# United States Court of Appeals for the Federal Circuit

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**IN RE ROSUVASTATIN CALCIUM PATENT LITIGATION**

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**ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS INC., AND SHIONOGI SEIYAKU KABUSHIKI KAISHA,**
*Plaintiffs-Appellees,*

**v.**

**AUROBINDO PHARMA LIMITED,**
*Defendant-Appellant,*

**AND**

**MYLAN PHARMACEUTICALS INC.,**
*Defendant-Appellant,*

**AND**

**APOTEX CORP.,**
*Defendant-Appellant,*

**AND**

**COBALT PHARMACEUTICALS INC. AND COBALT LABORATORIES INC.,**
*Defendants-Appellants,*

**AND**

**SUN PHARMACEUTICAL INDUSTRIES, LTD.,**
*Defendant-Appellant,*

**AND**

**TEVA PHARMACEUTICALS USA, INC.,**
*Defendant-Appellant,*

**AND**

**PAR PHARMACEUTICAL, INC.,**
*Defendant-Appellant,*

**AND**

**SANDOZ, INC.,**
*Defendant.*

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2010-1460,-1461,-1462,-1463,-1464,-1465,-1466,-1467, -1468,-1469,-1470,-1471,-1472,-1473

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Appeal from the United States District Court for the District of Delaware in case nos. 08-MD-1949, 07-CV-0810, 07-CV-0805, 07-CV-0809, 07-CV-0811, 07-CV-0806, 08-CV-0426, and 07-CV-0808, Judge Joseph J. Farnan, Jr.

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Decided: December 14, 2012

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CHARLES E. LIPSEY, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, of Reston, Virginia, argued for plaintiff-appellee. With him on the brief were KENNETH M. FRANKEL, and YORK M. FAULKNER. Of counsel on the brief were FORD F. FARABOW, JR., and HOWARD W. LEVINE, of Washington, DC, MARY K. FERGUSON, of Cambridge, Massachuettes, JOHN D. LIVINGSTONE, of Atlanta, Georgia, MARY W. BOURKE, Connolly Bove Lodge & Hutz, LLP, of Wilming-

ton, Delaware, HENRY J. RENK, Fitzpatrick, Cella, Harper & Scinto, of New York, New York, THOMAS STEVENS and JUDY YUN, AstraZeneca Pharmaceuticals, LP, of Wilmington, Delaware.

ROBERT B. BREISBLATT, Katten Muchin Rosenman, LLP, of Chicago, Illinois, argued for defendant-appellant. With him on the brief were JEREMY C. DANIEL and CHARLES B. PARADIS.

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STEVEN A. MADDOX, Knobbe, Martens, Olson & Bear, LLP, of Washington, DC, argued for defendant-appellant. With him on the brief were PAYSON LEMEILLEUR and JARED BUNKER, Knobbe, Martens, Olson & Bear, LLP, of Irvine, California.

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Before NEWMAN, MAYER, and PLAGER, *Circuit Judges*.

Opinion of the court filed by *Circuit Judge* NEWMAN. Concurring opinion filed by *Circuit Judge* PLAGER. Dissenting opinion filed by *Circuit Judge* MAYER.

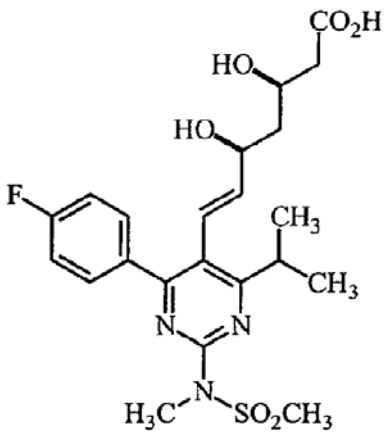
NEWMAN, *Circuit Judge*.

This patent litigation arises under the Hatch-Waxman Act, 21 U.S.C. §355, whereby producers of generic pharmaceutical products are authorized to challenge the patent status of a federally registered and approved drug product, before the generic producer has obtained approval to sell its counterpart of the approved product. The generic litigant who succeeds in eliminating the drug patent is granted a

180-day period of exclusivity against other potential providers of the generic product. 21 U.S.C. §355(j)(5)(B)(iv).

The drug product here at issue is the "statin" having the brand name Crestor®, which is federally approved for use in control of cholesterol and for treatment of atherosclerosis. In suit is United States Reissue Patent No. 37,314 ("the '314 patent"), which is a reissue of United States Patent No. 5,260,440 ("the '440 patent"). The patentee is Shionogi Seiyaku Kabushiki Kaisha ("Shionogi") and the exclusive licensee is Astrazeneca UK and its United States subsidiary IPR Pharmaceuticals Inc. (collectively "Plaintiffs").

The active ingredient of Crestor® is the calcium salt of a chemical compound whose common name is rosuvastatin, of the following structural formula:




rosuvastatin

Rosuvastatin is one of several statin products that lower cholesterol production in the liver by inhibiting the enzyme HMG-CoA reductase. Scientists working at the Shionogi laboratory in Japan were conducting research in search of a statin with reduced side effects as compared with the statin

products that were then known. In the course of this research, in 1991 they discovered rosuvastatin and its beneficial properties. Patents were obtained in Japan and other countries, including the '314 patent in the United States.

Federal approval for sale and use in the United States was granted on August 12, 2003, after over two decades of development. The product was highly successful, due to its superior efficacy in lowering low-density (LDL) cholesterol and elevating high-density (HDL) cholesterol, and its reduced side effects, as compared with other commercial statins. *See* Peter H. Jones et al., *Comparison of the Efficacy and Safety of Rosuvastatin Versus Atorvastatin, Simvastatin, and Pravastatin Across Doses (STELLAR Trial)*, 92 Am. J. Cardiology 152 (2003).

Several generic producers initiated a challenge to the '314 patent by filing an Abbreviated New Drug Application (ANDA) accompanied by a Paragraph IV certification, 21 U.S.C. §355(j)(2)(A)(vii)(IV). An ANDA permits a generic producer to market a drug product based on the federal approval obtained by the original registrant. Submission of an ANDA constitutes a statutory act of infringement pursuant to §271(e)(2) of the Patent Act, which provides:

> It shall be an act of infringement to submit an application under [section 355(j) of title 21] . . . for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. §271(e)(2)(A). If the challenge to the patent fails, the ANDA cannot be approved until expiration of the patent. 35 U.S.C. §271(e)(4)(A).

The infringement suits against the several generic challengers were consolidated in the United States District Court for the District of Delaware. The Defendants are Aurobindo Pharma Ltd., Mylan Pharmaceuticals Inc., Apotex Corp., Cobalt Pharmaceuticals Inc. and Cobalt Laboratories Inc., Sun Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., Par Pharmaceuticals, Inc., and Sandoz, Inc. The Defendants argued that the '314 patent is invalid on the ground of obviousness and improper reissue, and that the patent is unenforceable for inequitable conduct in the Patent and Trademark Office ("PTO").

The district court ruled that the '314 patent is valid, enforceable, and infringed.[1] The Defendants all admitted infringement, except for Apotex Corp. All of the Defendants appeal the rulings of validity and enforceability.

## I

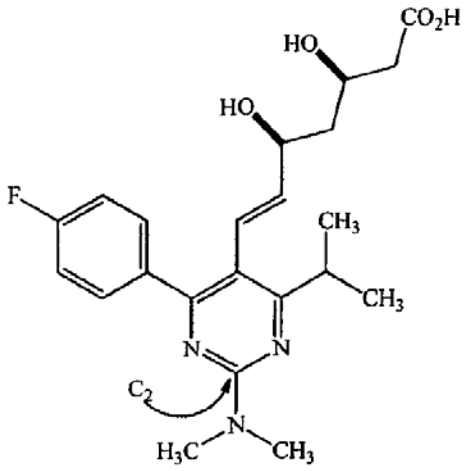
## VALIDITY

The Defendants challenge patent validity on the ground of obviousness. Obviousness is decided as a matter of law based on four basic factual inquiries, as set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966), and elaborated in *KSR International, Co. v. Teleflex Inc.*, 550 U.S. 398, 406–07 (2007), *viz.*, (1) the scope and content of the prior art, (2) the level of ordinary skill in the field of the invention, (3) the differences between the claimed subject matter and the prior art, and (4) any objective indicia of unobviousness,

[1] *In re Rosuvastatin Calcium Patent Litig.*, 719 F. Supp. 2d 388 (D. Del. 2010).

such as commercial success or long-felt need, or failure of others.

The Defendants identified as the closest prior art European Patent Office Publication No. 0 367 895 of the Sandoz company ("*Sandoz*"), published May 16, 1990, which describes numerous pyrimidine-based statin compounds, including a compound designated as Compound 1b. Compound 1b has two $-CH_3$ (methyl) groups on the amino side chain, instead of one $-CH_3$ and one $-SO_2CH_3$ group as in rosuvastatin. Compound 1b has the following structural formula:




Sandoz Compound 1b

The Sandoz European application describes Compound 1b as an "especially preferred embodiment of the invention." *Sandoz*, at *9. The Defendants argued in the district court that this statement suggests that Compound 1b would be a good "lead compound" for further research, and that with this selection as lead compound the change of the $-CH_3$ group to a $-SO_2CH_3$ group would have been obvious because it would make Compound 1b more hydrophilic. The Defendants stated that numerous publications taught that liver-

selective statins may have fewer undesirable side effects, and that hydrophilic statins are more liver-selective. The Defendants argued that persons of ordinary skill in this field would have been motivated to make Sandoz Compound 1b more hydrophilic, and that the $C_2$ position (as marked on the molecule *supra*) was the logical place to modify Compound 1b because the other parts of the structure were known to be essential to statin activity. The Defendants argued that a person of ordinary skill would have considered a limited number of common substitutions, including a sulfonyl "spacer" $–SO_2–$ at the $C_2$ position to increase hydrophilicity. The Defendants argued that a person of ordinary skill would have predicted that this change would produce a statin with fewer adverse side effects, thereby rendering the compound obvious.

In response, the Plaintiffs pointed out that Sandoz Compound 1b demonstrated unexpected increased toxicity, and therefore was not an encouraging lead compound. The Plaintiffs stated that other compounds in the Sandoz European application, such as Compound 11, demonstrated better *in vitro* potency. The Plaintiffs responded to the argument that in 1991 a scientist would have known that Compound 1b should be made more hydrophilic, by pointing to publications that state that lipophilic substituents at the $C_2$ position, the converse of hydrophilic, can increase statin potency. The Plaintiffs argued that the prior art provided no suggestion of rosuvastatin's unexpectedly superior properties as compared with Compound 1b or any other known compound, thus creating no "reasonable expectation of success." *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007) ("[T]he burden falls on the challenger of the patent to show by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed

invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.").

The Plaintiffs highlighted the unpredictability that was associated with statin development. For example, the pyrrole-based statin corresponding in all other structural aspects to the pyrimidine-based rosuvastatin displayed toxic side effects. The Plaintiffs pointed out that at least five pharmaceutical companies had abandoned their research on statins with pyrimidine cores, on the prevailing belief that pyrimidine-based statins were not promising leads to improved products. The Plaintiffs pointed out that no reference, or combination of references, suggested that the previously unknown molecule rosuvastatin would have its advantageous properties. *See KSR*, 550 U.S. at 421 ("A factfinder should be aware . . . of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning."); *Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1345 (Fed. Cir. 2000) (finding that "an ordinary medicinal chemist" would not have expected the specific chemical structure to have the "most desirable combination of pharmacological properties") (internal quotation omitted). The Plaintiffs pointed to objective indicia of non-obviousness, including commercial success, long felt but unfilled need, failure of others, and unexpected results, *Graham*, 383 U.S. at 17–18, as support for the district court's judgment of unobviousness.

The district court applied the correct standard, that the challenger must demonstrate by clear and convincing evidence that the invention would have been obvious to a person of ordinary skill in the field of the invention at the time the invention was made. *Pfizer*, 480 F.3d at 1359–60 ("Since we must presume a patent valid, the patent challenger bears the burden of proving the factual elements of invalidity by clear and convincing evidence. That burden of

proof never shifts to the patentee to prove validity."). The district court discussed the Defendants' argument that the insertion of a sulfonyl group at position $C_2$ was one of a "finite number of identified, predicable solutions" to existing problems with statins, in the words of *KSR*, 550 U.S. at 421, and thus that it would have been obvious to make this specific compound and test its properties. The district court found that this situation was similar to that discussed in *In re O'Farrell*, 853 F.2d 894 (Fed. Cir. 1988), where the court explained that obviousness is not shown when "what was 'obvious to try' was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it." *Id.* at 903. The district court concluded that the Defendants did not demonstrate the required motivation for selecting Sandoz Compound 1b as a lead compound, or for making this specific sulfonyl change in the Compound 1b molecule. *See Eli Lilly & Co. v. Zenith Goldline Pharms.*, 471 F.3d 1369, 1379 (Fed. Cir. 2006) (considering whether a prior art compound would have been chosen as a lead compound).

We agree that "obvious to try" was negated by the general skepticism concerning pyrimidine-based statins, the fact that other pharmaceutical companies had abandoned this general structure, and the evidence that the prior art taught a preference not for hydrophilic substituents but for lipophilic substituents at the $C_2$ position. *See Takeda Chem. Indus., Ltd. v. Alphapharm Pty.*, 492 F.3d 1350, 1357 (Fed. Cir. 2007) ("[I]n cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound.").

The district court correctly held that patent invalidity on the ground of obviousness had not been shown for the compound rosuvastatin. That ruling is affirmed.

## II

### INEQUITABLE CONDUCT

The Defendants also argued that the '314 patent is permanently unenforceable because of inequitable conduct during prosecution of the '440 patent from which the '314 patent was reissued. The Defendants attributed the inequitable conduct to two employees in Shionogi's in-house patent staff in Japan, Ms. Tomoko Kitamura and Mr. Takashi Shibata, who did not disclose three documents to the PTO during prosecution of the '440 patent. The documents were Bayer Japanese Patent Application No. HI-261377 (filed Feb. 2, 1989, published Aug. 31, 1989), the Sandoz published European application describing Compound 1b, and a European Patent Office search report that included the Sandoz application. The Defendants state that all three documents were highly material to patentability, that they were intentionally withheld during prosecution of the '440 patent, and that such inequitable conduct cannot be cured by a reissue action wherein Shionogi disclosed these patent documents. The Plaintiffs respond that there was no intent to deceive or mislead the PTO, and that any error in prosecution of the '440 patent was unintentional and was rectified by prompt filing of the reissue application and disclosure of the uncited references, as soon as Shionogi discovered the error.

To prove inequitable conduct, the challenger must show by clear and convincing evidence that the patent applicant (1) misrepresented or omitted information material to patentability, and (2) did so with specific intent to mislead

or deceive the PTO. *Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276, 1287 (Fed. Cir. 2011) (en banc). Materiality and intent must be separately established. *Id.* at 1290. To establish materiality, it must be shown that the PTO would not have allowed the claim but for the non-disclosure or misrepresentation. *Id.* at 1291. To establish intent, intent to deceive the PTO must be "'the single most reasonable inference able to be drawn from the evidence.'" *Id.* at 1290 (quoting *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008)). The district court's findings on materiality and intent are reviewed for clear error, and the court's ultimate decision as to inequitable conduct is reviewed on the standard of abuse of discretion. *Am. Calcar, Inc. v. Am. Honda Motor Co., Inc.*, 651 F.3d 1318, 1334 (Fed. Cir. 2011).

There was extensive evidence and argument before the district court, including the live testimony of the Shionogi personnel who were accused of acting inequitably. It was explained that when scientists at Shionogi obtained favorable results with certain modified pyrimidine compounds including rosuvastatin, the Shionogi patent department was asked to file a patent application on their results. Ms. Kitamura, then a Shionogi employee, obtained search reports relating to these products. The reports identified the Sandoz European application that included Compound 1b, and the Bayer Japanese application that described a large class of statin compounds that generically included the rosuvastatin class of substituents, but not showing the specific compounds that Shionogi submitted for patenting. Ms. Kitamura testified that because "[t]here were no instances of the same compounds as Shionogi," she did not believe that the references created a patentability problem. J.A. 21458–60. Ms. Kitamura prepared and filed the Japanese patent application and processed the foreign counterparts including the United States '440 application.

The '440 patent application was filed in the United States on June 12, 1992. The application described a class of compounds with a pyrimidine core as HMG-CoA reductase inhibitors. Table 4 of the application showed that rosuvastatin had the best HMG-CoA reductase inhibitory activity. Ms. Kitamura left Shionogi employment about six weeks after the '440 application was filed in the United States, and Mr. Shibata assumed responsibility for these applications. He received an EPO search report which identified the Sandoz application as "particularly relevant if taken alone." Mr. Shibata asked the Shionogi scientists to conduct tests to compare the Shionogi compounds with the preferred compounds described in the Sandoz and Bayer applications.

No Information Disclosure Statement ("IDS") was filed for the '440 application, and neither the Sandoz application nor the Bayer application was provided to the PTO or cited by the examiner of the '440 application. The '440 patent was issued in the United States on November 9, 1993.

In the fall of 1997 AstraZeneca and Shionogi began negotiating a license to rosuvastatin. During the negotiation it was discovered that no IDS had been filed during prosecution of the '440 application, and that the Sandoz and Bayer applications had not been cited by the examiner. U.S. patent counsel was consulted, and on November 4, 1997, Shionogi filed an application to reissue the '440 patent in order to file an IDS and to include the Sandoz and Bayer references in the examination. Shionogi certified to the PTO that it had erroneously not brought these references to the examiner's attention, and that it was through error and not due to deceptive intent. The reissue examiner then rejected the generic '440 claims as obvious in view of the Bayer reference. In response, Shionogi limited the '440 patent to the specific compound rosuvastatin and its salts.

The reissue was granted, and the application issued as the '314 reissue patent on August 7, 2001.

The Defendants argued that the Sandoz and Bayer references were material and that they were deliberately withheld with deceptive intent, and that such inequitable conduct could not be cured.

1. Materiality

In the district court, the Defendants argued that the Bayer and Sandoz applications and EPO search report are all highly material to patentability. The Defendants pointed to the reissue examiner's rejection of the claims as initially granted, and Shionogi's retrenchment in claim scope. The Defendants argued that Shionogi's prompt filing of the reissue application itself demonstrated that Shionogi recognized the materiality of these references.

Although we doubt that the act of taking prompt remedial action is appropriately viewed as an admission of wrongdoing, the district court found the Sandoz and Bayer references to be material to the prosecution of the '440 application. We agree that the reference compounds are sufficiently similar in structure to warrant citation. Although the references were held by the PTO not to negate patentability of rosuvastatin, as affirmed *ante*, we do not disturb the district court's finding of materiality.

2. Intent

The district court found that the Defendants did not establish that either Ms. Kitamura or Mr. Shibata withheld the Sandoz and Bayer references with deceptive intent. Although deceptive intent may be inferred from circumstantial evidence, the inference "must not only be based on

sufficient evidence and be reasonable in light of that evidence, but it must also be the single most reasonable inference able to be drawn from the evidence to meet the clear and convincing standard." *Star Scientific*, 537 F.3d at 1366; *see also Therasense*, 649 F.3d at 1290.

The Defendants argued that intent to deceive should be inferred from three situations. First, the Defendants point to Ms. Kitamura's possession of the Bayer reference at the time she filed the '440 patent application, and her testimony in the district court that she knew she had a duty to disclose the Bayer reference to the PTO. Second, the Defendants point to an internal Shionogi memorandum stating that "[d]evelopment information on S-4522 [rosuvastatin] must not be leaked to the outside because it is included in the text of the published unexamined Bayer patent application . . . ." J.A. 2406. Third, the Defendants state that Mr. Shibata knew about the Bayer and Sandoz references and the EPO search report, yet failed to disclose them to the United States examiner. Defendants state that this failure to disclose was due to deceptive intent, as evidenced by Mr. Shibata's delays in processing the patent applications.

The district court received testimony concerning the prosecution of the '440 application from Mr. Shibata, Ms. Kitamura, and Mr. Tamaki, a third Shionogi employee. Ms. Kitamura testified that the IDS for the '440 application was not due when she left employment at Shionogi. Mr. Shibata testified that he believed that it had been filed. Mr. Tamaki testified about the department's heavy work load and provided explanation of confusion and error. There was examination and cross-examination concerning the events at Shionogi. The district court found that "actions suggestive of malfeasance become no more than a string of mishaps, mistakes, misapprehensions and misjudgments on the part of inexperienced and overworked individuals." *Op.* 30. The

district court stated that it "is simply not persuaded that the single most reasonable inference to be drawn from these circumstances is deceptive intent." *Id.* at 24.

The Defendants argue that the district court clearly erred when it did not find an inference of deceptive intent. The Defendants stress that Ms. Kitamura did not remember details after twenty years, and they also stress her admission that she knew she had a duty to disclose the Bayer reference. The Plaintiffs reply that there was no evidence that she intended to withhold the reference in order to deceive the PTO, and that deceptive intent is not "the single most reasonable inference to be drawn from the evidence." *See Therasense*, 649 F.3d at 1290. The Plaintiffs point out that Ms. Kitamura left Shionogi a month after filing the '440 application, well before an IDS was due to be filed.

The district court heard the testimony, considered the credibility of the witnesses, and concluded that deceptive intent was not the single most reasonable inference to be drawn from the evidence. "This court may not reassess, and indeed is incapable of reassessing, witness credibility and motive issues on review." *LNP Eng'g Plastics, Inc. v. Miller Waste Mills, Inc.*, 275 F.3d 1347, 1361 (Fed. Cir. 2001). The Defendants have not shown clear error in the district court's finding that it was most likely that Ms. Kitamura acted without deceptive intent.

The Defendants also argued that the district court clearly erred in failing to find that Mr. Shibata possessed deceptive intent. The Defendants argued that Mr. Shibata's denials of deceptive intent, his apology and excuses, should not have been credited by the district court. The Defendants argued that his admission of negligence does not avoid the inference of intent to deceive, and stress that he had ordered comparative testing. The Plaintiffs cited a

report by Mr. Shibata dated July 14, 1993, which states (in the record translation):

> 'Novelty' and 'inventive step' are examined to determine patentability. It seems that the examination in the U.S. was fairly lenient regarding 'inventive step'. Since we expect a slightly stricter examination in Europe and Japan, we are in the process of implementing 'comparative tests' in the laboratory that we can use as countermeasures. If the superiority of S-4522 [rosuvastatin] is confirmed in these tests, a patent can be obtained in all countries in which we have filed.

J.A. 2752. The Plaintiffs argued that this report is not consistent with an inference of deceptive intent, but instead reflects his belief that the examination in the United States had been more "lenient" than was expected in Europe and Japan. The Plaintiffs argued that by requesting comparative tests Mr. Shibata was preparing to confront the prior art, not to conceal it.

The record and argument are extensive. Clear error has not been shown in the district court's finding that deceptive intent was not shown, and was not the single most reasonable inference based on all of the evidence. *See Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 873 (Fed. Cir. 1988) (en banc in relevant part) (The evidence "must be sufficient to require a finding of deceitful intent in light of all the circumstances."). The district court observed the witnesses under examination and cross-examination, examined the documents, and reasonably found that it was "equally plausible" that Mr. Shibata believed the requirements of the United States patent prosecution had been met. The district court found that the evidence as a whole "paints a more innocent explanation of Mr. Shibata as a new

and inexperienced manager attempting to handle an understaffed and overworked Patent Department." Op. 25.

We agree that clear and convincing evidence did not show that Ms. Kitamura and Mr. Shibata made a deliberate decision to withhold references from the PTO. *See Therasense*, 649 F.3d at 1290 ("In a case involving nondisclosure of information, clear and convincing evidence must show that the applicant *made a deliberate decision* to withhold a *known* material reference.") (quoting *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1181 (Fed. Cir. 1995)). The court in *Therasense* sought to impart objectivity to the law of inequitable conduct by requiring that "the accused infringer must prove that the patentee acted with the specific intent to deceive the PTO," 649 F.3d at 1290. Recognizing the complexity of patent prosecution, negligence—even gross negligence—is insufficient to establish deceptive intent. *See Kingsdown*, 863 F.2d at 876 ("a finding that particular conduct amounts to 'gross negligence' does not of itself justify an inference of intent to deceive"); *Lazare Kaplan Int'l, Inc. v. Photoscribe Techs., Inc.*, 628 F.3d 1359, 1379 (Fed. Cir. 2010) ("mistake or exercise of poor judgment . . . does not support an inference of intent to deceive"); *Molins*, 48 F.3d at 1181 ("[T]he alleged conduct must not amount merely to the improper performance of, or omission of, an act one ought to have performed.").

We affirm that unenforceability based on inequitable conduct was not established.

## III

## REISSUE

The Defendants also argued that the '314 patent was improperly reissued, arguing that the statutory reissue

requirement of error without deceptive intent had not been met. The statute, at the time of the reissue, authorized the reissue of "inoperative or invalid" patents, as follows:

> 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, on the surrender of such patent and the payment of the fee required by law, reissue the patent for the invention disclosed in the original patent . . .

35 U.S.C. §251 (1999).[2] The Defendants argued that (1) there was no error, and (2) there was deceptive intent.

The Defendants argued that Shionogi deliberately presented a claim in the '440 patent that overlapped the products in the Sandoz reference in an attempt to get greater protection. The Defendants also argued that Shionogi acted deliberately in obtaining only generic claims in the '440 patent in order to conceal the rosuvastatin species. The Plaintiffs pointed out that rosuvastatin was specifically described in the specification as the most effective of the four compounds that are described with test data.

The Defendants also argued that deliberate prosecution decisions can never be corrected through reissue, citing the

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[2] In 2011, Congress modified Section 251 in the American Invents Act, Pub. L. No. 112-29, to remove the statutory requirement that the error occur "without any deceptive intention." We consider the earlier version of the statute in this appeal.

statement in *In re Serenkin*, 479 F.3d 1359, 1362 (Fed. Cir. 2007) that "case law holds that the deliberate action of an inventor or attorney during prosecution generally fails to qualify as a correctable error under §251." However, the court in *Serenkin* did not hold that attorney action during prosecution is not correctable, for a principal purpose of the reissue statute is to permit correction of erroneous action during prosecution. Rather, the court held that it is appropriate to consider the nature of the action to determine whether it is a correctable error. The *Serenkin* court explained that "the extent to which the reissue statute prevents an applicant from obtaining claims that differ in form or substance from the cancelled claims 'necessarily depends upon the facts in each case and particularly on the reasons for the cancellation.'" *Id.* at 1365 (quoting *In re Willingham*, 282 F.2d 353, 357 (CCPA 1960).

On the facts of *Serenkin*, that court held that the proposed "correction" did not comport with the purposes of the reissue statute. In *Serenkin* the attorney wished to add eight sheets of drawings to his pending Patent Cooperation Treaty ("PCT") application, which had a filing date of January 28, 1997. For that purpose he filed a petition with the United States PTO Receiving Office under the PCT, requesting that the World Intellectual Property Organization "republish this application showing a filing date of 17 February 1998 with no priority claim and the eight sheets of drawings filed on 17 February 1998." *Id.* at 1361. The attorney had accepted the PTO's position that he must choose between keeping the earlier international filing date without the drawings, or accepting the later date with the drawings. The attorney chose the later date with the drawings, and the petition was granted. After the United States patent was issued, Serenkin sought through reissue to recover the original filing date, stating that its attorney erred in choosing the later date. The PTO refused, and this

court affirmed, stating that Serenkin was impermissibly "attempting to use the reissue process to undo the consequences of his attorney's conscious decision to give up an earlier filing date so that certain material, which was considered important at the time, would be considered with his PCT application." *Id.* at 1365. The court stressed that the actions had been taken with knowledge of their consequences, and compared these facts with those of *In re Wadlinger*, 496 F.2d 1200, 1207 (CCPA 1974), where the court explained that "error" for reissue purposes encompasses "inadvertence, accidents, and mistakes," and "is certainly inclusive of actions taken in full consciousness." In *Wadlinger* the court determined that the reissue claims were narrower in scope than the original claims, and held that this was correctable error under §251, "despite the fact that the cancellation of the original claims was deliberate," as explained in *Serenkin*, 479 F.3d at 1365.

Precedent establishes that for reissue purposes "error is established where there is no evidence that the appellant intentionally omitted or abandoned the claimed subject matter." *Ball Corp. v. United States*, 729 F.2d 1429, 1435–36 (Fed. Cir. 1984). Here, the district court found as fact that Shionogi erred by failing to file an IDS citing the Sandoz and Bayer references, and by omitting a specific claim to the preferred species. However, the court found no evidence of a deliberate choice to omit or abandon the rosuvastatin species, which was described in the specification as the most effective product.

The Defendants' argument that Shionogi cannot narrow the claims by reissue has been rejected in a variety of situations. *See, e.g.*, *In re Tanaka*, 640 F.3d 1246, 1250 (Fed. Cir. 2011) ("This court also rejects the PTO's assertion that the omission of a narrower claim from an original patent does not constitute an error under 35 U.S.C. §251 because the

omission of a dependent claim does not render the patent inoperative."); *Medtronic, Inc. v. Guidant Corp.*, 465 F.3d 1360, 1375 (Fed. Cir. 2006) ("An attorney's failure to appreciate the full scope of the invention is one of the most common sources of defects in patents, and is generally sufficient to justify reissuing a patent.") (citing *In re Wilder*, 736 F.2d 1516, 1519 (Fed. Cir. 1984)); *In re Handel*, 312 F.2d 943, 946 n.2 (CCPA 1963) ("adding dependent claims as a hedge against possible invalidity of original claims is a proper reason for asking that a reissue be granted"). The district court's affirmance of the PTO's holding that Shionogi had the right to a reissue in which it claimed only rosuvastatin and its salts, is in accordance with law.

Our colleague in dissent cites other cases in which reissue was denied, on other facts and circumstances. While these cases illustrate the factual nature of a determination of "intent," no precedent warrants a finding of deceptive intent in the situation herein. In *In re Youman*, 679 F.3d 1335 (Fed. Cir. 2012) the court determined whether the patentee was attempting to "recapture," through reissue, subject matter that had been surrendered during prosecution. In *In re Harita*, 847 F.2d 801 (Fed. Cir. 1998) the court held that reissue was available although, due to gross negligence, the foreign patent practitioner did not assure that the PTO was advised of prior art that was discovered after the patent application was filed; the court held that "intent to mislead" could not be inferred, even from gross negligence. In *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 882 F.2d 1556, 1566 (Fed. Cir. 1989) the court held that the patentee's submission of false affidavits to the PTO "eliminated the basis for reissue and rendered the '684 patent invalid" because the patentee's explanation of "error" was "factually untrue." In *In re Hounsfield*, 699 F.2d 1320, 1323 (Fed. Cir. 1983) the court held that "lack of 'intent to claim' is not an independent basis for denying a reissue application

under section 251," but only "sheds light upon whether the claims of the reissue application are directed to the same invention as the original patent. . . ." In *In re Whittelsey*, 83 F.2d 894 (CCPA 1936) the court held that the patentee could not use reissue to obtain claims which "were intentionally omitted from his original application under the belief that they could not properly be included therein. . . ." In *In re Murray*, 77 F.2d 651, 654–55 (CCPA 1935) the court held that the patentee could not use reissue to obtain broader claims to cover "improvements in the art which have occurred since the date of issuance of the original patent" and were "not intended to be incorporated in the original application." None of these cases supports rejection of a reissue application for an unintentional failure to file an IDS.

The district court considered the Defendants' arguments directed to both error and deceptive intent, and concluded that Shionogi did not act intentionally to make the error for which it seeks reissue. The district court received live testimony from the purported culprits, and found that "the evidence adduced in this case shows no such deliberate choices [as on the facts of *Serenkin*] and no violations of rules or statutes that would render the reissue of the '440 patent improper." Op. 43. In discussing the scope of the claims, the district court found that Ms. Kitamura credibly testified that she was unaware that there was overlap between the claims of the '440 application and the prior art because "the internal Shionogi search report of which she was aware, did not raise a patentability problem with respect to Sandoz, and a full copy of the Sandoz reference was not sent to her." Op. 41. These internal search reports do not show the chemical structures of the Sandoz reference. J.A. 2211, 2224, 2242. The district court found that the evidence showed that after Ms. Kitamura's departure, Shionogi was not alerted to the need for further attention to the Sandoz reference because of "chaos, confusion, and

inexperience," "lack of legal training within the Shionogi Patent Department, the changing and limited personnel within that department, . . . the ongoing confusion level," and "unintentional miscommunications" between Shionogi's patent personnel. *Id.* These findings have not been shown to be clearly erroneous. And the Defendants' charge that Shionogi deliberately obtained claims in the '440 patent that it knew to be invalid is not plausible.

The district court found that "the Court is ultimately not convinced that the claims of the '440 patent that overlapped the Sandoz reference were the result of some planned strategy or sinister motivation as opposed to mere mistake or oversight by overworked individuals with limited training and expertise." Op. 40. *See Hewlett-Packard Co.*, 882 F.2d at 1565 ("The language of the current statute, 'error without deceptive intent' . . . encompasses 'inadvertence, accident or mistake.'").

The Defendants argue that "deceptive intent" in the reissue statute requires less rigorous proof than "deceptive intent" in connection with charges of inequitable conduct. We discern no sound basis for this distinction, for the complexities of patent solicitation in all its stages have been shown susceptible to the "plague" of opportunistic accusations. *See Therasense*, 649 F.3d at 1289 ("'[T]he habit of charging inequitable conduct in almost every major patent case has become an absolute plague.'") (quoting *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988)). This court has repeatedly held in the context of inequitable conduct that nondisclosure of prior art by itself is not enough to create an inference of deceptive intent. *See Larson Mfg. Co. of S.D., Inc. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1340 (Fed. Cir. 2009) ("[N]ondisclosure, by itself, cannot satisfy the deceptive intent element."); *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1367

(Fed. Cir. 2003) ("Intent to deceive cannot be inferred simply from the decision to withhold the reference where the reasons given for the withholding are plausible."); *Aspex Eyewear Inc. v. Clariti Eyewear, Inc.*, 605 F.3d 1305, 1316 (Fed. Cir. 2010) ("Mistake or negligence, even gross negligence, does not support a ruling of inequitable conduct."); *Kingsdown*, 863 F.2d at 876 (en banc in relevant part) (holding even "'gross negligence' does not of itself justify an inference of intent to deceive"). Here, after considering all of the evidence, the district court found that the evidence did not support a finding of deceptive intent. Op. 40 ("To reach a contrary conclusion in this case would require the Court to credit a number of inferences, which the Court finds unsupported by the requisite clear and convincing standard."). *Id.* We find no error.

"The law does not require that no competent attorney or alert inventor could have avoided the error sought to be corrected by reissue." *Scripps Clinic & Res. Found. v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991), *overruled on other grounds by Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282 (Fed. Cir. 2009). The Shionogi error in failing to file an IDS was agreed to be an error, and was rectified promptly upon its discovery. Our colleague in dissent does not complain about the speed of the moves to correct the error, but would hold that the error should have been detected sooner, and that this failure of detection is fatal to the reissue patent. However, all of the cited cases relate to the absence of diligence in correcting the error after it was detected. *E.g.*, *Principle Bus. Enters., Inc. v. United States*, 7 Cl. Ct. 433, 438 (Cl. Ct. 1985) ("The delay of more than seven years after plaintiffs learned of the alleged error affecting their original patent is unreasonably long and not justified."); *Gen. Radio Co. v. Allen B. Dumont Labs., Inc.*, 129 F.2d 608, 612 (3d Cir. 1942) (delay of eight years was unreasonable when "invalidity of the patent should . . . have been clear to any-

one with even a rudimentary knowledge of patent law"); *Miller v. Bridgeport Brass Co.*, 104 U.S. 350 (1881) (delay of fifteen years was unreasonable when patentee sought a broadening reissue to cover newly discovered improvement). In contrast, the reissue application here was filed promptly upon discovery of the error.

The Defendants, and our colleague in dissent, propose that Shionogi omitted a claim specific to rosuvastatin from its application in order to conceal the compound from competitors. However, rosuvastatin was explicitly described in the Shionogi specification as the preferred compound. It was specifically identified, including its synthesis and test results. This is not compatible with concealment. Our colleague states that "[d]escribing a compound in the examples contained in the specification, however, is unlikely to be the 'red flag' that narrowly claiming a compound would be, particularly if that compound is the only one specifically claimed." Dissent at 11 n.4. However, this is not a case where the preferred product was "buried" in massive disclosure, for rosuvastatin was specifically described as the most potent product. The specification also states that the four tested compounds are "superior to Mevinolin," a statin known to be commercially successful and marketed by Merck under the brand name Mevacor®. The patentee's decision to limit the reissue to the compound that was described in the specification as the most potent of the compounds specifically described is not evidence that the most potent compound was deceptively concealed.

The dissent points to internal Shionogi documents that caution against "leaking" the discovery of rosuvastatin to Bayer. Such caution was indeed prudent, but when the discovery was presented for patenting, it was specifically identified as the most effective compound. Cautioning scientists against "leaks" is a distinct matter from the

concern for obtaining valid and strong patents, for specific claims are more reliable than broad claims that risk the citation of fringe prior art. The dissent also argues that the fact that Shionogi narrowed its reissue claims to the compound rosuvastatin, without seeking broader generic scope, is evidence of deceptive intent. Shionogi states that its concern was to obtain examination on the uncited references, and that limiting the claims to the preferred product implemented that concern. In view of the circumstances necessitating the reissue procedure in order to bring the uncited references before the examiner, it is not clear how the limitation of the claims to the compound of commercial interest suggests that the prior flawed procedures were based on deceptive intent.

We also take note of the dissent's concern that "[b]y failing to act promptly to narrow its overbroad claim, Shionogi deprived the public of the right to experiment with, and to improve upon, the compounds encompassed by claim 1." Dissent at 15. However, patenting does not deprive the public of the right to experiment with and improve upon the patented subject matter. As discussed in *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 142 (2001), "[t]he disclosure required by the Patent Act is 'the quid pro quo of the right to exclude,'" quoting *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 484 (1974). It is not necessary to wait for the patent to expire before the knowledge contained in the patent can be touched. The patent's right to exclude was explained by Justice Story in *Whittemore v. Cutter,* 29 F. Cas. 1120 (C.C.D.Mass. 1813):

> [I]t could never have been the intention of the legislature to punish a man who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.

*Id.* at 1121; *see Chesterfield v. United States,* 159 F. Supp. 371 (Ct. Cl. 1958) (experimental study is not infringement).

In sum, the district court correctly found that reissue was available, and that the scope of the reissue was in accordance with law.

## IV

## INFRINGEMENT

With the exception of Apotex Corp. (herein "Apotex U.S."), all of the Defendants admit infringement of claims 6 and 8 of the '314 patent. Apotex U.S. is a United States affiliate of the Canadian company Apotex Inc. (herein "Apotex Canada"). Apotex U.S. stated in the district court that it is a defendant to this action only because it signed and filed the ANDA on behalf of Apotex Canada. Apotex U.S. stated that it did not "submit" the ANDA within the meaning of §271(e)(2)(A) and thus cannot infringe the U.S. patent. Apotex U.S. also stated that Apotex Canada cannot be liable for infringement in this action because it is not a party to this suit.

The district court found Apotex U.S. to be the ANDA "submitter" because Apotex U.S. filed the ANDA and actively participated with Apotex Canada in preparation of the ANDA, and that Apotex U.S. intends to directly benefit from the ANDA by selling the drug product in the United States upon approval of the ANDA. The court found that Apotex U.S. acts as the marketing and distribution arm of Apotex Canada in the United States, a relationship that was not disputed. Apotex Canada is not a party to this suit only because the infringement case against Apotex Canada was transferred to the Southern District of Florida at the request of Apotex Canada, which pled the absence of personal

jurisdiction in Delaware. *In re Rosuvastatin Calcium Patent Litigation*, MDL No. 08-1949, 2010 WL 661559 (D. Del. Feb. 19, 2010).

Apotex U.S. argues that it cannot be bound by the district court's judgment of infringement because it only signed and filed the ANDA as the agent of Apotex Canada. The district court ruled that Apotex U.S. can be liable for infringement under §271(e)(2)(A), not only because Apotex U.S. is the entity that signed and filed the ANDA, but also because it intends to benefit from the application by selling the rosuvastatin product manufactured by its Canadian relative. The district court referred to testimony by the President of Apotex U.S., who stated that Apotex Canada "made the decision to 'develop Rosuvastatin calcium as a generic product for the United States, for Apotex U.S. to sell in the United States. . . .'" The district court found that Apotex U.S. actively participated in activities related to the ANDA submission in conjunction with Apotex Canada, and referred to activities of Mr. Kiran Krishnan, manager of regulatory affairs for Apotex U.S., at the headquarters of Apotex Canada in preparing the ANDA in consultation with the regulatory staff of Apotex Canada. Mr. Krishnan signed the ANDA on behalf of Apotex U.S., as the authorized U.S. agent. The district court concluded that Apotex U.S. may be held liable for infringement under Section 271(e)(2)(A) as a "submitter" of an ANDA.

Responding to the Apotex argument that the Hatch-Waxman Act does not provide a definition of "submit," the district court adopted the legal standard for a "submitter" set forth in *In re Rosuvastatin Calcium Patent Litig.*, 2008 WL 5046424, at *10 (D. Del. Nov. 24, 2008) ("*Rosuvastatin I*"), and in *AstraZeneca Pharms. LP v. Aurobindo Pharma Ltd.*, 2009 WL 483131, at *3 (D. Del. Feb. 25, 2009). In those cases the district court held that

> a wholly-owned subsidiary of a foreign ANDA applicant, which signs an ANDA as the agent of its parent-applicant, and which intends to benefit directly if the ANDA is approved by participating in the manufacture, importation, distribution and/or sale of the generic drug [i]s subject to suit under §271(e) as the one who has "submitted" the ANDA.

*Rosuvastatin I* at *10. Other courts have also applied liability to the ANDA "submitter" who signs the ANDA and intends to directly benefit from the ANDA. *See Wyeth v. Lupin Ltd.*, 505 F. Supp. 2d 303, 306–07 (D. Md. 2007); *Aventis Pharma Deutschland GmbH v. Lupin Ltd.*, 403 F. Supp. 2d 484, 492–94 (E.D. Va. 2005); *see generally Cephalon, Inc. v. Watson Pharms., Inc.*, 629 F. Supp. 2d 338, 349 (D. Del. 2009); *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 693 F. Supp. 2d 409, 417 (D. Del. 2010).

Apotex U.S. argues that 21 U.S.C. §355(j) identifies the applicant as "the person or entity who submits an ANDA, establishes what the applicant must do to submit an ANDA, creates incentives to encourage ANDA submission, and provides a means to obtain patent certainty." Apotex Br. 15. Apotex U.S. argues that 35 U.S.C. §271(e)(2)(A) incorporates §355(j), and consequently defines who submits an ANDA. Apotex U.S. explains that the Hatch-Waxman Act similarly defines an applicant in its section related to new drug applications, which states "[t]he applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the *applicant submitted* the application. . . ." 21 U.S.C. §355(b)(1) (emphasis by Apotex U.S.). Apotex U.S. argues that §271(e)(2)(A) makes no mention of "active involvement," "parent-subsidiary," "principal-agent," or intent to

benefit from ANDA approval, and argues that these factors are irrelevant to the "submitter" issue.

Apotex U.S. argues that FDA regulations identify the applicant as the person or entity who submits an ANDA, citing 21 C.F.R. §314.3(b) ("Applicant means any person who submits an application or abbreviated application or an amendment or supplement to them under this part to obtain FDA approval of a new drug or an antibiotic drug and any person who owns an approved application or abbreviated application."). Apotex U.S. states that Apotex Canada made the Paragraph IV certification, that a Paragraph IV certification is the infringing act under §271(e)(2), and therefore that Apotex U.S. cannot be bound by any judgment of patent infringement.

Apotex U.S. also argues that the district court's ruling is unfair because its orders can affect the interests of Apotex Canada, who is not before the Delaware court, and thus that the district court violated the due process rights of Apotex Canada. Apotex U.S. also argues that Apotex Canada is a necessary party to the suit against Apotex U.S.

The district court properly deemed these arguments unpersuasive. The court found that the interests of Apotex Canada in this action are represented by its agent and subsidiary, Apotex U.S., and that Apotex U.S. participated in preparation of the ANDA and represented that it would sell the product in the United States. That relationship is not denied.

We conclude that the district court did not err in holding that Apotex U.S. is properly named as a defendant in this action. The judgment of infringement against all of the Defendants is affirmed.

**AFFIRMED**

# United States Court of Appeals for the Federal Circuit

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**IN RE ROSUVASTATIN CALCIUM PATENT LITIGATION**

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**ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS INC., AND SHIONOGI SEIYAKU KABUSHIKI KAISHA,**
*Plaintiffs-Appellees,*

**v.**

**AURobindo PHARMA LIMITED,**
*Defendant-Appellant,*

**AND**

**MYLAN PHARMACEUTICALS INC.,**
*Defendant-Appellant,*

**AND**

**APOTEX CORP.,**
*Defendant-Appellant,*

**AND**

**COBALT PHARMACEUTICALS INC. AND COBALT LABORATORIES INC.,**
*Defendants-Appellants,*

**AND**

**SUN PHARMACEUTICAL INDUSTRIES, LTD.,**
*Defendant-Appellant,*

**AND**

**TEVA PHARMACEUTICALS USA, INC.,**
*Defendant-Appellant,*

**AND**

**PAR PHARMACEUTICAL, INC.,**
*Defendant-Appellant,*

**AND**

**SANDOZ, INC.,**
*Defendant.*

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2010-1460,-1461,-1462,-1463,-1464,-1465,-1466,-1467, -1468,-1469,-1470,-1471,-1472,-1473

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Appeal from the United States District Court for the District of Delaware in case nos. 08-MD-1949, 07-CV-0810, 07-CV-0805, 07-CV-0809, 07-CV-0811, 07-CV-0806, 08-CV-0426, and 07-CV-0808, Judge Joseph J. Farnan, Jr.

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PLAGER, *Circuit Judge*, concurring.

I join the opinion of Judge Newman.

I write to clarify my understanding of why Apotex U.S. should be treated as having "submit[ted]" an application for an ANDA, and therefore be held liable as an infringer under 35 U.S.C. § 271(e)(2). The question is whether, under the statute, Apotex U.S. "submit[ted] an application . . . for a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent." If so, the statute deems that to be an act of infringement. *Id.*

Apotex U.S. argues that, in filing the application for the ANDA, it was simply an agent for the true applicant,

Apotex Canada. As an agent for the applicant, Apotex U.S. argues that it is not an applicant and therefore cannot be deemed an infringer. The question of whether an agent-filer-submitter such as Apotex U.S. can be a party liable for infringement under § 271(e)(2) is a question of first impression in this court.

The statute nowhere addresses the question of agency in the submission of an application under § 271(e). However, in creating the artificial act of infringement by the submission of an ANDA, the statute does add the following qualifier related to the applicant's purpose in making the submission: "It shall be an act of infringement to submit an application . . . if the purpose of such submission is to obtain approval . . . *to engage in the commercial manufacture, use, or sale* of a drug . . . claimed in a patent . . . ." *Id.* (emphasis added). The phrasing leaves unclear what the consequences are if the party who submits the application is not the same as the principal party who will "engage in" the manufacture of the drug at issue.

Thus the question becomes whether the statute is intended to include within its scope 1) any agent who simply submits (*i.e.*, files) an application for another who is the principal commercial manufacturer; or 2) an agent who files on behalf of such another, but who has a financial interest beyond simply acting for the commercial manufacturer, and in this latter situation, what qualifies as a sufficient financial interest.

With regard to the first, there can be no doubt that many applications are in fact submitted to the FDA by attorneys or others acting as agents for the real party in interest, *i.e.*, the commercial manufacturer of the generic drug at issue. It would make little sense to read the statute as making such agents liable for the artificial "act

of infringement" created therein. Though presumably an attorney or other agent representing a principal commercial manufacturer could fashion some sort of hold-harmless provision in the employment contract, such unnecessary complication and the potential mischief associated therewith cannot be what Congress had in mind. An agent who simply prepares and submits the application as such is not an applicant; it is the real party in interest—the commercial manufacturer—who is the statutory applicant who "submit[s]" the application and commits the act of infringement. In the case before us, there is no doubt that Apotex Canada is the principal party in interest and intends "to engage in the commercial manufacture, use, or sale" of the drug, and thus is an applicant under the statute.

But there remains the second inquiry. What of the agent who has a financial interest in the manufacture or distribution of the drug that is the subject of the ANDA? Here, Apotex U.S. did indeed assist Apotex Canada in the planning, preparation, and submission of the application, but as discussed above, that alone cannot create liability. In this case, however, there is more—it is clear from the record that Apotex U.S. is not merely an agent who assisted the manufacturer in submitting an application under the statute.

The record indicates that Apotex U.S., by virtue of the relationships between itself and Apotex Canada, both corporate and otherwise, will become the entity—indeed, a real party in interest—that will use and sell the drug in the United States. The trial court found, based on the testimony of the President of Apotex U.S., that Apotex U.S. is the marketing arm of Apotex Canada and that Apotex Canada made the decision "to develop [the drug] as a generic product for the United States, for Apotex U.S. to sell in the United States . . . ." *See* Op. at 12. Fur-

thermore, in its brief to this court, Apotex U.S. acknowledged this relationship: "Apotex [U.S.] hopes to market the product described in the ANDA some day . . . [and] desire[s] to one day market the product described in the ANDA . . . ." Appellant's Reply Br. at 12.

The district court applied the following legal standard for determining liability for submission of an ANDA:

> a wholly-owned subsidiary of a foreign ANDA applicant, which signs an ANDA as the agent of its parent-applicant, and which intends to benefit directly if the ANDA is approved -- by participating in the manufacture, importation, distribution and/or sale of the generic drug -- [is] subject to suit under § 271(e) as one who has "submitted" an ANDA.

Slip Op. at 8-9 (modification in original). This was a standard derived from the approach several other district courts had taken.

There is some logic to the position that, when such a related agent expects to financially benefit from the approval of the ANDA in a significant way, for example by becoming a major if not sole distributor of the generic product in the United States, the statute can be understood broadly enough to include such an agent as a statutory "submit[ter]." Such an agent could thus be considered a party who may be held liable for the statutory act of infringement by virtue of submission of the application.[1]

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[1] Apotex U.S.'s effort to divert attention away from § 271(e) to other parts of the statutes—including the provision regarding Paragraph IV certifications and 21 U.S.C. § 355, relating to the New Drug Approval process, misses the point—it is the scope of "submit" in § 271 that is the issue.

Although Apotex U.S. is not a wholly-owned subsidiary of Apotex Canada, they are closely related through a complex corporate structure.[2] Both the statutory analysis suggested here and the evidentiary record in this case support the district court in bringing Apotex U.S. within the ambit of the party who submits an ANDA and thus is subject to liability as a deemed infringer.

More directly, however, in this case Apotex U.S. clearly intends to engage in, and presumably submitted the ANDA for the purpose of, selling the approved drug in the United States. The statute speaks not only in terms of engaging in commercial manufacture, but, disjunctively, in terms of engaging in the drug's "use or sale." As an acknowledged sales agent for the primary applicant, Apotex U.S. can be treated as simply having "submit[ted]" an application for an ANDA for the purpose of "engag[ing] in the commercial . . . sale of [the] drug . . . claimed in a patent." Under either analysis, the district court did not err in concluding that Apotex U.S. is liable for an act of infringement.[3]

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[2] See the district court opinion at 11 for a description of the corporate structure involved.

[3] In finding Apotex U.S. liable as an infringer under the statute by virtue of its having "submit[ted]" the application for the ANDA, we make no judgment regarding Apotex Canada, who was not a party to this law suit; any rights or obligations it may have when and if it is brought into a law suit involving the product that is the subject of this case are questions for another time.

# United States Court of Appeals for the Federal Circuit

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**IN RE ROSUVASTATIN CALCIUM PATENT LITIGATION**

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**PAR PHARMACEUTICAL, INC.,**
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2010-1460,-1461,-1462,-1463,-1464,-1465,-1466,-1467, -1468,-1469,-1470,-1471,-1472,-1473

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Appeal from the United States District Court for the District of Delaware in case nos. 08-MD-1949, 07-CV-0810, 07-CV-0805, 07-CV-0809, 07-CV-0811, 07-CV-0806, 08-CV-0426, and 07-CV-0808, Judge Joseph J. Farnan, Jr.

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MAYER, *Circuit Judge*, dissenting.

I respectfully dissent. There can be no infringement of U.S. Reissue Patent No. 37,314 (the "'314 patent") because that patent is invalid for improper reissue. Reissue is available under 35 U.S.C. § 251 to rectify an "error" resulting from inadvertence, accident, or mistake. No such error was present in U.S. Patent No. 5,260,440 (the "'440 patent"), so there is no basis upon which it could properly be reissued. Furthermore, Shionogi Seiyaku Kabushiki Kaisha ("Shionogi") has forfeited the right to obtain reissue by its failure to exercise due diligence in seeking to rectify the alleged defect in the '440 patent.

I.

"Congress limited reissue to instances where the patentee could demonstrate an 'error without any deceptive intention.'" *In re Youman*, 679 F.3d 1335, 1342 (Fed. Cir. 2012) (quoting 35 U.S.C. § 251); *see also In re Serenkin*, 479 F.3d 1359, 1363 (Fed. Cir. 2007) (concluding that reissue was not available where a patentee's attorney made a "conscious decision" to accept a later filing date for his application); *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 882 F.2d 1556, 1565 (Fed. Cir. 1989) (emphasizing that a party seeking reissue must establish "inadvertent error in conduct"); *In re Hounsfield*, 699 F.2d 1320, 1323 (Fed. Cir. 1983) (explaining that reissue is designed to "correct an inadvertent error in the original patent"); *In re Whittelsey*, 83 F.2d 894, 895 (C.C.P.A. 1936) (concluding that reissue was improper where "there was no inadvertence or mistake" in a patentee's decision to omit certain claims from his original application); *In re Murray*, 77 F.2d 651, 655 (C.C.P.A. 1935) (explaining that a patent may not be reissued "for the purpose of correcting errors of judgment"). Prior to 1952, the reissue statute specifically provided that defects correctible through reissue were those that had resulted from "inadvertence, accident, or mistake." 35 U.S.C. § 64 (1946); *In re Weiler*, 790 F.2d 1576, 1582 (Fed. Cir. 1986). When it enacted section 251, the current reissue provision, Congress intended to retain the "inadvertence, accident, or mistake" standard that had existed under the earlier statute.[1] *Hewlett-Packard*, 882 F.2d at 1565; *see In re*

[1] Section 251, during the relevant time period, provided:

> 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 pat-

*Wadlinger*, 496 F.2d 1200, 1207 (C.C.P.A. 1974) (emphasizing that when Congress substituted the word "error" for the words "inadvertence, accident, or mistake," it did not intend to make "a substantive change").

Here, Shionogi made an error in judgment when it elected to prosecute a broad genus claim which covered trillions of pyrimidine compounds and which clearly overlapped with a known prior art reference, European Published Application No. 0367895 ("Sandoz"). There is no evidence that the overlap between claim 1 of the '440 patent and Sandoz was the result of ignorance or inadvertence, rather than a deliberate attempt to obtain patent rights that were as broad in scope as possible. Not a single inventor or patent prosecutor testified that he or she unknowingly or inadvertently introduced the overlap between Sandoz and claim 1. Indeed, the only inventor to testify at trial, Haruo Koike, stated that he did not believe that there was any error in the '440 patent. Joint App. 22763-65.

It is undisputed that Shionogi was aware of Sandoz when it prosecuted and obtained the broad claims of the '440 patent. A June 1991 Shionogi internal search report identified Sandoz as relevant prior art. In October 1992,

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> entee claiming more or less than he had a right to claim in the patent, the Director shall, on the surrender of such patent and the payment of the fee required by law, 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. No new matter shall be introduced into the application for reissue.

35 U.S.C. § 251 (emphasis added). Pursuant to the Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 20(d), 125 Stat. 284, 333 (2011), the words "without any deceptive intention" were deleted from the statute.

Shionogi received a European Patent Office ("EPO") search report with an attached copy of Sandoz. This report identified Sandoz as an "X" reference, meaning that the reference was "particularly relevant if taken alone." Shionogi received the EPO search report a second time when the European counterpart to the '440 patent was published in January 1993.

Tomoko Kitamura, the Shionogi employee who filed the '440 application, testified at trial, but never stated that she misapprehended the Sandoz disclosure or that she failed to appreciate the overlap between it and claim 1 of the '440 patent. To the contrary, the record shows that Shionogi was well aware of Sandoz at the time Kitamura filed the '440 application. A November 1991 internal search report listed Sandoz as relevant prior art and explained that it disclosed a "pyrimidine skeleton" with statin activity. Given the obvious overlap between Sandoz and claim 1, it defies credulity to accept that Kitamura, who had had several years of experience preparing and prosecuting patent applications and who holds a degree in organic chemical synthesis, would fail to appreciate that claim 1 was directed to subject matter previously disclosed in Sandoz.[2]

When Kitamura left Shionogi in July 1992, Takashi Shibata assumed primary responsibility for prosecution of the '440 application. Shibata received the EPO search report declaring Sandoz to be "particularly relevant" stand-alone prior art. Shibata, moreover, specifically

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[2] At trial, Kitamura stated that she believed that none of the prior art cited in internal search reports raised "patentability concerns" with respect to Shionogi's pyrimidine statins. Joint App. 21458. Contrary to the majority's assertions, *ante* at 21, however, Kitamura never testified that she failed to appreciate that claim 1 of the '440 patent overlapped with Sandoz.

instructed Shionogi scientists to test and compare the preferred compounds disclosed in Sandoz with those disclosed in the '440 application. Although Shibata testified at trial, he, like Kitamura, never stated that he failed to appreciate the scope of the invention disclosed in the '440 patent or that he was unaware of the obvious overlap between claim 1 and Sandoz.

In 1997, Shionogi and Zeneca Limited ("Zeneca")[3] entered into discussions regarding a licensing agreement that would allow Zeneca to commercialize rosuvastatin, the most promising compound disclosed in the '440 patent. During these negotiations, Zeneca raised concerns that Sandoz was potentially invalidating prior art. Joint App. 2285-86. In response, Shionogi conceded that it "had been aware of [Sandoz] . . . prior to filing the ['440 application]" and that there was an overlap between claim 1 of the '440 patent and "the disclosure and claims of [Sandoz]." *Id.* at 2290. Shionogi asserted, however, that "not so much attention was paid" to Sandoz because it believed that rosuvastatin "did not fall within the scope of [Sandoz]." *Id.* Significantly, when responding to Zeneca's invalidity concerns, Shionogi did not assert that it had previously misunderstood the scope of the Sandoz disclosure or that it had unintentionally or inadvertently introduced the overlap between Sandoz and claim 1.

A patentee cannot establish correctible "error" under section 251 simply by demonstrating that his original patent contains a defect. *Hewlett-Packard*, 882 F.2d at 1565 (emphasizing that the fact that a patent is "defective" does not "give[] rise to an inference of 'oversight'"); *Weiler*, 790 F.2d at 1582-83 (concluding that reissue was

[3] Zeneca is the predecessor to AstraZeneca UK Limited.

not permitted where a patentee failed to establish that he had unintentionally omitted subject matter from his original claims); *In re Mead*, 581 F.2d 251, 257 (C.C.P.A. 1978) (holding that a "conscious choice" not to file a continuing application did not constitute correctible error); *In re Byers*, 230 F.2d 451, 454 (C.C.P.A. 1956) (emphasizing that the deliberate amendment of a claim did not constitute correctible error). Instead, reissue is warranted only where a patentee "supplies . . . facts indicating how . . . ignorance," accident, or mistake caused an error in his claims:

> [The patentee's] reliance on allegations of the inventors' ignorance of drafting and claiming technique and counsel's ignorance of the invention is unavailing. Those allegations could be frequently made, and, if accepted as establishing error, would require the grant of reissues on anything and everything mentioned in a disclosure. *[The patentee] supplies no facts indicating how the ignorance relied on caused any error* . . . . [Section] 251 does not authorize the patentee to re-present his application.

*Weiler*, 790 F.2d at 1583 n.4 (emphasis added); *see also In re Wittry,* 489 F.2d 1299, 1302 (C.C.P.A. 1973) (holding reissue claims invalid where "the declarations [did] not present any reasonable explanation of any errors in the original claims which the reissue would overcome").

*Serenkin*, 479 F.3d at 1362-65, is instructive on this issue. There, a prosecuting attorney chose to accept a later filing date in exchange for being allowed to include additional drawings with his application. The patentee later sought reissue, arguing that his attorney had "made the wrong procedural choice" by accepting the later filing date. *Id.* at 1362. We rejected this argument, explaining

that reissue is appropriate where there has been "a genuine error," but not where a patentee or his attorney has made "a deliberate, but subsequently found to be disadvantageous, choice." *Id.* at 1364.

A similar analysis applies here. Shionogi made an error in judgment when it prosecuted and maintained a broad genus claim that clearly overlapped with a known prior art reference. Absent any evidence showing that this overlap was the result of inadvertence or mistake, however, Shionogi had no right to invoke the reissue process in order to remedy its "deliberate, but subsequently found to be disadvantageous, choice." *Id.*; *Hewlett-Packard*, 882 F.2d at 1566 (rejecting the argument that "an error in conduct must be presumed, absent affirmative evidence that the defect in the patent which is asserted in the reissue application was intentional"); *see also Youman*, 679 F.3d at 1343 (explaining that section 251's "error" requirement covers "inadvertence or mistake," not "deliberate" choices made by the patentee). As we have previously made clear, section 251 "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." *Weiler*, 790 F.2d at 1582.

On appeal, Shionogi argues that the overlap with Sandoz must have been unintentional because "no rational patent applicant would intentionally pursue claims known to be invalid." This argument is unpersuasive for two reasons. First, the fact that claim 1 overlapped with Sandoz did not necessarily render that claim invalid. A subset of a broad genus of prior art compounds is potentially patentable. *See Eli Lilly & Co. v. Bd. of Regents*, 334 F.3d 1264, 1270 (Fed. Cir. 2003). Indeed, during the negotiations with Zeneca, Shionogi's U.S. patent attorney stated that claim 1 of the '440 patent was not necessarily

invalid in view of Sandoz "because it [could] be said that ours is a selection invention from within the genus of [Sandoz]." Joint App. 5187.

Second, patentees not infrequently intentionally draft very broad independent claims, but "hedge" against invalidity by drafting narrower dependent claims. *See In re Tanaka*, 640 F.3d 1246, 1249-51 (Fed. Cir. 2011). Here, Shionogi believed that even if the broad genus claim contained in claim 1 was subsequently found to be invalid, subgenus claims 2 and 3, which did not overlap with Sandoz, would protect rosuvastatin, its most important compound. *See* Joint App. 20513-15; 8532-37; 20208-09.

II.

In concluding that the '440 patent was properly reissued, the majority conflates the issue of whether Shionogi was guilty of inequitable conduct with the question of whether it met the requirements for reissue under section 251. Shionogi failed to cite *any* relevant prior art to the United States Patent and Trademark Office ("PTO") when it prosecuted the '440 application. Indeed, the record suggests that Shionogi acted with intent to deceive the PTO when it failed to disclose the highly material Bayer application, *see* Japanese Published Patent Application No. 1989-261377, and the EPO search report identifying Sandoz as a highly relevant stand-alone prior art reference. Prior to *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290-93 (Fed. Cir. 2011) (en banc), this conduct would surely have been censored as fraud on the patent office. Even accepting *arguendo* that Shionogi's malfeasance was insufficient to satisfy the standard for inequitable conduct articulated in *Therasense*, however, this does not mean that the '440 patent was validly reissued. Whether Shionogi intended to deceive the PTO by failing to disclose Sandoz is a wholly separate issue from

whether it deliberately introduced an overlap between Sandoz and the '440 patent.

Shionogi asserts that it failed to disclose material prior art to the PTO because of the "chaos" and "confusion" that ensued after Kitamura resigned in July 1992. *AstraZeneca Pharms. LP v. Mylan Pharms. Inc.*, 719 F. Supp. 2d 388, 400 (D. Del. 2010). Kitamura, however, had already filed the '440 application—with its overlap with Sandoz—when she left Shionogi. There is no evidence that there was any confusion or chaos in the Shionogi patent department before Kitamura's departure. Thus, while confusion within the Shionogi patent department may have led to the failure to disclose material prior art, there is no evidence that it led to the overlap between Sandoz and claim 1.

III.

When Shionogi submitted its reissue application, it filed a declaration stating that it had "claimed more than [it] had a right to claim by reason of the disclosure of [Sandoz]." Joint App. 2812. Shionogi could have remedied the overlap with Sandoz by simply revising claim 1. Instead, however, Shionogi ultimately cancelled all of the claims of the '440 patent—including claims 2 and 3 which did not overlap with Sandoz—and replaced them with new claims narrowly directed to rosuvastatin. If the overlap with Sandoz were the result of inadvertence or mistake and Shionogi was merely attempting to rectify this alleged error, it presumably would have simply revised claim 1 and left claims 2 and 3 intact.

Shionogi's initial failure to obtain a narrow claim directed to rosuvastatin was not the result of error or mistake, but was instead part of a deliberate effort to avoid alerting Bayer, its competitor, of its interest in the compound. Shionogi was very concerned that if Bayer discov-

ered that Shionogi was focusing on rosuvastatin it would try to include that compound in the claims of its pending patent application. In a November 1991 memorandum, for example, Shionogi advised its employees to be "on maximum alert" to prevent "leaks of secrets relating to the status of the Shionogi [rosuvastatin] development" because "Bayer might make an effort to assert" that rosuvastatin was included within the claims of its pending application. Joint App. 2241. Indeed, at trial Shibata acknowledged that Shionogi was concerned "that if Bayer found out that Shionogi was focusing on [rosuvastatin], Bayer would try to cover [rosuvastatin] in their pending . . . application." Joint App. 20760.

There is no evidence that the failure to include a claim directed to rosuvastatin was the result of "error" or mistake. Instead, the record contains strong evidence that Shionogi failed to specifically claim rosuvastatin in order to avoid "tipping off" Bayer about its interest in the compound.[4] It was only after the Bayer application had been withdrawn that Shionogi decided to add narrow claims directed to rosuvastatin and its salts.

Contrary to the majority's assertions, *ante* at 19, the situation presented here is far different from that presented in *Tanaka*. There, we concluded that reissue was proper where a patentee retained his original claims, but added a narrow dependent claim. 640 F.3d at 1249-51.

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[4] Shionogi presents no plausible alternative explanation for its failure to specifically claim rosuvastatin. Instead, Shionogi argues that it did not attempt to conceal rosuvastatin from Bayer because rosuvastatin was described in the '440 patent's specification. Describing a compound in the examples contained in the specification, however, is unlikely to be the "red flag" that narrowly claiming a compound would be, particularly if that compound is the only one specifically claimed.

In *Tanaka*, however, the inventor supported his claim of error by filing a declaration explaining that he "did not fully appreciate the process of claiming according to U.S. practice . . . ." *Id.* at 1247. Here, by contrast, there is no evidence that the overlap with Sandoz was due to any misunderstanding of PTO requirements or procedures. Shionogi had extensive experience prosecuting U.S. patents. Indeed, before November 1993 when the '440 patent issued, Shionogi had applied for and received more than 200 U.S. patents. Significantly, at approximately the same time that Kitamura filed the application for the pyrimidine compounds disclosed in the '440 patent, she also filed an application directed to pyrrole statin compounds. This pyrrole application contained a narrow claim directed to the preferred pyrrole compound. Kitamura, therefore, clearly understood how to draft a claim specifically directed to a preferred compound and yet failed to do so when she filed the '440 application.

"Reissue is an extraordinary procedure and must be adequately supported by the circumstances detailed in [section 251]." *Ball Corp. v. United States*, 729 F.2d 1429, 1435 (Fed. Cir. 1984) (footnote omitted); *see also Hewlett-Packard*, 882 F.2d at 1566 (concluding that reissue was not permitted where a patentee failed to provide an adequate "explanation of what his error was and how and why it occurred" (emphasis omitted)). Thus, a reissue patent is invalid where, as here, a patentee fails to substantiate assertions of "error" in the original claims. *See Hewlett-Packard*, 882 F.2d at 1565 ("[A] reissue applicant does not make a *prima facie* case of error in conduct merely by submitting a sworn statement which parrots the statutory language."); *Wittry*, 489 F.2d at 1302 (concluding that reissue was improper where "the declarations [did] not present any reasonable explanation of any errors in the original claims which the reissue would

overcome"). Here, Shionogi obtained claims which obviously overlapped with a known prior art reference and intentionally failed to seek a claim directed to its preferred compound in order to gain a competitive advantage in the marketplace. Such machinations constitute an abuse of the reissue process and are wholly contrary to the objectives of section 251, a statute predicated "on fundamental principles of equity and fairness," *Weiler*, 790 F.2d at 1579; *see also Serenkin*, 479 F.3d at 1362 (emphasizing that "the remedial function of the [reissue] statute is not without limits" and "the deliberate action of an inventor or attorney during prosecution generally fails to qualify as a correctable error under § 251"); *In re Harita*, 847 F.2d 801, 809 (Fed. Cir. 1988) ("In any given case, the [reissue] statute should be so applied to the facts that justice will be done both to the patentee and the public.").

The claims of a validly-issued patent serve an important notice function, alerting the public of the metes and bounds of an inventor's discovery. *See Superior Fireplace Co. v. Majestic Prods. Co.*, 270 F.3d 1358, 1371 (Fed. Cir. 2001) ("This court has previously noted the propriety of independently considering the public notice function in interpreting the patent statutes."). This public notice function will be subverted if the "error" requirement is read out of the reissue statute and patentees are given free reign to rewrite their claims whenever they find it expedient to do so. *See Hester Indus., Inc. v. Stein, Inc.*, 142 F.3d 1472, 1484 (Fed. Cir. 1998) ("[H]ere, the second attorney draft[ed] the [reissue] claims nearly a decade later and with the distinct advantage of having before him the exact product offered by the now accused infringer.").

## IV.

Equity dictates that a patentee exercise due diligence in seeking to rectify a defect in his patent. *See Miller v. Bridgeport Brass Co.*, 104 U.S. 350, 351 (1881) (explaining that where a "mistake was so obvious as to be instantly discernible on opening the letters-patent," any right to have the patent reissued "was abandoned and lost by unreasonable delay"); *Gen. Radio Co. v. Allen B. Dumont Labs., Inc.*, 129 F.2d 608, 612 (3d Cir. 1942) ("It has long been settled that due diligence must be exercised in discovering a mistake in a patent and that an unreasonable delay in making application for reissue invalidates the reissue patent."). The reasons for requiring prompt action to correct a patent defect "may be just as great in a case where the patentee seeks to narrow his claims as where he seeks to broaden them." *Gen. Radio*, 129 F.2d at 613. Where a patentee unjustifiably delays seeking reissue of overly broad claims, he "usurp[s] the right of the public to graze in the field erroneously claimed as a private preserve." *Principle Bus. Enters., Inc. v. United States*, 7 Cl. Ct. 433, 438 (Cl. Ct. 1985) (citations and internal quotation marks omitted); *Gen. Radio*, 129 F.2d at 613 (emphasizing that failure to take prompt action to narrow overly broad claims gives a patentee an "unwarranted claim of monopoly").

Here, Shionogi learned of the Sandoz reference no later than June 1991 when an internal search report issued in connection with the '440 application identified Sandoz as relevant prior art. The importance of Sandoz to the claims of the '440 patent was made clear when Shionogi received, in October 1992, the EPO search report that identified Sandoz as a "particularly relevant" standalone prior art reference. On February 21, 1996, the EPO rejected many of the claims in the European counterpart to the '440 patent based upon Sandoz. Shionogi thereaf-

ter narrowed claim 1 in the European application and added a claim specific to rosuvastatin. It waited for over two years, however, until August 1998, to seek reissue of the '440 patent. Thus, Shionogi maintained the broad claims of the '440 patent for more than seven years after learning of the Sandoz reference, for more than six years after receiving the EPO report identifying Sandoz as particularly relevant stand-alone prior art, for more than five years after issuance of the '440 patent, and for two years after surrendering the corresponding claims in the European application due to the Sandoz reference.[5] It has proffered no adequate justification for its failure to rectify the alleged error in the '440 patent in a timely manner.

"The privilege of correcting an acknowledged error in [an] original patent may in the public interest be validly conditioned upon the patentee proceeding promptly." *Gen. Radio*, 129 F.2d at 613. During the years when Shionogi maintained its overbroad claim, there was strong and widespread interest in the development of new and more effective statins. Joint App. 20148-51; 1755-57. By failing to act promptly to narrow its overbroad claim, Shionogi deprived the public of the right to experiment with, and to improve upon, the compounds encompassed by claim 1.[6] Because Shionogi's delay in seeking to rem-

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[5] On appeal, Shionogi asserts that it was not aware of the overlap between Sandoz and claim 1 until October 1997. This contention is belied by the record. Testimony at trial established that Shionogi was already aware of the overlap between Sandoz and claim 1 when it received the October 1997 letter from Zeneca pointing out this overlap. Joint App. 20463.

[6] The doctrine of "intervening rights," *see* 35 U.S.C. § 252, does nothing to protect "the rights of others unknown who wrongfully may have been deterred because of the apparent expansiveness of the patent," *Principle Bus.*, 7 Cl. Ct. at 438.

edy the alleged defect in the '440 patent was unreasonable, it has forfeited the right to obtain reissue under section 251.