IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

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| TAKEDA PHARMACEUTICALS USA, INC., | ) | |
| Plaintiff, | ) | |
| v. | ) | Civ. No. 14-1268-SLR |
| WEST-WARD PHARMACEUTICAL CORPORATION, HIKMA AMERICAS INC., and HIKMA PHARMACEUTICALS PLC, | ) | |
| Defendants. | ) | |

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**MEMORANDUM OPINION**

Dated: November 4, 2014
Wilmington, Delaware

**ROBINSON, District Judge**

## I. INTRODUCTION

On October 3, 2014, Takeda Pharmaceuticals U.S.A., Inc. ("Takeda") filed suit against West-Ward Pharmaceutical Corporation, Hikma Americas Inc., and Hikma Pharmaceuticals PLC (collectively, "Hikma"), asserting induced infringement of five patents[1] under 35 U.S.C. § 271(b).[2] (D.I. 1) Takeda is the owner of the asserted patents, all of which cover methods of administering colchicine products for the treatment of acute gout flares, as well as for concomitant administration of colchicine with other drugs for prophylaxis (prevention) of gout flares.

Hikma has launched the accused product, Mitigare™, an oral single-ingredient colchicine product, "indicated for prophylaxis of gout flares in adults" (D.I. 1, ex. H at 1), and intends to launch a generic version of such at a price significantly below that of Takeda's pricing structure. Although Mitigare™ has the same active ingredient, route of administration, and strength as Takeda's colchicine product (Colcrys®), Hikma did not file its application with the Food and Drug Administration ("FDA") as an Abbreviated New Drug Application ("ANDA"). Instead, Hikma sought approval through the New

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[1]U.S. Patent Nos. 7,964,648 ("the '648 patent"); 7,981,938 ("the '938 patent"); 8,097,655 ("the '655 patent"); 8,440,722 ("the '722 patent"); and 7,964,647 ("the '647 patent") (collectively, "the asserted patents"). The '655, '648 and '722 patents are directed to methods for administering reduced doses of colchicine for the prophylaxis of gout flares in patients who are concomitantly taking clarithromycin ('655 patent), ketoconazole ('648 patent), or verapamil ('722 patent). The '938 patent is directed to a method of treating a gout flare using a specific low-dose regiment in patients already undergoing prophylactic treatment with colchicine. The '647 patent is directed to a method of treating a gout flare using a low-dose regiment of colchicine.

[2]For all of the asserted patents, Takeda alleges that Hikma "will intentionally encourage acts of direct infringement immediately by healthcare providers administering and/or patients using MITIGARE™." (D.I. 1 at ¶¶ 40, 47, 54 and 61)

Drug Application ("NDA") pathway under § 505(b)(2) of the Hatch-Waxman Act. Moreover, in its proposed label, Hikma has omitted specific mention of uses for which Takeda has patent protection.

On October 5, 2014, Takeda requested a temporary restraining order ("TRO") to preserve the status quo while the parties more fully briefed (and the court considered) Takeda's motion for a preliminary injunction. (D.I. 5) On October 9, 2014, the court issued a memorandum order granting Takeda's motion for a TRO. (D.I. 21) The parties jointly stipulated to extend the period for which the TRO was in force through the end of November 4, 2014. (D.I. 54) Presently before the court is Takeda's motion for a preliminary injunction. (D.I. 5) The court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a). For the reasons discussed more fully below, the court denies Takeda's motion for a preliminary injunction.

## II. STANDARD OF REVIEW

"The decision to grant or deny . . . injunctive relief is an act of equitable discretion by the district court." *eBay, Inc. v. MercExchange, LLC*, 547 U.S. 388, 391 (2006). The grant of such relief is considered an "extraordinary remedy" that should be granted only in "limited circumstances." *See Kos Pharma, Inc. v. Andrx Corp.*, 369 F.3d 700, 708 (3d Cir. 2004) (citation omitted). A party seeking preliminary injunction relief must demonstrate: (1) a reasonable likelihood of success on the merits; (2) the prospect of irreparable harm in the absence of an injunction; (3) that this harm would exceed harm to the opposing party; and (4) the public interest favors such relief. *See, e.g., Sciele Pharma Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1259 (Fed. Cir. 2011); *Antares Pharma, Inc.*

*v. Medac Pharma, Inc.*, Civ. No. 14-270, 2014 WL 3374614, at *2 (D. Del. July 10, 2014). The burden lies with the movant to establish every element in its favor or the grant of a preliminary injunction is inappropriate. *See P.C. Yonkers, Inc. v. Celebrations, the Party and Seasonal Superstore, LLC*, 428 F.3d 504, 508 (3d Cir. 2005). If either or both of the fundamental requirements—likelihood of success on the merits and probability of irreparable harm if relief is not granted—are absent, an injunction cannot issue. *See McKeesport Hosp. v. Accreditation Council for Graduate Med. Educ.*, 24 F.3d 519, 523 (3d Cir. 1994).

## III. DISCUSSION

### A. Likelihood of Success

As noted, Takeda has asserted inducement of infringement under 35 U.S.C. § 271(b). Under § 271(b), "[w]hoever actively induces infringement of a patent shall be liable as an infringer." It is a plaintiff's burden to demonstrate that the accused infringer's "actions induced infringing acts and that [the accused infringer] knew or should have known [its] actions would induce actual infringements." *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 553 (Fed. Cir. 1990). "[M]ere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven." *Warner Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003). Therefore, "if an entity offers a product with the object of promoting its use to infringe, as shown by clear expression or other affirmative steps taken to foster infringement, it is liable for the resulting acts of infringement by third parties. . . . 'The inducement rule . . . premises liability on purposeful, culpable

expressions and conduct . . . .'" *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1305-1306 (Fed. Cir. 2006) (quoting *Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd.*, 545 U.S. 913, 937 (2005)). "[W]here a product has substantial noninfringing uses, intent to induce infringement cannot be inferred even when [the accused infringer] has actual knowledge that some users of its product may be infringing the patent." *Warner Lambert,* 316 F.3d. at 1365.[3]

In addition to the above precedent, the parties addressed two subsequent Federal Circuit decisions, *AstraZeneca LP v. Apotex, Inc.,* 633 F.3d 1042 (Fed. Cir. 2010) ("*AZ 2010*"), and *AstraZeneca Pharmaceuticals LP v. Apotex Corp.,* 669 F.3d 1370 (Fed. Cir. 2012) ("*AZ 2012*"). In *AZ 2010*, the Federal Circuit affirmed the grant of a preliminary injunction barring defendant Apotex from launching a generic version of a budesonide drug made and distributed by plaintiff AstraZeneca and covered under method and kit claims disclosed in several of AstraZeneca's patents. It was AstraZeneca's contention, *inter alia*, that Apotex's proposed label would induce consumers to infringe the asserted method claims "because the label implicitly instructed users to administer the generic drug once daily" by advising that, "[i]n all patients, it is desirable to downward-titrate to the lowest effective dose" once "the desired clinical effect is achieved." *AZ 2010*, 633 F.3d at 1057. Given the available strengths (0.25 mg and 0.5 mg per 2 ml vial) and the recommended starting dose (0.5

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[3]Under the facts of record in *Warner Lambert,* where there were many uses for the product at issue and the evidence demonstrated that "fewer than 1 in 46 sales of that product [were] for infringing uses," the Federal Circuit concluded that it was "not in a position to infer or not infer intent" on the part of the accused infringer "without any direct evidence" of intent. *Id.*

mg total daily dose administered twice daily in divided doses, i.e., 0.25 mg administered twice daily) of the generic, the district court reasoned that "the first step in titrating down from [the starting] dose would have to be 0.25 mg once daily." The district court concluded that the downward titration language included in the proposed label "**would necessarily lead patients" to infringe** the asserted method claims which disclosed once-daily administration. *Id.* (emphasis added). By my reading, the district court found more in the label than an "implicit" instruction.

The Federal Circuit, for its part, acknowledged that when evidence of substantial noninfringing uses exists, a court may not infer intent from the mere knowledge of possible infringing uses, but must find affirmative intent from "[e]vidence of active steps . . . taken to encourage direct infringement, such as advertising an infringing use or instructing how to engage in an infringing use." *Id.* at 1059 (quoting *Grokster*, 545 U.S. at 935). In other words, the evidence of specific intent must go "'beyond a product's characteristics or the knowledge that it may be put to infringing uses, and [instead show] statements or actions directed to promoting infringement.'" *Id.* at 1059 (quoting *Grokster,* 545 U.S. 913 at 936). According to the Court, then, "[t]he pertinent question is whether the proposed label instructs users to perform the patented method." *Id.* at 1060. Based on the proposed label under review and Apotex's decision to proceed with its plan to distribute its generic "despite being aware that the label presented infringement problems,"[4] the Federal Circuit found that is was "not left with a definite and firm conviction that a mistake [had] been made," thus affirming the district court's

[4]The record contained correspondence with the FDA wherein AstraZeneca had argued that the downward titration language taught "once-daily dosing." *Id.* at 1057-58.

determination that AstraZeneca would likely prove induced infringement at trial. *Id.* at 1061. Not exactly a ringing endorsement of the decision to enjoin Apotex.

In *AZ 2012*, defendants - all generic drug manufacturers - only sought approval in their ANDAs for unpatented methods of using rosuvastatin calcium and, consequently, submitted section viii statements[5] regarding AstraZeneca's use patents. AstraZeneca filed a § 271(e)(2)(A) action[6] against defendants based on its belief that the FDA would require the defendants to make labeling amendments explicitly incorporating the indications covered by the use patents. The Federal Circuit affirmed dismissal of AstraZeneca's claims, based on the nature of the ANDA regime. More specifically, § 271(e)(2)(A) confines the scope of the infringement analysis in the context of ANDA litigation to the scope of approval sought in the ANDA. Because generic manufacturers are permitted to limit the scope of regulatory approval they seek, they also can forego a § 271(e)(2) infringement suit "by excluding patented indications from their ANDAs." *AZ 2012*, 669 F.3d at 1379. The fact that "market realities" suggested that some users may ignore the warnings in the proposed label and use the

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[5]Pursuant to 21 U.S.C. § 355(j)(2)(A)(viii), an applicant seeking approval for a method of use not claimed in a "method of use patent" associated with the listed drug must submit a section viii statement declaring that the patent does not claim such a use. The applicant must also remove or "carve out" any mention of the patented method of use from the proposed label for the generic drug. *See* AZ 2010, 633 F.3d at 1046; 21 C.F.R. § 314.92(a)(1).

[6]35 U.S.C. § 271(e)(2)(A) provides that "[i]t shall be an act of infringement to submit" an ANDA "for a drug claimed in a patent or the use of which is claimed in a patent."

patented method[7] was deemed "unpersuasive" in the context of specific intent, with the Federal Circuit rejecting AstraZeneca's "expansive view of § 271(e)(2)." *Id.* at 1380. And, indeed, it is not surprising that "market realities" are not persuasive in the context of § 271(e)(2) litigation, where the infringement analysis starts and ends with the scope of the ANDA, defined by statute as constituting the artificial act of infringement.

Applying the principles gleaned from the above precedent to the record at bar, I start my analysis with several facts that I consider beyond dispute. First, colchicine had been used for the treatment of gout flares long before Takeda's patents issued, as evidenced by Hikma's colchicine product that was sold in the 1970s before the FDA withdrew all such drugs from the market. (D.I. 9, ex. F at ¶ 5) Second, Hikma's proposed label omits explicit directions for uses covered by Takeda's patent. (D.I. 9, ex. B at ¶ 4) Finally, regardless of whether the right number is 43.75% (Takeda's number, D.I. 67, ¶ 6) or 95% (Hikma's number, D.I. 38 at ¶ 6; D.I. 43 at ¶¶ 31, 38),[8] the use of colchicine for the prophylactic treatment of gout flares - as opposed to its use for the treatment of acute gout flares - is substantial, that is, considerable. Therefore, specific intent cannot be inferred from the knowledge (actual or based on "market realities"[9]) that a generic product may be used in infringing ways. There must instead be affirmative evidence of specific intent and action to induce infringement.

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[7]It was AstraZeneca's contention that, "even if a generic drug is formally approved only for unpatented uses, pharmacists and doctors will nonetheless substitute the generic for all indications once it becomes available." *AZ 2012*, 669 F.3d at 1380.

[8]I suspect the actual number lies somewhere in between.

[9]I agree with Takeda that market realities are relevant to a non-§ 271(e)(2) analysis such as the one at bar.

As an initial note, I decline to invoke the doctrine of willful blindness to establish Hikma's intent to induce infringement. The Supreme Court in *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060 (2011), was reviewing a record of already completed actions (copying and marketing a competitor's product) when it ruled.[10] The doctrine of willful blindness, if invoked at bar where the generic has not even launched and there are substantial noninfringing uses, would make this already predictive exercise one that borders on mere speculation.

I also need to explain that my focus in the TRO proceeding was on whether it was likely that patients who were taking colchicine for prophylaxis of gout flares would follow the patented methods of treating acute flares and when co-administering with other drugs. I found there to be sufficient evidence of record in this regard. On the expanded record submitted by the parties, I find reason to question my earlier conclusions. Most significantly, however, I have come to realize that the issue is not just whether some patients and/or healthcare providers may directly infringe. The issue is whether Hikma has actively encouraged them to do so, as demonstrated by Takeda through record evidence. I address that issue now.

**1. Induced infringement of acute gout flare patents**

The '938 and '647 patents disclose methods of treatment of acute gout attacks, including where the patient is already undergoing treatment for the prophylaxis of gout flares. The treatment consists of administering 1.2 mg oral colchicine followed by 0.6

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[10]The Court found that the evidence "was more than sufficient for a jury to find that Pentalpha subjectively believed there was a high probability that SEB's fryer was patented, that Pentalpha took deliberate steps to avoid knowing that fact, and that it therefore willfully blinded itself to the infringing nature of Sunbeam's sales." *Id.* at 2072.

mg oral colchicine one hour later.

Hikma's proposed label includes the following information. As to "indications and usage:" "Mitigare™ is indicated for prophylaxis of gout flares in adults." As to "limitations of use:" "The safety and effectiveness of Mitigare™ for acute treatment of gout flares during prophylaxis has not been studied." According to the Mitigare™ Medication Guide: "If you have a gout flare while taking Mitigare™, tell your healthcare provider." The dosage and administration of Mitigare™ is described as: "0.6 mg (one capsule) once or twice daily. Maximum dose 1.2 mg/day. Mitigare™ is administered orally, without regard to meals." (D.I. 46, ex. 7)

Hikma argues that its proposed label not only lacks any affirmative directions for the treatment of acute gout flares,[11] but it actually disclaims an indication for acute gout flares. Takeda nonetheless contends that the record has sufficient evidence of induced infringement, based on a series of postulations: (1) oral colchicine is used for prophylaxis of gout flares (as proposed in Hikma's label); (2) oral colchicine is one of the appropriate primary modality options to treat acute gout flares (D.I. 9, ex. T); (3) Hikma in its label advises patients to consult with their healthcare providers if they suffer an acute gout flare; (4) sources available to healthcare providers, such as the FDA and the American College of Rheumatology ("ACR"), refer to Colcrys®' prescribing information for the treatment of acute gout flares (D.I. 9, ex. T at 1454, ex. N; D.I. 70, ex. D at 1); therefore (5) Hikma's proposed label inevitably leads doctors to the patented treatment regime of the Colcrys® label.

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[11]As conceded by Takeda. (D.I. 6 at 12-13)

Even if the above evidence were undisputed, which is not the case on this expanded record,[12] the question remains whether the proposed label is a sufficient catalyst to constitute "active steps taken to encourage direct infringement" of the '938 and '647 patents. I conclude that Takeda has not carried its burden of persuasion in this regard. Unlike the facts reviewed in *AZ 2010*, where the generic's label itself gave the information needed to infringe (the downward titration language), Hikma's label only "necessarily leads" to consultation with a healthcare provider who may, or may not, consult Colcrys®' prescribing information and who may, or may not, follow the patented method of use for treatment of the acute gout flare. Especially with the heavy burden associated with injunctions, Takeda has not demonstrated that such a consultation will "inevitably" lead to infringing acts.

**2. Induced infringement of drug-drug interaction ("DDI") patents**

The three DDI patents disclose methods for prophylaxis of gout flares when colchicine is co-administered with: (1) verapamil (the '722 patent, which claims a reduced colchicine dose of 50% of the usual dose); (2) clarithromycin (the '655 patent, which claims a reduced colchicine dose of 75% of the usual dose); and (3) ketoconazole (the '648 patent, which claims a reduced colchicine dose of 25% of the usual dose). Hikma's proposed label provides the following with respect to co-administration:

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[12]Hikma has produced evidence, e.g., that because colchicine can cause nausea, vomiting, diarrhea and other side effects, nonsteroidal anti-inflammatory drugs "have become the treatment choice for most acute attacks of gout." (American College of Rheumatology, *Diseases & Conditions: Gout*, http://www.rheumatology.org/Practice/Clinical/Patients/Diseases_And_Conditions/Gout/ (last visited November 4, 2014).

> Co-administration of P-gp or CYP3A4 inhibitors or inhibitors of both P-gp and CYP3A4 (e.g., clarithromycin or cyclosporine) have been reported to lead to colchicine toxicity. The potential for drug-drug interactions must be considered prior to and during therapy.
>
> Concomitant use of MITIGARE™ and inhibitors of CYP3A4 or P-gp should be avoided if possible. If co-administration of MITIGARE™ and an inhibitor of CYP3A4 or p-gp is necessary, the dose of MITIGARE™ should be reduced and the patient should be monitored carefully for colchicine toxicity.

(D.I. 46, ex 7)

In connection with the DDI drugs, Hikma argues that Takeda has failed to meet its burden of proving either direct or indirect infringement. With respect to the former, direct infringement of the '655 and '648 patents requires a 0.3 mg dose of colchicine, which (according to Takeda's expert) is not feasible with Mitigare™ because it is a 0.6 mg capsule that cannot be split. (D.I. 7 at ¶ 18) Takeda responds that "a dose of 0.3 mg once a day may be accomplished by altering the frequency of a 0.6 mg dose." (D.I. 65 at 3; D.I. 7 at ¶¶ 17-18) Under the circumstances, however, where the DDI patents themselves describe colchicine as having a "narrow" or "low" therapeutic index,[13] Takeda's postulation (even if consistent with arguments made by Hikma to the FDA in other contexts, *see* D.I. 41, ex. E), is not persuasive evidence of direct (certainly not

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[13]*See, e.g.,* '648 patent, 1:38-47:

> Colchicine has a narrow therapeutic index. The margin between an effective dose and a toxic dose of colchicine is much narrower than that of many other widely used drugs. Consequently, actions that result in increased colchicine levels in patients receiving colchicine therapy are particularly dangerous. Co-administration of colchicine to patients along with certain other drugs can have the effect of increasing colchicine levels. Such drug-drug interactions with colchicine have been reported to result in serious morbid complications and, in some cases, death.

literal) infringement.

With respect to induced infringement, Takeda concedes that Hikma's label "fails to specify how to reduce the dose or dose frequency." (D.I. 6 at 12) Indeed, unlike the label reviewed in *AZ 2010,* which characterized downward titration to the lowest effective dose as "desirable" "for all patients," Hikma's proposed label characterizes the concomitant use of Mitigare™ and CYP3A4 inhibitors as something that "should be avoided." As explained by the court in *United Therapeutic Corp. v. Sandoz*, Civ. No. 12-01617, 2014 WL 4259153 (D.N.J. Aug. 29, 2014), "there is a rather significant difference between a warning and an instruction." *Id.* at *18-19.

In response, once again Takeda relies on a predictive course of conduct to demonstrate that Hikma has induced infringement. According to the logic that must be followed in this regard: (1) a patient undergoing prophylaxis of gout flares with a colchicine regime must also be prescribed one of the three drugs at issue; (2) the healthcare provider must then determine that avoidance of co-administration is not possible; and (3) the healthcare provider must follow the patented method claims. For the '655 and '648 patents, that requires a 0.3 mg dose of colchicine to be administered, even though Mitigare™ is available only in 0.6 mg capsules. Consistent with the expanded record, there is no evidence that any healthcare provider has actually practiced the methods of the DDI patents[14] and, indeed, there are declarations of record

[14]Notably, Takeda's experts essentially hypothesize that, if co-administration of colchicine and medications "such as" any of the named drugs were required, they "would . . . typically reduce the patient's Colcrys® dose based on the dose adjustment guidelines in the Colcrys® label" (D.I. 7 at ¶ 18) or, even more generally, have in the past "trusted guidance regarding dose reduction" (D.I. 70 at ¶ 32).

that include evidence that "avoidance" of co-adminstration is the normal practice, given the risks of toxicity and the many options for each of the DDI drugs. (D.I. 43 at ¶ 29, D.I. 38 ¶ 7, D.I. 42 ¶ 9) In sum, even if Takeda's theory of infringement were supported by evidence in the record, I find more persuasive the court's analysis in *United Therapeutic Corp. v. Sandoz*, where it rejected the theory "that a scholarly scavenger hunt - which may be incited by [the label]" - can "constitute evidence of [defendant's] intent to induce physicians to engage in infringing conduct." 2014 WL 4259153 at *19. Hikma's label, "taken in its entirety, fails to recommend or suggest to a physician" that the patented methods of co-administration should be followed. *Bayer Schering Pharma AG v. Lupin, Ltd.,* 676 F.3d 1316, 1324 (Fed. Cir. 2012).

With respect to the remaining DDI patent, the '722 patent requires not only a reduced dosage of colchicine (50% to 75% of the usual dose), but is confined to those instances "wherein the concomitantly administered dose of verapamil is 240 mg per day." ('722 patent, col. 30:36-37) Aside from the concerns raised above and equally applicable to the '722 patent, there is the added complication that there are multiple dosing options for using verapamil other than 240 mg (D.I. 49, ex. C; D.I. 43 ¶ 42) and, again, there is no evidence that any physician has ever followed the patented method of use. Takeda has not submitted persuasive evidence of direct infringement. For the reasons stated above, neither has Takeda offered sufficient evidence of induced infringement.

**3. Validity of patents-in-suit**

I agree with Takeda that Hikma has failed to raise a substantial question

regarding the validity of the acute gout flare patents, as the prior art proferred in this regard either does not disclose the low dose regimen of the acute gout flare patents (D.I. 43, ex. S; D.I. 70 at ¶ 46) or does not corroborate the use of such a regimen. Likewise, with respect to the DDI patents, although the prior art suggested that the colchicine dose should be reduced or stopped if co-administered with, e.g., PGP inhibitors, there is no disclosure of what the amount of reduction should be. (D.I. 70 at ¶ 49, ex. R)

**B. Irreparable Harm**

In connection with granting Takeda's request for a preliminary restraining order, I found that Takeda had demonstrated irreparable harm based on the prospect that generic Mitigare™ will likely take over the colchicine market, that is, substitution from Takeda's Colcrys® product will be immediate and significant.[15] The expanded record has drawn that conclusion into some doubt, not because the anticipated market shift will not happen, but because of the principle that "[s]ales lost to an infringing product cannot irreparably harm a patentee if consumers buy that product for reasons other than the patented feature." *Apple, Inc. v. Samsung Electronics Co.*, 678 F.3d 1314, 1324 (Fed. Cir. 2012). Having found substantial noninfringing uses for colchicine, I cannot say with confidence that Takeda has linked its harm to the allegedly infringing conduct. Even the Adheris Health study does not specifically relate Colcrys® use to the patented method. (D.I. 67 at ¶¶ 6-7) Under these circumstances, I conclude that

[15]Such a market shift would also impact, e.g., key relationships with prescribers and other market participants, damage goodwill and reputation, effect formulary displacement, etc. (D.I. 18; 69)

Takeda has not carried its burden to prove irreparable harm.

### C. Remaining Factors

The expanded record has not given me cause to change my analysis of the remaining factors.

## IV. CONCLUSION

Because Takeda has failed to demonstrate that it will likely prove induced infringement at trial or suffer irreparable harm, the extraordinary relief sought is not warranted. However, given the significance of this dispute to both parties, I will maintain the status quo pending appeal if: (1) Takeda takes an immediate appeal[16] and requests expedited review of both the merits and this ruling by the Federal Circuit; and (2) the conditions included in my order of October 31, 2014 (D.I. 72) continue to govern the conduct of the parties, except that the bond shall increase $500,000 per day until further order of this court or the Federal Circuit.

An appropriate order shall issue.

[16]On or before Wednesday, November 5, 2014 at 4:30 p.m..