No.

IN THE

Supreme Court of the United States

TYCO HEALTHCARE GROUP LP,
MALLINCKRODT INC., LIEBEL-FLARSHEIM COMPANY,
AND NEMOTO KYORINDO CO., LTD.

Petitioners,

v.

MEDRAD, INC.,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether the Federal Circuit erred, and destabilized patent law, by effectively abrogating the express statutory limitations on reissuing defective patents set forth in 35 U.S.C. § 251, and thereby permitting such patents to be reissued as a matter of course.

CORPORATE DISCLOSURE STATEMENT

Pursuant to this Court's Rule 29.6, petitioners Tyco Healthcare Group LP, Mallinckrodt Inc., and Liebel-Flarsheim Company hereby state that they are subsidiaries of Tyco International Ltd., a publicly-traded company. No publicly held company owns 10% or more of the stock of Tyco International Ltd.

Petitioner Nemoto Kyorindo Co., Ltd. is a Japanese corporation. No publicly held company owns 10% or more of the stock of Nemoto Kyorindo Co., Ltd.

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INTRODUCTION

The patent reissue statute, 35 U.S.C. § 251, provides expressly when a patent may be reissued to cure a defect. Under the plain language of that statute, a reissue patent is authorized *only* where the original patent was defective either [1] "by reason of a defective specification or drawing," or [2] "by reason of the patentee claiming more or less than he had a right to claim in the patent." But the Court of Appeals for the Federal Circuit now has effectively abrogated these express statutory limitations. According to the Federal Circuit, the holder of a patent suffering from any defect that would render it invalid *invariably* "claim[s] more ... than he had a right to claim in the patent," simply because, by definition, the holder of an invalid patent may not claim any rights in the patent. By thus holding that a reissue patent is authorized for *any* defect, notwithstanding the specific defects authorized for remediation by Congress in the statute, the Federal Circuit not only violated fundamental rules of statutory construction and overturned settled law, but destabilized the patent system by authorizing reissue of defective patents as a matter of course, and far beyond legal authorization.[1]

In particular, the Federal Circuit held in this case that a patentee who made *no changes* to the specification, drawings, claims, or any other part of the patent could nevertheless obtain a reissue patent. The patent at issue here was invalid because the patentee failed to file a required supplemental declaration, as specified in the rules governing the application process. But that ground simply does not fit within the statutory categories, if

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[1] This is similar to the Federal Circuit's failure to abide the express statutory limits of Rule 50(a) of the Federal Rules of Civil Procedure. *See Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*, 546 U.S. 394 (2006).

those categories are to have any meaning. The Federal Circuit concluded otherwise only by relying on "the remedial nature of the statute," and the consequent supposed need to provide a "liberal construction." But such maxims are devices to aid in statutory construction, not excuses to ignore statutory language. If Congress wanted to authorize reissue for *any* defect in a patent, it could and would have done so. It is not the Federal Circuit's proper role to judicially amend the statute to accomplish that result.

The principle of finality is important in patent law, just as in other areas of law. Thus, Congress did not authorize patent reissuance for any reason or as a matter of course, but only for specified defects. Because the Federal Circuit has effectively overruled Congress' policy decision, and no other judicial avenue to correct that error exists, absent review by this Court, this Court should grant the petition and either set the case for review on the merits or summarily reverse the decision below. At a minimum, this Court may wish to call for the views of the Solicitor General on this important question of patent law.

OPINIONS BELOW

The District Court's decision granting petitioners' motion for summary judgment of invalidity of U.S. Patent RE37,602 ("the '602 patent") is reported at 391 F. Supp. 2d 374 (W.D. Pa. 2005) and reprinted in the Appendix ("App.") at 13-28a. The Federal Circuit's decision reversing the District Court's decision is reported at 466 F.3d 1047, and reprinted at App. 1-10a. The Federal Circuit's unpublished order denying petitioners' combined petition for rehearing and rehearing *en banc* is reprinted at App. 11-12a.

JURISDICTION

The Federal Circuit rendered its decision on October 16, 2006, App. 1-10a, and denied a timely combined

petition for rehearing or rehearing *en banc* on January 3, 2007. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS AND REGULATIONS INVOLVED

Section 251 of Title 35 of the United States Code provides, in pertinent part:

> Whenever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, *by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent,* the Director shall ... reissue the patent for the invention disclosed in the original patent, and in accordance with a new and amended application, for the unexpired part of the term of the original patent.

35 U.S.C. § 251 (emphasis added).

Section 1.175(a) of Title 37 the Code of Federal Regulations provides that:

> The reissue oath or declaration in addition to complying with the requirements of § 1.63, must also state that:
>
> (1) The applicant believes the original patent to be wholly or partly inoperative or invalid by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than the patentee had the right to claim in the patent, stating at least one error being relied upon as the basis for reissue; and
>
> (2) All errors being corrected in the reissue application up to the time of filing of the oath or declaration under this paragraph arose

without any deceptive intention on the part of the applicant.

Section 1.175(b)(1) of Title 37 the Code of Federal Regulations provides that:

> For any error corrected, which is not covered by the oath or declaration submitted under paragraph (a) of this section, applicant must submit a supplemental oath or declaration stating that every such error arose without any deceptive intention on the part of the applicant. Any supplemental oath or declaration required by this paragraph must be submitted before allowance and may be submitted:
>
> (i) With any amendment prior to allowance; or
>
> (ii) In order to overcome a rejection under 35 U.S.C. 251 made by the examiner where it is indicated that the submission of a supplemental oath or declaration as required by this paragraph will overcome the rejection.

STATEMENT OF THE CASE

A. Factual Background

Respondent Medrad, Inc. filed an original patent application on November 26, 1993 relating to a mechanical injector for injecting a contrast agent into a patient undergoing a magnetic resonance procedure. That application issued as U.S. Patent No. 5,494,036 ("the '036 patent") on February 27, 1996. Federal Circuit Appendix ("CAFed App.") 454-59.

On February 23, 1998, Medrad filed an application for reissue of the '036 patent and submitted reissue declarations stating that the inventors had claimed less than they had a right to claim (an "underclaiming" error). CAFed App. 470-74. During prosecution of this first reissue application, Medrad corrected the underclaiming

error by adding additional claims. CAFed App. 476-84. Medrad also attempted to correct an alleged "overclaiming" error by narrowing certain claims, and it attempted to correct inventorship by adding two additional inventors to the patent. CAFed App. 488-94, 503-12. Medrad failed, however, to submit supplemental reissue declarations regarding the overclaiming or inventorship errors, as required by 37 C.F.R. § 1.175(b)(1). Despite this failure, the reissue application issued as U.S. Patent No. RE36,648 ("the '648 patent") on April 11, 2000. CAFed App. 228-35.

On April 25, 2000, Medrad filed a complaint with the U.S. International Trade Commission ("the ITC Action") alleging that the Optistar MR contrast delivery system manufactured by petitioner Nemoto Kyorindo Co., Ltd. in Japan and imported and/or sold by petitioner Mallinckrodt Inc. and its subsidiary, Liebel-Flarsheim Company,[2] infringed the '648 patent. CAFed App. 109-14, 134-38, 514-17. On September 26, 2000, the administrative law judge in the ITC Action entered an Initial Determination that the '648 patent was invalid due to Medrad's failure to file the required supplemental declarations regarding the overclaiming and inventorship errors. CAFed App. 237-61. The ITC denied Medrad's petition to review the Initial Determination and terminated the ITC action on February 12, 2001. CAFed App. 526-31.

On November 16, 2000—before the ITC's Initial Determination had become final—Medrad filed a second reissue application, seeking to reissue the '648 patent. CAFed App. 269-79. Medrad's re-reissue patent application was *identical* to the '648 patent. Medrad

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[2] Tyco International, the parent of petitioner Tyco Healthcare LP, acquired Mallinckrodt in 2000.

made no changes to the specification, drawings, claims, or any other part of the '648 patent. Medrad filed the second reissue application for one purpose—to submit supplemental declarations regarding the overclaiming and inventorship errors. CAFed App. 351-72. The re-reissue patent application issued as U.S. Patent No. RE37,602 on March 26, 2002 (the '602 patent"). CAFed App. 149-56.

B. Procedural History

On October 24, 2001, Medrad filed a complaint for patent infringement in the United States District Court for the Western District of Pennsylvania against petitioners Tyco Healthcare Group LP, Mallinckrodt Inc., Liebel-Flarsheim Company, and Nemoto Kyorindo Co., Ltd. (hereinafter collectively "Tyco"). CAFed App. 109-16. Medrad and Tyco thereafter filed cross motions for summary judgment regarding the validity of the '602 patent. CAFed App. 196-561.

Realizing that the "'602 Patent does not change the specification, drawings, claims, or any other part of the '648 Patent," App. 16a, the District Court (Lancaster, J.) stated that the dispositive question was "whether the reissue statute, 35 U.S.C. § 251, can be used to correct a mistake that [Medrad] made during the prosecution of the predecessor patent, *i.e.* failing to file supplemental reissue declarations in compliance with PTO Rule 1.175." App. 17a. The District Court granted Tyco's motion for summary judgment of invalidity based on its interpretation of Section 251:

> Because we find that *section 251 requires that some error in the specification, drawings, or claims of the patent be corrected as a result of the reissue process*, we grant defendants' motion for summary judgment. Although we recognize that the reissue statute is remedial and must be construed broadly, we cannot

> interpret a federal statute in a way that eliminates the very phrases of limitation from its text. Were we to adopt plaintiffs reasoning that a patent holder could secure, by reissue, a patent that is the same in all respects on its face, but corrects a mistake made during the prosecution of a predecessor patent that results in the patent being invalid, we would do just that. Neither the statute, nor the cases interpreting it, justifies such a result.

App. 18a (emphasis added).

Medrad appealed the District Court's decision to the Federal Circuit. In its opening brief, Medrad argued that "[b]y not filing the supplemental declarations, Medrad's inventors thus claimed *less* than they had a right to claim because without the supplemental declarations, the patent was deemed inoperative and invalid and so there were no claims." App. 39a (emphasis added). The Federal Circuit, basing its decision on a different rationale than that presented by Medrad, reversed the District Court's decision, holding in pertinent part that

> by including changes to the language of the claims that narrowed the scope of coverage and by correcting inventorship, the resulting '648 reissue patent claimed *more* than it had a right to claim in the patent without submitting a supplemental declaration to support the narrowing subject matter and the change in inventorship. The correction of such an error [*i.e.*, by submitting a supplemental declaration] meets the express terms of section 251 and thus serves as a basis for reissue.

App. 10a (emphasis added). The Federal Circuit noted that "we do not interpret the disputed language in section 251—'by reason of the patentee claiming more or less than he had a right to claim in the patent'—to require

that the error occur in the actual language of the claims." App. 8a.

Petitioners filed a combined petition for rehearing and rehearing en banc, but the Federal Circuit denied the petition. App. 11-12a. This petition follows.

REASON FOR GRANTING THE WRIT

I. THE FEDERAL CIRCUIT ERRED, AND DESTABILIZED PATENT LAW, BY EFFECTIVELY ABROGATING THE EXPRESS STATUTORY LIMITATIONS ON REISSUING DEFECTIVE PATENTS SET FORTH IN 35 U.S.C. § 251, AND THEREBY PERMITTING SUCH PATENTS TO BE REISSUED AS A MATTER OF COURSE.

A. By Rendering Superfluous the Express Limitations of the Reissue Statute, the Federal Circuit's Decision Conflicts With Supreme Court Precedent Regarding Statutory Interpretation.

The Federal Circuit's decision renders superfluous the express limitations of 35 U.S.C. § 251, thereby conflicting with established Supreme Court precedent regarding statutory interpretation. For more than a century, this Court has taught that statutes should be construed so that "no clause, sentence, or word shall be superfluous, void, or insignificant." *Market Co. v. Hoffman*, 101 U.S. 112, 115-16 (1879) (quoting Bacon's *Abridgement of the Law*, Section 2), *quoted in TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) and *Duncan v. Walker*, 533 U.S. 167, 174 (2001))); *see also United States v. Alaska*, 521 U.S. 1, 59 (1997) ("The Court will avoid an interpretation of a statute that 'renders some words altogether redundant.'") (quoting *Gustafson v. Alloyd Co.*, 513 U.S. 561, 574 (1995)); *Pennsylvania Dep't of Pub. Welfare v. Davenport*, 495 U.S. 552, 562 (1990) ("Our cases express a deep reluctance to interpret a statutory provision so as to

render superfluous other provisions in the same enactment."); *South Carolina v. Catawba Indian Tribe*, 476 U.S. 498, 510 n.22 (1986) ("It is an 'elementary canon of construction that a statute should be interpreted so as not to render one part inoperative.'"); *United States v. Menasche*, 348 U.S. 528, 538-39 (1955) ("It is our duty to give effect if possible, to every clause and word of a statute."); *National Labor Relations Bd. v. Jones & Laughlin Steel Corp.*, 301 U.S. 1, 30 (1937) ("The cardinal principle of statutory construction is to save and not to destroy."); *Inhabitants of Montclair Tp. v. Ramsdell*, 107 U.S. 147, 152 (1883) ("It is the duty of the court to give effect, if possible, to every clause and word of a statute....").

In *Colautti v. Franklin*, 439 U.S. 379 (1979), this Court addressed such a statutory construction issue. At issue was Section 5 of the Pennsylvania Abortion Control Act, which required a physician "to observe the prescribed standard of care if he determines 'that the fetus is viable or if there is sufficient reason to believe that the fetus may be viable.'" *Colautti*, 439 U.S. at 392 (quoting Pennsylvania Abortion Control Act, 1974 Pa. Laws, Act No. 209, Pa. Stat. Ann., Tit. 35, § 6605(a) (Purdon 1977)). This Court rejected appellants' argument that "may be viable" is synonymous with "viable," stating that

> [t]he syntax clearly implies that there are two distinct conditions under which the physician must conform to the standard of care. Appellants' argument that "may be viable" is synonymous with "viable" would make either the first or the second condition redundant or largely superfluous, in violation of the elementary canon of construction that a statute should be interpreted so as not to render one part inoperative.

Colautti, 439 U.S. at 392 (quoting *Menasche*, 348 U.S. at 538-539).

This Court faced the issue again in *Duncan v. Walker*, addressing a portion of the Habeas Corpus statute that stated that the time during which an "application for State post-conviction or other collateral review" is pending tolls the limitation period for filing federal habeas petitions. 533 U.S. at 167 (quoting 28 U.S.C. § 2244(d)(2)). This Court rejected respondent's attempt to construe the phrase "State post-conviction or other collateral review" to encompass both state and federal collateral review, noting that under this construction the "word 'State' places no constraint on the class of applications for review that toll the limitation period. The clause instead would have precisely the same content were it to read 'post-conviction or other collateral review.'" *Duncan*, 533 U.S. at 174.

Similarly, in this case, the Federal Circuit's reading of Section 251 renders part of that statute—namely, the express limitations on the right to obtain a reissue patent—superfluous. The express terms of Section 251 limit the patents that can be reissued to those that are invalid or inoperative "by reason of a defective specification or drawing," or those that are invalid or inoperative or "by reason of the patentee claiming more or less than he had a right to claim in the patent." But according to the Federal Circuit, a patentee who simply failed to follow a procedural requirement can also obtain a reissue patent. App. 8-10a. Thus, the Federal Circuit erred by rendering superfluous the express limitations of the patent reissue statute, 35 U.S.C. § 251.

B. The Federal Circuit's Broad Interpretation of the Limitation "By Reason Of The Patentee Claiming More Or Less Than He Had A Right To Claim" Conflicts With Federal Circuit and CCPA Precedent.

The Federal Circuit arrived at its statutory construction by an overly broad interpretation of Section 251's express limitation "by reason of the patentee

claiming more or less than he had a right to claim," stating that "we do not interpret th[is] disputed language in section 251 ... to require that the error occur in the *actual language of the claims*." App. 8a (emphasis added). Based on this interpretation, the Federal Circuit held that the correction of even unspecified procedural errors meets the express terms of Section 251. App. 8-10a. However, the Federal Circuit's interpretation of this express limitation conflicts squarely with numerous statements in earlier Federal Circuit and Court of Customs and Patent Appeals ("CCPA") decisions.

In *In re Handel,* 312 F.2d 943 (C.C.P.A. 1963), for example, the CCPA provided an interpretation directly at odds with the Federal Circuit's recent decision:

> [T]he whole purpose of the statute, so far as claims are concerned, is to permit limitations to be added to claims that are too broad or to be taken from claims that are too narrow. *That is what the statute means in referring to "claiming more or less than he had a right to claim."*

312 F.2d at 948 (emphasis added).

The CCPA applied the same statutory interpretation in an earlier decision in *In re Rogoff,* 261 F.2d 601 (C.C.P.A. 1958):

> [Section 251] provides for the reissue of a patent when it is "deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent." There is no contention here that the specification or drawing of appellant's patent is defective nor that he claims in the patent more than he had a right to claim as new. *The only remaining ground for reissue, therefore, must be that he*

> *claimed less than he had a right to claim as new, but if that were the case, the only appropriate remedy would be a reissue with broadened claims.*

261 F.2d at 605 (emphasis added).

The Federal Circuit itself has adopted this interpretation of the "claiming more or less than he had a right to claim" language of Section 251. In *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 882 F.2d 1556 (Fed. Cir. 1989), the Federal Circuit explained that the expression "less than he had a right to claim" "covers the situation where the claims in the patent are narrower than the prior art would have required the patentee to claim and the patentee seeks broader claims." 882 F.2d at 1564. "Conversely, the alternative that the patentee claimed 'more ... than he had a right to claim' comes into play where a claim is too broad in scope in view of the prior art or specification and the patentee seeks narrower claims." *Id.* at 1565.

The Federal Circuit reiterated this interpretation of the reissue statute in *In re Amos*, 953 F.2d 613 (Fed. Cir. 1991), indicating that there are only four grounds available for reissue under Section 251:

> First, an asserted defect may arise from an error in a specification. Second, the patentee may correct a defective drawing. The final two reasons for which the patentee may seek reissue concern *original claims subsequently discovered to have been either too narrow or too broad.*

953 F.2d at 616 (emphasis added).

Similarly, in *Slip Track Sys., Inc. v. Metal Lite, Inc.*, 159 F.3d 1337 (Fed. Cir. 1998), the Federal Circuit noted that "a reissue application is available to Slip Track only if it can allege that there is an error in the drawings,

specification, *or scope of the claims* of the Brady patent." 159 F.3d at 1341 (emphasis added).

The Federal Circuit upheld Medrad's '602 patent, even though Medrad asserted no error in the specification, drawings, or scope of the claims. In so doing, the Federal Circuit misinterpreted the express statutory limitation "by reason of the patentee claiming more or less than he had a right to claim," deviating from earlier decisions of the Federal Circuit and the CCPA.

C. The Federal Circuit's Decision Improperly Allows Reissue of a Patent in Identical Form to the Original Patent, Conflicting With Federal Circuit and CCPA Precedent.

The Federal Circuit's decision also conflicts with prior Federal Circuit and CCPA decisions that declined to allow the reissue of a patent in identical form to the original patent.

For example, in *In re Dien*, the CCPA noted that "it goes without saying that reissue of a patent in identical form with the original patent is not a possibility." 680 F.2d 151, 153 n.4 (C.C.P.A. 1982). The Federal Circuit reiterated this statement in *In re Clement*, 131 F.3d 1464, 1472 (Fed. Cir. 1997). Yet this is exactly what happened in the instant action—the '602 patent is identical in form with it predecessor patent, the '648 patent.

The legislative history of Section 251 confirms that Congress intended for reissued patents to be changed from the predecessor patents. As the pertinent committee report explained,

> Sections 251 and 252 are a development of the present statute relating to what are called reissues. Under certain circumstances *the patentee may obtain a new patent* to replace the old one to correct certain defects that he may have discovered *in the patent.*

S. Rep. No. 1979, 82nd Cong., 2d Sess. 5 (1952) (emphasis added).

By upholding Medrad's '602 patent, which was identical to the '648 patent, the Federal Circuit ignored this legislative history and earlier Federal Circuit and CCPA decisions.

D. The Federal Circuit's Decision Improperly Allows Re-Prosecution of the Original Patent Application, Conflicting With Federal Circuit Precedent.

The Federal Circuit's decision also improperly allows a patentee to use reissue proceedings to re-prosecute the original patent, conflicting with prior decisions that indicate that this is an impermissible use of the reissue statute.

In *In re Weiler*, for example, the Federal Circuit stated that—although the reissue statute "is remedial in nature, based on fundamental principles of equity and fairness, and should be construed liberally," 790 F.2d 1576, 1579 (Fed. Cir. 1986)—"the reissue statute was not enacted as a panacea for all patent prosecution problems, nor as a grant to the patentee of a second opportunity to prosecute *de novo* his original application." *Id.* at 1582; *accord In re Serenkin,* Nos. 06-1242, 10/134, 10/550, 2007 WL 656254, at *3 (Fed. Cir. Mar 06, 2007) (declining to allow patentee to use the reissue statute to undo the consequences of his attorney's deliberate choice during original prosecution); *Hewlett-Packard,* 882 F.2d at 1565-66 (finding that factual inaccuracy of affidavits eliminated basis for reissue and rendered certain claims of reissue patent invalid).

Medrad utilized the reissue statute to obtain a second opportunity to prosecute its patent application. In the prosecution of the application leading to the '648 patent, Medrad could and should have submitted supplemental reissue declarations. As Medrad admitted, "had Medrad

filed the requisite supplemental reissue declarations with the '648 patent, Medrad would have perfected its claim to a reissue patent and enjoyed the full scope of patent protection provided by the '648 reissue claims." App. 40a. By applying for reissue of the '648 patent for the sole purpose of adding these declarations, Medrad obtained a second opportunity to prosecute its original application for the identical patent. The Federal Circuit's decision improperly upheld the patent despite this conduct, in conflict with prior Federal Circuit decisions.

CONCLUSION

This Court should grant the petition for writ of certiorari, and either grant plenary review or summarily reverse the decision below.

Respectfully submitted,

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