UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TAKEDA PHARMACEUTICAL CO., LTD.,	
Plaintiff,	
v.	**Civ. No. 06-1640 (TFH)**
HON. JON W. DUDAS, Under Secretary of Commerce for Intellectual Property and Director of the Patent and Trademark Office,	
Defendant.	

MEMORANDUM OPINION

Pursuant to 35 U.S.C. § 145, Takeda Pharmaceutical Company ("Takeda") challenges the Patent and Trademark Office ("PTO") Board of Patent Appeals and Interferences' ("Board") reexamination rejection of Takeda's patent covering a process to make certain cephem compounds. Pending before the Court are the parties' motions for summary judgment. For the reasons that follow, the Court will grant Takeda's motion and, accordingly, deny the PTO's motion.

BACKGROUND

In 1974, Takeda filed a patent application in Japan covering, among other things, a new product (a "cephem" chemical compound) and processes for making the product. It then filed a similar application in Great Britain in 1975, again applying for protection of cephem products and processes.

In December 1975, Takeda filed a patent application in the United States. Although

describing seven processes to create cephem products, unlike the international applications, Takeda claimed only cephem products in its first United States patent application. In July 1988, U.S. Patent No. 4,098,888 ("'888 patent") issued with 12 claims to cephem compounds.

In August 1979, Takeda filed a divisional application for 12 cephem compounds that differed slightly from those claimed in the '888 patent. The claims issued as U.S. Patent No. 4,298,606 ("'606 patent" or "product patent").

On January 8, 1990, Takeda filed its first process claims relating to cephem compounds in the United States. Filing a preliminary amendment on April 3, 1990, Takeda presented 13 process claims for examination. The PTO initially rejected the process claims as obvious under 35 U.S.C. § 103. The Federal Circuit, however, reversed the PTO, *see In re Ochiai*, 71 F.3d 1565 (Fed. Cir. 1995), and, on December 10, 1996, Takeda's process claims issued as U.S. Patent No. 5,583,216 ("'216 patent" or "process patent"). Claim 1 of the '216 patent claims a specific manufacturing process for making certain cephem compounds claimed in the '606 patent. Pl.'s SOMF ¶ 15.

In 1998, E. Thomas Wheelock, Esq., on behalf of an anonymous requester, filed two requests for reexamination of the '216 patent. Pl.'s SOMF ¶ 7. Wheelock asserted that '216's process claims were invalid for obviousness-type double patenting over the product claims of Takeda's earlier patents, including the '606 patent. The PTO granted the requests and merged them into a consolidated reexamination proceeding. Pl.'s SOMF ¶ 7. On May 11, 2005, the patent examiner rejected the '216 patent as unpatentable based on double patenting. Pl.'s SOMF ¶ 8. Takeda timely appealed the examiner's final decision to the Board.

In the Board's view, Takeda's appeal from the examiner's denial "boil[ed] down to the

following issue: Having taken out a full-term cephem compound patent (Ochiai[1] '606), are Appellants also entitled to take out yet another full-term patent to a method of making some of those cephem compounds where (1) the claimed method for making the cephem compounds is described in the cephem compound patent and (2) there is no credible alternative[2] method for making the cephems which does not involve an infringement of the method patent?" Board Op. at 13. Answering its own question, the Board stated, "We think not." *Id.* After noting the two recognized categories of double patenting—i.e., "same invention" and "obviousness-type"—the Board rejected the "tendency to try to 'pigeon hole' every double patenting situation into one of these two recognized categories" and "decline[d] to hold that every double patenting must fit precisely into one of the two categories." Board Op. at 14. Rather, the Board held, "the focus should be on whether the second patent unjustly extends the patent rights of a first patent." Board Op. at 14. The Board then proceeded to affirm the examiner's rejection of claims 1-5 of the '216 patent. Board Op. at 14-17.

In the end, the Board concluded, "It should suffice to justify double patenting that some or all of the compound claims of an expired compound patent continue to be monopolized by virtue of patent rights in a narrow method patent." Board Op. at 23-24. "[T]he focus" of double patenting, according to the Board, "should be on an analysis of whether all or some of a patentee's patent rights are being unjustly extended." Board Op. at 24. In Takeda's case, the

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[1] Michihiko Ochiai was the lead name on the patent application. As the assignee of the '216 patent, Takeda is the real party in interest.

[2] The Board upheld the examiner's rejection as speculative of Takeda's argument that various possible alternative pathways exist to make the cephum compound produced by the process of '216's claim 1. Board Op. at 9, 21.

Board found that, "to the extent the Ochiai '216 patent extends the monopoly as to the compounds which can be made [only] by that process which are the same as the compounds covered by claim 1 of Ochiai '606, the monopoly of Ochiai '606 is also extended." Board Op. at 24. Thus, the Board affirmed the examiner's rejection of the '216 patent's claims based on double patenting over certain claims of the expired '606 patent. Board Op. at 26.

Following the Board's decision, Takeda timely filed suit in this Court, pursuant to 35 U.S.C. § 145, challenging the Board's decision and requesting this Court hold that Takeda is entitled to a reexamination certificate from the PTO confirming the patentability of claims 1-5 of the '216 patent. Compl. ¶ 18. Now pending before the Court are the parties' motions for summary judgment. In its motion, Takeda argues it is entitled to judgment because (1) the Board's decision rests on the erroneous factual finding that the '216 patent claims the only method of making the cephem compounds of claims 1 and 15 of the '606 patent, (2) the Board applied an incorrect legal standard for its double patenting rejection and, thus, its rejection is not in accordance with the law, and (3) the Board's equitable arguments in support of its double patenting rejection are factually and legally incorrect. Pl.'s Mot. 6-7. The PTO opposes Takeda's motion and cross moves for summary judgment, contending that substantial evidence supports the Board's rejection of the '216 patent on the grounds of double patenting over the claims of the now-expired '606 patent.

DISCUSSION

I. LEGAL STANDARDS

A. Standard of Review

A dissatisfied patent applicant may challenge a Board decision by either appealing directly to the Federal Circuit, *see* 35 U.S.C. § 141, or by filing a civil action to obtain a patent in the United States District Court for the District of Columbia, *see* 35 U.S.C. § 145. Here, Takeda chose the latter route.

In pertinent part, § 145 provides:

> An applicant dissatisfied with the decision of the Board of Patent Appeals and Interferences in an appeal under section 134(a) of this title may . . . have remedy by civil action against the Director in the United States District Court for the District of Columbia. . . . The court may adjudge that such applicant is entitled to receive a patent for his invention, as specified in any of his claims involved in the decision of the Board of Patent Appeals and Interferences, as the facts in the case may appear.

35 U.S.C. § 145. Thus, in a matter brought pursuant to § 145, a "district court has the power to set aside any ruling refusing a patent," *Mazzari v. Rogan*, 323 F.3d 1000, 1004 (Fed. Cir. 2003), and to determine patentability de novo, *Newman v. Quigg*, 877 F.2d 1575, 1579 (Fed. Cir. 1989).

Because the PTO is an agency subject to the Administrative Procedure Act, *see Mazzari*, 323 F.3d at 1004, the Court will uphold the Board's legal conclusions unless "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." 5 U.S.C. § 706. And the Court generally applies the deferential "substantial evidence" standard to the Board's factual findings. *Mazzari*, 323 F.3d at 1004-05.

An action under § 145, however, is not merely a form of administrative review. Rather, it is a "hybrid of an appeal and a trial de novo." *Winner Int'l Royalty Corp. v. Wang*, 202 F.3d

1340, 1345 (Fed. Cir. 2000) (citation omitted). *See also Newman*, 877 F.2d at 1579 ("A district court action under 35 U.S.C. § 145 is a *de novo* determination of patentability."). As more fully explained below, § 145 review "affords the applicant an opportunity to present additional evidence." *Mazzari*, 323 F.3d at 1004. To the extent the applicant presents new evidence challenging particular factual findings, the Court reviews the Board's factual findings de novo, and the Court applies the substantial evidence standard to the Board's factual findings as to which the applicant presents no new evidence. *Mazzari*, 323 F.3d at 1005.

B. Summary Judgment

Summary judgment is proper if the pleadings, depositions, answers to interrogatories, admissions on file and affidavits, if any, show no genuine issue of material fact exists and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). While the moving party "bears the initial responsibility" of demonstrating the absence of a genuine issue of material fact, *see Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986), in opposing a properly supported summary judgment motion, "an adverse party may not rest upon the mere allegations or denials of the adverse party's pleading," Fed. R. Civ. P. 56(e). Rather, the nonmovant's burden is to "set forth specific facts showing that there is a genuine issue for trial." *Celotex*, 477 U.S. at 323. If the nonmovant fails to point to "affirmative evidence" showing a genuine issue for trial, *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 257 (1986), "summary judgment, if appropriate, shall be entered against the adverse party." Fed. R. Civ. P. 56(e). A nonmovant meets its burden "only 'if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.'" *Laningham v. U.S. Navy*, 813 F.2d 1236, 1241 (D.C. Cir. 1987) (quoting *Anderson*, 477 U.S. at 248).

II. THRESHOLD ISSUES

Before turning to the Board's decision, the Court finds it logical to first decide the following points of contention: (1) whether certain evidence Takeda presents in support of its motion is properly before this Court; and, (2) if such evidence is properly before this Court, whether it is legally relevant to deciding whether the process claim in the '216 patent is subject to a double patenting rejection over the product claims in the '606 patent.

A. New Evidence

Before this Court, Takeda presents evidence it did not present to the Board, namely, the declaration of Dr. Angelina J. Duggan, in which Dr. Duggan explains that the processes disclosed in U.S. Patent Nos. 6,552,186 ("Gerlach patent" or "'186 patent") and 7,071,329 ("Monguzzi patent" or "'329 patent") are viable alternatives to the process of making cephem compounds claimed in the '216 patent.[3] *See* Pl.'s Ex. 6 ¶¶ 125-39. The PTO argues this Court should ignore the Duggan declaration and, correspondingly, the processes disclosed in the Gerlach and Monguzzi patents because they constitute evidence on issues Takeda failed to raise before the Board and Takeda was negligent in not submitting such evidence to the Board. Countering, Takeda argues it is entitled to present new evidence to this Court on issues already presented to the PTO during reexamination, contending the "principle is firmly rooted in Supreme Court, Federal Circuit and this Court's precedent." Pl.'s Reply 16.

Takeda is correct. As stated above, when a patent applicant seeks "direct review [of a

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[3] As explained *infra*, the PTO does not dispute that, for purposes of the competing summary judgment motions, the processes described in the Gerlach and Monguzzi patents make the cephem compounds contained in claims 1 and 15 of the '606 patent. Def.'s Mot. 21 n.5 ("For purposes of this motion only, the USPTO does not dispute the technical merits of Dr. Duggan's declaration.").

Board decision] in federal district court" pursuant to 35 U.S.C. § 145, the applicant may "present to the court evidence that the applicant did not present to the PTO." *Dickinson v. Zurko*, 527 U.S. 150, 164 (1999) (citation omitted). *See also Mazzari v. Rogan*, 323 F.3d 1000, 1004 (Fed. Cir. 2003) ("A section 145 review is distinct from a section 141 appeal in that it affords the applicant an opportunity to present additional evidence . . . ."). "While the evidentiary record before the Board serves as the 'evidentiary nucleus' of the district court proceeding in a section 145 action, the parties are entitled to submit additional evidence." *Gould v. Quigg*, 822 F.2d 1074, 1076 (Fed. Cir. 1987) (citation omitted). Parties are, however, "precluded from presenting new issues, at least in the absence of some reason of justice put forward for failure to present the issue to the Patent Office." *DeSeversky v. Brenner*, 424 F.2d 857, 858 (D.C. Cir. 1970). And "the plaintiff may not submit for the first time evidence [that] he was negligent in failing to submit to the Patent Office." *MacKay v. Quigg*, 641 F. Supp. 567, 570 (D.D.C. 1986) (citation omitted).

As Takeda correctly contends, the Duggan declaration presents only new evidence, not new issues, given that Takeda raised before the PTO the issue of whether alternative, non-infringing processes exist to produce the cephem compounds claimed in the '606 patent. Pl.'s Reply 17. As for not submitting evidence of the processes contained in the Gerlach and Monguzzi patents to the Board, Takeda claims, and the PTO does not rebut, that when it first learned of the process described in the Gerlach patent, it submitted the patent to the Board, which chose not to review the patent on procedural grounds,[4] and it did not learn of the Monguzzi

[4] The PTO also argues that Takeda expressly waived its right to rely on the Gerlach patent. Without citing any law, the PTO argues this is so because, when Takeda attempted to present the patent to the Board and the Board offered Takeda the choice to remand the appeal to

patent until after briefing before the Board was complete. Pl.'s Reply 20. In these circumstances, the Court finds that Takeda's failure to submit to the Board the evidence contained in the Duggan Declaration is not negligent. Therefore, the Duggan declaration is competent evidence the Court will consider in ruling on the parties' motions for summary judgment. *See MacKay*, 641 F. Supp. at 571 (finding no negligence or suppression before the Board of evidence on issue raised below and, thus, allowing introduction of new evidence on previously raised issue).

B. Subsequent Developments in the Art

Even assuming evidence of the Gerlach and Monguzzi patents is properly before this Court, the PTO urges the Court to disregard the evidence, arguing it is "irrelevant to the legal issue raised," Def.'s Mot. 27, because, to defeat the claim of double patenting over the '606 patent, argues the PTO, an alternative process to that claimed in the '216 patent had to exist at the time Takeda filed its initial product claims in 1975, Def.'s Reply 8, or, "[a]t the very least," Takeda had to disclose such an alternative process in its process patent application in 1990, Def.'s Reply 10. Takeda, on the other hand, argues that, "despite the PTO's misguided arguments to the contrary, there is no requirement that this alternative process have been known as of the filing date of the '216 patent[;] [r]ather, existing case law expressly holds that subsequent processes may be considered in a double patenting analysis." Pl.'s Reply 2.

Takeda relies on a case from the United States District Court for the District of Delaware to support its argument that this Court, in conducting a double patenting analysis, can look to

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the examiner or proceed without the evidence, Takeda chose to withdraw its reliance on the patent. Def.'s Mot. 28-29. No case law supports the PTO's position and, in any event, the process disclosed in the Monguzzi patent is sufficient for purposes of deciding this matter.

advances in the art subsequent to its invention, namely, *Phillips Petroleum Co. v. United States Steel Corp.*, 604 F. Supp. 555 (D. Del. 1985) ("*Phillips I*"). In *Phillips I*, Phillips Petroleum developed a chromium oxide catalyst for use in polymerizing propylene that resulted in a solid product. In 1953, Phillips filed an application for a process patent that described both the process of making the product and the product itself, crystalline polypropylene. Three years later, Phillips applied for a product patent covering crystalline polypropylene. While the product application was pending, Phillips applied for a patent claiming 44 processes using the chromium oxide catalyst. In March 1958, patent '721 issued on Phillips' process application. After protracted litigation led to Phillips being awarded priority of invention of crystalline polypropylene, with a priority date based on Phillips' 1953 application, the Patent Office finally issued patent '851 on Phillips' product claim in March 1983. Thereafter, Phillips sued two companies for patent infringement and, separately, various entities (collectively "defendants") filed suit against Phillips to obtain declaratory judgment that Phillips' '851 product patent was invalid for double patenting over claim 16 of its '721 process patent. The district court consolidated the actions. Pretrial, defendants sought summary judgment to declare the '851 patent invalid on double patenting grounds. Judge Murray M. Scwartz denied the summary judgment motions,[5] holding that, because a process other than that contained in claim 16 of the '721 patent could make the '851 patent product, and because the process of claim 16 could make a product other than that covered by the '851 patent, the double patenting doctrine did not invalidate the '851 patent. *Id.* at 567.

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[5] As more fully described below, Judge Joseph Longobardi conducted a bench trial on the remaining issues. *See Phillips Petroleum Co. v. U.S. Steel Corp.*, 673 F. Supp. 1278 (D. Del. 1987) ("*Phillips II*").

Although, as the PTO submits, the court in *Phillips I* found that the process claimed in the '721 patent also resulted in a product other than crystalline polypropylene[6] and, thus, the case is not on all fours with the present matter, Takeda cites to *Phillips I* for the court's holding that, in conducting a double patenting analysis in a product-process case, a court can look to processes developed after the product's invention. Indeed, the defendants in *Phillips I*, like the PTO here, argued that the court could not look to the alternative process in conducting its analysis because, while known and mentioned in Phillips' '851 specification, it was not known at the time Phillips invented the product. *Id.* at 567-68. In rejecting the defendants' argument, the court noted that courts in several cases considered developments in the art arising after the invention of the patented subject matter in resolving a double patenting analysis. But, the court noted, in none of the cases did a party object to the court's consideration of such evidence. *Id.* at 567 n.49. The court also cited to a case in which the Board deemed subsequent developments in the art relevant to the double patenting inquiry, noting that,

> [i]n Ex Parte Hogan, *supra*, the Board of Patent Appeals was asked to determine whether a later-disclosed process could be considered in defeating a double patenting challenge. The Board deemed such subsequent developments in the art relevant to the double patenting inquiry. *See Hogan*, No. 436-63, slip op. at 5. Although that decision is of no precedential value, it does illustrate the procedure which the Board of Patent Appeals, with its particular expertise, deems appropriate.

See id.[7]

While noting that the argument against considering subsequent developments in the art

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[6] The court found that making the '851 product required subjecting the product of the '721 process to fractionation. *Phillips I*, 604 F. Supp. at 567.

[7] Takeda attempted to obtain a copy of the Board's *Hogan* decision from the PTO, but the PTO was apparently unable to locate one. *See* PX 28 (emails between counsel).

"contains superficial appeal," *id.* at 568, the court rejected the defendants' arguments for three reasons. First, the court held that not considering such development

> inappropriately weds priority of invention with the double patenting doctrine. The purpose of former is to determine who, among potential inventors, is considered first for purposes of United States Patent law. The primary, albeit not the only purpose of the latter doctrine is to prevent the claim of like subject matter in more than one patent.

Id. Second, the court held "consideration of subsequent advancements in the art in double patenting analysis neither expands nor contracts the scope of the invention claimed. It merely serves as an aid in determining whether the whole of the inventor's contribution to the art was deserving of one or more than one patent." *Id.* Third, the court noted that the "peculiar sequence of events" resulted in Phillips obtaining a product patent on an application in which Phillips disclosed a process undeveloped and unknown at the time of its initial application in 1953. Concluding, the court "decline[d] to conduct the double patenting analysis with blinders so as to avoid recognition or discourage disclosure of advances in process technology as a means of making a product patent." *Id.*

The PTO argues that *Phillips I* does not support Takeda's position for a variety of reasons that the Court finds unpersuasive. First, the PTO contends the court held that double patenting did not exist because it found the process, unlike the process in Takeda's '606 patent, made products other than that claimed in the product patent. Def.'s Reply 8-9. While this is true, the court also held that there was no double patenting because the product could be made by other processes, *see* 604 F. Supp. at 567, which is the exact argument Takeda advances in support of its process patent.

Second, the PTO notes that the *Phillips I* opinion is 22 years old and from another district

and that no other court adopted its reasoning. Def.'s Reply 9. These, however, are not reasons why the decision does not support Takeda's position; rather, they are attacks on the persuasive value of the case—the only case either party cited, and that this Court found, addressing the precise proposition for which Takeda offers it.

Third, the PTO claims the opinion "cannot be analogized to the facts in this case" because, unlike Takeda, Phillips disclosed the alternative process in its patent application. Def.'s Reply 10. While this is true, Phillips was able to do so because the alternative process existed at the time it applied for its patent, which is not the case here. Regardless, the *Phillips I* decision is easily analogized to the facts of the present case. Both involve product-process double patenting challenges where development in the art subsequent to the invention is offered to show that the patented process is not the only way to make the patented product.

Lastly, and similar to its third argument, the PTO contends that, even if this Court were to follow the reasoning in *Phillips I*, the alternative processes Takeda offers "come much too late." Def.'s Reply 10. The PTO argues that, to obtain the benefit of the reasoning in *Phillips I*, Takeda would have had to disclose the alternative processes, "[a]t the very least," in its 1990 process patent application. Def.'s Reply 10. This is not so. That Phillips disclosed the alternative process in its product patent is only tangential to the court's reasoning for looking to subsequent advances in art. *See Phillips I*, 604 F. Supp. at 568-69 (holding that, along with Phillips' disclosure, the court would look to subsequent advances in the art in conducting double patenting analysis because limiting alternative processes to those known at the time of the invention "inappropriately weds priority of invention with the double patenting doctrine" and looking to subsequent developments "neither expands nor contracts the scope of the invention"). Moreover,

following the PTO's logic, if disclosure of alternative processes at the time of applying for the process patent were required to avoid a double patenting rejection, and the first alternative process, according to the PTO, came into being in 2002, then Takeda could have avoided any double patenting challenge by waiting to file for its process patent until 2002. This surely is not the result the PTO seeks.

Along with asserting that *Phillips I* does not support Takeda's position, the PTO also argues the reasoning of *Phillips I* is unsound because issues relating to patentability are determined as of the date of the invention or the filing date for the patent. Def.'s Mot. 22; Def.'s Reply 10-11. In support of its argument, the PTO cites cases dealing with patent application sufficiency, *e.g., In re Hogan*, 559 F.2d 595 (C.C.P.A. 1977), *In re Glass*, 492 F.2d 1228 (C.C.P.A. 1974), *Eli Lilly*, 251 F.3d at 963, and statutory patentability, *e.g., DyStar Textilfarben GmbH & Co. v. C.H. Patrick Co.*, 464 F.3d 1356, 1360 (Fed. Cir. 2006). Unlike double patenting, however, either case law or the statutory scheme governing patents requires these issues be determined as of the date of filing or invention. *See, e.g.*, 35 U.S.C. § 103 ("A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made . . . ."); *In re Glass*, 492 F.2d 1228, 1232 (C.C.P.A. 1974) ("The sufficiency [of an application's specification] must be judged as of the filing date."). No such requirement exists here, and the only explicit, relevant authority, albeit not controlling, holds that a court may look to subsequent developments in the art when conducting a double patenting analysis.

Moreover, the Federal Circuit, whose decisions are controlling on issues relating to patentability, *see Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356, 1359 (Fed. Cir.

1999) (en banc), rejected the PTO's exact argument in an appeal related to *Phillips I*, *see U.S. Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247 (Fed. Cir. 1989) (*Phillips III*). After Judge Schwartz in *Phillips I* denied the defendants' summary judgment motions, Judge Longobardi, sitting without a jury, tried the remaining issues and held that the '851 patent was valid, enforceable, and infringed. *Phillips II*, 673 F. Supp. at 1358. Although the defendants stipulated pretrial that no new evidence would be introduced on the double patenting issue at trial, Judge Longobardi allowed a proffer and limited testimony. Judge Longobardi then chose to again rule on the double patenting issue, holding that the '851 patent was not invalid on that ground. In his opinion, with one exception not relevant here, Judge Longobardi "accept[ed] and incorporat[ed]" Judge Schwartz's opinion denying the defendants' summary judgment motions. *Id.* at 1311. Thereafter, the defendants appealed to the Federal Circuit.

On appeal, the defendants attacked, among other things, the district court's holding that they had not proved the '851 patent invalid on double patenting grounds. *Phillips III*, 865 F.2d at 1249. The defendants raised the precise argument the PTO raises here, i.e., that a court cannot look to subsequent developments in the art when conducting a double patenting analysis. Indeed, in their brief to the Federal Circuit, the defendants argued that Judge Schwartz erred in "conclu[ding] that later-developed technology can be relied on to avoid double patenting," contending such a conclusion "is not consistent with the rationale of the double patenting doctrine, which is to prevent the unwarranted extension of an exclusive right." Brief for Appellants at 44-45, *U.S. Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247 (Fed. Cir. 1989) (Nos. 88-1166, 88-1167, 88-168, 88-169, 88-1170, 88-1171). In sum, the defendants argued, as does the PTO here, the "availability of alternative processes should thus be judged as of the

invention date for the product and the process." *Id.* at 45.

The Federal Circuit disagreed. After dispensing with the defendants various other arguments, the Federal Circuit stated, "We have carefully considered defendants' arguments regarding . . . double patenting . . . . We find none persuasive of error in the district court's disposition of any of those issues and none of sufficient import to require discussion here of that disposition." *Phillips III*, 865 F.2d at 1253.

In light of the Federal Circuit's rejection of the precise arguments the PTO raises before this Court and the sound reasoning Judge Schwartz articulated in *Phillips I*, the Court holds that, in conducting a double patenting analysis in a product-process case, it may look to subsequent developments in the art when determining whether an alternative process exists to make the previously patented product. Therefore, the processes disclosed in the Gerlach and Monguzzi patents are legally relevant to the Court's double patenting analysis.

III. THE BOARD'S DECISION

A. Alternative Processes for Making the Compounds of the '606 Patent

Takeda contends the Board's opinion is flawed because it is based on the erroneous factual premise that the '216 patent claims the only process to make the cephem compounds claimed in the '606 patent. Pl.'s Mot. 6. In support of its argument, Takeda points to the processes described in Dr. Duggan's declaration. Pl.'s Mot. 13-16.

As stated, the Board opined that Takeda's appeal "boil[ed] down" to whether Takeda was entitled to secure a patent to the process of making some of the compounds claimed in its previously secured patent where two conjunctive factual underpinnings exist, one of which being that "there is no credible alternative method for making the cephems [that] does not involve an

infringement of the ['216] patent." Board Op. at 13. This factual finding—that no alternatives exist—formed the basis of the Board's entire opinion. Indeed, the Board used the following analysis to reject the '216 patent on double patenting grounds: (1) the process described in the '216 patent makes some of the cephem compounds of the expired '606 patent, Board Op. at 15; (2) Takeda failed to establish that credible "independent and distinct" methods exist to make those compounds, Board Op. at 22, 26; (3) the '216 patent thus extends Takeda's patent rights as to the those compounds in the expired '606 patent, Board Op. at 24; (4) Takeda provided no justification for waiting 15 years after applying for cephem compound patents to first present the process claim in the '216 patent, Board Op. at 24-25; and, (5) therefore, the '216 patent unjustly extends Takeda's patent rights, Board Op. at 24.

The new evidence Takeda presents to this Court—Dr. Duggan's declaration and the alternative processes disclosed therein—renders the Board's factual premise for rejecting the '216 patent on double patenting grounds in error. The declaration explains, and the PTO does not dispute, Def. Mot. 21 n.5, that the "'329 patent[, i.e. the Monguzzi patent,] discloses an alternative method for making compounds claimed in the '606 patent that are also produced by the '216 patent," PX 6 ¶ 125, and that the Monguzzi patent's process is a "viable alternative" to that of the '216 patent. PX 6 ¶ 130. Similarly, according to Dr. Duggan, the Gerlach patent discloses a "variation of the method used in . . . the '329 patent for making the cephem compounds claimed in the '606 patent," PX 6 ¶ 136, and, like the Monguzzi patent's process, the Gerlach patent's process is a "viable alternative to the method of making cephem compounds recited in the claims of the '216 patent," PX 6 ¶ 141, which, again, the PTO does not dispute, Def.'s Mot. 21 n.5.

In light of these undisputed facts, and contrary to the Board's finding, the '216 patent does not claim the only process for making the compounds claimed in the '606 patent. The Board's factual basis for rejecting the '216 patent on double patenting grounds—i.e, "that some or all of the compound claims of an expired compound patent continue to be monopolized by virtue of patent rights in a narrow method patent," Board Op. at 23-24—is, therefore, patently incorrect. Given the admittedly alternative processes disclosed in the Gerlach and Monguzzi patents, the '216 patent does not grant Takeda the right to exclude members of the public from making the cephem compounds claimed in the now-expired '606 patent and, thus, does not extend Takeda's patent rights (or, as the Board put it, "monopoly") over those compounds.

B. Unexplained Delay

The PTO also contends this Court should uphold the Board's decision because "the Federal Circuit recognized that an unexplained delay in prosecuting claims could support a double patenting rejection." Def.'s Mot. 19 (citing *Geneva Pharms.*, 349 F.3d at 1382). Countering, Takeda challenges as unsound the Board's reliance on Takeda's "unexplained delay" in filing its application for a process patent to reject the '216 patent on double patenting grounds.[8] Pl.'s Mot. 16-18.

Takeda is correct. Indeed, as the Federal Circuit stated in *General Foods Corp. v.*

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[8] Takeda also contends the delay is explained, arguing "the record is clear that Takeda filed its process claims shortly after a change in law that strengthened U.S. process patent protection and for the first time made the instant process claims meaningful in the U.S." Pl.'s Reply 4-7. While a change in United States law did strengthen process patents, *see Eli Lilly*, 82 F.3d at 1571 (noting that, prior to passage of 35 U.S.C. § 271(g), "a patentee holding a process patent could sue for infringement if others used the process in this country, but had no cause of action if such persons used the patented process abroad to manufacture products, and then imported, used, or sold the products in this country"), the Court cannot say that substantial evidence does not support the Board's finding that Takeda failed to justify its delay.

Studiengeselschaft Kohle mbH, "the determining factor in deciding whether or not there is double patenting is the existence vel non of *patentable difference* between two sets of claims." 972 F.2d at 1278-79. The PTO cites to no case based on a pre-GATT application, and this Court found none, in which the Federal Circuit relied solely on the delay in filing a continuation application to reject a claim on double patenting grounds.

The PTO's reliance on *Geneva Pharmaceuticals v. GlaxoSmithKline PLC*, 349 F.3d 1373 (Fed. Cir. 2003), is misplaced. In that case, a patent holder facing a double patenting challenge sought to invoke the statutory protection of 35 U.S.C. § 121.[9] The Federal Circuit held that § 121 applies only to a restriction requirement that the PTO documents in enough clarity and detail to show a clear line of demarcation between the independent and distinct inventions that prompted the restriction requirement. 349 F.3d at 1381. Finding no clear demarcation of the allegedly restricted subject matter, the court held that § 121's shield did not apply. *Id.* at 1382. In reaching its holding, the court noted that the applicant, GSK, took almost 25 years to prosecute its divisional and continuing patent applications and that the effect of such delay could potentially extend patent protection for the invention in the original application. *Id.* The court concluded, "For that reason as well, this thin and insufficient record simply does not operate to shield these patents under § 121 against double patenting rejections." *Id.* In the next sentence, the court noted that, because § 121 "can extend the patent term for inventions that are not

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[9] When an applicant formally submits multiple claims in an application, the PTO has discretion to require the applicant to withdraw claims that are patentably distinct, i.e., not the same invention. This is known as a restriction requirement. Applicants then typically submit the withdrawn claims in separate divisional applications. Put simply, § 121 shields the withdrawn claims presented in a later divisional application from rejection on double patenting grounds over a patent that issues from the original application. *Geneva Pharms.*, 349 F.3d at 1378.

patentably distinct, as apparently would be the case here[,] . . . this court applies a strict test for application of §121." *Id.* Thus, the court referenced GSK's prosecution delay in holding that § 121 did not apply for the purpose of explaining why the court strictly applies the clear demarcation rule,[10] not for the reason the PTO proffers here, i.e., to support a double patenting rejection.[11] Indeed, it did not even conduct a double patenting analysis of the claims at issue because, as to the patents discussed in the section in which the court noted GSK's delay, GSK only appealed the district court's determination that § 121 was unavailable to protect its patentably indistinct claims from a double patenting rejection; GSK did not contend the claims were patentably distinct. *See id.* at 1377 (noting that GSK "contends the district court erred . . . because 35 U.S.C. §121 should shield the [later] patents against nonstatutory double patenting"). *Geneva Pharmaceuticals*, therefore, does not stand for the proposition that a double patenting rejection is proper where an applicant fails to explain prosecution delay.[12]

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[10] Similarly, the PTO's manual warns examiners to carefully apply restriction requirements because, if claims withdrawn pursuant to such a requirement are not patentably distinct, two patents may issue for the same invention. *Geneva Pharms.*, 349 F.3d at 1378-79.

[11] Additionally, the unexplained delay reference is dicta, as it was not germane to the decision in the case. Indeed, the court's holding was that application of § 121 protection required that the alleged restriction requirement contain a clear demarcation between restricted subject matter and no such clear demarcation appeared in the record before the court. *Geneva Pharms.*, 349 F.3d at 1380-82.

[12] Even further from the holding in *Geneva* is the PTO's blatantly incorrect assertion in its reply brief that, "in *Geneva*, the Federal Circuit explained that the patentee's delay in diligently filing its patent claims meant that the later filed claims were invalid for obviousness-type double patenting," Def.'s Reply 5 (citing *Geneva Pharms.*, 349 F.3d at 1382).

C. *Mosler Safe & Lock Company v. Mosler Bahmann & Company*

Takeda also contends the Board's reliance on *Mosler Safe & Lock Company v. Mosler, Bahmann & Company*, 127 U.S. 354 (1888), to support a double patenting rejection is misplaced. Pl.'s Mot. 9. In *Mosler*, the Court held invalid a patent covering a "purely mechanical" process for bending angle irons where the inventor had first secured a patent for angle bars described as made by that process:

> After a patent is granted for an article described as made by causing it to pass through a certain method of operation to produce it, as, in this case, cutting away the metal in a certain manner, and then bending what is left in a certain manner, the inventor cannot afterwards, on an independent application, secure a patent for the method or process of cutting away the metal and then bending it so as to produce the identical article covered by the previous patent, which article was described in that patent as produced by the method or process sought to be covered by taking out the second patent.

127 U.S. at 361-62. The Court, in holding that the process patent was invalid, specifically noted the lower court's finding that the steps of the process were "not new" and were "known and used before the date of the patentee's invention" and that the use in the process of an "old and familiar method" required no "inventive faculty." *Id.*

As the PTO notes, sixteen years after the *Mosler* decision, the Court, citing the "well-settled rule that two valid patents for the same invention cannot be granted either to the same or to a different party," stated that, in *Mosler*, "it was held that, a patent having issued for a product as made by a certain process, a later patent could not be granted for the process which results in the product." *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 197 (1894). The Court later clarified, however, stating that the

> process [in *Mosler*] was a purely mechanical process, and the ruling, it would seem, *must be confined to the exact facts of the case*, for in *Miller v. Eagle Mfg.*

> *Co.*, it was said that 'a single invention may include both the machine and the manufacture it creates, and in such cases, if the inventions are really separable, the inventor may be entitled to a monopoly of each.' And *Sewall v. Jones*, 91 U.S. 171 [(1875)], was cited for the purpose of showing that there might be a patent for the process and one for the product.

Fireball Gas Tank & Illuminating Co. v. Commercial Acetylene Co., 239 U.S. 156, 166 (1915) (emphasis added).

The Court agrees with Takeda that *Mosler* does not save the Board's decision from error. Unlike in *Mosler*, the process at issue here is not purely mechanical. Nor is there any argument that the entirety of the '216 process is not new or that the process is merely the use of an old method that requires no inventive faculty. Overall, neither *Mosler* nor any other Supreme Court case broadly prohibits an inventor from receiving a process patent after earlier obtaining a product patent where the inventor could have presented the claims in a single patent. Rather, precedent is to the contrary. *See, e.g.*, *Providence Rubber Co. v. Goodyear*, 76 U.S. 788, 796 (1869) (holding that where a process and the resulting product are new, both are separately patentable: "Patentability may exist as to either, neither, or both, according to the fact of novelty, or the opposite. The patentability, or the issuing of a patent as to one, in nowise affects the rights of the inventor or discoverer in respect to the other"); *see also* 3A Chisum on Patents § 9.02[3] at 9-8 (2005) ("The statement in *Mosler* falls short of a position that one may never obtain a later patent on a method of making a product that is the subject of a prior patent.").

V. PATENTABILITY

The PTO contends Takeda is not entitled to a reexamination certificate for the '216 patent, arguing that, as a matter of law, the '216 patent is invalid based on nonstatutory double patenting over the '606 patent. Def.'s Mot. 11 ("The underlying issue of patentability is whether

Takeda's claims are invalid for obviousness-type double patenting over one of Takeda's earlier patents—the '606 patent . . . ."). Takeda asserts entitlement to a reexamination certificate on the basis that the subject claims of the '216 and '606 patents are patentably distinct and, thus, not subject to a double patenting rejection because there are independent and distinct methods for making the cephum products claimed in the '606 patent. Pl.'s Mot. 6, 13. Because the Court finds that the '216 and '606 patents' claims are patentably distinct, it will grant Takeda's summary judgment motion.

By statute, Congress limits the duration of a patentee's right to exclude others from practicing a claimed invention. See 35 U.S.C. § 154(a)(2). The double patenting doctrine precludes a patentee from improperly extending its limited patent period by obtaining more than one valid patent for either the "same invention"or an "obvious" modification of the same invention. *In re Longi*, 759 F.2d 887 (Fed. Cir. 1985). Same-invention double patenting is based on 35 U.S.C. § 101, which allows for only one patent per invention. "The judicially-created doctrine of obviousness-type double patenting," which is not statutorily based and which the PTO raises here, "prohibit[s] a party from obtaining an extension of the right to exclude through claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent." *Eli Lilly and Co. v Barr Labs., Inc.*, 251 F.3d 955, 967 (Fed. Cir. 2001). The Federal Circuit summarized double patenting law as follows: "Is the same invention being claimed twice? If the answer to that is no, a second question must be asked: Does any claim in the application define merely an obvious variation of an invention claimed in the patent asserted as supporting double patenting? If the answer to that question is no, there is no double patenting." *General Foods Corp. v. Studiengeselschaft Kohle mbH*, 972 F.2d 1272,

1278 (Fed. Cir. 1992).

To determine whether obviousness-type double patenting exists, the Court must (1) "construe[] the claim in the earlier patent and the claim in the later patent and determine[] the differences" and (2) "determine[] whether the differences in subject matter between the two claims render the claims patentably distinct." *Eli Lilly*, 251 F.3d at 968. In sum, "the determining factor" for this Court "in deciding whether or not there is double patenting is the existence vel non of patentable difference between" the '216 and '606 patents. *General Foods*, 972 F.2d at 1278-79.

As the parties agree, the '606 patent claims cephem compounds and the '216 patent claims a process for making certain of those compounds. *See* Pl.'s Mot. 4 ("The '216 patent claims one specific manufacturing method for making cephem compounds that are claimed in Takeda's expired '606 patent."); Def.'s Mot. 18 ("[T]he process in the '216 patent makes most of the products that were claimed in the now-expired '606 patent."). Thus, the difference between the patents is that one claims a process and one claims a product.

Both parties also agree that, for purposes of this Court's determination as to whether the claims are patentably distinct, "a double patenting rejection on a later process claim is not appropriate where more than one viable process exists to make a product claimed in an earlier patent." Def.'s Reply 7-8; *see* Pl.'s Mot. 6 (citing *In re Cady*, 77 F.2d 106, 109 (C.C.P.A. 1935), for proposition that a process claim is "patentably distinct" from a product claim if "independent and distinct" methods exist for making the product), 13.

In *In re Cady*, the Federal Circuit's predecessor, whose decisions are binding on the Federal Circuit, *see South Corp. v. United States*, 690 F.2d 1368, 1370 (Fed. Cir. 1982) (en

banc), held that "the legal precedents are uniformly to the effect that double patenting is not sustainable when the product can be fabricated by processes other than that secured by the issued process patent," 77 F.2d at 109 (internal quotation marks omitted) (citing *Providence Rubber Co. v. Goodyear* 76 U.S. 788 (1869); *Seymour v. Osbourne*, 78 U.S. 516 (1870); *Leeds & Catlin Co. v. Victor Talking Machine Co.*, 213 U.S. 301 (1909); *United States ex rel. Steinmetz v. Allen*, 192 U.S. 543 (1904)). Similarly, the PTO's Manual of Patent Examining Procedure directs that process and product claims are "distinct inventions" where "the product as claimed can be made by another materially different process." MPEP § 806.05(f). *See also Phillips*, 604 F. Supp. at 562 (noting that, in product-process cases, the C.C.P.A., in some instances, held that "a charge of double patenting will not be sustained if the product can be made by processes other than that secured by the issued process patent" (citing *In re Taylor*, 360 F.2d 232, 235-36 (C.C.P.A. 1966); *Cady*, 77 F.2d at 109; 1 Horowitz, *Patent Office Rules and Practice* § 79.12).

Here, the parties agree that the processes described in Dr. Duggan's declaration—i.e., the processes disclosed in the Gerlach patent and the Monguzzi patent—are alternative processes to make the cephum compounds contained in the '606 patent. Pl.'s Mot. 13-15; Def.'s Mot. 21 n.5 ("For purposes of this motion only, the USPTO does not dispute the technical merits of Dr. Duggan's declaration."). Because viable, alternative processes exist to make the products claimed in the '606 patent, the Court finds that the '216 patent's process claim is patentably distinct from the '606 patent and, therefore, holds that, as a matter of law, the '216 patent is not invalid on double patenting grounds. *See General Foods*, 972 F.2d at 1278-79 ("[T]he determining factor in deciding whether or not there is double patenting is the existence vel non of *patentable difference* between two sets of claims."); *Phillips I*, 604 F. Supp. at 567 (holding that

double patenting does not exist where product can be made by process other than patented process); *cf. Eli Lilly*, 251 F.3d at 967 ("A later claim that is not patentably distinct from an earlier claim in a commonly owned patent is invalid for obvious-type double patenting.").

CONCLUSION

Because the Duggan declaration is new evidence on an issue Takeda presented to the Board and Takeda was not negligent in failing to present such evidence to the Board, the declaration is competent evidence on which Takeda can rely in challenging the Board's decision before this Court. The Court can look to the processes disclosed in the Duggan declaration in conducting its double patenting analysis, as subsequent developments in the art are relevant to determining whether alternative processes exist to fabricate a previously patented product. Because the processes disclosed in the Duggan declaration make the same cephem products contained in the '606 patent as does the '216 patent process claim, the '216 patent and the '606 patent are patentably distinct. Consequently, as a matter of law, the '216 patent is not invalid on double patenting grounds over the claims of the now-expired '606 patent. The Court will, therefore, **GRANT** Takeda's motion for summary judgment that it is entitled to a reexamination certificate confirming its rights to the '216 patent and **DENY** the PTO's summary judgment motion.

A separate order accompanies this memorandum opinion.

September 18, 2007

/s/
Thomas F. Hogan
Chief Judge