

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

DIGENE CORPORATION)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 01-752-MPT
)	
VENTANA MEDICAL SYSTEMS, INC.,)	
and BECKMAN COULTER, INC.)	
)	
)	
Defendants.)	

MEMORANDUM ORDER

I. INTRODUCTION

This is a patent infringement case. Digene Corporation (“Digene”) commenced litigation against Ventana Medical Systems, Inc. (“Ventana”) on November 19, 2001, alleging infringement of U.S. Patent Nos. 4,849,332 (“the ‘332 patent”) and 4,849,331 (“the ‘331 patent’). Digene’s ‘332 patent is embodied in its “HPV products,” which are tests that screen for the presence of the Human Papillomavirus (“HPV”) 35, a virus known to cause cervical cancer.¹ In its complaint, Digene alleges that Ventana infringes

¹ The ‘332 patent issued to Life Technologies Inc. (“LTI”) on July 18, 1989 and is embodied by the HPV 35 cell paste. In August 1990, LTI, Digene’s predecessor, entered into a cross-licensing agreement (“CLA”) with a foreign competitor, Institut Pasteur (“IP”), to exploit the emerging technology related to HPV products. IP owned two patents which covered certain DNA probe technology. The CLA involved a number of patents, including the ‘332 patent. LTI transferred its HPV business to Digene, including the CLA, in December 1990. The CLA was intended to benefit only five companies, (also known as the “Group of Five”), who were permitted to create and sell products using the patent strains from LTI and IP. D.I. 414, at 6-7 (Oral Argument/Preliminary Injunction Hearing, Judge Mary Pat Thyng, February 22, 2007). Pursuant to the CLA, LTI cross-licensed its HPV patents to IP and subsequently permitted IP to sublicense Beckman Coulter, Inc. (“Beckman”). In June 1991, under the Sublicensing Agreement (“SLA”), IP sub-licensed its rights obtained in the CLA to Beckman. In the mid-1990s, Ventana began selling HPV products manufactured from cell paste acquired from Beckman. In September 2002, Ventana allegedly acquired Beckman’s rights in the CLA and SLA through an Asset Purchase Agreement (“APA”). Beckman and Ventana also executed a Side Letter Agreement which afforded Beckman the opportunity to buy cell paste from Ventana and to make probes.

the '332 patent by selling HPV tests that were made with cell paste purchased from Beckman and further, that Beckman's assignment of its right, title and interest to Ventana violates the terms of the CLA.² Following the arbitration proceedings against Beckman, on August 29, 2006, Digene moved for a preliminary injunction to prohibit Ventana from making, using, selling, and offering for sale, reagents that contain HPV 35.³ On October 6, 2006, Ventana filed its opposition to Digene's Motion for Preliminary Injunction.⁴

II. POSITION OF THE PARTIES

Digene urges that a preliminary injunction is the only method by which it can obtain any benefit from the "right to exclude" Ventana from infringing the patent, especially in light of the fact that the '332 patent expires on May 26, 2007.

A. Likelihood of Success on the Merits

Digene asserts a strong likelihood of succeeding on the merits of its infringement claim. Digene alleges that Ventana does not have a license defense to an infringement

² Digene initially filed suit against Ventana in November 2001. Following the APA between Ventana and Beckman in 2002, Digene amended its complaint and added Beckman as a defendant. In May 2004, the court ordered Digene to arbitrate all of its claims against Beckman arising out of the CLA before the International Centre for Dispute Resolution ("ICDR") and stayed the proceedings against Ventana. The arbitration panel issued its decision in July 2006 and concluded that the CLA permitted Beckman to assign its rights through the SLA, and further, by entering into the SLA, Beckman did not violate the CLA. However, it held that "when the purported assignment by Beckman to Ventana is viewed as a whole (including the Addendum and the Side Letter Agreement), the transaction violates" the CLA's prohibition against further sub-licensing. D.I. 317, Ex. B at 74 (Declaration of David E. Moore in Support of Digene Corporation's Motion for Preliminary Injunction) (*Digene v. Beckman*, ICDR Final Award). On August 15, 2006, the court lifted the stay against Ventana.

³ D.I. 315 (Plaintiff Digene Corporation's Opening Brief in Support of Motion for Preliminary Injunction).

⁴ D.I. 347 (Defendant Ventana Medical Systems, Inc.'s Answering Brief in Opposition to Digene's Motion for Preliminary Injunction).

claim because the ICDR invalidated the purported assignment by Beckman of its rights to the '332 patent to Ventana occurring in 2002.⁵ Digene propounds that Ventana's arguments about validity, specifically prior art and enablement, are without merit, noting that an issued patent is presumed valid and that the '332 patent stood unchallenged for nineteen years. Digene also points to evidence that Ventana previously attempted to obtain rights to the '332 patent, rather than challenge its validity.

Ventana, on the other hand, argues that it raises a "substantial question" concerning its license defense; thus, Digene does not have a likelihood of success on the issue of infringement. Ventana claims that the assignment of rights in the '332 patent is valid because the ICDR did not invalidate the Asset Purchase Agreement. In the alternative, Ventana argues that it is not bound by the ICDR award because it was not a party to the proceedings.

B. Irreparable Harm

Digene alleges that it will suffer irreparable harm without an injunction. According to Digene, while the matter was in arbitration, Ventana built a market presence by continually infringing the '332 patent, and therefore, Digene's exclusive position cannot be restored through a damage award after a competitor has entered the marketplace. Digene notes that currently approximately 50 accounts use Ventana's product rather than Digene's product.

⁵ D.I. 315 at 12-13. The ICDR panel determined that Beckman's purported assignment to Ventana, when viewed as a whole, violated the prohibition against further sublicensing under the CLA. Digene maintains that the ICDR opinion is binding on Ventana, although it was not a party to the arbitration. It contends that Ventana substantially participated the arbitration because its counsel, who, during the arbitration proceedings only, represented Beckman and presented an opening statement, examined and cross-examined witnesses and submitted post-hearing briefs. Ventana, however, vehemently disagrees that *it* participated in the arbitration proceedings in any capacity. D.I. 414 at 58-63.

Ventana counters that there is no irreparable harm because Digene delayed for five years in seeking a preliminary injunction and it dominates the market with respect to HPV sales. Ventana claims that Digene, though it had multiple opportunities to move for injunctive relief, failed to do so. As a result, Ventana maintains that Digene's delay and repeated failure to seek a preliminary injunction demonstrates an absence of irreparable harm. Moreover, Ventana notes that its sales have little or no effect on Digene's market share of 85-95% as shown by the evidence. Finally, Ventana claims that by licensing the '332 patent to four other entities, Digene has proven that money damages are adequate to compensate for any alleged infringement.⁶

Digene, in its reply, challenges Ventana's position of no irreparable harm simply because Digene is the dominant market player. Digene argues that because Ventana took opportunities – potential customers – from Digene, a monetary award alone is insufficient to compensate for lost customer relations, the ability to sell other products to that potential customer, and the impact of pricing negotiations related to having competition in the marketplace. It also claims that Ventana's allegation that it “sat on its rights” for five years is misleading. Digene posits that not seeking injunctive relief was appropriate based on its reasonable belief that the court lacked jurisdiction to resolve the issues between Digene and Beckman.⁷ Further, Digene claims that it was entitled to

⁶ Ventana points to a declaratory judgment action filed by Third Wave Technologies in 2005, asserting the claims of the '332 were invalid. D.I. 351, Ex. 41 (Third Wave Technologies' Complaint for Declaratory Action, at 3 ¶ 2). Digene and Third Wave settled their dispute whereby Third Wave dismissed its complaint, without prejudice, and agreed not to initiate another action for one year. Digene did not license the '332 patent to Third Wave. D.I. 352, Ex. 56 (S.E.C. Form 8-K Current Report for Digene Corporation, filed Jan. 11, 2006). The parties announced the agreement on January 13, 2006; thus, the one year hiatus ends (January 2007) prior to the expiration of the '332 patent, in May 2007.

⁷ Digene added Beckman as a defendant in 2002.

explore other legal options during the pendency of the Beckman arbitration.

In response, Ventana suggests that Digene's argument of lost customer relations is insufficient to establish irreparable harm because Digene has not specifically identified any lost sales. Moreover, Ventana reiterates that Digene has not presented a legitimate excuse for its delay in seeking a preliminary injunction and such a delay indicates the absence of irreparable injury.

III. STANDARD

The grant or denial of a preliminary injunction under 35 U.S.C. § 283 in a patent infringement case is within the sound discretion of the district court.⁸ Section 283 permits the court to grant injunctions "in accordance with principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable."⁹ The moving party must establish four factors to obtain a preliminary injunction: (1) likelihood of success on the merits of infringement; (2) irreparable harm in the absence of an injunction; (3) consideration of the balance of hardships tipping in its favor; and (4) favorable impact on the public interest.¹⁰

Each of these factors, when taken individually are not dispositive; rather, the district court must weigh each factor against the other factors and against the form and magnitude of the relief requested.¹¹ The movant, in seeking a preliminary injunction pursuant to § 283, must demonstrate both a reasonable likelihood of success on the

⁸ *Polymer Technologies, Inc. v. Bridwell*, 103 F.3d 970, 973 (Fed. Cir. 1996).

⁹ 35 U.S.C. § 283.

¹⁰ *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001).

¹¹ *Hybritech, Inc. v. Abbott Laboratories*, 849 F.2d 1446, 1451 (Fed. Cir. 1988).

merits and irreparable harm.¹² The reasonable likelihood of success on the merits encompasses two components: (1) plaintiff will likely show that its patent is infringed; and (2) any challenges to the validity and enforceability of the patent “lack *substantial merit*.”¹³ A movant who clearly establishes a reasonable likelihood of success on the merits receives the benefit of the presumption of irreparable harm.¹⁴ This presumption does not override the evidence on record; rather, it merely shifts the burden of production with respect to the question of irreparable harm onto the alleged infringer.¹⁵ A movant, however, who cannot establish *both* likelihood of success on the merits and irreparable harm cannot be granted a preliminary injunction.¹⁶

IV. ANALYSIS

A. Likelihood of Success on the Merits

Infringement

In determining whether a preliminary injunction should be granted, a patentee is not required to prove infringement beyond all question; rather, there must be a likelihood that the moving party will meet its burden at trial of showing infringement.¹⁷

Digene contends that Ventana’s manufacture, use and sale of HPV 35 probes

¹² *Reebok Int’l Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1555-56 (Fed. Cir. 1994).

¹³ *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1366 (Fed. Cir. 2001) (emphasis added).

¹⁴ *H.H. Robertson Co. v. United Steel Deck, Inc.*, 820 F.2d 384 (Fed. Cir. 1987).

¹⁵ *Roper Corp. v. Litton Sys., Inc.*, 757 F.2d 1266, 1272 (Fed. Cir. 1985).

¹⁶ *Reebok Int’l Ltd.*, 32 F.3d at 1555-56.

¹⁷ *H.H. Roberston Co.*, 820 F.2d at 390.

infringes the '332 patent. Digene primarily focuses on Ventana's license defense as void because of the ICDR's conclusion which invalidated the attempted assignment of rights from Beckman to Ventana in the '332 patent. Digene also argues that the ICDR's decision is binding on Ventana and precludes it from asserting that it holds a valid license, relying on *Montana v. United States*¹⁸ and *Caterpillar Tractor Co. v. International Harvester Co.*¹⁹

Ventana first argues that the ICDR did not invalidate the APA, and therefore, it has a valid license. In the alternative, Ventana argues that the ICDR award is not binding against it. As evidence, Ventana points to its motion to intervene, which was subsequently denied upon Digene's objection to Ventana's participation in the arbitration proceedings. Moreover, it claims that the mere fact that Mr. Shulman, counsel to Ventana in the district court proceedings, represented Beckman at the arbitration is insufficient to establish "substantial participation" because Beckman was free to hire the counsel of its choice. Further, Ventana asserts that Mr. Shulman, as counsel for Beckman, did not present evidence or make arguments on Ventana's behalf. Ventana also submits that a contractual provision with Beckman, formed at the time of the 2002 APA agreement, which requires it to reimburse expenses incurred in the arbitration, is irrelevant because Ventana itself was precluded from participating in or presenting a defense.

Although the ICDR concluded that the CLA allowed Beckman to assign its rights

¹⁸ 440 U.S. 147 (1979).

¹⁹ 120 F.2d 82, 84-85 (3d Cir. 1941).

in the '332 patent, in its review of the various components of the complete transaction with Ventana, including the APA, the SLA and the Side Letter Agreement, the ICDR determined that their entire transaction violated the CLA's prohibition against further sub-licensing.²⁰ Therefore, the specific issue of whether Beckman's purported assignment of its rights to Ventana violated the terms of the CLA, was decided by the ICDR.²¹ The ICDR's determination that the purported assignment between Beckman and Ventana as invalid is final and binding between Digene and Beckman under the terms of the CLA.²²

Digene's reliance on *Montana v. United States* and *Caterpillar Tractor Co. v. International Harvester Co.* is misplaced. In *Caterpillar*, the plaintiff initially sued the defendant's dealer, who sold tractors manufactured by International for infringement of its patents.²³ In the first action, International admittedly retained counsel to defend the

²⁰ D.I. 317, Ex. B at 74.

²¹ D.I. 317, Ex. B at 71, 74. Beckman requested the ICDR to determine the validity of the assignment to Ventana. In reaching its conclusion that the assignment was invalid, the ICDR found that Beckman did not have the right to sell cell paste under the CLA and the SLA. The ICDR also examined the Side Letter Agreement between Beckman and Ventana, which allowed Ventana to sell the paste to Beckman and found that the Letter Agreement was an impermissible sub-license. Even though the ICDR concluded that the CLA gave Beckman the right to assign, the ICDR ultimately concluded that the total transaction constituted a sub-license and not an assignment. As such, the entire transaction violated the provisions against sub-licensing. However, the International Chamber of Commerce ("ICC"), in an arbitration involving IP, Beckman and Ventana which concerned whether IP had standing to terminate the SLA on the basis of the APA, the SLA and Article 1134 of the French Civil Code, commented that the Side Letter Agreement "does not negate a real transfer of ownership and is not a disguised sublicense as alleged by Respondent [IP]." D.I. 317, Ex. B at 58.

²² D.I. 317, Ex. B at 2. The CLA compelled arbitration of disputes. Specifically, paragraph 11 of the CLA unambiguously requires that, "If such dispute or controversy cannot be settled by Agreement between the parties, it *shall be* submitted to arbitration pursuant to the rules of the American Arbitration AssociationThe decision of the arbitrator *shall be binding* upon the parties, and may be *entered as a judgment* by any court of competent jurisdiction." (emphasis added).

²³ *Caterpillar*, 120 F.2d at 84.

suit on the dealer's behalf to protect its own interests and furnished documents and other evidence in preparation of litigation.²⁴ In a second suit, the plaintiff alleged that International was the real party-defendant in the original action brought against the dealer.²⁵ International claimed that it was not bound by principles of collateral estoppel unless the plaintiff knew of its participation.²⁶ The United States Court of Appeals for the Third Circuit squarely rejected International's position and held that International was a "secret adversary" in the initial proceedings and should be estopped in the subsequent suit because it clearly was an adversary.²⁷

In support of its argument, Digene paraphrases a footnote in *Caterpillar* which is irrelevant to the final disposition, wherein the Third Circuit, after concluding that the defendant could not relitigate the issues raised in the initial suit, casually mentioned a then *preliminary draft of the Restatement (Second) of Judgments*, which similarly analyzed the doctrine of collateral estoppel and its application to non-parties.²⁸

Digene also contends that the Supreme Court's decision in *Montana v. United States* prohibits Ventana from re-litigating the issues decided by the ICDR because its attorney, Mr. Shulman, served as counsel to Beckman during the arbitration proceedings and therefore, Ventana was fully represented though it was a not a party to those

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.* at 85.

²⁸ D.I. 315 at 12. A "non-party who *controls* litigation individually or in cooperation with others is bound by adjudications of litigated matters if he has the proprietary or financial interest in the determination." (citing *Caterpillar*, 120 F.2d at 85 n.5 (emphasis added)).

proceedings. The Supreme Court, in its analysis of the doctrine of collateral estoppel, held that

the persons *for whose* benefit and *at whose direction* a cause of action is litigated cannot be said to be “strangers to the cause . . . [or] one who assists in the prosecution or defense of an action aid of some interest of his own . . . is as much bound . . . as he would be if he had been a party to the record.”²⁹

In *Montana*, the Supreme Court determined that the United States, although not a party to the suit, was a “laboring oar” in conducting the prior state litigation, particularly since it reviewed and approved the complaints, paid the attorney’s fees and costs, directed the appeal from the state judgment, and appeared as amicus in the later proceedings.³⁰ Therefore, in a subsequent federal suit regarding the same issue, the United States was bound by the state court’s resolution of the issues.³¹

Digene’s argument that Ventana participated in the arbitration “through” Mr. Shulman, because of his representation of Beckman, is without merit. Issue preclusion, or collateral estoppel bars a potential claim if four requirements are met: (1) the issue decided in the prior adjudication is identical with the one presented in the later action, (2) there was a final judgment on the merits, (3) the party against whom collateral estoppel is asserted was a party or in privity with the party to the prior adjudication, and (4) the party against whom collateral estoppel is asserted had a full and fair opportunity to

²⁹ 441 U.S. at 154 (citing *Souffront v. Campagnie de Sucrieries*, 217 U.S. 475, 486-487 (1910)) (emphasis added).

³⁰ *Id.* at 155.

³¹ *Id.*

litigate the issue in question in the prior adjudication.³²

Even assuming that the issues presented are identical, the doctrine of collateral estoppel does not apply because the third and fourth requirements are not met in the present action. Of note, Ventana petitioned to intervene in the arbitration proceedings, asserting that it had a direct interest in those proceedings.³³ Digene, however, opposed Ventana's petition, and argued that Ventana had *no direct interest* in the arbitration because it was not a party to the CLA and that its interests would be adequately represented by Beckman.³⁴ When the ICDR denied Ventana's petition to intervene, it remarked that the impact, if any, of its decision on Ventana's rights is inherent any adjudication of contractual rights involving related agreements when "dual judicial tracks" are used.³⁵ More importantly, the ICDR noted in its final decision when it denied certain

³² *Witkowski v. Welch*, 173 F.3d 192, 199 (3d Cir. 1999) (citing *Restatement (Second) of Judgments* § 27).

³³ D.I. 351, Ex. 29 (Petition of Ventana Medical Sys., Inc. to Participate as a Party to the Arbitration).

³⁴ D.I. 351, Ex. 31 (Digene's Opposition to Ventana's Petition to Participate as a Party to the Arbitration). Actually, there have been three proceedings in total including the present matter. In the ICC and ICDR arbitration proceedings, certain parties to this case have litigated some, but not all, of the relevant agreements. Hence, the procedural morass which presently exists.

³⁵ D.I. 351, Ex. 34 at 2-3 (ICDR Ruling on Ventana's Petition to Participate as a Party). When the ICDR denied Ventana's Petition to Participate, it recognized the potential impact of its findings on Ventana and relied upon Digene's representation about its scope of relief.

[T]he question remains how far the Tribunal should venture in potentially granting relief to Digene that would directly affect the rights of a non-party to the arbitration under an agreement (the APA) to which Digene is not a party.

Digene recognized the concern about the scope of relief in its submission on the Petition. It *unequivocally* represented that "Digene *is not* asking this panel to make any finding or award as to the APA" and further quoted *its counsel's similar representation* to the Delaware Court. . . . (emphasis added).

relief requested by Digene:³⁶

[t]he first two post-hearing requests specifically seeking relief invalidating agreements to which Digene is not a party but to which Ventana – a non-party to the arbitration – is (namely the APA and the Manufacturing Agreement). *Digene had the opportunity to litigate fully* in this proceeding *issues involving* Ventana when the latter sought to participate as a party to the arbitration but, instead, Digene chose to oppose Ventana’s Petition . . .

In its post-hearing requests Digene attempts to honor the letter of [the ICDR’s prior] ruling by seeking invalidation of the purported “assignment” and other agreements between Beckman and Ventana without expressly naming the APA. However, the relief Digene requests would have the *direct, practical effect* of impairing the APA, *contrary to Digene’s representations*.³⁷

The ICDR acknowledged the possible preclusive effects of its decision on Ventana and, by limiting the relief requested by Digene, directly attempted to avoid that from occurring, and tacitly recognized that Ventana was denied the opportunity to fully and fairly litigate certain issues.

Although Ventana was contractually obligated to reimburse Beckman for attorneys’ fees and costs associated with the arbitration, that fact alone is not dispositive. In *Montana*, the United States’ direct, substantial involvement and participation in the original litigation, including the appeal process, made it in privity and provided it the full and fair opportunity to litigate the issues. There is no indication that Ventana itself, and not just its attorney, had any involvement in the preparation of Beckman’s defense or any part of the arbitration proceedings. In fact, as discussed

³⁶ The findings requested by Digene which the ICDR refused to address were for that Tribunal to invalidate the assignment to Ventana of Beckman’s right to the patents cross-licensed in the CLA and “any rights conveyed to Beckman” via the SLA and to invalidate the Manufacturing Agreement.

³⁷ D.I. 317, Ex. B at 61 (emphasis added).

above, there is significant evidence to the contrary that Ventana was either a party to the arbitration or in privity with Beckman during those proceedings or was allowed the full and fair opportunity to litigate any issue in the arbitration. Digene made a strategic decision to oppose Ventana's participation, a decision that was directly addressed by the ICDR and is not lost on this court. Therefore, based on the evidence, it cannot be said that the ICDR's decision has a preclusive effect on Ventana under the doctrine of collateral estoppel.³⁸

B. Irreparable Harm

Assuming *arguendo* that the presumption of irreparable harm applies, the court finds that Ventana has sufficiently demonstrated that there is an absence of irreparable harm.

Ventana offers two central arguments as to why Digene cannot establish irreparable harm: (1) Digene failed to seek injunctive relief for a period of five years, and (2) Digene's dominant market position and increasing sales were unaffected by Ventana's presence in the market. Digene responds that it exercised every reasonable step to prevent Ventana from marketing its infringing HPV products.

Ventana submits that Digene could have sought injunctive relief when it filed the original complaint in November 2001; in September 2002 when it amended the

³⁸Although the court has only addressed whether by operation of issue preclusion, Digene will likely show that its patent is infringed, in light of the findings herein, the court need not address whether any challenges to the validity and enforceability of the patent lack substantial merit. Where a preliminary injunction is denied, "the absence of an adequate showing with regard to any one of the four factors may be sufficient, given the weight or lack of it discretionarily assigned the other factors by the trial court, to justify the denial." *Reebok*, 32 F.3d at 1556. Since Digene must show both a likelihood of success on the merits *and* irreparable harm, a preliminary injunction may be denied in the absence of either of these two crucial factors. *Id.*

complaint to add Beckman as a defendant; or, in 2003 during discovery relating to the arbitrability of its claims against Beckman. Ventana also cites to Digene's motion to preliminarily enjoin Ventana from entering into any agreements with third parties concerning HPV products filed in October 2003. Further, Ventana points to Digene's representation to the court that the motion was "not seeking to preliminarily restrain Ventana's manufacture and sale of its [accused] . . . probe products" as evidence that Digene was not concerned about any alleged harm caused by Ventana's presence in the market place.³⁹

Digene counters that a preliminary injunction was not pursued in 2001 and 2002 because it believed that the FDA would "force Ventana's product off the market."⁴⁰ It relies on *Moltan Co. v. Eagle-Picher Indus.* to show that it did not "sit on its rights" as Ventana alleges.⁴¹ That argument is without merit. In *Moltan*, Eagle-Picher accused Moltan of false advertising and labeling and obtained a preliminary injunction against Moltan. On appeal, Moltan argued that laches barred Eagle-Picher from seeking a preliminary injunction because Eagle-Picher learned of the label changes at issue in 1992, but did not file a counterclaim until late 2003. In upholding the injunction, the Sixth Circuit affirmed the district court's finding of irreparable harm and commented that

³⁹ D.I. 350, Ex. 25 at 61:5-14 (Declaration of Roger J. Chin in Support of Ventana's Opposition to Digene's Motion for Preliminary Injunction) (Dep. Tr. [confidential 30(b)(6) witness] Sept. 22, 2006); D.I. 347 at 33-34.

⁴⁰ D.I. 375 at 23; D.I. 377, Ex. L at 19:1-13 (Dep.Tr. Digene's 30(b)(6) witness). The witness stated that "technically we could have filed a motion. We had other activities we thought would be successful and we thought this was a very straightforward case . . . [t]he Ventana product was not FDA approved . . . we had notified the [FDA] and we expected that the [FDA] would enforce their laws, enforce [sic] the Ventana product off the market." See *also*, D.I. 377, Ex. L at 27:3-11.

⁴¹ 55 F.3d 1171, 1176 (6th Cir. 1995).

“it would not ‘penalize’ the party seeking the injunction for attempting to use other avenues” to resolve the matter.⁴² In *Moltan*, the delay in filing for injunctive relief was less than 2 years after the action was filed. Insofar as Digene insinuates that it was merely “pursuing more economic avenues,” the court is unpersuaded.

The Federal Circuit has consistently recognized that a delay in seeking a preliminary injunction is a significant factor bearing on the need for it.⁴³ In the instant action, almost 58 months elapsed since Digene filed its initial complaint against Ventana before it filed a motion for a preliminary injunction. Therefore, even if the court accepts Digene’s proposition regarding the FDA, the record contains no plausible explanation why it continually opted not to file for a preliminary injunction until 2006. The deposition of a Digene 30(b)(6) witness referenced herein confirms that Digene sought focused relief in 2003 to prevent Ventana from entering into a deal with a larger, more sophisticated company. Digene fails to adequately explain why when seeking a more limited restraint in 2003, the irreparable harm it alleges is presently happening was not occurring before.

Further, when the period of time that this matter was stayed during the pendency of the arbitration proceedings is subtracted, the total elapsed time is almost 30 months. Digene never petitioned the court for a preliminary injunction *before* the order for

⁴² *Moltan Co.*, 55 F.3d at 1176. Eagle-Picher attempted to resolve its claims against Moltan through negotiations and by filing complaints with OSHA and other state agencies.

⁴³ *T.J. Smith & Nephew, Ltd. v. Consolidated Medical Equip. Corp.*, 821 F.2d 646, 648 (Fed. Cir. 1987); see also *High Tech Medical Instrumentation v. New Images Indus.* 49 F.3d 1551, 1557 (Fed. Cir. 1995) (stating that 17 months is a substantial period of delay that “militates against the issuance of a preliminary injunction” and shows that there is no apparent urgency to the moving party’s request for relief).

arbitration in 2004. Moreover, by opposing Ventana's petition to participate in the ICDR arbitration, Digene effectively delayed seeking such relief for the 19 months while that proceeding was pending. Delay for a significant period of time before seeking a preliminary injunction intimates that the *status quo* is not causing irreparable harm.

Second, Digene proposes that it did not pursue injunctive relief after joining Beckman as a defendant because the "possibility of arbitration created a question about whether this Court had jurisdiction to resolve issues in the case."⁴⁴ Digene's argument is belied by the fact that in October 2003, Digene filed a motion *with this court to enjoin* Ventana from entering into agreements for its HPV products with third parties.⁴⁵ For Digene to question *this court's* jurisdiction over the arbitration issue in 2002, but then in late 2003, file a motion with the *same* court to limitedly enjoin Ventana, is wholly contradictory and undermines its position. Simply put, Digene could have, but voluntarily chose not to, seek injunctive relief to prohibit Ventana from making and selling the accused products. Moreover, Digene's reliance on an unsupported, ad-hoc explanation, that it sought "narrow relief to allay any concerns that the Court might have that Digene was asking it to resolve the complicated issues that were bound up in the question of whether arbitration was necessary" is equally unpersuasive.⁴⁶

Ventana also posits that Digene "so thoroughly" dominates the market that its

⁴⁴ D.I. 375 at 23.

⁴⁵ D.I. 347 at 34. Ventana also relies on testimony, which indicates that the irreparable harm Digene sought to avoid through the 2003 motion was the introduction of new competitors in the HPV market. Digene could have, but did not, ask the court to prohibit Ventana from infringing through its HPV products.

⁴⁶ D.I. 375 at 24 n.13. Frankly, the manner in which Digene approached the ICDR arbitration proceedings has put the court in the middle of those "complicated issues . . . bound up" in arbitration.

sales have little or no effect on Digene's market share. Ventana directs the court to *Rosemount Inc. v. United States International Trade Comm.*,⁴⁷ and *Nutrition 21 v. Thorne Research, Inc.*⁴⁸ In *Rosemount*, the Federal Circuit upheld the International Trade Commission's holding that the presumption of irreparable harm had been rebutted by evidence of Rosemount's delay in bringing the action, its large market share, the presence of twelve other non-infringing competitors in the market, and the availability of a damage remedy.⁴⁹ As evidence of Digene's position in the HPV market, Ventana points to the substantial growth in Digene's annual sales which have occurred since 2001.⁵⁰ Digene's annual sales in 2001 were reported as \$18 million, while Ventana sales were \$394,0000. By 2006, Digene's annual sales had burgeoned to \$134 million, a average growth rate of approximately 125% per year, while Ventana's share in the sales of HPV products total less than \$6 million, around 4% of Digene's sales.

Digene's contention of Ventana causing possible loss of customer relations or effect on its market share is speculation. The sales numbers show continued, substantial growth by Digene in the HPV market. Moreover, as noted in *Nutrition 1*, "reliance on possible market share loss would apply in every patent case where the patentee practices the invention," and is not justification for the extraordinary relief of a preliminary injunction.⁵¹ "[T]here is no presumption that money damages will be

⁴⁷ 910 F.2d 819, 821 (Fed. Cir. 1990).

⁴⁸ 930 F.2d 867 (Fed. Cir. 1991).

⁴⁹ *Rosemount*, 910 F.2d at 821.

⁵⁰ D.I. 414; D.I. 347 at 36.

⁵¹ 930 F.2d at 871.

inadequate in connection with a motion for injunction pendente lite.⁵² “The availability of damages is particularly significant,” since Digene has not shown any specific interest that needs protection through a preliminary injunction.⁵³ There is no evidence that money damages are not available or potentially recoverable against Ventana. As a result, the court finds that irreparable harm is not substantiated.⁵⁴

V. CONCLUSION

For the reasons contained herein, IT IS ORDERED and ADJUDGED that Digene’s motion for a preliminary injunction (D.I. 314) is DENIED.

Date: May 9, 2007

/s/ Mary Pat Thyng

UNITED STATES MAGISTRATE JUDGE

⁵² *Id.* at 872.

⁵³ *High Tech Medical Instrumentation, Inc.*, 49 F.3d at 1556.

⁵⁴ As noted previously herein in footnote 36, the court need not analyze the remaining two factors for a preliminary injunction since Digene has not established a likelihood of success on the merits and irreparable harm.