IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WARNER CHILCOTT COMPANY, LLC, and HOFFMANN-LA ROCHE INC., Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. Defendant.	C.A. No. 08-627-LPS C.A. No. 11-81-LPS REDACTED - PUBLIC VERSION
WARNER CHILCOTT COMPANY, LLC, and HOFFMANN-LA ROCHE INC., Plaintiffs, v. APOTEX, INC. and APOTEX CORP. Defendant.	C.A. No. 09-143-LPS C.A. No. 10-1111-LPS
WARNER CHILCOTT COMPANY, LLC, and HOFFMANN-LA ROCHE INC., Plaintiffs, v. MYLAN PHARMACEUTICALS, INC. Defendant.	C.A. No. 10-285-LPS C.A. No. 11-286-LPS

WARNER CHILCOTT COMPANY, LLC, and HOFFMANN-LA ROCHE INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 09-61-LPS C.A. No. 10-1085-LPS
SUN PHARMA GLOBAL FZE,	)	
Defendant.	)	

PLAINTIFFS WARNER CHILCOTT COMPANY, LLC AND HOFFMANN-LA ROCHE INC.'S REPLY BRIEF IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT OF INFRINGEMENT

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I. INTRODUCTION

Defendants'[1] Brief In Opposition to Plaintiffs'[2] Motion for Summary Judgment of Infringement (Defendants' "Opposition" or "Def. Opp.") attempts to obscure the undisputed evidence that Defendants' proposed products and labels induce infringement and that Defendants should be liable for contributory infringement. Defendants' arguments that their labels allow for substantial, non-infringing uses of their products are simply inconsistent with the plain language of the labels themselves – which provides clear instructions for a patient to commence treatment by taking a 150 mg risedronate sodium tablet on a single day, and continue the treatment by taking another 150 mg tablet on the same day of the month each month thereafter (i.e., approximately every 30 days). The mere possibility that some number of patients – a number that is likely to be insignificant based on admissions by Defendants' own expert – will switch from Warner Chilcott's branded product to Defendants' proposed generic tablets does not absolve Defendants of liability for induced infringement for patients initiating treatment with Defendants' generic products. Similarly, Defendants' unsupported assertions that patients and physicians will deviate from the label instructions are insufficient to create a substantial, non-infringing use in light of the undisputed evidence that such situations are unlikely and aberrant. In any case, none of Defendants' arguments apply to Defendants' infringement of claim 10 of the '634 patent, which does not involve "commencing" and "continuing" steps. Defendants' specific intent to induce infringement, as evidenced by the language of their labels, and their inability to

[1] The Defendants in this consolidated litigation are Apotex Inc. and Apotex Corp. (collectively, "Apotex"), Mylan Pharmaceuticals Inc. ("Mylan"), Teva Pharmaceuticals USA Inc. ("Teva USA"), and Sun Pharma Global FZE ("Sun") (all together, "Defendants").

[2] The Plaintiffs in this litigation are Warner Chilcott Company, LLC and Hoffmann-La Roche Inc.

establish any substantial non-infringing uses for their products establish that they should be liable for infringement as a matter of law.

II. ARGUMENT

A. Defendants' Labeling Instructs Patients to Infringe.

1. *Defendants' labels do not instruct people to start with branded Actonel® and then switch to a generic.*

Defendants appear to base their opposition on the idea that their proposed labels for their generic versions of the Actonel® Once-A-Month product are "just as consistent" with allegedly non-infringing uses of their proposed product. *See, e.g.*, Def. Opp. at 7. This argument, however,

Not for the first time, Apotex attempts to mask its intent to infringe the patents-in-suit with language from *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1365 (Fed. Cir. 2003).

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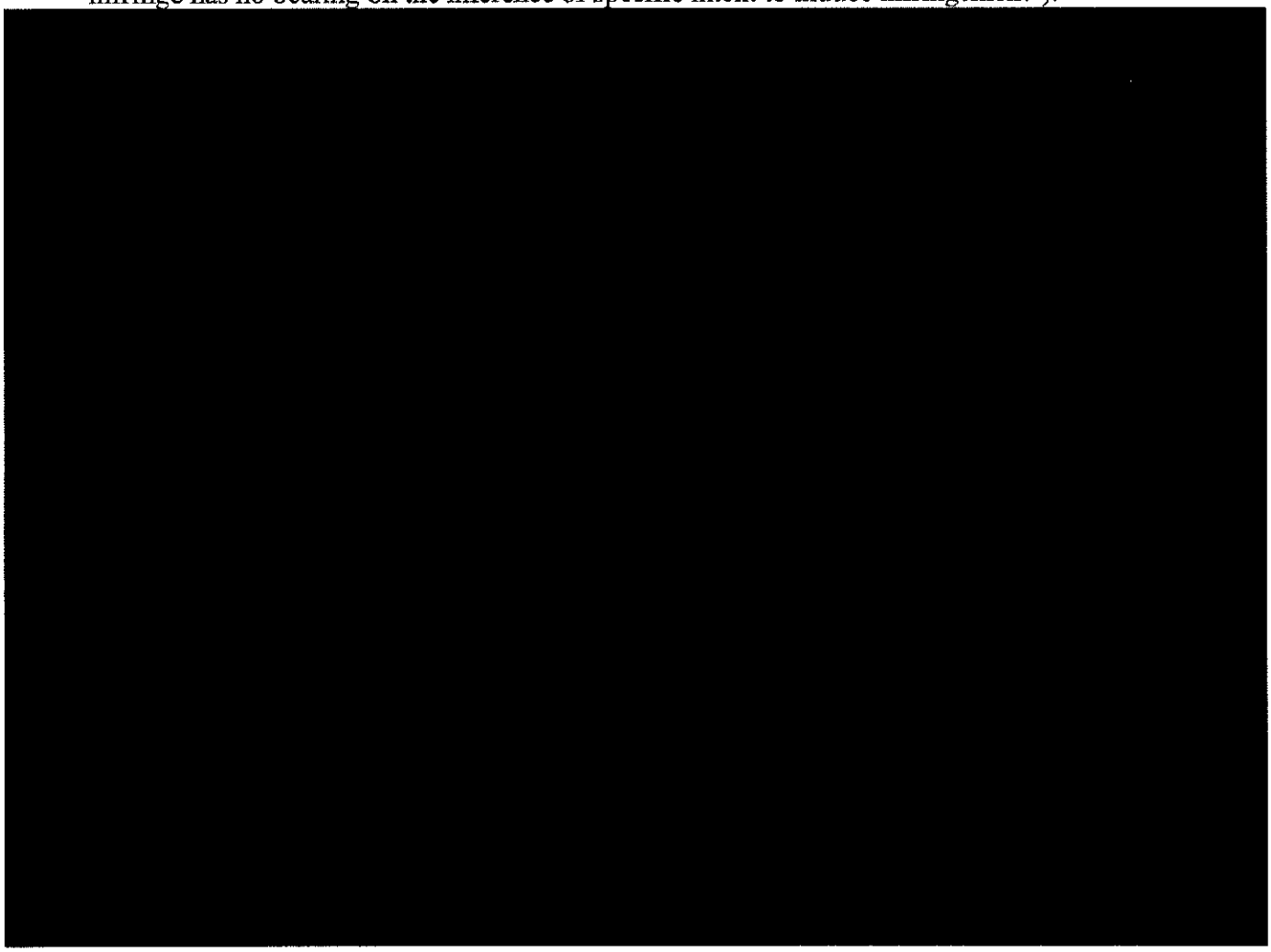
[3] Unless otherwise noted, exhibits on which Plaintiffs rely in support of this brief are attached to the Declarations of Jaclyn C. Levy ("Levy Decl."), filed under seal in conjunction with Plaintiffs' Motion for Summary Judgment of Infringement. (D.I. Nos. 335, 337-339.) *See* Levy Decl. (Apotex), Ex. K (AP-RISE0009955); Levy Decl. (Teva), Ex. K (TRM0000346); Levy Decl. (Mylan) (MYL-RIS0003000), Ex. K; Levy Decl. (Sun), Ex. M (SUN0000116).

[4] Levy Decl. (Apotex), Ex. K (AP-RISE0009955); Levy Decl. (Teva), Ex. K (TRM0000346); Levy Decl. (Mylan) (MYL-RIS0003000), Ex. K Levy Decl. (Sun), Ex. M (SUN0000116).

That case, however, dealt with a patent that claimed an off-label use of a drug and is therefore unavailing because the asserted claims in this case cover only approved uses for the Defendants' products. *See id.*; *see also Hoffmann-La Roche Inc. v. Apotex Inc.*, Nos. 07–4417 etc., 2010 WL 3522786, at *3-*4 (D.N.J. Sept. 2, 2010) (distinguishing *Warner-Lambert* and noting that the fact that the alleged infringers "may, in addition, be instructing others to do things which do not infringe has no bearing on the inference of specific intent to induce infringement").



[5] Levy Decl. (Apotex) Ex. I (AP-RISE0009998); Levy Decl. (Teva) Ex. K, (TRM0000346); Levy Decl. (Mylan) Ex. K, (MYL-RIS0003000); Levy Decl. (Sun) Ex. M (SUN0000116).
[6] See Levy Decl. (Apotex), Ex. J (AP-RISE0001536); Levy Decl. (Teva), Ex. J (TRM0046076); Levy Decl. (Mylan) (MYL-RIS0056136), Ex. J; Levy Decl. (Sun), Ex. J (SUN0010942).

[redacted] "In the context of specific intent, it is irrelevant that some users may ignore the warnings in the proposed label. The pertinent question is whether the proposed label instructs users to perform the patented method." *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010). Defendants' hypothetical "example" of a "forgetful" patient – *see* Def. Opp. at 6 – is another improper attempt by the Defendants to substitute lawyer argument for actual evidence and distract from Defendants' plain induced infringement.

B. Patients Who Ignore the Approved Label Instructions and/or Physicians Who Advise Patients Inconsistently with Them Are Irrelevant to Inducement and Do Not Give Rise to a Substantial Non-Infringing Use.

Contrary to Defendants' assertions, a patient's non-compliance with Defendants' instructions, or a doctor's suggestion that departs from Defendants' labels, has no bearing on the fact that Defendants' labels instruct patients to infringe the asserted claims. There is no dispute that Defendants intend for patients to follow the instructions provided in their label, as required [redacted]

[7] Levy Decl. (Apotex), Ex. J (AP-RISE0001535); Levy Decl. (Teva), Ex. J (TRM0046075); Levy Decl. (Mylan) (MYL-RIS0056135), Ex. J; Levy Decl. (Sun), Ex. J (SUN0010941).
[8] Levy Decl. (Apotex) Ex. J (AP-RISE0001533); Levy Decl. (Teva) Ex. J (TRM0000384); Levy Decl. (Mylan) Ex. J (MYL-RIS0056134); Levy Decl. (Sun) Ex. J (Sun0010939).
[9] *Id.*

[redacted] *See AstraZeneca LP*, 633 F.3d at 1060 (affirming district court's issuance of preliminary injunction and finding that defendant had requisite intent to induce infringement because defendant included instructions in its proposed label that would cause at least some users to infringe the asserted method claims and because, despite being aware of the infringement problem presented by the proposed label, defendant nonetheless proceeded with its plans to distribute its generic drug product). As described above, the label is not at all "consistent with" any non-infringing use. In light of these facts, whether some patients ignore the label is irrelevant. *See id.* at 1060 ("In the context of specific intent, it is irrelevant [to intent to induce infringement] that some users may ignore the warning in the proposed label.") As Defendants explicitly admit in their Opposition, the relevant inquiry is "whether [the] instructions teach an infringing use of the [product] such that [the Court is] willing to infer from those instructions an affirmative intent to infringe the patent." *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1329 n.2 (Fed. Cir. 2009); *see* Def. Opp. at 16. Such an intent is readily apparent from the Defendant's application to the FDA, which includes a proposed label instructing patients to infringe. *See i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 851-852 (Fed. Cir. 2010) ("The instructional materials were thus substantial evidence that Microsoft intended the product to be used in an infringing manner."). Defendants' hypothetical "forgetful" patient example does not change this outcome.

In addition, patients who may eventually stray from label and/or physician instructions (in many cases after having already infringed by taking a first dose and a second dose about one month later) are insufficient to constitute a substantial non-infringing use of Defendants' ANDA

[10] Levy Decl. (Apotex), Ex. J (AP-RISE0001520); Levy Decl. (Teva), Ex. J (TRM0046074); Levy Decl. (Mylan), Ex. J (MYL-RIS0056136); Levy Decl. (Sun), Ex. J (SUN0010921).

products. Defendants' reliance on *Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358 (Fed. Cir. 2012) is misplaced. In that case, the accused products were not accompanied by instructions that explicitly directed a user to infringe; rather, the accursed products were advertised as standard-compliant and recommended a use under that standard that would have infringed, but, in fact, the standard itself acknowledged the non-infringing use. *Toshiba*, 681 F.3d at 1362-63. Here, as in *i4i Ltd.*, any use contrary to clear directives to use the product in an infringing manner can fairly be classified as at least "unusual," "occasional," or "aberrant." *See i4i Ltd.*, 598 F.3d at 851-52. Even Defendants' use of the word "forgetful" to describe a patient that does not follow label instructions implies that such administration of the medication is not a matter of course, but instead refers to an oversight. *See, e.g.*, Def. Opp. at 11.

Moreover, uncontroverted evidence establishes that physicians will instruct their patients to follow the infringing label instructions and take their 150 mg risedronate sodium tablets once a month.[11] In any case, Defendants' attempts to distinguish *Eli Lilly & Co. v. Actavis Elizabeth LLC*, 435 Fed. Appx. 917, 919 (Fed. Cir. 2011) on the basis that that case involved "off-label" prescriptions fails on its own terms – here, too, a physician prescribing one of the Defendants' tablets to be taken in a manner different from once approximately every 30 days would be prescribing the drug off-label.[12] Thus, Defendants are making the very argument they disavow in their Opposition – that the off-label use of their products would constitute a substantial non-infringing use.

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[11] *See* Supplemental Declaration of Jaclyn C. Levy In Support of Plaintiffs' Reply Brief In Support of Motion For Summary Judgment of Infringement ("Levy Decl. II"), Ex. 1 (Wimalawansa Tr.) at 142:15-20, 22-25; *see also*, Levy Decl. II Ex. 2 (Bilezekian Opening Rep.), ¶ 38.

[12] *See, e.g.*, Levy Decl. II, Ex. 2 (Bilezekian Opening Rep.), ¶ 41 ("An "off-label" use of a pharmaceutical product is a use for which the product is not indicated on its label."); Levy Decl. II, Ex. 1 (Wimalawansa Tr.) at 106:10-12, 14.

C. Product Labeling that Instructs Infringement Gives Rise to an Inference of the Specific Intent Required for Inducement.

Defendants' speculation of a hypothetical, small number of patients switching from branded Actonel® Once-A-Month to one of Defendants' generic products does not undercut the inferred intent element for induced infringement. As described above, at the very least, Defendants unmistakably intend for new patients, who have not previously taken branded Actonel® Once-A-Month, to take Defendants' products to take in a manner that would infringe the asserted claims. Defendants have presented no evidence or argument (nor can they) to indicate that they do not intend for patients to follow the instructions in their labels submitted to the FDA for approval. *See, e.g., Research Found. of State Univ. of New York v. Mylan Pharm. Inc.*, 809 F. Supp. 2d 296, 331 (D. Del. 2011) ("no serious dispute" as to generic company's expectation that its product will be used according to the "uses enumerated on its label"). The intent established on these undisputed facts is sufficient to establish induced infringement because Defendants' labels "would inevitably lead some consumers to practice the claimed method." *AstraZeneca LP*, 633 F.3d at 1060.

D. Exclusion of a Loading Dose from the Claims Is Irrelevant to Infringement Because Defendants Labels Do Not Instruct Patients to Use a Loading Dose.

The fact that the asserted claims exclude a loading dose has no bearing on the issue of infringement. Actonel® Once-A-Month is not FDA-approved for use in a loading dose regimen, and, as such, its labeling does not contain instructions incorporating a loading dose. Likewise, because ANDA filers must adhere to the same dosing instructions as the innovator drug, none of Defendants' labels contain instructions involving a loading dose. Therefore, the strained hypothetical that some patients may take the Defendants' product following a loading dose is speculative, unsupported by any facts or evidence, and indeed, contrary to the course of treatment for which the Defendants' proposed products are indicated. *See i4i Ltd.*, 598 F. 3d at

851-52 (distinguishing "unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental" uses from substantial uses).

E. Patients Switching from Actonel® Once-a-Month to a Generic Monthly Product Do Not Affect Inducement and Do Not Exemplify a Substantial Non-Infringing Use.

1. *Defendants' instructions induce new monthly prescription holders to infringe, and Defendants are therefore liable for inducement.*

Even assuming that some number of patients will have already commenced treatment with Actonel® Once-A-Month before switching to a generic risedronate 150 mg tablet – and as discussed below, that will infrequently be the case – Defendants' labels induce infringement by patients who are new to once-monthly dosing with 150 mg risedronate tablets. Once the generic products launch, there can be no legitimate dispute that patients are far more likely to commence and continue a treatment regimen of risedronate 150 mg on the same day every month with the generic risedronate 150 mg tablet than with Actonel® Once-A-Month branded risedronate tablets. Defendants' prescribing instructions thus "inevitably lead some consumers to practice the claimed method[s]," which is what the law requires to demonstrate inducement to infringe. *See Astra-Zeneca LP*, 633 F.3d at 1060.

2. *Switching from branded Actonel® OAM to generic risedronate does not constitute a substantial non-infringing use.*

Pharmaceutical economist Dr. Joel Hay, who was retained by three of the Defendants to argue against the commercial success of Actonel® Once-A-Month, has indicated that switching from Actonel® Once-A-Month to a generic risedronate sodium tablet will not be a substantial non-infringing use.[13] In particular, Dr. Hay told the Los Angeles Times in 2008, "Once you start on a drug you tend to stay on it, even if there is a good generic. That's why the drug companies

[13] Dr. Hay submitted an expert report on behalf of Apotex, Teva, and Mylan.

spend billions of dollars on sampling."[14] Moreover, Dr. Hay contended in this litigation that Actonel® Once-A-Month was the beneficiary of "hundreds of millions of dollars" of marketing, and that promotional spending on Actonel was "striking – it is an extremely high amount."[15] Under the economic theories espoused by Defendants, the "striking" amount of spending on Actonel should lead to a high rate of loyalty to the Actonel® brand, rather than any substantial number of instances of switching from Actonel® to a generic product. Accordingly, any switch from Actonel® Once-A-Month to generic risedronate 150 mg tablets would be "unusual" at best. *i4i Ltd.*, 598 F.3d at 851-852. And even if Defendants were to take issue with their own expert's statement to the Los Angeles Times regarding the effect of marketing on switching to generics, and instead contend that many patients who currently use Actonel® Once-A-Month will switch to generic risedronate 150 mg tablets when the generic versions launch, there is no reason to believe that future patients – or their insurance companies – would pay for one dose of Actonel® Once-A-Month and then immediately switch to a generic. Such a theory would be economically irrational for a patient and goes beyond "impractical" to "bizarre."

Regarding blister packaging, Defendants assert that "[n]othing on the Draft Blister Carton directs patients not to commence treatment with the Actonel® branded product." Def. Opp. at 7. The absence of an explicit instruction to avoid infringing the asserted claims neither neutralizes Defendants' specific intent to infringe the claims of the patent, nor indicates any substantial non-infringing use of their proposed products.

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[14] Levy Decl. II, Ex. 3 (Hirsc, Jerry. "YOUR MONEY; The medicine game; With a lot of knowledge and a little bit of begging, you can make your prescription bill much easier to swallow," Los Angeles Times (Mar 15, 2009)) at p. B.1.

[15] Levy Decl. II, Ex. 4 (Reply Expert Report of Joel W. Hay, Ph.D.), ¶¶ 44, 53.

In fact, the rate of new prescriptions will far outstrip the rate of any switching within the lifetime of the patents, which expire in 2023. Defendants' own theories belie their claims of substantial non-infringing use. In his report contesting the commercial success of Actonel® Once-A-Month, Dr. Hay relied upon data from the SDI Vector One database for his analysis of the rate of persistence with bisphosphonates. Dr. Hay concluded that only 9% of patients used a bisphosphonate for more than 3 years, and only 0.74% of patients used a bisphosphonate for more than 5 years. In approximately five years from the launch date of the generics, according to these statistics, 99.26% of all prescriptions for 150 mg once-monthly risedronate tablets will be "new" as opposed to refills. In other words, over 99% of the use of Defendants' products will infringe the asserted patents.

F. Defendants Are Liable for Induced and Contributory Infringement of Claim 10 of the '634 Patent, Which Does Not Require "Commencing and Continuing," for Patients New to Monthly Dosing and Those Switching from Branded Actonel® Once-A-Month.

Finally, Defendants have mounted no colorable argument that their proposed product will not infringe claim 10 of the '634 patent, which does not recite "commencing" and "continuing" limitations. In the absence of this hook for Defendants' flawed arguments denying infringement of the other asserted claims, Defendants are left with their argument relating to the exclusion of a loading dose. As discussed above, the exclusion from the asserted claims of a loading dose is irrelevant and does not overcome Defendants' induced and contributory infringement of claim 10 by the instructions provided in their labels and their proposed sale of products having no substantial non-infringing use.

III. CONCLUSION.

For the foregoing reasons, Plaintiffs respectfully request that this Court grant their Motion for Summary Judgment of Infringement.

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