

United States Court of Appeals for the Federal Circuit

2009-1032

BOEHRINGER INGELHEIM INTERNATIONAL GMBH
and BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,

Plaintiffs-Appellants,

v.

BARR LABORATORIES, INC.
and BARR PHARMACEUTICALS, INC.,

Defendants,

and

MYLAN PHARMACEUTICALS, INC.,

Defendant-Appellee.

Bruce M. Wexler, Paul, Hastings, Janofsky & Walker LLP, of New York, New York, argued for plaintiffs-appellants. With him on the brief were Joseph M. O'Malley, Jr., Eric W. Dittmann and Angela C. Ni; and Stephen B. Kinnaird, of Washington, DC.

Shannon M. Bloodworth, Perkins Coie LLP, of Washington, DC, argued for defendant-appellee. With her on the brief was David J. Harth, of Madison, Wisconsin. Of counsel was Sarah C. Walkenhorst, Perkins Coie LLP, of Madison, Wisconsin.

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

Judge Joseph J. Farnan, Jr.

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Appeal from the United States District Court for the District of Delaware in consolidated cases 05-CV-700 and 05-CV-854, Judge Joseph J. Farnan, Jr.

DECIDED: January 25, 2010

Before LINN, DYK, and PROST, Circuit Judges.

Opinion for the court filed by Circuit Judge LINN. Opinion dissenting-in-part filed by Circuit Judge DYK.

LINN, Circuit Judge

This is a patent infringement case involving the effectiveness of a terminal disclaimer to overcome obviousness-type double patenting and the safe-harbor provision of 35 U.S.C. § 121. Boehringer Ingelheim International GmbH and Boehringer Ingelheim Pharmaceuticals, Inc. (collectively “Boehringer”) appeal from a final judgment

that Boehringer's U.S. Patent No. 4,886,812 (the "812 patent") is invalid for obviousness-type double patenting. Boehringer Ingelheim Int'l GmbH v. Barr Labs., Inc., No. 05-CV-700 (D. Del. Sept. 18, 2008); Boehringer Ingelheim Int'l GmbH v. Barr Labs., Inc., 562 F. Supp. 2d. 619 (D. Del. 2008). Because the district court incorrectly concluded that the safe-harbor provision of 35 U.S.C. § 121 is inapplicable in this case, we reverse and remand.

I. BACKGROUND

Boehringer is the record owner of the '812 patent, which claims certain tetrahydrobenzthiazole compounds. Boehringer, 562 F. Supp. 2d at 623; '812 patent [57], col.23 l.67-col.26 l.22. One of the claimed tetrahydrobenzthiazole compounds is 2-Amino-6-dimethylamino-4,5,6,7-tetrahydrobenzthiazole, known more commonly as pramipexole. Boehringer, 562 F. Supp. 2d at 623; '812 patent col.25 ll.19-21 (claim 7). Boehringer manufactures, markets, and sells pharmaceutical tablets containing pramipexole under the brand name Mirapex. Boehringer, 526 F. Supp. 2d at 624. On July 1, 1997, the United States Food and Drug Administration ("FDA") approved Boehringer's New Drug Application ("NDA") for Mirapex, for the treatment of "signs and symptoms of idiopathic Parkinson's disease." Id.; J.A. 947, 1017-18.

The '812 patent is the third in a chain of related patents, all of which share a common specification. The first application in the chain is U.S. Patent Application No. 06/810,947 (the "'947 application"), filed December 19, 1985. '812 patent [62]; Boehringer, 562 F. Supp. 2d at 625. The '947 application originally contained fifteen claims. Boehringer, 562 F. Supp. 2d at 625. During prosecution of the '947 application, the examiner issued a restriction requirement listing ten groups of claims related to what the examiner considered to be independent and distinct inventions:

I. Claims 1-8 (at least part of each), drawn to benzothiazole compounds and a pharmaceutical composition, classified in Class 548, subclasses 161, 163 and 164.

II. Claims 1-5 and 8-10 (at least part of each), drawn to pyrrolidinyl-substituted benzothiazole compounds and a pharmaceutical composition, classified in Class 514, subclass 367.

III. Claims 1-4 and 8 (at least part of each), drawn to piperidinyl-substituted benzothiazole compounds and a pharmaceutical composition, classified in Class 546, subclass 192.

IV. Claims 1-4 and 8 (at least part of each), drawn to hexamethylimino substituted benzothiazole compounds and a pharmaceutical composition, classified in Class 540, subclass 603.

V. Claims 1-4 and 8, drawn (at least part of each) [to] morpholinyl-substituted benzothiazole compounds and a pharmaceutical composition, classified in Class 544, subclass 135.

VI. Claim 14, drawn to a method of preparing benzothiazole compounds using a thiourea reactant.

VII. Claim 15, drawn to a method of preparing benzothiazole compounds using a disulfide reactant classified based on type of compound formed.

VIII. Claims 9 and 10, drawn to a method of lowering blood pressure or heart rate classified based on type of compound used.

IX. Claims 11 and 12, drawn to a method for treating Parkinsonism, classified based on type of compound used.

X. Claim 13, drawn to a method for treating schizophrenia, classified based on type of compound used.

U.S. Patent Appl. Serial No. 06/810,947, Office Action, at 2-3 (Sept. 4, 1986) (“Office Action”). Although the restriction requirement stated that each of the ten groups was a distinct invention, the examiner allowed the applicant to elect “either (A) one of the compound groups I-V and one of the utility groups VIII-X (composition and utility to be

limited to elected compound type for examination) or (B) one of the process groups VI and VII.” Id. at 4.

In response to the restriction requirement, the applicants elected to prosecute claims directed to the invention of Group II (pyrrolidinyl-substituted benzothiazole compounds) and to the invention of Group IX (a method for treating Parkinsonism using those compounds). Boehringer, 562 F. Supp. 2d at 625. The applicants amended the claims of the '947 application accordingly, and U.S. Patent No. 4,731,374 (the “374 patent”) issued from the application on March 15, 1988. Id.

While the '947 application was pending, the applicants filed U.S. Patent Application No. 07/124,197 (the “197 application”) as a divisional of the '947 application. Id. A different examiner was assigned to the '197 application. Id. at 625 n.2. The '197 application originally contained all of the claims of the original '947 application, but, following a rejection, the applicants amended the '197 application so that it claimed various methods of using tetrahydrobenzthiazole compounds to treat certain medical conditions. Id. at 625. The method-of-use claims of the '197 application encompassed the examiner’s demarcated inventions of Groups VIII and X of the restriction requirement, as well as that of Group IX directed to the use of compounds other than the compound of Group II elected in the '947 parent. Id.; see also Br. for Plaintiffs-Appellants 12, 14-17 (noting that “new claims 16 through 55 [of the '197 application] claimed the methods of use set forth in Groups VIII-X”). Thus, none of the claims of the '197 application covered subject matter elected in the '947 parent. The respective claims of the '197 and '947 applications were therefore divided as between applications along the lines of demarcation drawn by the examiner in the restriction

requirement. These new claims were ultimately allowed, and U.S. Patent No. 4,843,086 (the “’086 patent”) issued from the application on June 27, 1989. Boehringer, 562 F. Supp. 2d at 626. The ’086 patent expired on June 27, 2006.

On October 12, 1988, during the pendency of the ’197 application, the applicants filed U.S. Patent Application No. 07/256,671 (the “’671 application”), which was the application from which the ’812 patent issued. Id. The ’671 application was filed as a division of the second application in the chain—the ’197 application. It was not filed as a division of the first application—the ’947 application. In fact, at the time that the ’671 application was filed, the ’374 patent had already issued from the ’947 application, so no further divisionals from the ’947 application were permitted. See ’374 patent [45]; 35 U.S.C. § 120. Like the ’197 application, the ’671 application originally contained all of the claims of the original ’947 application, but it was later amended to include only compound claims other than those directed to the pyrrolidiny-substituted benzothiazoles previously claimed in the ’374 patent. Boehringer, 562 F. Supp. 2d at 626. No restriction requirement was made in the ’197 application. As Boehringer acknowledges, the amended claims encompass Groups I, III, IV, and V of the restriction requirement made in the grandparent ’947 application and do not cross the examiner’s lines of demarcation with either the claims of the grandparent ’947 application or those of the parent ’197 application. See Br. for Plaintiffs-Appellants at 16-17. The ’812 patent issued from the ’671 application on December 12, 1989—approximately six months after the issuance of the ’086 patent. Boehringer, 562 F. Supp. 2d at 626.

After the issuance of the ’812 patent and after the FDA approved Boehringer’s NDA for Mirapex, Boehringer applied for a patent term extension for the ’812 patent

under 35 U.S.C. § 156. Id. at 629. Boehringer's application stated that claims 1, 2, 3, 4, 7, 8, 9, and 10 of the '812 patent read on Mirapex. Claims 5 and 6 of the '812 patent were not listed in the application. The United States Patent and Trademark Office ("Patent Office" or "PTO") granted the application and extended the term of the '812 patent by 1,564 days, "with all rights pertaining thereto as provided by 35 U.S.C. § 156(b)." J.A. 1030. The '812 patent's original expiration date was December 12, 2006. The consequence of the 1,564-day extension was to extend Boehringer's rights in the '812 patent under § 156 until March 25, 2011.

On October 26, 2005, Mylan Pharmaceuticals, Inc. ("Mylan") notified Boehringer that it had submitted an Abbreviated New Drug Application ("ANDA") for generic pramipexole. Boehringer, 562 F. Supp. 2d at 624. In response, Boehringer brought a patent infringement action against Mylan, and the action was consolidated with Boehringer's previously filed patent infringement action against an earlier ANDA filer, Barr Laboratories, Inc. ("Barr").¹ Id. Specifically, Boehringer alleged that, by filing an ANDA, Mylan infringed claims 5, 7, 9, and 10 of the '812 patent. Id. at 623. As a defense, Mylan argued that the asserted claims of the '812 patent were invalid for obviousness-type double patenting in view of the '086 patent. Id. Mylan also counterclaimed seeking a declaration that claims 3, 4, 5, 7, 9, and 10 of the '812 patent are invalid for obviousness-type double patenting. Id.

The district court conducted a bench trial in March 2008. On the last day of trial, Boehringer sought to overcome the obviousness-type double patenting defense based on the then-expired '086 patent by filing a terminal disclaimer of the '812 patent with the

¹ Barr and Boehringer have settled, and Barr is not a party to this appeal.

Patent Office. Boehringer's terminal disclaimer purported to disclaim "only the terminal part of the statutory term of the '812 patent which would extend beyond 1,564 days after the full statutory term of the '086 patent as that term is defined in 35 U.S.C. [§] 154, so that, by virtue of this disclaimer, the ['812 patent will expire on October 8, 2010." J.A. 4199. In other words, Boehringer sought to disclaim the approximately six months of the '812 patent's original term that extended beyond the term of the '086 patent, and then to apply its 1,564-day extension to this shortened original term.

The district court concluded that Boehringer's terminal disclaimer was ineffective to overcome the obviousness-type double patenting rejection, because the disclaimer was filed after the '086 patent had expired. Boehringer, 562 F. Supp. 2d at 631. The district court also rejected Boehringer's argument that the safe-harbor provision of 35 U.S.C. § 121 precluded the use of the '086 patent as an invalidating reference. Id. at 635. On the merits, the district court concluded that the compound claims of the '812 patent were obvious in view of the method-of-use claims of the '086 patent. Id. at 640. The district court therefore held that the '812 patent was invalid for obviousness-type double patenting. Id.

The district court entered final judgment in favor of Mylan, and Boehringer timely appealed. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1) (2006).

II. DISCUSSION

Boehringer raises two issues on appeal: (1) whether its retroactive terminal disclaimer was effective to overcome invalidity based on obviousness-type double patenting; and (2) whether the safe-harbor provision of 35 U.S.C. § 121 precluded a finding of obviousness-type double patenting. Boehringer does not appeal the district

court's conclusion on the merits that the claims of the '812 patent were obvious in view of the claims of the '086 patent. We address each appealed issue in turn.

A. Retroactive Terminal Disclaimer

Because 35 U.S.C. § 101 “states that an inventor may obtain ‘a patent’ for an invention,” the statute “permits only one patent to be obtained for a single invention.” In re Lonardo, 119 F.3d 960, 965 (Fed. Cir. 1997) (emphasis added). “A double patenting rejection precludes one person from obtaining more than one valid patent for either (a) the ‘same invention,’ or (b) an ‘obvious’ modification of the same invention.” In re Longi, 759 F.2d 887, 892 (Fed. Cir. 1985). Obviousness-type double patenting is a “judicially created doctrine grounded in public policy (a policy reflected in the patent statute)” that “prevent[s] the extension of the term of a patent, even where an express statutory basis for the rejection is missing, by prohibiting the issuance of the claims in a second patent not patentably distinct from the claims of the first patent.” Id.

The purpose for the doctrine of obviousness-type double patenting is well established:

The doctrine of double patenting is intended to prevent a patentee from obtaining a time-wise extension of patent [rights] for the same invention or an obvious modification thereof.

Lonardo, 119 F.3d at 965; see also Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 967 (Fed. Cir. 2001) (“The judicially-created doctrine of obviousness-type double patenting cements [the] legislative limitation [of § 101] by prohibiting 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.”).

The doctrine of obviousness-type double patenting is an important check on improper extension of patent rights through the use of divisional and continuation

applications, at least for patents issued from applications filed prior to the amendment of 35 U.S.C. § 154 to create twenty-year terms running from the date of the earliest related application. See 35 U.S.C. § 154; Uruguay Round Agreements Act, Pub. L. No. 103-465, 108 Stat. 4809 (1994); see also In re Fallaux, 564 F.3d 1313, 1318 (Fed. Cir. 2009) (discussing rationales for obviousness-type double patenting rejections for patents issued from applications filed both before and after the amendment of the Patent Act). “The policy underlying a double patenting rejection is an important policy because it precludes the improper extension of the statutory term of patent protection for an invention.” Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc., 98 F.3d 1563, 1577 (Fed. Cir. 1996).

“For obviousness-type double patenting, [the improper extension of the statutory term] can sometimes be avoided for co-owned patents or applications through the use of a terminal disclaimer.” Id. Terminal disclaimers are expressly permitted under 35 U.S.C. § 253:

A patentee, whether of the whole or any sectional interest therein, may, on payment of the fee required by law, make disclaimer of any complete claim, stating therein the extent of his interest in such patent. . . .

In like manner any patentee or applicant may disclaim or dedicate to the public the entire term, or any terminal part of the term, of the patent granted or to be granted.

“[A] terminal disclaimer may restrict the slight variation to the term of the original patent and cure the double patenting rejection.” Geneva Pharms., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1378 (Fed. Cir. 2003).

In this case, in response to Mylan’s assertion that the ’812 patent was invalid for obviousness-type double patenting over its parent, the ’086 patent, Boehringer attempted to disclaim the terminal portion of the original term of the ’812 patent, so that

its original term would end on the date of the expiration of the '086 patent. See J.A. 4199; see also Br. for Plaintiffs-Appellants 22 (showing that, after Boehringer's terminal disclaimer, the expiration date of the original term of the '812 patent was the same as the expiration date of the '086 patent). Because the terminal disclaimer was filed on March 13, 2008—long after the expiration of the '086 patent on June 27, 2006—the district court held that the terminal disclaimer was ineffective and did not preclude the '812 patent from being held invalid on the basis of obviousness-type double patenting. Boehringer, 562 F. Supp. 2d at 631. Boehringer appeals the district court's holding. Our review is de novo. See, e.g., NTP, Inc. v. Research In Motion, Ltd., 418 F.3d 1282, 1314 (Fed. Cir. 2005) (“This court reviews the statutory construction of a district court de novo.”); Lonardo, 119 F.3d at 965 (“Double patenting is a question of law that we review de novo.”).

Preliminarily, we reject Boehringer's argument that the district court, in expressing concerns about “gamesmanship” in filing terminal disclaimers during litigation, somehow improperly imported a bar of disclaimers during litigation into the statute authorizing terminal disclaimers, 35 U.S.C. § 253. See Boehringer, 562 F. Supp. 2d at 632 n.8. The basis for the district court's rejection of Boehringer's terminal disclaimer was not that it was filed during litigation, but rather that it was filed after the expiration of the '086 patent and therefore purported to operate retroactively to disclaim a part of the term of the '812 patent that was in the past. See id. at 631 (“[A] terminal disclaimer may overcome [an obviousness-type] double patenting rejection only if the earlier patent has not yet expired.”).

We agree with Boehringer—and Mylan does not dispute—that a patentee may file a disclaimer after issuance of the challenged patent or during litigation, even after a finding that the challenged patent is invalid for obviousness-type double patenting. See, e.g., Perricone v. Medicis Pharm. Corp., 432 F.3d 1368, 1375 (Fed. Cir. 2005) (noting that there is no “prohibition on post-issuance terminal disclaimers” and that “[a] terminal disclaimer can indeed supplant a finding of invalidity for double patenting”). The question here is whether a retroactive terminal disclaimer—i.e., a terminal disclaimer that is filed after the expiration date of an earlier commonly owned patent—is effective to overcome obviousness-type double patenting.

“The 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.” In re Van Ornum, 686 F.2d 937, 943-44 (CCPA 1982) (quoting In re Schneller, 397 F.2d 350, 354 (CCPA 1968)); see also Lonardo, 119 F.3d at 965 (emphasizing purpose of doctrine of double patenting of precluding “patentee from obtaining a time-wise extension of patent [rights] for the same invention or an obvious modification thereof”). When the claims of a patent are obvious in light of the claims of an earlier commonly owned patent, the patentee can have no right to exclude others from practicing the invention encompassed by the later patent after the date of the expiration of the earlier patent. But when a patentee does not terminally disclaim the later patent before the expiration of the earlier related patent, the later patent purports to remain in force even after the date on which the patentee no longer has any right to exclude others from practicing the claimed subject matter. By permitting the later patent to remain in force beyond the date of the earlier patent’s

expiration, the patentee wrongly purports to inform the public that it is precluded from making, using, selling, offering for sale, or importing the claimed invention during a period after the expiration of the earlier patent. Cf. Paragon Solutions, LLC v. Timex Corp., 566 F.3d 1075, 1091 (Fed. Cir. 2009) (discussing importance of ability of “potential infringers to ascertain the propriety of particular activities” and “the notice function central to the patent system”); PSC Computer Prods., Inc. v. Foxconn Int’l, Inc., 355 F.3d 1353, 1361 (Fed. Cir. 2004) (emphasizing “the important public notice function of patents—the mechanism whereby the public learns which innovations are the subjects of the claimed invention, and which are in the public domain”).

By failing to terminally disclaim a later patent prior to the expiration of an earlier related patent, a patentee enjoys an unjustified advantage—a purported time extension of the right to exclude from the date of the expiration of the earlier patent. The patentee cannot undo this unjustified timewise extension by retroactively disclaiming the term of the later patent because it has already enjoyed rights that it seeks to disclaim. Permitting such a retroactive terminal disclaimer would be inconsistent with “[t]he fundamental reason” for obviousness-type double patenting, namely, “to prevent unjustified timewise extension of the right to exclude.” Van Ornum, 686 F.2d at 943-44 (emphasis removed). We therefore hold that a terminal disclaimer filed after the expiration of the earlier patent over which claims have been found obvious cannot cure obviousness-type double patenting.

We note that this holding is consistent with our treatment of this issue in Lonardo:

With obviousness-type double patenting, . . . a terminal disclaimer may overcome that basis for unpatentability, assuming that the first patent has not expired. In this case, the [patent] over which the claims have been

rejected . . . has expired, so a terminal disclaimer cannot cure these rejections.

Lonardo, 119 F.3d at 965 (emphasis added). Boehringer argues that this language in Lonardo is dicta, and that it “merely observed that there would be no reason to issue a patent application terminally disclaimed to an expired patent since that application would theoretically issue without any term.” Br. for Plaintiffs-Appellants 42. Boehringer is correct that the applicant in Lonardo did not actually file a terminal disclaimer or rely on a terminal disclaimer to cure obviousness-type double patenting. Even though we may not technically be bound by this language in Lonardo, it is instructive and our holding is consistent with it.

In this case, assuming that the claims of the '812 patent are obvious in light of the claims of the '086 patent, Boehringer would have had no right to exclude others from practicing the subject matter encompassed by the '812 patent after the expiration date of the '086 patent. However, because the '812 patent purported to remain in force after June 27, 2006, and because Boehringer did not disclaim it before then, Boehringer enjoyed an unjustified advantage—a purported time extension of the right to exclude from June 27, 2006 forward. There is nothing that Boehringer can do now to “un-exercise” the right that it has already improperly enjoyed. Boehringer’s terminal disclaimer therefore cannot cure a finding of invalidity of the '812 patent for obviousness-type double patenting.²

² Before the 1952 amendments, the predecessor to 35 U.S.C. § 253 provided that the disclaimer must be filed without unreasonable delay. See 35 U.S.C. §§ 65, 71 (1934). The 1952 amendments deleted this language. See 35 U.S.C. § 253; 66 Stat. 809. We do not see this deletion as having any bearing on whether the disclaimer must be filed before the expiration of the patent.

Boehringer argues that it did not enjoy any unjustified advantage because it had properly obtained a term extension under 35 U.S.C. § 156. More specifically, Boehringer argues that, even if the original expiration date of the '812 patent should have been June 27, 2006, the term of the '812 patent was properly extended by 1,564 days under § 156, so Boehringer has not enjoyed any rights to which it was not entitled. We disagree. Boehringer's argument rests on the faulty premise that the rights enjoyed by a patentee during the term of a patent are the same as the rights enjoyed by a patentee during the term of an extension under § 156. As the statute makes clear, however, the rights of a patentee during a term extension are limited in ways that do not normally apply to granted patents:

The rights derived from any patent the term of which is extended under this paragraph shall, during the period of interim extension—

- (i) in the case of a patent which claims a product, be limited to any use then under regulatory review;
- (ii) in the case of a patent which claims a method of using a product, be limited to any use claimed by the patent then under regulatory review; and
- (iii) in the case of a patent which claims a method of manufacturing a product, be limited to the method of manufacturing as used to make the product then under regulatory review.

35 U.S.C. § 156(d)(5)(F) (emphases added). Thus, if Boehringer had disclaimed the terminal portion of the '812 patent prior to the expiration of the '086 patent, then a competitor would have been placed on notice that, during the § 156 extension period following June 27, 2006, Boehringer only had the right to exclude the “use then under regulatory review”—namely, the use of pramipexole for the treatment of the “signs and symptoms of idiopathic Parkinson's disease,” J.A. 947, 1017-18. Likewise, because Boehringer's application for term extension was limited to claims 1, 2, 3, 4, 7, 8, 9, and

10 of the '812 patent, the public would have been on notice that Boehringer had no right to exclude the practice of claims 5 and 6 during the § 156 extension period. However, because Boehringer did not disclaim the terminal portion of the '812 patent prior to the June 27, 2006 expiration of the '086 patent, a competitor that performed a patent search on June 28, 2006 would have wrongly been led to believe that the '812 patent continued to cover the specific compounds claimed in claims 5 and 6, and that it precluded use of pramipexole for treatment of conditions beyond those approved by the FDA. This is precisely the type of “unjustified timewise extension of the right to exclude” that the doctrine of obviousness-type double patenting is designed to prevent. Van Ornum, 686 F.2d at 943-44 (emphasis removed).

We also reject Boehringer’s argument that the outcome in this case is dictated by our decision in Merck & Co. v. Hi-Tech Pharmacal Co., 482 F.3d 1317 (Fed. Cir. 2007). In Merck, the court held simply that “a patent term extension under § 156 may be applied to a patent subject to a terminal disclaimer.” Id. at 1324. The court said nothing about whether a terminal disclaimer filed after the expiration of the earlier patent over which claims have been rejected could cure obviousness-type double patenting. To the contrary, the terminal disclaimer in Merck occurred well before the expiration of the patent over which obviousness-type double patenting was asserted. See id. at 1318-19 (noting that terminal disclaimer was filed during prosecution of later patent, which issued on January 10, 1989, but that term of earlier patent extended until June 30, 2004). Merck in fact emphasized that its holding was entirely consistent with “prevent[ing] extension of patent term for subject matter that would have been obvious over an earlier filed patent.” Id. at 1323. By contrast, permitting a retroactive terminal disclaimer to

cure obviousness-type double patenting would not be consistent with preventing improper extension of a patent term. Boehringer is therefore wrong to rely on Merck.

We conclude that Boehringer's terminal disclaimer cannot overcome obviousness-type double patenting based on the '086 patent because the terminal disclaimer was filed after the expiration of the '086 patent.

B. Safe-Harbor Provision of 35 U.S.C. § 121

Boehringer argues in the alternative that the safe-harbor provision of 35 U.S.C. § 121 shields the '812 patent from invalidity on the basis of double patenting in view of the '086 patent. Section 121 provides in relevant part:

If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. If the other invention is made the subject of a divisional application which complies with the requirements of section 120 of this title it shall be entitled to the benefit of the filing date of the original application. A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application

35 U.S.C. § 121 (emphasis added).

The emphasized third sentence of § 121 is the so-called safe-harbor provision. "Prior to the 1952 Patent Act, courts and patentees were aware of the unfairness that resulted when the Patent Office required restriction or division between claims in a patent application, thus requiring that a second patent application be carved out of the first, and then rejected the second application on the basis of the first." Studiengesellschaft Kohle mbH v. N. Petrochemical Co., 784 F.2d 351, 358 (Fed. Cir. 1986) (Newman, J., concurring); see also Gerber Garment Tech., Inc. v. Lectra Sys.,

Inc., 916 F.2d 683, 688 (Fed. Cir. 1990) (approving of the description of the purpose of § 121 set forth in concurring opinion in Studiengesellschaft). “When the PTO requires an applicant to withdraw claims to a patentably distinct invention (a restriction requirement), § 121 shields those withdrawn claims in a later divisional application against rejection over a patent that issues from the original application.” Geneva Pharms., 349 F.3d at 1378.

The safe harbor is provided to protect an applicant from losing rights when an application is divided. The safe harbor of § 121 is not lost if an applicant does not file separate divisional applications for every invention or when independent and distinct inventions are prosecuted together. The statute, in referring to “two or more independent and distinct inventions,” recognizes that the safe harbor is not limited to only one divisional application. 35 U.S.C. § 121 (emphasis added). Thus, where the third sentence of § 121 refers to a patent issuing on an application filed as a result of a restriction requirement, it is referring to patents issuing from any number of multiple divisional applications and precludes any one from being used as a reference against any other.

The district court held that § 121 was inapplicable because the application resulting in the '812 patent was not filed “as a result of” the restriction requirement entered during the prosecution of the '947 application but because of concerns over potentially interfering matter in a patent owned by Eli Lilly. Boehringer, 562 F. Supp. 2d at 634-35. Boehringer first argues that the district court erred in reading the “as a result of” language of § 121 to apply to the '812 patent rather than merely the patent that is being used as a reference—here, the '086 patent. Boehringer next contends that if the

“as a result of” requirement does apply to the ’812 patent, the requirement is met on this record. Mylan counters that the safe harbor of § 121 is unavailable to Boehringer because the ’812 patent resulted from neither the “application with respect to which a restriction requirement . . . [was] made” (the ’947 application), nor the divisional “filed as a result of such a requirement” (the ’197 application). 35 U.S.C. § 121. Rather, the ’812 patent resulted from a divisional of a divisional of the application in which the restriction requirement was entered. According to Mylan, § 121 applies only to a divisional of a patent in which a restriction requirement was entered and does not apply to a divisional of a divisional.

Thus, on appeal, the parties present us with two issues related to § 121: (1) whether § 121 can ever apply to a divisional of a divisional of the application in which a restriction requirement was entered; and (2) whether the “as a result of” requirement of § 121 applies to the ’812 patent and is satisfied here. We address each issue in turn. Our review is de novo. See, e.g., NTP, 418 F.3d at 1314; Lonardo, 119 F.3d at 965.

1. Applicability of § 121 to a Divisional of a Divisional

Section 121 refers to restriction among “two or more independent and distinct inventions” and provides that a patent issuing on either the original application subject to a restriction requirement (“an application with respect to which a requirement for restriction under this section has been made”) or a divisional application (“an application filed as a result of such a requirement”) cannot be used as a reference against either “the original application” or “a divisional application.” 35 U.S.C. § 121. The most straightforward reading of the statutory text is that the safe harbor of § 121 applies even when the PTO issues a restriction requirement that leads to more than two separate applications. See, e.g., Applied Materials, 98 F.3d at 1568 (“[W]hen two or more

patents result from a PTO restriction requirement, whereby aspects of the original application must be divided into separate applications, § 121 insulates the ensuing patents from the charge of double patenting.” (emphases added)). Moreover, § 121 refers broadly to “a divisional application,” and does not state that the divisional must be a direct divisional of the original application. Had Congress intended to limit the safe harbor only to a divisional of the application in which the restriction requirement was entered, it could have said “a divisional application of the original application,” rather than simply “a divisional application.”

We have recognized the reach of § 121 in situations where the patent subject to a double-patenting challenge and the application in which the restriction requirement was entered share a common lineage. See Geneva Pharms., 349 F.3d at 1378 (“[I]f the [patent subject to the double-patenting challenge] and the [patent that is the basis of the challenge] trace their lineage back to a common parent which was subject to a restriction requirement, then § 121 intervenes to prevent [an obviousness-type] double patenting rejection.”). We have also held that § 121 applies specifically to continuing applications deriving from a divisional application filed as a result of a restriction requirement. See, e.g., Symbol Techs., Inc. v. Opticon, Inc., 935 F.2d 1569, 1580 (Fed. Cir. 1991) (extending the protection of § 121 to a patent issuing from a continuation application that descended from a divisional application filed as a result of a restriction requirement); Amgen Inc. v. F. Hoffman-La Roche Ltd, 580 F.3d 1340, 1354 (Fed. Cir. 2009) (“[I]ntervening continuation applications do not render a patent ineligible for § 121 protection so long as they descended from a divisional application filed as a result of a

restriction requirement.”). We see no reason why § 121 would not likewise extend to a divisional of a divisional.

We therefore reject Mylan’s argument that § 121 is inapplicable solely because the ’812 patent issued from an application that was a divisional of a divisional and hold that, assuming all other requirements of § 121 are met, the safe-harbor provision may apply to a divisional of a divisional of the application in which a restriction requirement was entered. We note that this holding is fully consistent with the purpose of § 121—namely, to prevent a patentee who divides an application in which a restriction requirement has been made from risking invalidity due to double patenting. See Geneva Pharms., 349 F.3d at 1378; Studiengesellschaft, 784 F.2d at 358 (Newman, J., concurring).

2. The “as a result of” Requirement

The district court held that the “as a result of” requirement of § 121 must be satisfied by both the ’086 and ’812 patents. The court then found that while the ’086 patent met the “as a result of” requirement, the restriction did not “carry over” to the application that had matured to the ’812 patent because it was not filed because of the restriction requirement but instead because of a patent owned by Eli Lilly.

Boehringer first argues that while the district court was correct as to the ’086 patent, it erred by requiring the “as a result of” requirement to “carry over” to the next patent in the chain. According to Boehringer, the “as a result of” requirement of § 121 need only apply to the patent that is being used as a reference—here, the ’086 patent—and not to the challenged patent.

We agree with the district court that the “as a result of” requirement must be satisfied by both the ’086 reference patent and the ’812 challenged patent. We have

repeatedly held that the “as a result of” requirement applies to the challenged patent as well as the reference patent. See, e.g., Pfizer, Inc. v. Teva Pharm. USA, Inc., 518 F.3d 1353, 1360 (Fed. Cir. 2008) (“[T]he third sentence of [§ 121] provides a safe harbor (for patents or applications derived as the result of a restriction requirement) from attack based on the original application (or a patent issued therefrom), or based on applications or patents similarly derived from the same restriction requirement.” (emphases added)); Bristol-Myers Squibb Co. v. Pharmachemie B.V., 361 F.3d 1343, 1347-48 (Fed. Cir. 2004) (“As section 121 has been interpreted by this court, [the patentee] is entitled to invoke the statutory prohibition against the use of the [reference] patent ‘as a reference’ against the divisional application that resulted in the [challenged] patent only if the divisional application was filed as a result of a restriction requirement and is consonant with that restriction requirement.” (emphasis added)); Gerber Garment, 916 F.2d at 687 (“The prohibition against use of a parent application ‘as a reference’ against a divisional application applies only to the divisional applications that are ‘filed as a result of’ a restriction requirement.” (emphasis added)).

Boehringer next contends that the application that matured into the '812 patent does meet the “as a result of” requirement. Boehringer argues that the '812 patent traces its lineage to the '374 patent and claims a subset of the non-elected subject matter from the '947 application. Moreover, it asserts that but for the restriction requirement, it could have pursued all the claims of the '812 patent in the '947 application and that any motivation with regard to the Eli Lilly patent is irrelevant. Boehringer finally argues that when an examiner issues a restriction requirement identifying more than two independent and distinct inventions, the choice of how to

prosecute non-elected inventions is up to the applicant and is constrained neither by the terms of an examiner's restriction requirement nor by the language of § 121. According to Boehringer, so long as consonance is met, it makes no difference in terms of compliance with the "as a result of" requirement whether the applicant responds to the examiner's restriction requirement by filing one or more divisional applications from the original application, or instead files a single divisional application followed by successive additional divisionals.

We agree with Boehringer. The restriction requirement entered in the '947 application required only an election in that application of a subset of the ten identified inventions. It also had the effect of obligating Boehringer to file one or more divisional applications if it wanted patent protection for the non-elected subject matter. Boehringer did so not by filing separate divisional applications on each of the inventions grouped by the examiner in the restriction requirement, but instead, by filing two successive divisionals to different combinations of the inventions identified in the restriction requirement. In doing so, Boehringer neither violated the examiner's restriction requirement nor risked loss of the safe harbor of § 121.³

³ According to the dissent, because the restriction requirement did not explicitly require the applicant to carve out the child application (the '671 application) from the parent application (the '197 application) and the examiner did not impose a separate restriction in the parent application, the child application fails to satisfy the "as a result of" requirement. Dissenting Op. at 9-10. We believe that this interpretation of the "as a result of" requirement is too narrow. The child application was "due to the administrative requirements imposed by the Patent and Trademark Office," Applied Materials, 98 F.3d at 1568, in the sense that, absent the restriction requirement, the applicant could have retained in the grandparent application (the '947 application) the claims prosecuted in the child application. We see no principled distinction between filing one or more divisional applications from an original application and filing successive divisional applications as was done here, so long as no two applications claim the same "invention" as defined by the examiner.

As noted, *supra*, the safe harbor is provided to protect an applicant from being penalized for dividing an application. Section 121 is not concerned with any overlap in non-elected inventions prosecuted within any particular divisional application or in how any such applications are filed. To prevent loss of the safe harbor in dividing out claims to non-elected inventions, what is required is consonance with the restriction requirement. As we explained in Gerber Garment, “[c]onsonance requires that the line of demarcation between the ‘independent and distinct inventions’ that prompted the restriction requirement be maintained. . . . Where that line is crossed the prohibition of the third sentence of Section 121 does not apply.” Gerber Garment, 916 F.2d at 688.

According to Mylan, this means that an applicant must strictly follow an examiner’s election procedure and not overlap claims to independent and distinct inventions in any single divisional application. We disagree. An overlap of claims to independent and distinct inventions within a given divisional application is neither contrary to the restriction requirement nor relevant to the requirements of the third sentence of § 121. Rather, what consonance requires is that the claims prosecuted in two or more applications having common lineage in a divisional chain honor, as between applications, the lines of demarcation drawn by the examiner to what he or she considered independent and distinct inventions in the restriction requirement. As we stated in Gerber Garment:

Plain common sense dictates that a divisional application filed as a result of a restriction requirement may not contain claims drawn to the invention set forth in the claims elected and prosecuted to patent in the parent application. The divisional application must have claims drawn only to the “other invention.”

Id. at 687. We later reiterated that “[t]o gain the benefits of Section 121 . . . Gerber must have brought its case within the purview of the statute, i.e., it must have limited the claims in its divisional application to the non-elected invention or inventions.” Id. at 688 (emphases added). The divisions need not be limited to a single one of the examiner’s demarcated inventions to preserve the right to rely on the safe harbor of § 121.

Here, as noted earlier, the restriction requirement imposed during prosecution of the ’947 application divided the claims into groups, each covering what the examiner demarcated as an invention “independent and distinct, each from the other.” Office Action at 3. None of the inventions claimed as between the ’374 original patent, the ’086 division, and the ’812 division of the division, crosses the examiner’s lines of demarcation of inventions identified in the restriction requirement. Thus, consonance is met and the ’086 patent cannot be used as a reference against the ’812 patent any more than if both patents had issued from direct divisions from the application in which the restriction requirement was made.⁴

III. CONCLUSION

For the foregoing reasons, we conclude that Boehringer’s terminal disclaimer does not overcome obviousness-type double patenting with respect to the ’086 patent, but that the safe-harbor provision of § 121 is applicable. We therefore reverse the district court’s judgment of invalidity and remand for further proceedings consistent with this opinion.

⁴ The dissent believes that the rule the majority has adopted will have the untenable result of tolerating the filing of repeated divisionals beyond anything intended by Congress when it passed § 121. To the contrary, applicants will be entitled to the safe harbor of § 121 for the same number of divisional applications, corresponding to the number of “independent and distinct” inventions demarcated by the examiner, whether filed separately or serially, provided consonance is met.

REVERSED and REMANDED

COSTS

Costs to Boehringer.

United States Court of Appeals for the Federal Circuit

2009-1032

BOEHRINGER INGELHEIM INTERNATIONAL GMBH
and BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,

Plaintiffs-Appellants,

v.

BARR LABORATORIES, INC.
and BARR PHARMACEUTICALS, INC.,

Defendants,

and

MYLAN PHARMACEUTICALS, INC.,

Defendant-Appellee.

Appeal from the United States District Court for the District of Delaware in consolidated cases 05-CV-700 and 05-CV-854, Judge Joseph J. Farnan, Jr.

DYK, Circuit Judge, dissenting in part.

The majority has adopted a construction of section 121 that significantly expands its coverage. 35 U.S.C. § 121. In my view the majority opinion works an unfortunate and unsupported change in our jurisprudence defining the scope of section 121, and in doing so, loses sight of its purpose. I respectfully dissent.

I

The prohibition against double patenting contained in 35 U.S.C. § 101 represents an important protection against the undue extension of patent rights. It bars patentees from securing an extension of the patent term through the filing of a divisional

application that claims the same invention (or an obvious variant) as the original application. See 35 U.S.C. § 101; In re Longi, 759 F.2d 887, 892 (Fed. Cir. 1985) (“A double patenting rejection precludes one person from obtaining more than one valid patent for either (a) the ‘same invention,’ or (b) an ‘obvious’ modification of the same invention.”).¹ The policy underlying the double-patenting doctrine “is an important policy because it precludes the improper extension of the statutory term of patent protection for an invention.” Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc., 98 F.3d 1563, 1577 (Fed. Cir. 1996); see Geneva Pharms., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1378 (Fed. Cir. 2003). There is no question here but that the inventions claimed in the '086 patent and the '812 patent are either the same invention or obvious variants thereof, and that the '812 patent would typically fall on double patenting grounds. The majority avoids this result through the application of section 121.

Section 121 was adopted as part of the 1952 Patent Act, Pub. L. No. 82-593, 66 Stat. 792 (current version at 35 U.S.C. § 1 et seq.). It was designed to prevent an unfair result under prior law whereby a patentee’s compliance with an examiner’s incorrect restriction requirement (separating out supposedly patentably distinct inventions that were in fact the same or not patentably distinct) resulted in the original application’s being used as a reference against the later divisional application. The use of the original application as a reference could result in a subsequent rejection based on double patenting. Before the 1952 Patent Act, no protection was afforded to patent applications filed as a result of an incorrect restriction requirement. See In re Eisler,

¹ The prohibition against obviousness type double patenting is based on an interpretation of the statute. See In re Longi, 759 F.2d at 892.

203 F.2d 726 (CCPA 1953). The PTO and the courts were not precluded from rejecting an application filed as a result of a requirement for division based on the very same application from which the subsequent application was divided. See In re Kauffman, 152 F.2d 991, 993 (CCPA 1946); see also In re Isherwood, 46 App. D.C. 507, 512 (D.C. Cir. 1917) (holding that an examiner is not estopped from rejecting a divisional application because of an earlier requirement for division). To avoid such a result, a patent applicant was required to appeal an examiner's requirement for division, see United States ex rel. Steinmetz v. Allen, 192 U.S. 543 (1904), and "his failure to litigate the question was at his peril," Kauffman, 152 F.2d at 993.

Section 121 was designed to ameliorate the inequity of this rule, and to allow applicants to reasonably rely on an examiner's restriction requirements. Pfizer, Inc. v. Teva Pharms. USA, Inc., 518 F.3d 1353, 1361 (Fed. Cir. 2008). The purpose of the rule was to ensure that "when the existence of multiple patents is due to the administrative requirements imposed by the Patent and Trademark Office . . . the inventor shall not be prejudiced by having complied with those requirements." Applied Materials, 98 F.3d at 1568. Section 121 thus carved out a narrow exception from the obviousness-type double patenting doctrine, by providing that "[a] patent issuing on an application with respect to which a requirement for restriction . . . has been made, or on an application filed as a result of such a requirement, shall not be used as a reference . . . against a divisional application or against the original application." 35 U.S.C. § 121 (emphasis added). Because section 121 can extend the patent term for inventions that are not patentably distinct, we have held that "this court applies a strict test for application of § 121." Geneva Pharms., 349 F.3d at 1382.

I agree with the majority that section 121 is not limited to the first divisional application filed as a result of the restriction requirement, but extends to later divisional applications filed “as a result of” the restriction and that are consonant with the restriction requirement.

However, as the majority at least purportedly recognizes, the “as a result of” and consonance requirements must be satisfied by both the reference patent and the challenged patent. Majority Op. at 19-20 (citing Bristol-Myers Squibb Co. v. Pharmachemie B.V., 361 F.3d 1343, 1347-48 (Fed. Cir. 2004) (“As section 121 has been interpreted by this court, [the patentee] is entitled to invoke the statutory prohibition against use of the [reference] patent ‘as a reference’ against the divisional application that resulted in the [challenged] patent only if the divisional application was filed as a result of the restriction requirement and is consonant with that restriction requirement.”)). Thus, it is not enough that the original application was filed as a result of the restriction requirement; the subsequent contested patent application itself must have been the result of the restriction, and must be consonant with the restriction requirement. See Pfizer, 518 F.3d at 1360 (“[T]he third sentence of [section 121] provides a safe harbor (for patents or applications derived as the result of a restriction requirement) from attack based on the original application (or a patent issued therefrom), or based on applications or patents similarly derived from the same restriction requirement.” (emphases added)). We have held that section 121 should only be used to protect those applicants who are compelled to comply with a restriction imposed by a patent examiner, and who faithfully follow the restriction requirement in a

later application. See, e.g., Texas Instruments Inc. v. U.S. Int’l Trade Comm’n, 988 F.2d 1165, 1179 (Fed. Cir. 1993) (holding that the post-restriction addition of a claim to the divisional application was “consonant with the grouping restriction actually imposed by the examiner,” and thus the safe harbor of section 121 applied (emphasis added)).

III

In my view, the majority has misinterpreted both the “consonance” and “as a result of” requirements. Necessary to an understanding of these issues is an understanding of the actual restriction requirement imposed by the examiner in this case. The examiner of the ’947 application (the grandparent) imposed a restriction requirement, thus requiring the filing of a later divisional application (the ’197 parent application), which later matured into the ’086 patent.² The examiner imposed the restriction on the grounds that “each of groups I-V is a patentably distinct invention,” J.A. 577, and that each of the compounds “could be used in each of the materially different processes as set forth in VIII-X,” J.A. 576. The restriction thus required the applicant to elect “one of the compound[] group[s] I-V and one of the utility groups VIII-X,” or “one of the process groups VI and VII.” J.A. 577. Accordingly, the applicants

² For purposes of clarity, I provide a timeline of the various patents and applications at issue:

December 19, 1985:	Boehringer files the ’947 patent application.
September 4, 1986:	PTO examiner issues a restriction requirement forcing Boehringer to separate the inventions claimed in the ’947 patent application.
November 23, 1987:	Boehringer files the ’197 application, a divisional of the ’947 application.
March 15, 1988:	’374 patent issues from the ’947 patent application.
October 12, 1988:	Boehringer files the ’671 application, a divisional of the ’197 application.
June 27, 1989:	’086 patent issues from the ’197 application.
December 12, 1989:	’812 patent issues from the ’671 application.

elected to prosecute claims directed to the invention of Group II (pyrrolidinyl-substituted benzothiazole compounds) and Group IX (a method for treating Parkinson's disease), resulting in the '374 patent (the grandparent). Boehringer Ingelheim Int'l GMBH v. Barr Labs., Inc., 562 F. Supp. 2d 619, 625 (D. Del. 2008).

The '197 application (the parent), a divisional of the '947 application, was not consonant with the original restriction requirement, as the applicants combined in a single application claims that the original examiner determined were drawn to separate inventions, namely Groups VIII, IX, and X of the '947 application.³ The child application (the '671 application) was also not consonant because it contained separate inventions, namely claims encompassing Groups I, III, IV, and V of the '947 application.⁴

Despite the fact that the '197 and the '671 applications impermissibly combine claims drawn to independent and distinct inventions identified by the original examiner, the majority concludes that the consonance requirement is met. The majority concludes that the requirements of section 121 are met because “[n]one of the inventions claimed as between the '374 original patent, the '086 division, and the '812 division of the division, crosses the examiner's lines of demarcation of inventions identified in the restriction requirement.” Majority Op. at 24. It is unclear what the majority means by

³ The '197 application originally contained all of the claims of the original '947 application, but, following a rejection, the applicant amended the '197 application so that it claimed methods of using benzothiazole compounds to treat certain medical conditions (high blood pressure, Parkinson's disease, and schizophrenia), excluding the method of using Group II compounds in accordance with the method of Group IX (i.e. the use of pyrrolidinyl-substituted compounds to treat Parkinson's disease), which was elected in the '947 grandparent.

⁴ Like the '197 application, the '671 application originally contained all of the claims of the '947 grandparent application, but it was later amended to include only compound claims other than those directed to the pyrrolidinyl-substituted benzothiazoles previously claimed in the '374 patent.

stating that the “inventions” here did not cross the examiner’s “lines of demarcation of inventions.” It is not the inventions that must preserve the examiner’s line of demarcation among separate inventions, but rather, the applications that must be consonant with the restriction requirement. Here it is clear that the patent examiner’s line of demarcation between independent and distinct inventions was not preserved, as is required by our case law, because both the parent and the child applications combined distinct inventions.

In effect, it appears that the majority is dispensing with the requirement that the restriction requirement be followed at all in any later divisional applications, so long as the original application in which the restriction requirement was imposed complies with the restriction. This is apparently what the majority means in stating that what consonance requires is that “the claims prosecuted in two or more applications having common lineage in a divisional chain honor, as between applications, the lines of demarcation drawn by the examiner to what he or she considered independent and distinct inventions in the restriction requirement.” Majority Op. at 23.

To support its position that later divisional applications need not comply with the restriction requirement, the majority cites language from our case law for the proposition that section 121 is satisfied if later divisional applications are limited to the “non-elected invention or inventions” of the parent application. This suggests to the majority that separate inventions may be combined in a single later application. But our decisions do not in fact countenance this. In my view, the majority’s decision is inconsistent with our case law clearly establishing that “[c]onsonance requires that the line of demarcation between the ‘independent and distinct inventions’ that prompted the restriction

requirement be maintained.” Gerber Garment Tec., Inc. v. Lectra Sys. Inc., 916 F.2d 683, 688 (Fed. Cir. 1990); see Geneva Pharms., 349 F.3d at 1381 (“Section 121 shields claims against a double patenting challenge if consonance exists between the divided groups of claims and an earlier restriction requirement.” (citing Symbol Techs., Inc. v. Opticon, Inc., 935 F.2d 1569, 1569 (Fed. Cir. 1991))); Applied Materials, 98 F.3d at 1568 (noting that “the examiner’s demarcation among the separate inventions should be preserved” (emphasis added)).

In Texas Instruments Inc. v. U.S. International Trade Commission, 988 F.2d 1165 (Fed. Cir. 1993), the original examiner found that the claims of the original application were drawn to three separate inventions, and grouped the claims in Groups I, II, and III. Id. at 1179. The applicant duly followed the restriction requirement laid out by the examiner and separated out the claims into three separate patents, with claims drawn to Group I issuing as the original patent (the ’238 patent), and claims drawn to Group II and III issuing as divisionals of the parent application (the ’027 and the ’764 patent, respectively). However, the examiner’s description of what was contained in Group III differed from the actual grouping in the restriction requirement, which in fact incorporated a claim drawn to Group II. The Commission held that the “actual restriction groupings, not the written descriptions thereof, control for purposes of ascertaining if subsequent amendments to original claims are consonant with the substantive restrictions drawn by the examiner.” Id. We adopted this reasoning, and concluded that the inclusion of the claim drawn to Group II in the ’764 patent was “consonant with the grouping restriction actually imposed by the examiner.” Id. (emphasis added). In other words, the later application was consonant because the

applicant followed the original examiner's groupings. That was not done here, and consonance accordingly was not maintained.

Applied Materials, Inc. v. Advanced Semiconductor Materials America, Inc., 98 F.3d 1563 (Fed. Cir. 1996), is to the same effect. There, the examiner issued a restriction requirement and divided the claims into three groups: an oven-type radiation-heated reactor, a reactor with means for introducing gaseous reactants, and a gaseous epitaxial coating process. The applicant initially elected the radiation-heated reactor, then "duly prosecuted the other two inventions in separately filed divisional applications." Id. at 1567. During the prosecution of the patent for the gaseous epitaxial coating process, the claims were amended to include non-epitaxial deposition as well as epitaxial deposition. The alleged infringer in that case argued that consonance was lost when the claims were enlarged. However, the original examiner had not determined that non-epitaxial deposition and epitaxial deposition were separate inventions. The court held that section 121 still applied. Id. at 1569. The amendments to the process claims did not violate the restriction requirement, "for the process claims remained in separate patents from the apparatus claims although the scope of the process claims was modified." Id. at 1568 (emphasis added). This language makes clear that the patentee's conformity with the examiner's restriction requirement, by separating out the three patentably distinct inventions into three separate applications, was the key to invoking section 121. In other words, later applications must keep separate the inventions that the original examiner identified as being separate. It seems to me plain that the parent and child applications in this case did not satisfy the consonance requirement.

But even if the majority were correct as to consonance, the benefit of the section 121 safe harbor should be denied because the '671 child application which issued into the '812 patent was not filed "as a result of" the restriction requirement. The only justification the majority offers for concluding that the "as of result of" requirement is met in this case is that the restriction requirement was imposed with respect to the grandparent application, resulting in the filing of one or more later divisional applications. But this rationale completely fails to explain why the child is protected from the parent application as a reference. There is in fact no basis for protecting the child against the use of the parent application as a reference, since there is absolutely nothing in the majority's reading of the original (grandparent) restriction that in any way required separation of the child from the parent. Nor did the examiner of the parent application require separation of the child. The second examiner did not follow the reasoning or views of the first examiner as to the distinctiveness of the various inventions. In other words, the child was not separated from the parent "as a result of" the restriction requirement, but rather as the result of the applicant's voluntary choice. Since the separation was not "due to the administrative requirements imposed by the Patent and Trademark Office," id. at 1568, the child application should not be afforded the protections of section 121 with respect to the parent application.

The majority opinion not only fails to follow a "strict test" for the application of section 121, see Geneva Pharms., 349 F.3d at 1382, it fails to recognize any meaningful restriction on section 121's application in the present context. Under the majority's theory, if an applicant faced with a restriction requirement filed a series of divisional applications claiming essentially the same invention or an obvious variant

again and again, each successive application would be protected from all of the earlier applications—whether or not the later applications followed the original restriction requirement. None of the earlier applications could be cited as prior art. Thus, the applicant could thereby have achieved multiple unjustified extensions of the patent term. The potential for this abuse is illustrated in this case: by breaking up the parent and child applications while ignoring the line of demarcation between patentably distinct inventions drawn by the first examiner, Boehringer was able to extend the term of the '812 patent (the child) six months longer than the '086 patent (the parent's) term, although the '812 patent was obvious in light of the '086 patent. The majority's opinion is devoid of any justification for this untenable result. It hardly requires argument to demonstrate that Congress could not have intended section 121 to operate in this perverse fashion.

I respectfully dissent.