

SLEET, District Judge.

I. INTRODUCTION

Stamicarbon BV (“Stamicarbon”) filed this action against Sepracor, Inc. (“Sepracor”) in January 1997. This case arises from an interference proceeding before the United States Patent and Trademark Office (“PTO”), which was held to determine whether Stamicarbon or Sepracor was the first to invent in the United States a method of synthesizing certain compounds that are used as intermediates in making the drug diltiazem. In its complaint, Stamicarbon asks the court to determine, pursuant to 35 U.S.C. § 146,¹ whether a ruling by the PTO in the interference action was erroneous.

Presently before the court are cross motions for summary judgment. Because the court finds that the Board of Patent Appeals and Interferences erred in concluding that Sepracor did not use reasonable diligence in reducing its invention to practice, the court will grant the defendant’s motion for summary judgment and deny the plaintiff’s motion for summary judgment.

II. BACKGROUND

A. Interference Action

In May of 1989, Stamicarbon filed a patent application with the PTO. At the time, Sepracor was already moving forward with three of its own patent applications before the same body.² In May of 1991, the PTO declared an interference (Interference No. 102,465)³ between applications

¹35 U.S.C. § 146 reads in relevant part: “Any party to an interference dissatisfied with the decision of the Board . . . may have remedy by civil action . . .” *Id.* (1994).

² Sepracor had filed these patent applications on October 26, 1988, February 10, 1989, and April 10, 1989. All three of these dates occurred before the day on which Stamicarbon filed its patent application.

³Interference proceedings are held pursuant to 35 U.S.C. § 135(a), which reads in relevant part: “Whenever an application is made for a patent which . . . would interfere with any pending

submitted by Stamicarbon and Sepracor. An interference is a proceeding initiated in the PTO whereby two or more parties, having independently made the same invention in approximately the same time period, seek a determination as to which party has priority of invention. The party with priority of invention is the one who is determined to have made the invention first, and thus, is entitled to the patent on that invention.

The subject matter of the single Count in the Interference relates to a method of utilizing enzymes to prepare an optically active isomer of certain compounds, 3-phenylglycidic acid esters. These esters have utility as intermediates in the chemical synthesis of diltiazem, a compound that is widely used as a drug to treat angina pectoris, hypertension, and several other disorders.⁴

During the PTO interference, the parties conducted extensive discovery, including taking depositions, and submitted formal motions and briefs concerning the priority dispute to the Board of Patent Appeals and Interferences (“Board”). On June 18, 1995, a final hearing on the interference was conducted before three administrative patent judges of the Board. The Board issued a written opinion on November 7, 1995.

B. The Board of Patent Appeals and Interferences’s Decision

In its November 7th opinion, the Board entered judgment in favor of Sepracor, thus, awarding it priority of invention. In rendering its decision, the Board addressed two issues:

- 1) Is the party [Stamicarbon] entitled to the benefit of its earlier Netherlands

application, or with any unexpired patent, an interference may be declared The Board of Patent Appeals and Interferences shall determine questions of priority of the inventions and may determine questions of patentability.” *Id.* (1994).

⁴The technology established by this invention is not at issue in the motions before the court and, therefore, does not need to be described further.

application?⁵

- 2) Has the party [Sepracor] established priority of invention?

Board Decision, at 4-5

First, the Board considered whether Stamicarbon was entitled, under 35 U.S.C. § 119,⁶ to the benefit of the filing date of its Netherlands patent application, which was May 20, 1988. As the Board recognized, if Stamicarbon was not entitled to this date, it would have to rely on the May 17, 1989 filing date of its first United States patent application. Thus, if Stamicarbon had to rely on the May 17, 1989 date, Sepracor would have priority of invention by virtue of its earlier United States filing date. On this first issue, the Board found that Stamicarbon was not entitled to the Netherlands filing date because its application failed to disclose the best mode of practicing the invention and, therefore, did not comply with the requirements of 35 U.S.C. § 112.⁷ As a result of this finding, the Board awarded Sepracor priority of invention.

Second, the Board also considered whether Sepracor would be entitled to an award of priority

⁵During the interference proceeding the PTO referred to the parties by the names of the actual inventors. For the purposes of this opinion, the court will simply refer to the parties as Stamicarbon and Sepracor.

⁶35 U.S.C. § 119 reads in relevant part: “An application for patent for an invention filed in this country by any person who has . . . previously regularly filed an application for a patent for the same invention in a foreign country which affords similar privileges in the case of applications filed in the United States . . . shall have the same effect as the same application would have if filed in this country on the date on which the application for patent for the same invention was first filed in such foreign country.” *Id.* (1994)

⁷ Pursuant to 35 U.S.C. § 112, a patent specification must set forth the “best mode contemplated by the inventor of carrying out his invention.” *Id.* (1994)

of invention in the event that Stamicarbon was entitled to its Netherlands filing date.⁸ Thus, for this second basis, the Board presumed, contrary to its ruling, that Stamicarbon was entitled to the benefit of the May 20, 1988 filing date. On this second issue, the Board unanimously held that Sepracor had conceived of the invention prior to May 20, 1988, and reduced it to practice by June 20, 1988. However, the Board found that Sepracor had not acted with “reasonable diligence” within the meaning of 35 U.S.C. 102(g) to reduce the invention to practice. As a result of these finding, the Board concluded that if the May 20, 1988 Netherlands filing date had been valid, Sepracor would not have priority of invention.

With this factual and procedural background in mind, the court will address the substance of the parties’ cross motions for summary judgment.

III. STANDARD OF REVIEW

The court may grant summary judgment “if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.” Fed. R. Civ. P. 56(c); *see also Robotic Vision Sys., Inc. v. View Engineering, Inc.*, 112 F.3d 1163, 1165 (Fed. Cir. 1997). Thus, summary judgment may be granted when no reasonable jury could return a verdict for the nonmoving party. *Robotic Vision*, 112 F.3d at 1165 (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). In determining whether there is a genuine issue of material fact, the evidence must be viewed in the light most favorable to the party opposing the motion, with doubts resolved in favor of the nonmovant. *Id.* Summary judgment is just as appropriate

⁸The Board considered this second issue: “[f]or the sake of completeness, . . . if, in the event of an appeal, [its] decision denying [Stamicarbon]’s benefit is reversed and the case is remanded.” Board Decision, 13

in a patent case as in any other case. *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1576-77 (Fed. Cir. 1989). Finally, the court notes that the issue presently before it is particularly appropriate for summary judgment because both parties acknowledge that resolution of the cross motions does not turn on facts outside the factual record that was before the Board.

IV. DISCUSSION

In their cross motions for summary judgment, the parties dispute whether the Board's decision concerning whether Sepracor established priority of invention was correct. Sepracor argues that the Board's legal conclusion regarding its exercise of reasonable diligence was erroneous. Specifically, Sepracor argues that based on the factual record before it, the PTO erred when it concluded that Sepracor would not be independently entitled to priority (assuming the May 20, 1988 date to be valid) because it had not exercised reasonable diligence in reducing its invention to practice. Thus, in its motion, Sepracor urges the court to reverse the PTO and find that it would be entitled to priority even if Stamicarbon's May 20, 1988 filing date were valid.

Stamicarbon takes a contrary position to Sepracor on this issue in its cross motion for summary judgment. Stamicarbon insists that the Board had a sufficient factual basis to find that Sepracor had not used reasonable diligence in reducing its invention to practice.⁹

⁹In its complaint, Stamicarbon asks the court to rule that the PTO erred when it awarded priority to Sepracor. According to Stamicarbon, the Board erred when it concluded that the Netherlands patent application filed on May 20, 1988 did not sufficiently "set forth the best mode contemplated by the inventor of carrying out his invention." In Stamicarbon's opinion, it should have been awarded priority at the conclusion of the interference action because the PTO was obligated to give effect to this earlier date, *see* 35 U.S.C. § 119 (1994). As a result, it asks the Court to reverse the PTO while awarding fees and costs.

Although this issue is not the subject of either party's motion for summary judgment, the court's resolution of the motions in favor of Sepracor effectively moots the issue of whether Stamicarbon is entitled to the May 20, 1988 Netherlands filing date. Still the court recognizes that: "Section 146 actions may also have elements of a trial: the record in such actions may

At the outset, the parties dispute the standard of review the court should apply in reviewing the Board's findings. In view of this disagreement, the court will initially discuss the appropriate standard of review it must use in examining the Board's findings.

A. Standard for Reviewing the Board's Legal Conclusion and Findings of Fact

Sepracor asserts that the court should "apply a 'clearly erroneous' standard in reviewing the factual findings that support the Board's legal conclusions, but must apply a *de novo* standard in reviewing the legal conclusions themselves." In contrast, Stamicarbon contends that the court should apply a "substantial evidence" standard, which is more deferential than a clearly erroneous standard.

A review of applicable precedent demonstrates that both parties are partially correct.¹⁰ A determination of priority of invention and its constituent issues of conception and reduction to practice are questions of law predicated on subsidiary factual findings. *See Eaton v. Evans*, 204 F.3d 1094, 1097 (Fed. Cir. 2000) (citing *Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir.1998)). *See also Conservolite, Inc. v. Widmayer*, 21 F.3d 1098, 1100 (Fed. Cir. 1994). Thus, the court will review the Board's legal conclusions concerning priority, conception, and reduction to practice *de novo*. *See Eaton*, 204 F.3d at 1097; *see also Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1345 (Fed. Cir. 2000) (acknowledging that a district court should review the Board's legal

include new evidence, and, if the new evidence raises factual disputes not considered by the Board, the court must resolve those disputes *de novo*." *Allied-Signal, Inc. v. Allegheny Ludlum Corp.*, 29 U.S.P.Q.2d 1039, 1042 (D. Conn. 1993) (citing *Fregeau v. Mossinghoff*, 776 F.2d 1034, 1038 (Fed. Cir. 1985)).

¹⁰An action under 35 U.S.C. § 146 is essentially a suit to set aside the decision of an administrative agency. *See Allied-Signal*, 29 U.S.P.Q.2d at 1042 (D. Conn. 1993). Thus, a Section 146 action is a hybrid proceeding having characteristics of both an appeal and a trial *de novo*. *Id.* The hybrid nature of Section 146 actions has created some confusion regarding which standard of review is to be applied. *Id.*

conclusions *de novo*).

As for the Board's factual determinations, the United States Supreme Court in *Dickinson v. Zurko*, 520 U.S. 150 (1999), held that the Administrative Procedure Act governed appeals from the PTO, and hence, the proper standard of review is whether the facts are supported by "substantial evidence." *Id.* at 152. *Zurko* describes the substantial evidence standard as "requiring a court to ask whether a 'reasonable mind might accept' a particular evidentiary record as 'adequate to support a conclusion.'" *Id.* at 162 (quoting *Consolidated Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938)). As a result of the Court's ruling in *Dickinson v. Zurko*, the court will apply the more deferential "substantial evidence" standard in reviewing the Board's factual finding. *See Carefree Trading, Inc. v. Life Corp.*, 83 F. Supp. 2d 1111, 1114 (D. Ariz. 2000) (holding that in light of *Zurko*, the district court would apply a substantial evidence standard in reviewing PTO decisions).¹¹

Next, in order to determine whether the Board came to an erroneous legal conclusion regarding Sepracor's diligence, a description of the Board's findings regarding Sepracor's activities after it conceived of the invention is needed in order to resolve the motions presently before the court.

B. The Board's Findings Regarding Sepracor's Activities After Conceiving of Its Invention

Before the court describes Sepracor's conduct in reducing its invention to practice, it will briefly outline the relevant dates as determined by the Board.

- Pre- May 20, 1988: The Board held that Sepracor conceived of the invention prior

¹¹The court also calls attention to the Federal Circuit's decision in *Winner Int'l Royalty Corp.* In *Winner*, the court held that the introduction of new evidence to the district court that was not before the Board can trigger a *de novo* review of the Board's fact finding. *See id.*, 202 F.3d at 1346. This case is clearly distinguishable from *Winner*, however, in that both parties agree that the issue presently before the court does not turn on facts outside the interference record that was before the Board.

- May 20, 1988: to May 20, 1988. Stamicarbon's patent filing date in the Netherlands.
- June 20, 1988: The Board determined that Sepracor had reduced the subject matter of its invention to practice on this date.¹²
- October 26, 1988: Sepracor's first United States Patent application filing.
- May 17, 1989: Stamicarbon's United States patent application filing.

In determining if the Sepracor acted with reasonable diligence in reducing its invention to practice, the Board focused on Sepracor's action from just prior to May 20, 1988, until June 20, 1988. This period is known as the "critical period." Specifically, the Board looked at a 22 day period¹³ commencing on May 19, 1988, and ending on June 20, 1988. In its decision, the Board concluded that:

[n]ot counting weekends and . . . Memorial Day, we find that the party [Sepracor]'s record contains numerous gaps (three-one day gaps; one two-day gap and one-three day gap) during the critical period, i.e., no activity was directed to the reduction to practice of the invention of count 1 for Friday May 20; Friday, May 27; Tuesday and Wednesday, May 21 and June 1; Monday, June 6; and Monday to Wednesday, June 12 to 15. The party [Sepracor]'s main brief advances no reason to explain the failure of action on the aforementioned dates. Accordingly, we are constrained to hold that the party Dodds was not reasonably diligent during the critical period.

Board Decision, at 15-16 Therefore, Sepracor had demonstrated that it took specific steps to reduce the invention to practice on the following business days during the critical period: May 19, 23, 24, 25, and 26, 1988, and June 2, 3, 7, 8, 9, 10, 16, 17, and 20, 1988. *Id.* Thus, the Board concluded that Sepracor worked on the project on 14 out of the 22 business days.

¹²Stamicarbon believes that the Board erred as a matter of law in concluding that Sepracor reduced the invention to practice on June 20, 1988, but believes that this will not impact the outcome of the motion. Thus, this fact is undisputed for the purpose of this motion.

¹³During that same time period there were 10 weekend days and one holiday, Memorial Day which fell on May 30, 1988.

C. Priority of Invention

If a party files a patent application for a claimed invention that would interfere with the claim of another pending application or with a claim of an unexpired patent, the PTO Commissioner has authority to declare an interference to determine which party was the first to invent the claimed subject matter. *See* 35 U.S.C. § 135(a) (1994). Generally, the person who first reduces an invention to practice is “prima facie the first and true inventor.” *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1577 (Fed. Cir. 1996) (quoting *Christie v. Seybold*, 55 F. 69, 76 (6th Cir.1893) (Taft, J.)). “However, the person ‘who first conceives, and, in a mental sense, first invents . . . may date his patentable invention back to the time of its conception, if he connects the conception with its reduction to practice by reasonable diligence on his part, so that they are substantially one continuous act.’” *Id.* Hence, 35 U.S.C. § 102(g) “provides basic protection for the inventive process, shielding in particular the creative steps of conception and reduction to practice” *Id.*

Priority of invention, therefore, belongs “to the first party to reduce an invention to practice unless the other party can show that it was the first to conceive the invention and that it exercised reasonable diligence in later reducing the invention to practice.” *Price v. Symsek*, 988 F.2d 1187, 1190 (Fed. Cir.1993); *see also Eaton v. Evans*, 204 F.3d 1094, 1097 (Fed. Cir. 2000); *Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998); *Mahurkar*, 79 F.3d at 1577. “Conception is the formation in the inventor's mind of a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice.” *Monsanto Co. v. Mycogen Plant Science, Inc.*, 61 F. Supp. 2d 133, 180 (D. Del. 1999) (citations omitted). “An actual reduction to practice occurs when the inventor: (1) constructs a product that is within the scope of the claimed invention, and (2) demonstrates that his invention actually worked for its intended purpose.” *Id.* (citations omitted).

In this case, neither the issue of conception or reduction are contested for the purpose of this motion. The Board has determined that Sepracor was the first to conceive of the invention, that is, that Sepracor had conceived of the invention prior to May 20, 1988, when Stamicarbon filed its Netherlands patent application. The Board also determined that Sepracor had reduced the invention to practice by June 20, 1988. In their motions, the parties do not claim that the Board erred in making these determination. Therefore, the only issue in dispute is whether Sepracor exercised reasonable diligence between May 20, 1988 and June 20, 1988.

1. Whether Sepracor exercised reasonably diligence

“Where a party is the first to conceive the invention but reduces it to practice after another party's reduction to practice, the party that was the first to conceive the invention will be the first inventor if he can show reasonable diligence during the time from a date just prior to the conception date of the other party until the party that was the first to conceive the invention reduces it to practice. *Monsanto Co.*, 61 F. Supp. 2d at 180 (citing *Mahurkar*, 79 F.3d at 1577-78)). The time period between just prior to conception and reduction to practice is known as the “critical period.” *See id.* In this case the critical period falls between May 20, 1988 and June 20, 1988.

Diligence is defined “as reasonably continuous activity toward reduction to practice so that the invention’s conception and reduction to practice are substantially one continuous act.”¹⁴ *Id.* (quoting *Mahurkar*, 79 F.3d at 1577). Thus, “diligence must be considered in light of all the circumstances,” and the court must make a determination as to “whether the inventor was pursuing

¹⁴The purpose of the reasonable diligence standard is to balance the interest in rewarding and encouraging invention with the public’s interest in the earliest possible disclosure of innovation. *See Griffith v. Kanamaru*, 816 F.2d at 626; *see also Hunter v. Beissbarth*, 230 U.S.P.Q. 365, 368 (Bd. Pat. App. & Int’f 1986).

his goal in a reasonably continuous fashion.” *See id.*

In order to establish that it exercised reasonable diligence, Sepracor must account for the entire period from just before May 20, 1988 and June 20, 1988. *See Griffith v. Kanamaru*, 816 F.2d 624, 626 (Fed. Cir. 1987); *see also K & K Jump Start/Chargers, Inc. v. Schumacher Electric Corp.*, 82 F. Supp. 2d 1012, 1021 (W.D. Missouri 2000). “During this period there must be reasonably continuous activity. Evidence which is of a general nature to the effect that work was continuous and which has little specific as to dates and facts does not constitute the kind of evidence required to establish diligence in the critical period.” *Hunter v. Beissbarth*, 230 U.S.P.Q. 365, 368 (Bd. Pat. App. & Int’f 1986) (citations omitted); *Weisner v. Weigert*, 666 F.2d 582, 588 (Bd. Pat. App. & Int’f 1981)(holding that general testimony that did not refer to specific dates and events could not establish reasonable diligence).

In this case, Sepracor provided a detailed, date specific account of its activities during the critical period. Based on this evidence, the Board found that Sepracor had worked on the project on 14 out of the 22 business days during the critical period. In referring to the three one-day, one two-day, and one-three day periods of inactivity, the Board found that Sepracor’s “main brief advances no reason to explain the failure of action on the aforementioned dates. Accordingly, we are constrained to hold that the party Dodds was not reasonably diligent during the critical period.” Board Decision, at 16.

Based on the evidence that was before the Board, the court rules that the Board erred in holding that Sepracor had not established reasonable diligence. First, the court concludes that Board erred because Sepracor did provide some explanation as to why there were short gaps between the days when they worked to reduce the invention to practice. For example, Sepracor did offer evidence

to the Board that one of the key inventors on the project, Dodds, was on vacation for some of the days when they were not working on the project. “[P]eople may be sick or even take vacations (thereby creating gaps in activity) while still being diligent.” *Hybritech, Inc. v. Abbott Laboratories*, 4 U.S.P.Q.2d 1001, 1006 (C.D. Cal. 1987) (quoting *Reed & Wilkinson v. Tornqvist*, 436 F.2d 501, 503-05 (C.C.P.A. 1971)). Sepracor also offered evidence that would indicate that the burdens of being a “small startup” company made it difficult for the company to work on the project everyday. This is also a valid excuse for inactivity. See *id.* (holding inventors were reasonably diligent in reducing invention to practice in light of all the circumstances, including the fact that the company was new and that the process involved a number of laboratory tests). Sepracor also attributes some of the period of inactivity to problems that a small company would face. For example, there is clear evidence that on Thursday May 26, 1998, there was a discussion about creating a Technical Proposal for the invention. A Technical Proposal was then forwarded on June 1, 1988. Although there is an apparent period of inactivity for May 27, 28, 29, 30, 31, “the Technical Proposal was undoubtedly prepared over many days, but is listed as only one entry on the calendar.”

Moreover, the court concludes that the board erred because its decision does not indicate that the Board considered Sepracor’s circumstances as described in the preceding paragraph. “It is a principle of diligence that consideration must be given to the circumstances of the inventor, including his skill and available time, and that the inventor may avail himself of the activities of others.” *De Solms v. Shoenwald*, 15 U.S.P.Q.2d 1507, 1511 (Bd. Pat. App. & Int’f 1990); see also *Hybritech*, 4 U.S.P.Q.2d at 1006 (“The question of diligence is considered in light of all the circumstances.”). Also, in determining if a party has exercised reasonable diligence, the court may consider the reasonable everyday problems and limitations encountered by an inventor. See *Griffith v. Kanamaru*,

815 F.2d at 626 (citations omitted). Furthermore, the court recognizes that “an inventor need not abandon his or her means of livelihood in order to be diligent.” *K & K Jumpstart*, 82 F. Supp.2d at 1022 . [T]he law requires only reasonable (and not heroic) diligence.” *Id.*; *see also Disonics, Inc. v. Acuson, Corp.*, No. C-91-3118-DLJ, 1993 WL 248654, at *16 (N.D. Cal. June 24, 1993) (noting that diligence must be “accomplished in a reasonably prompt manner, considered in light of all the attendant circumstances”).

Finally, the court finds that the Board erred because evidence of constant effort is not required to establish reasonable diligence. *Weisner*, 666 F.2d at 588; *see also Hybritech*, 4 U.S.P.Q.2d at 1006 (holding that an inventor had exercised reasonable diligence even though the inventor’s log book showed some days of inactivity). Although a party must account for the entire critical period, a party does not have to take the most expeditious course to the actual reduction to practice, so long as the party’s efforts are reasonably diligent under the circumstances. *See De Solms*, 15 U.S.P.Q.2d at 1511. Thus, the question is whether the inventors pursued their goal in a reasonable fashion. *See Hybritech*, 4 U.S.P.Q.2d at 1006. In other words, “[i]f they were doing the things reasonably necessary to reduce the idea to practice, then they were diligent *even if they did not actually work on the invention each day.*” *Id.* (emphasis added)

V. CONCLUSION

After a careful consideration of the parties submissions, the evidence presented to the Board during the Interference, and relevant precedent, the court concludes that based on the record before it, the Board erred in concluding that Sepracor failed to establish the requisite reasonable diligence in reducing its invention to practice. Thus, the court rules as a matter of law that Sepracor has established priority under 35 U.S.C. § 102.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

STAMICARBON BV,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 97-8-GMS
)	
SEPRACOR, INC.,)	
)	
Defendant.)	

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MEMORANDUM OPINION

March 12, 2001.

Wilmington, Delaware.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

STAMICARBON BV,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 97-8-GMS
)	
SEPRACOR, INC.,)	
)	
Defendant.)	

ORDER

For the reasons stated in the court's opinion of this date, IT IS HEREBY ORDERED,
ADJUDGED, and DECREED that:

1. Pursuant to Rule 56 of the Federal Rules of Civil Procedure, the Motion for Summary Judgment filed by the Defendants is GRANTED;
2. The plaintiffs Cross Motion for Summary Judgment is DENIED.

Date: March 12, 2001

Gregory M. Sleet
UNITED STATES DISTRICT JUDGE