

# United States Court of Appeals for the Federal Circuit

2008-1131

TAKEDA PHARMACEUTICAL CO., LTD.,

Plaintiff-Appellee,

v.

John J. Doll, ACTING UNDER SECRETARY OF COMMERCE FOR  
INTELLECTUAL PROPERTY and ACTING DIRECTOR, UNITED STATES  
PATENT AND TRADEMARK OFFICE,

Defendant-Appellant.

Harold C. Wegner, Foley & Lardner LLP., of Washington, DC, argued for plaintiff-appellee. With him on the brief were Stephen B. Maebius, Leon Radomsky, and C. Edward Polk, Jr.

Sarang Vijay Damle, Attorney, Commercial Litigation Branch, Civil Division, United States Department of Justice, of Washington, DC, argued for defendant-appellant. With him on the brief was Scott R. McIntosh, Attorney. Of counsel on the brief was William G. Jenks, Associate Solicitor, Office of the Solicitor, United States Patent and Trademark Office, of Arlington, Virginia. Of counsel were Raymond T. Chen, Solicitor, and Shannon M. Hansen, Associate Solicitor.

Appealed from: United States District Court for the District of Columbia

Senior Judge Thomas F. Hogan

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Defendant-Appellant.

Appeal from the United States District Court for the District of Columbia in case no. 06-CV-1640, Senior Judge Thomas F. Hogan.

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DECIDED: April 10, 2009

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Before RADER, SCHALL, and MOORE, Circuit Judges.

Opinion for the court filed by Circuit Judge, RADER. Opinion concurring-in-part and dissenting-in-part filed by Circuit Judge, SCHALL.

The United States District Court for the District of Columbia held that later developments in the art may inform the “patently distinct” determination for double patenting. Double patenting doctrines and case law permit this court to agree in part, but only to the extent that the subsequent developments predate the secondary application that triggers a double patenting rejection. Because genuine issues of fact cloud the date of availability of materially distinct processes, as well as the viability of those processes, this court vacates and remands.

I.

Takeda Pharmaceutical Co., Ltd. (Takeda) filed a patent application disclosing certain cephem compounds and the process for making those compounds in Japan on December 19, 1974. Takeda filed later applications in the United Kingdom on June 9, 1975, and in the United States on December 19, 1975. Takeda developed these new cephem compounds through an acylation process, introducing a new acyl group (RC=O) to an amino group (-NR<sub>3</sub>).

Takeda obtained a number of patents claiming these cephem compounds through a series of continuations, continuations-in-part, and divisional applications, including the compound patents that issued as U.S. Patent No. 4,098,888 (the '888 product patent) (application filed Dec. 19, 1975) and its divisional, U.S. Patent No. 4,298,606 (the '606 product patent) (application filed Aug. 28, 1979). This court refers to the December 19, 1975 application as the "primary application." Takeda filed these applications before June 8, 1995, making them subject to the seventeen year patent term regime. See 35 U.S.C. § 154(c). In other words, the patent terms on these inventions began on their grant date, not on their filing date.

On January 8, 1990, Takeda filed its secondary application covering the process for making the cephem compounds claimed in the '888 and '606 product patents—sixteen years after the 1974 priority date, and more than fourteen years after the filing of the '888 product patent application. The process patent issued as U.S. Patent No. 5,583,216 (the '216 process patent) on December 10, 1996, claiming the sole process known and disclosed in the Japanese priority patent application. The '216 process patent led to the double patenting issue in this appeal.

In 1998, the United States Patent and Trademark Office (PTO) received two anonymous requests for reexamination of the '216 process patent. These requests asserted that the '216 process patent was invalid for “obviousness-type” double patenting in view of Takeda’s prior patents, as well as other prior art. During reexamination, Takeda relied upon the declaration of Dr. Wuest disclosing an alternative process (displacement process) for making the cephem compounds claimed in the '216 patent. Not persuaded by the Wuest declaration, the examiner rejected the '216 process patent claims as patentably indistinct over the '606 product patent claims. Takeda appealed the rejection to the Board of Patent Appeals and Interferences (the Board). The Board dismissed Dr. Wuest’s declaration as “speculative” and upheld the examiner’s double patenting rejection.

Takeda challenged the Board’s decision in the District Court for the District of Columbia under 35 U.S.C. § 145. Before the district court, Takeda presented new evidence in the form of a declaration of Dr. Duggan. In her declaration, Dr. Duggan explained that the process disclosed in U.S. Patent Nos. 6,552,186 (the Gerlach patent, published on Sept. 12, 2002, issued Apr. 22, 2003) and 7,071,329 (the Monguzzi patent, published June 2, 2005, issued July 4, 2006) provides a viable alternative, non-infringing process for making the certain cephem compounds claimed in the '606 product patent.

For purposes of cross-motions for summary judgment, the parties stipulated that “Method B” of the Duggan declaration described a materially distinct alternative process. Therefore, before the district court, the parties disputed whether the

alternative process—Method B, developed after the date of invention—could defeat the double patenting rejection.

The district court concluded that “subsequent developments in the art [are relevant to] determining whether alternative processes exist” when weighing patentable distinctions for double patenting. Takeda Pharm. Co. v. Dudas, 511 F. Supp. 2d 81, 91 (D.D.C. 2007). Relying on Dr. Duggan’s disclosure of Method B (published in the Gerlach and Monguzi patents in 2002 and 2005, respectively) the district court found that the product and process are “patentably distinct” and overturned the double patenting rejection. Id. at 92. The district court therefore granted Takeda’s motion for summary judgment that it was entitled to a reexamination certificate, confirming its right to the ’216 patent. At the same time, the court denied the PTO’s motion for summary judgment. The PTO timely filed a notice of appeal with this court.

## II.

This court reviews a grant of summary judgment without deference. Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp., 149 F.3d 1309, 1315 (Fed. Cir. 1998). Summary judgment is appropriate if the record discloses no genuine issues of material fact. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986). A material fact is one “that might affect the outcome of the suit under the governing law”; an issue is genuine “if the evidence is such that a reasonable [factfinder] could return a verdict for the nonmoving party.” Id. at 248. This court reviews the Board’s factual findings for “substantial evidence.” Mazzari v. Rogan, 323 F.3d 1000, 1005 (Fed. Cir. 2003). However, this court reviews the ultimate legal conclusion regarding double patenting without deference. In re Goodman, 11 F.3d 1046, 1050 (Fed. Cir. 1993).

A.

Double patenting generally prevents a patentee from receiving two patents and extending the term of exclusivity for a single invention. See Perricone v. Medicis Pharm. Corp., 432 F.3d 1368, 1372 (Fed. Cir. 2005). The proscription against double patenting takes two forms: statutory and non-statutory. Id. Statutory, or “same invention,” double patenting finds its origin in the statutory grant of “a patent” for any new and useful invention. 35 U.S.C. § 101; Perricone, 432 F.3d at 1372-73. Non-statutory, or “obviousness-type,” double patenting is a judicially created doctrine designed to foreclose “claims in separate applications or patents that do not recite the ‘same’ invention, but nonetheless claim inventions so alike that granting both exclusive rights would effectively extend the life of patent protection.” Perricone, 432 F.3d at 1373.

In other words, the double patenting doctrine is designed to prevent “unjustified timewise extension of the right to exclude.” In re Van Ornum, 686 F.2d 937, 943-44 (CCPA 1982). For instance, the doctrine bars an applicant from obtaining separate patents with separate terms for both a product and process for making that product, unless the product and process are “patentably distinct.” See In re Taylor, 360 F.2d 232, 234 (CCPA 1966); In re Cady, 77 F.2d 106, 109 (CCPA 1935) (instructing that “double patenting is not sustainable when the product can be fabricated by processes other than that secured by the issued process patent”) (quotation marks omitted). The PTO’s Manual of Patent Examining Procedure (MPEP) explains that a product and its process are patentably distinct if “the product as claimed can be made by another materially different process.” MPEP § 806.05.

The parties agree that product and process claims are patentably distinct if multiple processes for creating a product exist at the time of the invention. See, e.g., In re Cady, 77 F.2d at 109 (finding that the process of manufacturing roofing material was patentably distinct from roofing composition when “appellant’s product as defined in the appealed claims may be produced by processes other than the processes patented”).

The novel legal question in this case asks if later-developed alternative processes are relevant in the product-process “patentably distinct” inquiry. The PTO contends that the date of invention, in this case December 19, 1974, governs the relevance of products and processes in the double patenting context. Thus, the PTO submits that the date of invention governs the timing of double patenting analyses because other issues relating to patentability are judged from the date of invention. For example, the patentability requirements set forth in §§ 112, 102, and 103 are judged as of the date of invention or filing. See 35 U.S.C. §§ 112, 102, 103. The PTO does not cite statutory or case support for the “date of invention” approach other than analogizing to these other patentability requirements. In the alternative, the PTO posits that alternative processes must at least appear before issuance of the primary patent application.

Takeda, on the other hand, argues that the PTO’s approach is too limited. In its view, processes developed after the date of invention deserve a role in the double patenting calculus. Acknowledging that this court has not directly addressed this legal question before, Takeda relies on a district court case for the proposition that a court can look to processes developed after the date of invention for product-process double

patenting situations. See Phillips Petroleum Co. v. U.S. Steel Corp., 604 F. Supp. 555 (D. Del. 1985) (Phillips).

In Phillips, the district court considered a process developed in 1954, one year after the date of invention. Id. at 567. In a footnote, the district court noted that courts have considered developments in the art arising after the date of invention when resolving double patenting issues. In those cases, however, the parties did not object to the court's consideration of post-date inventive developments. Id. at 568. The district court further noted the Board's discussion in Ex Parte Hogan, No. 436-63, (Pat. & Tr. Office Bd. App. Mar. 30, 1981), a non-precedential case from the Board of Patent Appeals. In Ex Parte Hogan, the Board considered a later-disclosed process in a double patenting challenge. See slip op. at 5. Agreeing that later-developed processes are relevant to the "patentably distinct" inquiry, the Phillips 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." Phillips, 604 F. Supp. at 568. This court affirmed Phillips on appeal. U.S. Steel Corp. v. Phillips Petroleum Co., 865 F.2d 1247 (Fed. Cir. 1989) (Phillips II).

In this case, Takeda argues that this court's affirmance of Phillips rejected the PTO's exact "date of invention" position. But on closer look, the only mention of double patenting in Phillips II is in the penultimate paragraph:

### III. Remaining Arguments

We have carefully considered defendants' arguments regarding: (1) 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.

#### IV. Conclusion

The judgment of the district court is affirmed in all respects.

Id. at 1253 (emphasis added). While Phillips II affirmed Phillips “in all respects,” this court did not address the double patenting argument. Thus, Phillips II did not present a rule or reasoning that decides the case before this court in this appeal. See Nat'l Cable Television Ass'n, Inc. v. Am. Cinema Editors, Inc., 937 F.2d 1572, 1581 (Fed. Cir. 1991) (“When an issue . . . is ignored in a decision, such decision is not precedent to be followed in a subsequent case in which the issue arises.”).

The PTO argues that here, the product and process were not “patently distinct” as of the date of invention, so the double patenting doctrine should bar consideration of later-filed process claims. However, adopting the PTO’s approach of the “date of invention” is only appealing at first glance. It appears to provide a bright-line test that conforms to the perspective used in other patentability determinations. But as Takeda points out in its brief, the “date of invention” raises other substantive questions such as: is the filing date the presumptive “date of invention”? If so, what is the date of invention, the domestic or foreign filing date? If foreign, must a claim have been “perfected” under § 119(e) with the filing of a certified copy of the original foreign application and an English language translation? What if the priority application contains support for some but not all of the patent claims? Would some of the claims be judged as of different cutoff dates? What if the inventor swears behind a reference?

In contrast, the district court’s “doing away with blinders” approach allows an applicant to come forward with any evidence that its product and process are patentably distinct, even if the alternative process is developed decades after the filing dates of the

product and process applications. The approach provides the patentee with the best of both worlds: the applicant can use the filing date as a shield, enjoying the earlier priority date in order to avoid prior art, and rely on later-developed alternative processes as a sword to defeat double patenting challenges. Here, the primary application, directed to certain cephem compounds, was filed in the United States on December 19, 1975. The secondary application, directed to the process for making these cephem compounds, was filed in 1990. Yet the district court relied on patent applications published several decades later to show a patentable distinction between the product and process.

This court is not persuaded by either approach. Neither approach addresses the policies underlying the double patenting doctrine. The secondary application (in this case, the process application of January 8, 1990) actually triggers the potential of an “unjustified extension of patent term.” When filing the secondary application, the applicant essentially avers that the product and process are “patently distinct.” Thus, the relevant time frame for determining whether a product and process are “patently distinct” should be at the filing date of the secondary application. In this case, Takeda filed the ’216 process patent application on January 8, 1990. This approach allows an applicant to rely on some later-developed methods to show that the product and process are “patently distinct,” even though the alternative processes for making that product may not have been known at the filing date of the primary application. This rule gives the applicant the benefit of future developments in the art. At the same time, however, it prevents the inequitable situation that arises when an applicant attempts to

rely on developments occurring decades after the filing date of the secondary application.<sup>1</sup>

This approach should encourage the swift development of materially distinct, alternative processes. It is also consistent with the district court's opinion in Phillips, 604 F. Supp. at 567 (considering an alternative process developed one year after the filing date of the primary application, and prior to the filing of the secondary application).

Therefore, in this case, the applicant can rely on subsequent developments in the art up to January 8, 1990, the filing date of the secondary application, in order to show a patentable distinction between the cephem compounds claimed in the '606 product patent and the process for making those compounds claimed in the '216 process patent. In that regard, Takeda indicates that it disclosed an unclaimed process (which it terms the "Displacement Process" or the "Unelected Method") in the '888 product patent application. The PTO, however, has continually "dispute[d] the viability of the . . . [D]isplacement [P]rocess." Additionally, Takeda asserts that Method B, disclosed in the Gerlach and Monguzzi patents and described in the Duggan Declaration, was disclosed as early as 1979. On this point, the PTO states that it "di[d] not dispute the technical merits of Dr. Duggan's declaration" only for purposes of cross-motions for summary judgment. Further, the PTO stated in its motion for summary judgment that "[t]he only

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<sup>1</sup> The dissent's hypothetical is a stretch. It assumes nineteen years of co-pendency. Today, patent terms are triggered by the filing date, not the grant date. In other words, both the product and process patents will expire around the same time (although there may be slight variance due to patent term adjustment). As such, an applicant is less likely to maintain co-pendency for nineteen years. Moreover, this court's prosecution laches doctrine "may render a patent unenforceable when it has issued only after an unreasonable and unexplained delay in prosecution." Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found., 422 F.3d 1378, 1384-85 (Fed. Cir. 2005).

'alternative' processes that Takeda (through Dr. Duggan's declaration) has identified to this Court are the processes described in . . . the 'Gerlach' patent[ ] and in . . . the 'Monguzzi' patent[ ]." Today, this court holds that the district court may not rely on the Gerlach and Monguzzi patents. But questions of material fact remain as to (1) the viability of the Displacement Process, and (2) the disclosure date of Method B. On remand, the district court should determine whether these processes were disclosed before January 8, 1990, the date of filing of the '216 process patent.

### III.

Because genuine issues of material fact exist with respect to whether the cephem compound and later-developed processes are "patentably distinct," this court vacates and remands for further factual development.

### VACATED AND REMANDED

### COSTS

Each party shall bear its own costs.

# **United States Court of Appeals for the Federal Circuit**

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Defendant-Appellant.

Appeal from the United States District Court for the District of Columbia in case no. 06-CV-1640, Senior Judge Thomas F. Hogan.

SCHALL, Circuit Judge, concurring-in-part and dissenting-in-part.

I agree with the majority that, in arguing against the claim of obviousness-type double patenting in the reexamination proceeding, Takeda should not be able to rely on the disclosures of the Gerlach and Monguzzi patents. However, I respectfully part company with the majority in its conclusion that Takeda should be able to rely on developments in the art up to January 8, 1990, the date of the filing of the '216 process patent application. In my view, in arguing against the claim of obviousness-type double patenting, Takeda should not be able to rely on disclosures after the December 19,

1974 invention date.<sup>1</sup> I believe that tying the inquiry to the invention date is most commensurate with patent law as a whole and the policy goals relating to obviousness-type double patenting.

First, it seems to me that the date of invention is most appropriate because it comports with current patentability doctrines, and, as I explain later, I view product-process obviousness-type double patenting as a patentability doctrine. See, e.g., 35 U.S.C. § 102(a) (“A person shall be entitled to a patent unless . . . the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.” (emphasis added)); 35 U.S.C. § 102(e) (“A person shall be entitled to a patent unless . . . the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent . . .” (emphases added)); Apotex Corp. v. Merck & Co., 507 F.3d 1357, 1359 (Fed. Cir. 2007) (“35 U.S.C. § 102(g) provides that an applicant is not entitled to a patent if ‘before such person’s invention thereof, the invention was made in this country by another, who had not abandoned, suppressed, or concealed it.’” (quoting 35 U.S.C. § 102(g)) (emphasis added)); In re Translogic Tech., Inc., 504 F.3d 1249, 1259 (Fed. Cir. 2007) (“An invention is unpatentable as obvious if the differences between the patented subject matter and the prior art would have been obvious at the time of invention to a person of ordinary skill in the art.” (emphasis added)); cf. Phillips v. AWH Corp., 415 F.3d 1303,

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<sup>1</sup> The PTO and Takeda used this date as the “presumed date of invention” in briefing and argument, so I will use it here as well.

1313 (Fed. Cir. 2005) (en banc) (“We have made clear . . . that the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” (emphasis added)); Plant Genetic Sys., N.V. v. DeKalb Genetics Corp., 315 F.3d 1335, 1339 (Fed. Cir. 2003) (“Enablement is determined as of the effective filing date of the patent.” (emphasis added)).

Second, we have previously emphasized the invention date with respect to obviousness-type double patenting:

The public should . . . be able to act on the assumption that upon the expiration of the patent it will be free to use not only the invention claimed in the patent but also modifications or variants which would have been obvious to those of ordinary skill in the art at the time the invention was made, taking into account the skill of the art and prior art other than the invention claimed in the issued patent.

In re Longi, 759 F.2d 887, 893 (Fed. Cir. 1985) (emphases from original omitted, emphasis added). Pertinent to this case, I view product-process obviousness-type double patenting as a patentability doctrine. At the date of invention, if only one process exists to make the product, the two are “substantially co-extensive.” See PTO’s Br. 17. To allow two patents to issue at that time would essentially run afoul of 35 U.S.C. § 101, as the applicant would be receiving two patents on one invention.<sup>2</sup> See, e.g., In re Vogel, 422 F.2d 438, 441 (CCPA 1970); In re Ockert, 245 F.2d 467, 469 (CCPA 1957).

In a difficult case, the majority settles upon what I would characterize as a not-unreasonable attempt at compromise. Rejecting the approaches of both Takeda and

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<sup>2</sup> Although this view is admittedly overly simplistic, tracing the product-process double patenting doctrine back to its § 101 origins serves to bolster the connection between the doctrine and other questions of patentability.

the government, it holds that “the relevant time frame for determining whether a product and process are ‘patentably distinct’ should be at the filing date of the [‘216 process patent application].” It thus concludes, in the setting of a pre-1995 filing, that art developed after a product/process invention date, but before a subsequent process patent application filing date, can render a previously unpatentable process patentable. Through its approach, the majority concludes it is preventing the patentee from having the best of both worlds, whereby “the applicant can use the filing date as a shield, enjoying the earlier priority date in order to avoid prior art, and rely on later-developed alternative processes as a sword to defeat double patenting.” Maj. op. at 8. However, while the majority’s approach is more restrictive than that urged by Takeda, it still allows Takeda to exclude sixteen years of prior art for invalidity purposes (such as 35 U.S.C. §§ 102, 103), while simultaneously taking advantage of that art to overcome a double-patenting rejection. This is what troubles me about the majority’s understandable desire to find a middle ground in this case. It allows Takeda to have it both ways. In addition, as far as I can tell, there is no other doctrine or rule that allows unpatentable material to spring back into patentability based on later developments in the field.

As correctly stated by the majority, “[t]he fundamental reason for the rule [of obviousness-type double patenting] is to prevent unjustified timewise extension of the right to exclude granted by a patent no matter how the extension is brought about.” Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 967–68 (Fed. Cir. 2001) (quoting In re Van Ornum, 686 F.2d 937, 943–44 (CCPA 1982)) (alterations in original). The majority’s approach, it seems to me, allows for such an extension. The product and the unpatentable process should both have entered into the public domain in 1998, when

the '606 patent expired. At that point, members of the public should have been able to make the cephem compounds without paying royalties to Takeda or to another company. However, Takeda's rights in the '216 process patent will not expire until 2013—almost forty years after its process was first disclosed. In my view, this is an “unjustified timewise extension” of the right to exclude. Although the cephem compounds are in the public domain, no currently unpatented method exists for making them.

I am also concerned that the majority's approach could, in certain cases, result in the upsetting of reasonable expectations as to what is in the public domain. For example, let us assume we are in the seventeen-year regime, as we are in this case. Takeda is granted a product patent in year one. At that time, only one process exists (Process A). That process is disclosed, but not claimed, in the patent. In year eighteen, the product patent expires, putting Process A fully into the public domain. In addition, during the seventeen-year patent term, no other process has been developed, and thus Process A remains unpatentable separately because it is coextensive with the product patent. See In re Taylor, 360 F.2d 232, 234 (CCPA 1966); In re Cady, 77 F.2d 106, 109 (CCPA 1935) (“[D]ouble patenting is not sustainable when the product can be fabricated by processes other than that secured by the issued process patent.”). Then, in year nineteen, a second process, called Process B, is invented for making the patented product. The initial inventor then files a patent application on Process A (assume proper co-pendency with the product patent), triggering double-patenting concerns. According to the majority's approach, this second process would cause Process A to become patentable, despite the fact that Process A and the resulting product were in

the public domain for one year. It seems to me such a result runs counter to public expectation and patent law's public notice function.

Finally, the majority sets forth various questions which it says counsel toward its approach:

[A]dopting the PTO's approach of the "date of invention" is only appealing at first glance. It appears to provide a bright-line test that conforms to the perspective used in other patentability determinations. But as Takeda points out in its brief, the "date of invention" raises other substantive questions such as: is the filing date the presumptive "date of invention"? If so, what is the date of invention, the domestic or foreign filing date? If foreign, must a claim have been "perfected" under § 119(e) with the filing of a certified copy of the original foreign application and an English language translation? What if the priority application contains support for some but not all of the patent claims? Would some of the claims be judged as of different cutoff dates? What if the inventor swears behind a reference?

Maj. op. at 8.

I do not share the majority's concern. I think we must keep in mind these kinds of questions are faced regularly and have been manageable. For example, interference proceedings provide a parallel to double-patenting: a court (or the Board of Patent Appeals and Interferences) must look to the date of invention while evaluating two competing applications. That additional questions may have to be addressed if the approach urged by the government is adopted does not mean that we should ignore that approach if we feel it is correct.

It may be that the new patent term will cure many of the concerns enumerated in this opinion. However, that does not mean that we should ignore those concerns. Obviousness-type double patenting is a judicially created doctrine, and using the date of invention best comports with our previously stated policy goals underlying the doctrine.

For the foregoing reasons, I respectfully dissent from the majority's decision allowing Takeda to use developments in the art that post-date the date of invention in arguing against the obviousness-type double patenting rejection.