

Thynge, Magistrate Judge

I. INTRODUCTION

In July 2002, this court issued a claim construction opinion after a *Markman* hearing¹ held in May 2002. In November 2002, a trial was held on the patent infringement dispute between Genzyme and Atrium over designs for pulmonary drainage devices. Genzyme sued for damages for the marketing and sale of Atrium's "OASIS" and "EXPRESS" devices, which allegedly infringed Genzyme's "Elliot patents" (U.S. Patent Nos. 4,544,370; 4,715,856; 4,747,844 and 4,822,346) and its "D'Antonio patent" (U.S. Patent No. 4,899,531). Both parties reserved the right at the close of evidence to have the court make a determination of certain issues of law and fact after the jury verdict. After an eight day trial, the jury found that Atrium did not infringe any claims of the patents-in-suit and that all patents-in-suit were invalid.

Presently before the court are post trial motions for a new trial on the defense of laches, for judgement as a matter of law on validity and infringement of both the Elliot and D'Antonio patents and an award for damages. D.I. 284. This opinion is directed only to Atrium's laches motion. D.I. 282.

II. BACKGROUND

A. The Chronology of Events

Knowledge of Competitive Devices and Product Introduction

In 1989, Deknatel released the "first" pulmonary drainage device using a dry

¹*Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970-71 (Fed. Cir. 1995). For a more complete review of the asserted claims of the D'Antonio and Elliot patents, see the court's claim construction opinion, *Genzyme v. Atrium*, 212 F. Supp.2d 292 (D. Del. 2002). The description of the claims in this opinion cover only those claim limitations that are germane to the current motion addressed by the court.

suction regulator based on the technology outlined in the '531 D'Antonio patent. D.I. 269 at 576. This patent application was filed in August 1986, and issued in December 1989. In September 1991, Atrium began development of its OASIS chest drainage device with knowledge of the D'Antonio patent. D.I. 272 at 1940 - 1942. During the research and development phase, Atrium sought the opinions of two law firms with regard to potential infringement of the patent. D.I. 272 at 1956 -1957. In the Spring of 1996, Atrium released the OASIS device and in May 1996, Deknatel approved a competitive testing protocol which specified Atrium's new OASIS device. Deknatel obtained an OASIS device and analyzed it. D.I. 269 at 512 - 513. Thereafter, a recommendation was made to Deknatel management concerning the review of the OASIS device and the D'Antonio patent. D.I. 269 at 516.

In the same year, Genzyme acquired Deknatel and the patents-in-suit.² Shortly after this acquisition, Genzyme introduced its SAHARA device, incorporating technology from the Elliot patents, which it believed would render the OASIS device obsolete. D.I. 269 at 518. In the Fall of 1997, after a corporate reorganization, a new manager joined Genzyme's R&D and in 1998, that manager was advised that Atrium's OASIS product infringed. At that time, Genzyme started to "think seriously" about infringement. D.I. 268 at 336 - 337 and 381. Through information from an industry research report, Genzyme concluded that OASIS sales of 67 thousand units in 1997 accounted for nearly \$900,000 in lost profits. During 1998, OASIS sales nearly doubled to

²The acquisition included the Elliot patents, as well. The '370 patent was filed in May 1982 and issued in October 1985. The '856 patent was filed in August 1985 and issued in December 1987. The '844 patent was filed in September 1986 and issued in May 1988. The '346 patent was filed in April 1988 and issued in April 1989.

approximately 130 thousand units. As a result, Genzyme announced in a 1999 report to shareholders that Atrium was a competitor who hurt performance and sales. D.I. 271 at 1573 - 1574. In 2000, Atrium introduced the EXPRESS device which Genzyme viewed as “knock-off” of its SAHARA device and infringed the Elliot patents. D.I. 268 at 400. After losing over \$2 million in profits to OASIS sales (170,000 units) in 1999, and the prospect of new competition from the EXPRESS product, Genzyme determined that no other alternative existed and filed suit. D.I. 268 at 336.

In November 2000, Genzyme filed this action against Atrium alleging that its OASIS and EXPRESS products infringed the D’Antonio and Elliot patents. During trial, Atrium moved, pursuant to Fed. R. Civ. P. 52 and 58, for judgement in its favor on sales of its OASIS product prior to November 14, 2000, relying on the equitable doctrine of laches. The court reserved decision until after post trial briefing was completed.

B. The Technology

The Elliot Patents

Chest drainage devices remove fluid and air from a patient’s chest cavity through the use of vacuum suction. Body fluids are drained through a tube into a collection chamber within the device. Because of the negative pressure exerted on the device when a patient inhales, proper operation requires the use of one-way “valves” to prevent the reverse flow of collected fluids. Prior art devices used a water column to act as a one-way valve or “water seal” to prevent reverse flow. The Elliot patents disclose a “waterless” (or “dry”) device that replaces water seals with a mechanical one-way valve. The patents further disclose a number of pressure relief and control valves to

allow for accurate pressure regulation and reverse flow protection.

The D'Antonio Patent

Chest drainage devices that used water columns as one way valves to prevent the flow of fluid back into the patient also act to regulate the suction applied to the patient by preferentially allowing air from the atmosphere into the suction and collection chambers. Medical personnel would regulate the suction by varying the amount of water in U-shaped tubes within the device. Instead of employing a water-based control mechanism, the D'Antonio patent utilizes mechanical valves that “self-adjust” to regulate the pressure in the suction chamber. This is accomplished, in part, by a gas port closing member positioned between the vacuum and collection chambers within the device.

III. Laches

The law on laches is rooted in the equitable principle that courts will not assist one who has “slept on his rights.” *Jarrow Formulas, Inc. v. Nutrition Now, Inc.* 304 F.3d 829, 835 (9th Cir. 2002). In the interest of fairness and equity, those who are granted a monopoly under the patent system have an obligation to enforce their rights in a timely manner. *Advanced Hydraulics, Inc. v. Eaton Corp.*, 415 F. Supp. 283, 286 (N.D. Ill. 1976). Laches protects a potential infringer from unfair damage claims resulting from the intentional or neglectful delay of a patent holder to file suit. Two elements underlie this defense: (a) the patentee's delay in bringing suit was unreasonable and inexcusable, and (b) the alleged infringer suffered material prejudice attributable to the delay. *Bayer AG v. Sony Electronics, Inc.*, 229 F. Supp.2d 332, 366 (D. Del. 2002).

Delay in Bringing Suit

Laches, as defined under 35 U.S.C. § 282 (1988), is an equitable defense to a claim for patent infringement. This provision in the Patent Act bars recovery of damages for any infringement committed more than six years prior to the filing of the complaint or a counterclaim for infringement. Courts have almost unanimously “borrowed” this six year time provision in order to protect a potential infringer from damages due to either the intentional or negligent delay of a patent holder in bringing suit. This period can be described as the “reasonable” period required to create a presumption of laches. It begins when the patentee knew or should have known of the alleged infringer's activity. The presumption of six years “represents an equitable balancing of the interests of the parties.” *A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020, 1035 (Fed. Cir. 1992). It also represents the point at which the burden of proof shifts from the defendant to the plaintiff. A six-year delay requires the patentee to rebut the presumption of laches. But where the delay is less than six years, no presumption operates, and an accused infringer relying on laches must demonstrate the existence of both elements, namely, inexcusable delay and resulting prejudice. *Id.* at 1034-1037.

The degree of infringement may be relevant to the issue of when the period of delay begins. See, *Lever Bros. v. Procter & Gamble Distributing Co.*, 668 F. Supp. 924 (D. N.J. 1987). A delay of less than 6 years in bringing an infringement action has been excused where the infringer's actions are not commercially significant. *Illinois Tool Works Inc. v. Grip-Pak, Inc.*, 725 F. Supp. 951, 953 (N.D. Ill. 1989). In *ITW*, the

patentee waited 5 years to determine whether it would be economically prudent to initiate an action against Grip-Pak, an infringer. The court determined that patent owners are not expected to incur considerable expense to silence commercially insignificant infringers. In a similar finding, the court in *Mead Digital Systems, Inc. v. A.B. Dick Co.*, 521 F. Supp. 164, 183 (S.D. Ohio 1981) found that a 3 year wait to file suit *after* the infringer reached *profitability* was not unreasonable.

Finally, the court will consider these factors, the evidence, and other relevant circumstances to determine whether equity should intercede to bar pre-filing damages. “Laches is not *established* by undue delay and prejudice. These factors merely lay the foundation for the trial court's exercise of discretion.” *Aukerman*, 960 F.2d at 1036. Ultimately, it is within the court's prerogative, based on its evaluation of all relevant evidence, to determine whether a delay of fewer than 6 years is unreasonable or inexcusable.

Material Prejudice

In order to satisfy the second element of laches, a defendant must prove that he suffered material prejudice attributable to the delay. Material prejudice is defined to be either economic or evidentiary prejudice. See *Pappan Enterprises, Inc. v. Hardee's Food Systems, Inc.*, 143 F.3d 800, 804 (3rd Cir. 1998). Economic prejudice requires a change in the economic position of a defendant as a result of delay, while evidentiary prejudice arises when a defendant is impeded from presenting a full and fair defense on the merits. See *Bayer*, 229 F. Supp.2d at 366.

Economic Prejudice

To establish economic prejudice, a change in the economic position of the alleged infringer during the period of delay must have occurred. See *Aukerman*, 960 F.2d at 1033. "The change must be *because of and as a result of* the delay, not simply a business decision to capitalize on a market opportunity." *Hemstreet v. Computer Entry Systems Corp.*, 972 F.2d 1290, 1294 (Fed. Cir. 1992) (emphasis added). Therefore, economic prejudice is shown by evidence of either loss of investment expenditures or damages from increasing sales which might have been prevented by the institution of an earlier suit. *Aukerman* and *Hemstreet* make it clear that damages or monetary losses must be, "because of and as a result of" the delay. In order for this required nexus to exist, the defendant must have had reason to believe that the patentee did not intend to file suit for infringement. *ABB Robotics, Inc. v. GM Fanuc Robotics Corp.*, 828 F. Supp. 1386, 1395 (E.D. WI. 1993). See also, *Mead Digital Systems, Inc. v. A.B. Dick Co.*, 723 F.2d 455 (6th Cir. 1983) (a three-year wait to file suit after an infringer achieved profitability is not unreasonable); *E.I. du Pont de Nemours & Co. v. Polaroid Graphics Imaging, Inc.*, 706 F. Supp. 1135 (D. Del. 1989) (where the court found that it was not unreasonable for Dupont to notify Polaroid of infringement until it was economically worthwhile to file suit).

Evidentiary Prejudice

Evidentiary prejudice arises where the "defendant's inability to present a full and fair defense on the merits due to the loss of records, the death of a witness, or the unreliability of memories of long past events . . ." undermines the court's ability to judge facts. *Aukerman*, 960 F.2d at 1033. When a party has met its burden of production, "the presumption evaporates" with respect to evidentiary prejudice. *Id.*

Thus, for laches, the length of delay, the seriousness of the prejudice or harm suffered, the justification for the delay, and the defendant's conduct or culpability must be weighed to determine whether the patentee dealt unfairly with the alleged infringer by not promptly bringing suit. In sum, a court must weigh all pertinent facts and equities in making a decision on the laches defense.

IV. DISCUSSION

Parties Positions

Unreasonable Delay

Atrium claims that Genzyme's 4½ year delay in filing claims of infringement on the D'Antonio patent is unreasonable since Genzyme had notice of the potential infringement in 1996 and failed to notify Atrium of its intention to file suit. Atrium further argues that there is direct evidence of Genzyme's intention to file suit, as evidenced by the relevant documents unearthed during discovery. Atrium implies in its argument that Genzyme has an affirmative duty to inform, and that its failure to do so was unreasonable. Atrium cites *Odetics Inc. v. Storage Tech. Corp.*, 919 F. Supp. 911 (E.D. Va. 1996) as a case where the court found that 3 year delay was unreasonable. Atrium further relies on *Bott v. Four Star Corp.*, 807 F.2d 1567 (Fed. Cir. 1986) (defining constructive notice) and *Gallier v. Cadwell*, 145 U.S. 368 (1862) (determining that reasonableness depends on the circumstances) and several other cases where a delay shorter than six years was found to be unreasonable.

Alternately, Genzyme asserts that, as pronounced by the Federal Circuit, delays of less than 6 years are not unreasonable. In support of its position, Genzyme relies on

Meyers v Asics Corp., 974 F.2d 1459 (Fed. Cir. 1990) (where a 5½ year delay was not unreasonable), *Gasser Chair Co. v. Infanti Chair Manufacturing Corp.*, 60 F.3d 770 (Fed. Cir. 1995) and *Hall v. Aqua Queen Manufacturing Inc.*, 93 F.3d 770 (Fed. Cir. 1996) (delays of 5 or more years were not unreasonable). According to Genzyme, Atrium has an affirmative obligation to prove that a 4½ year delay is unreasonable and has failed to do so. Genzyme “blends” these arguments with the principles of equitable estoppel to support its position that a delay of less than 6 years is unreasonable only when a patent holder misleads a potential infringer into believing that it is “safe from suit.”

Genzyme’s delay in bringing suit was not unreasonable. In contrast to *Bott* and *Odetics*, actual or constructive notice of potential infringement and the delay in bringing suit is not in dispute. At issue, here, is whether the 6 year guideline set forth in previous opinions is reasonable under the circumstances. See *Aukerman*, 960 F.2d at 1033. In the majority of cases, while a patent holder is under an obligation to bring suit in a timely manner, a 6 year wait is reasonable. In contrast, where a patent holder was found to have clearly mislead an infringer and its reliance ultimately led to material prejudice, the courts have applied equitable estoppel and ruled that a time period of less than 6 years was unreasonable. See *Wafer Shave, Inc. v. Gillette Co.*, 857 F. Supp. 112 (D. Mass. 1993) and *Digital Sys. Int’l. v. Davox Corp.*, 1993 WL 664647 (W.D. Wash. July 1, 1993). Although equitable estoppel has not been directly raised, its application has been cited in defense of laches claims and should be considered herein. See *Odetics*, 919 F. Supp. at 923 (where intentional delay caused evidentiary prejudice).

While providing notice to an infringer may be the typical start to licensing

negotiations, it is not required to excuse delay associated with initiating an infringement suit. *Odetics*, 919 F. Supp. at 921. This court is unable to find an authoritative or reasonably persuasive source which would require the conclusion that Genzyme was under an affirmative duty to disclose future plans to file suit.³ In fact, it would be illogical for companies in a highly competitive market to provide this information in advance, particularly in the absence of any intent to license intellectual property.

In conclusion, Genzyme's 4½ year delay in bringing suit is within the range set forth in the majority of cases. Its conduct is consistent with the "borrowed" statutory guideline set forth under 35 U.S.C. § 282, and the principles set forth under equitable estoppel, and is not unreasonable based on lack of notice.

Inexcusable Delay

While the court agrees that a patent holder has an obligation to enforce its rights in a timely manner, applying this concept in equity should only bar a plaintiff whose "institution of the action was inexcusably delayed." *Advanced Hydraulics, Inc. v. Eaton Corp.*, 415 F. Supp. 283, 286 (N.D. Ill. 1976).

Atrium argues that no reasonable excuse for the 4½ year delay has been offered by Genzyme, particularly since it did not lack the necessary financial resources to pursue a claim, was not preoccupied with other litigation, nor involved in licensing negotiations. Genzyme's excuse that litigation is a "painful and crude alternative" is a *non sequitur* since it enthusiastically pursued litigation four years later. Further, delaying litigation until Atrium's EXPRESS product was introduced does not make

³Nothing cited by Atrium is authoritative for this proposition.

sense since it only constitutes a small portion of the revenues lost compared to the losses incurred due to the OASIS product.

Contrary to Atrium's position, Genzyme presents several valid reasons for its delay. According to the testimony, Genzyme underwent a change in management during the relevant time period. As a result, litigation remained a low priority until the "dust settled." Delay to minimize litigation costs and to combine litigation against one potential infringer is appropriate. Similarly, in *ITW*, the court found "ripeness" to be a reasonable excuse for delay. "Patent owners are not expected to incur such large costs to silence commercially insignificant infringers." *Id.* at 953. While a court cannot precisely define when a sum or percentage of sales reaches "commercial significance" in every circumstance, based on the evidence, Genzyme initiated suit when it was compelled to do so by weighing the cost of litigation with the risk of potential losses by the introduction of Atrium's EXPRESS product. Waiting until litigation makes clear economic sense is reasonable. Interestingly, Atrium supports this conclusion by its argument that large, publically-held corporations move more slowly in the decision-making process than smaller, privately-held companies.

Material Prejudice

Economic Prejudice

Atrium claims that, while Genzyme delayed, there was 30 fold increase in sales of its OASIS product, that Genzyme knew of this increase, and as a result, intentionally procrastinated to cause greater economic harm to Atrium. The thrust of

this argument is that Genzyme “laid in wait” for damages to build, while providing no notice to Atrium of its intention to file suit. *Raber v. Pittway Corp.*, 1994 WL 374542 (N.D. Cal. July 11, 1994). Further, since Genzyme had market share information (IMS data), it had knowledge of Atrium’s product sales, and acted upon that knowledge by deferring suit. In support of this argument, Atrium relies on the *Aptargroup*, *Manus* and *Digital Systems*⁴ cases where sales and damages increased during the time when a patent holder might have filed suit. In those cases, the *potential* for damages during the period of delay was enough to support a finding of laches. *Actual* damages were not required.⁵

Genzyme argues that there is no reason to believe that Atrium would have changed its conduct as a result of being notified of potential infringement. Economic prejudice is shown by evidence of either loss of investment expenditures or damages (from increasing sales) which might have been prevented by an earlier suit. As a result, to prove economic prejudice necessarily requires Atrium to produce facts that, for example, show expenditures made in reliance upon Genzyme’s inaction. Genzyme points out that Atrium continued selling the OASIS device and developed new devices based on its original design *after* this action was filed. In addition, the testimony establishes that Atrium believes that it is not infringing the D’Antonio patent. Further, mere proof of investment in research and development and increased sales, in and of

⁴*Aptargroup Inc. v. Summit Packing Sys., Inc.*, 1996 WL 114781 (N.D. Ill. March 14, 1996); *Manus v. Playworld Systems, Inc.*, 893 F. Supp. 8 (E.D. Pa. 1995); *Digital Sys. Int’l., Inc. v. Davox Co.*, 1993 WL 664647 (W.D. Wash. July 1, 1993).

⁵*Aptargroup*, 1996 WL 114781 at *9; *Manus*, 893 F. Supp. at 10; *Digital*, 1993 WL 664647 at *3-*4.

themselves, are not evidence of economic prejudice. Genzyme also contends that Atrium fails to provide a “causal nexus,” the connection between the patent holder’s actions and the change in the economic position of the alleged infringing party, during the period of the delay. Thus, Atrium’s knowledge of its potential infringement and its continued infringement after suit reinforces Genzyme’s position.

Atrium did not suffer economic prejudice during the 4½ years that Genzyme waited to file this action for infringement. To demonstrate the impact of delay on its unit sales, Atrium compares the sales of its OASIS product (30 fold increase over 4½ years) to the *Raber* and *ABB* cases, which, respectively, involved a six- and three-fold increase. In *Raber*, the delay of 11 years in filing suit was clearly beyond the six year limit for a presumption of laches. In that case, there was both intentional delay and acquiescence on the part of the patent holder, which created a presumption of laches by shifting the burden of proof and by raising an assumption of material prejudice. In *ABB*, the defendant’s (Fanuc) sales tripled over 5 years. However, the court found evidence that if Fanuc had knowledge of ABB’s intentions to file suit, it would have modified its conduct. *Id.* at 1397. In addition, there was evidence that ABB led Fanuc to believe that it would license the technology, but then delayed doing so. ABB failed to offer evidence to rebut the presumption of economic prejudice, and the court found the defense of laches to be valid.

There is no similar delay in this case, and therefore, no shift in the burden of proof nor assumption of material prejudice. In contrast, Atrium has failed to offer any evidence to suggest that it considered altering its business strategies or operations as a result of Genzyme’s action or inaction. Further, Genzyme did not induce Atrium into

believing that a license was imminent, only to delay and then file suit 4½ years later.

The law protects the potential infringer from economic hardships due to intentional or negligent delay by the patent holder who neither informs of infringement nor files suit. The underlying reasoning behind this element is to protect an infringer, who is ignorant of his potential infringement. Here, Atrium had reason to believe that it would be sued by Genzyme for infringement as shown by the evidence at trial.⁶

Moreover, although Atrium's sales significantly increased during the 4½ year period, exponential growth in product sales are a normal consequence of new product introduction. Between 1998 and 1999, when Genzyme focused on the impact of OASIS sales, the growth in those sales was far less than the thirty-fold increase that Atrium contends. A more accurate number is approximately a thirty *percent*, or roughly one-third, increase. Further, the testimony reveals that Genzyme did evaluate sales of the OASIS product and their effect and filed suit when it made economic sense. Efficiency and economy resulted in combining the claims for infringement on both the D'Antonio and Elliot patents.

Despite Atrium's contention that a large, financially successful corporation should be less concerned about the economic impact of litigation and, therefore, should not delay filing a claim, it does not make economic sense for a company to hastily rush into litigation over losses to a competitor which are less than 1.2% of its overall revenues.⁷ Equity notwithstanding, applying significantly different standards to small and large

⁶ Atrium admitted to reviewing the D'Antonio patent and Genzyme's Pleur-Evac A-6000 device. D.I. 272 at 1937 - 1943. Atrium sought the opinion of two law firms on potential infringement. D.I. 272 at 2085 - 2091.

⁷In 1998, Genzyme's annual revenues were approximately \$560 million, while Atrium's OASIS sales were approximately \$6.3 million.

corporations is not reasonable in determining when the obligation to file suit exists. In addition, courts have held that an individual plaintiff could reasonably delay bringing suit until he could determine that the possible infringement made litigation “monetarily ripe.” *Tripp v. U.S.*, 406 F.2d 1066, 1071 (Ct. Cl. 1969) (where plaintiff waited 5 years after advising the United States government of infringement). In contrast, courts have not found delay in excess of six years to be reasonable, where there was insufficient evidence to support the argument of lack of “ripeness.” See *Cooper v. North American Phillips Corp.*, 1989 WL 205666 (D. Alaska 1989) and *Jensen v. Western Irr. and Mfg., Inc.*, 650 F.2d 165, 168 (9th Cir. 1980). In conclusion, there is ample evidence that Genzyme waited for the matter to be economically justified prior to filing suit. Moreover, the delay here was less than the prescribed 6-year period.

Evidentiary Prejudice

Atrium claims that the jury made its decision under several evidentiary handicaps that prevented a full and fair presentation of its defense on the merits. The basis for this claim is that several important witnesses were unavailable or failed to remember key events that would have “further debunked” Genzyme’s copying allegations and its arguments regarding the scope of the claims of the patents-in-suit. Atrium asserts that the advanced age and ill health of one of its key witnesses prevented him from appearing in court, and required his video-taped deposition be taken. Therefore, the delay caused a prejudicial evidentiary presentation to the jury.

Genzyme responds that video-taped depositions are not prejudicial, and that Atrium could have subpoenaed witnesses that they claimed were unavailable. Citing *Aukerman*, Genzyme further asserts that Atrium must demonstrate how unavailable

evidence was important to its defense. *Id.* at 1034. Since Atrium has failed to meet this requirement, it has not established evidentiary prejudice.

This court finds that 4½ year delay in filing suit did not substantially contribute to evidentiary prejudice against Atrium. A witness's failure to remember specific past events is not, in and of itself, indicative of evidentiary prejudice. Here, no evidence has been presented suggesting that, due to delay, either the destruction of records or incapacity of witnesses vital to Atrium should compel this court to find such prejudice. Records disclosed during discovery adequately support the positions of both parties. While it is difficult to determine what allegedly "missing" information would impact a jury's decision, juries are expected to weigh a witness's inability to remember, along with the other information presented, to determine the facts. Further, neither party in this action legitimately complained during the pretrial conference nor in their pretrial motions that they were unable to obtain necessary information due to delay to prepare their case.

Further, the burden of proof falls on Atrium to clearly establish how unavailable evidence would be important to its defense. Atrium has failed to demonstrate to the court that the delay prevented it from presenting a full and fair defense on the merits.

V. Conclusion

In conclusion, based on the above analysis, Genzyme's delay in bringing suit was not unreasonable or inexcusable, and thus Atrium suffered no material prejudice attributable to the delay. As a result, Atrium's motion on the defense of laches (D.I. 282) is DENIED.