to the local rules of this Court, Rule 33.3(c), no contention interrogatories have yet been served, since other discovery is ongoing (Shapiro Decl. ¶¶ 7-9).

2. Should This Court Decline To Deny Defendants' Motion With Respect To Past Damages, Merck Should Be Granted A Continuance To Take Discovery Relevant to Its Election Of Which Claims To Assert

As detailed above and in the Shapiro declaration at ¶¶ 12-13, although Merck has diligently pursued discovery in these cases, because fact discovery is in its early stages, Merck has received very little substantive information from defendants other than the very limited information available in initial disclosures. Thus, Merck has received no discovery at all relevant to which patent claims should be asserted in this case.

Merck submits that it should not be obligated to decide now, prior to relevant discovery, which patent claims it should assert. Most significantly, Merck has very little information about what defenses to the validity of the '784 patent defendants intend to raise. Should defendants pursue some defenses that pertain to the '784 compound claims but not to the claim covering a method of use, Merck may elect to pursue only the method claim. Also, if discovery shows that defendants have no defense to either the compound or method claims, Merck may choose to proceed only on the method claims to limit the scope of issues to be tried, and to eliminate the patent marking issues from this case. And, the burden of proof on damages issues may vary under an inducement of infringement analysis (relevant to assertion of method of use claims) as compared to a direct infringement analysis (relevant to compound claims) under

applicable case law[12/] and Merck is therefore entitled to take damages discovery before deciding on whether to assert only its method claims.

Merck has outstanding discovery requests relating to all of these issues (see Shapiro Decl. ¶¶ 13, Tab 9). Once Merck has reviewed relevant discovery on these issues, which involves information exclusively within defendants' control and not otherwise available to Merck, Merck will be able to elect which patent claim or claims to assert in these cases.

3. Should This Court Decline To Deny Defendants' Motion With Respect to Post-Patent Expiration Damages, Merck Should Be Granted A Continuance To Pursue Discovery of AME Damages

Given the early stage of discovery in these cases, Merck also has received no discovery at all relevant to its AME damages claims. There are a number of areas of inquiry that Merck will need to pursue in order to support its claim for AME damages. In his declaration, Merck's expert Mr. Sims has detailed what these areas are (Sims' Decl. ¶¶ 16-19) and why they are relevant to AME damages (Id. at ¶¶ 6-19). For example, in addition to the basic information and data that is required for any patent damages analysis, including data on product sales and costs, Merck will require information in many additional areas, including what marketing and promotional steps defendants have taken to facilitate entry into the U.S. market, what their customer relationships have been, and the means by which they have acquired new customers. (See Sims Decl. ¶¶ 17).

Merck has long had outstanding document requests calling for much of the information relevant to AME damages, and recently has served additional requests directed

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12/ See, e.g., Emberx, Inc. v. Service Eng'g Corp., 216 F.3d 1343, 1352 (Fed. Cir. 2000) (proof of direct use of infringing device necessary before damages can be recovered for indirect infringement of method patent).

exclusively to these issues (Shapiro Decl. ¶¶ 14, Tabs 9, 10). Of course, deposition and possibly other additional discovery undoubtedly will be required to follow up documentary information that is produced.

Finally, all of the required information detailed in Mr. Sims' declaration (at ¶¶ 16-19) is exclusively within defendants' possession, and cannot be obtained by Merck in any fashion other than through discovery of defendants.

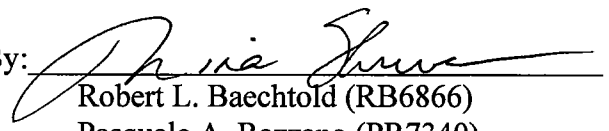
CONCLUSION

For the foregoing reasons, Merck submits that defendants' joint motion should be denied or, alternatively, continued pending the discovery described above.

Dated: November 23, 2005

Respectfully submitted,

FITZPATRICK, CELLA, HARPER & SCINTO

By: 

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CERTIFICATE OF SERVICE

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

1. Merck's Notice Of Alternative Rule 56(f) Cross Motion For A Continuance Of Defendants' Joint Motion For Partial Summary Judgment On Patent Remedies, In The Event The Court Declines To Deny The Same
2. Merck's Memorandum In Opposition To Defendants' Joint Motion For Partial Summary Judgment On Patent Remedies, And In Support Of Merck's Alternatve Rule 56(f) Cross Motion For A Continuance Of Defendants' Joint Motion
3. Declaration Of Peter Shapiro In Opposition To Defendants' Joint Motion For Partial Summary Judgment On Patent Remedies And In Support Of Merck's Alternative Rule 56(f) Cross Motion For A Continuance Of Defendants' Joint Motion
4. Declaration of Raymond S. Sims

were caused to be served this 23rd day of November, 2005 by Electronic Filing upon the following:

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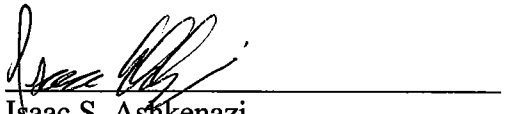

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