United States Court of Appeals for the Federal Circuit

2007-1271

PFIZER, INC., PHARMACIA CORP., PHARMACIA & UPJOHN, INC., PHARMACIA & UPJOHN COMPANY, G.D. SEARLE & CO., G.D. SEARLE LLC, SEARLE LLC (Delaware) AND SEARLE LLC (Nevada),

Plaintiffs-Appellees,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant-Appellant.

Appeal from the United States District Court for the District of New Jersey in case no. 04-754, Judge John C. Lifland.

DECIDED: March 7, 2008

Before MICHEL, Chief Judge, DYK, Circuit Judge, and KENNELLY, District Judge.[*]

DYK, Circuit Judge.

Appellant Teva Pharmaceuticals USA, Inc. ("Teva") appeals from a final judgment of the United States District Court for the District of New Jersey, entered after a bench trial, in favor of Appellees Pfizer, Inc. et al. (collectively "Pfizer"). Pfizer Inc. v. Teva Pharms. USA, Inc., 482 F. Supp. 2d 390 (D.N.J. 2007). The district court held that Teva infringed three patents owned by Pfizer: specifically, claims 1-3, 7-9, 11, and 13 of U.S. Patent No. 5,466,823 ("the '823 patent"), claims 1-5 and 15-18 of U.S. Patent

[*] Honorable Matthew F. Kennelly, District Judge, United States District Court for the Northern District of Illinois, sitting by designation.

No. 5,563,165 ("the '165 patent"), and claims 1-4 and 11-17 of U.S. Patent No. 5,760,068 ("the '068 patent"). The district court also held that the asserted claims of the three patents were not invalid for a best mode violation and that the asserted claims of the '068 patent were not invalid for obviousness-type double patenting. The district court held that none of the patents was unenforceable on grounds of inequitable conduct. We find that the asserted '068 patent claims are invalid based on double patenting. However, we agree that claim 9 of the '823 patent and claim 17 of the '165 patent are not invalid for a best mode violation. The '823, '165 and '068 patents also are not unenforceable for inequitable conduct. We therefore affirm-in-part and reverse-in-part.

BACKGROUND

Pfizer produces and sells the drug Celebrex, a non-steroidal anti-inflammatory drug ("NSAID"), for the treatment of osteoarthritis and rheumatoid arthritis. Pfizer owns the patents-in-suit, which encompass a broad genus of non-steroidal anti-inflammatory compounds, compositions using those compounds, and methods of using those compositions. The claims of the patents include celecoxib—the active ingredient in Celebrex.

Teva is a generic drug manufacturer. Pursuant to the provisions of the Hatch-Waxman Act, 21 U.S.C. § 355, Teva filed an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA") addressed to a proposed drug identified as "Celecoxib Capsules, 100 mg, 200 mg, and 400 mg." Pfizer, 482 F. Supp. 2d at 398. Because the patents covering celecoxib are listed in the Orange Book, Teva was required to certify that those patents "[are] invalid or will not be infringed by the

manufacture, use or sale of the new drug for which the [ANDA] is submitted." 21 U.S.C. § 355(j)(2)(A)(vii)(IV).[1] Teva's ANDA contained the required "Paragraph IV certification." That certification did not dispute that the filing of Teva's ANDA would infringe the patents, but challenged the validity of the patents covering celecoxib. In February 2004, in response to the submission of Teva's ANDA, Pfizer initiated this litigation by filing a patent infringement action against Teva pursuant to 35 U.S.C. § 271(e). Pfizer alleged that Teva's ANDA filing was an act of patent infringement because the ANDA sought approval to manufacture, use or sell a drug claimed in a patent or the use of which is claimed in a patent. In May 2004, Teva filed an answer. It did not argue that its ANDA was not within the scope of the claims but rather asserted affirmative defenses that the patents-in-suit were invalid or unenforceable. Teva did not counterclaim. Understanding these affirmative defenses requires an understanding of the history of NSAIDs and the prosecution history of the three patents.

Traditional NSAIDs have been used for many years to treat people suffering from pain and other symptoms associated with inflammation. Aspirin, for example, has been on the market for nearly a century. Aspirin was followed several decades later by the introduction of other similar drugs, such as ibuprofen and naproxen. Although these traditional NSAIDs were effective in treating pain from inflammation, they were also associated with harmful gastrointestinal side effects, ranging from slight stomach discomfort to serious life-threatening ulcers.

[1] The Hatch-Waxman process is described in detail in prior decisions. See, e.g., Andrx Pharms., Inc. v. Biovail Corp., 276 F.3d 1368, 1370-71 (Fed. Cir. 2002).

In the early 1970s, scientists made a breakthrough in understanding the operative mechanism of the traditional NSAIDs when they discovered that the drugs inhibited the cyclooxygenase ("COX") enzyme in the body, which produces small molecules associated both with pain and inflammation and also with good housekeeping functions that contribute to, for example, good gastrointestinal physiology. Several years later, scientists made another significant breakthrough when they discovered that there were in fact at least two different kinds of COX enzymes: the first, COX-1, produces the molecules associated with the good housekeeping functions inside the body, and the second, COX-2, produces the molecules associated with pain and inflammation. Traditional NSAIDs were found to inhibit both of these COX enzymes. In the years following and leading up to the discovery of celecoxib, scientists began searching for a compound that would selectively inhibit the COX-2 enzyme to treat pain and inflammation without inhibiting the COX-1 enzyme. In other words, they began to focus their efforts on identifying a compound that would effectively treat pain without the harmful side effects identified with the traditional NSAIDs. See generally Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 917-18 (Fed. Cir. 2004) (describing the development of modern NSAIDs).

By 1993, Pfizer had identified several new compounds that it believed would selectively inhibit COX-2. On November 30, 1993, Pfizer filed U.S. Patent Application No. 08/160,594 ("the '594 application") with the Patent and Trademark Office ("PTO") that claimed a broad range of these chemical compounds. The application included claims directed to the chemical compounds themselves, to compositions using these

compounds, and to methods of using these compounds, including specific claims to celecoxib.

In an office action dated July 12, 1994, the patent examiner issued a restriction requirement, which identified the compound claims, the composition claims, and the method claims as each directed to patentably distinct subject matter. The restriction requirement required Pfizer to select for prosecution one of these three claim groups. In the same office action, the examiner further required the applicant "to elect a single disclosed species" that the examiner identified.[2] J.A. at 26326. In response, Pfizer elected to prosecute the generic compound claims and, within that genus, the single

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[2] The examiner's restriction requirement provided:

> No generic claim being allowable, the following action is also taken. Restriction to one of the following inventions is required under 35 U.S.C. [§] 121:
>
> I. Claims 1-20, compounds.
> II. Claims 21-26, compositions.
> III. Claims 27-37, methods of use.
>
> The above groups are identified as general areas. Accordingly, as groups they are independent or distinct as the compounds of Group I would differ in scope from the compositions of Group II, the products would be capable of more than one use and separate search considerations are involved.
>
> The above groups themselves are inclusive of patentably distinct subject matter. Accordingly, along with the election of one of the above groups the following action is also taken.
>
> Claims 1, 16, 21 and 27 are generic to a plurality of disclosed patentably distinct species comprising for example: the compounds of (1) Example 1, (2) Example 3, (4) [sic] Example 4, (5) Example 16, etc., the method of treating fever using (5) the compound of Example 1, etc. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species, even though this requirement is traversed.

J.A. at 26325-26.

compound species celecoxib. The resulting compound claims remaining in the original '594 application were ultimately allowed, and the application issued as the '823 patent.

Subsequent to the restriction requirement but before the '594 application issued, Pfizer filed a series of continuation applications claiming priority to the '594 application and covering the non-elected subject matter which it had elected not to prosecute in the original '594 application.[3] In particular, Pfizer filed a divisional application, which ultimately issued as the '165 patent, that included the restricted-out composition claims, and a continuation-in-part application ("CIP"), which ultimately issued as the '068 patent, that included the restricted-out method claims.

Following an 18-day bench trial, the district court rejected each of Teva's invalidity arguments and found Pfizer's patents infringed. The district court first rejected Teva's defense that the asserted patents were invalid as obvious over the prior art. Teva does not appeal that aspect of the district court's decision, and we do not discuss it here. The district court rejected Teva's best mode defense as to all of the asserted patents because it held that Pfizer's subjective preference for COX-2 selectivity was not the type of preference that best mode requires an applicant to disclose. The district court also rejected Teva's double patenting argument based on the theory that the '165 patent was prior art to the '068 patent. The district court held that, under 35 U.S.C. § 121, the '165 patent could not be used as prior art against the '068 patent. Finally, the district court held that there was no inequitable conduct. Teva asserted that two Merck references, International Application No. WO 95/00501 ("the '501 application") and U.S.

[3] Several of these applications were directed to the several non-elected species of compounds. Those applications ultimately issued as patents, but since they do not cover celecoxib, they are not at issue here.

Patent No. 5,474,995 ("the '995 patent") should have been disclosed to the PTO. The district court held that they were not material because they did not qualify as prior art under 35 U.S.C. § 102(e). The latter holdings are the subject of this appeal.

After trial, the district court issued a judgment, concluding that Teva infringed each of the '823, '165, and '068 patents and ordering that Teva's ANDA not be approved earlier than the expiration date of the '823, '165, and '068 patents. The judgment also included an order enjoining Teva from engaging in the manufacture, use, offer to sell, sale, or importation into the United States of any product comprising the chemical compound celecoxib. Teva timely appealed. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

I

We first consider whether the claims of the '068 method patent are invalid based on obviousness-type double patenting over the '165 composition patent. If the '068 patent is invalid, Pfizer is not entitled to an injunction beyond the expiration date of the '165 patent. The district court held that the safe-harbor provision of 35 U.S.C. § 121 prevented the '165 patent from serving as prior art with respect to the '068 patent. This was so because both the '165 patent and the '068 patent derived from applications filed in response to the restriction requirement made in the common parent application. Because it found that the '165 patent was not prior art, the district court held that the '068 patent was not invalid on grounds of double patenting.

A

The third sentence of section 121 provides a safe harbor to patents that issue on applications filed as a result of a restriction requirement:

> A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application.

35 U.S.C. § 121 (2000). In addition to the express requirements of section 121, we have also construed the statute to require consonance: the applicant must maintain the line of demarcation between the independent and distinct inventions that prompted the restriction requirement. Gerber Garment Tech. v. Lectra Sys., Inc., 916 F.2d 683, 688 (Fed. Cir. 1990). This consonance requirement prevents an applicant from amending the claims in the divisional application in a way that would violate the originally imposed restriction requirement and thereby impermissibly extend the patent term as to that subject matter. Id.[4]

[4] Teva argues that the '165 patent was not consonant with an election of species restriction requirement made in the parent application. The district court disagreed, finding that the election of species was not a restriction requirement under section 121, and that the '165 patent maintained consonance with the compound/composition/method restriction requirement. We do not reach these issues because we find that section 121 is inapplicable.

Teva contends that section 121 applies exclusively to divisional applications, and that because the '068 patent issued on a CIP rather than on a divisional application, it does not fall within the terms of the statute.[5]

Although both are types of continuing applications, divisionals and CIPs differ significantly in at least one respect: a divisional application contains an identical disclosure to its parent application, but a CIP introduces new matter. A CIP is "just what its name implies. It partly continues subject matter disclosed in a prior application, but it adds new subject matter not disclosed in the prior application." Univ. of W. Va. Bd. of Trs. v. Vanvoorhies, 278 F.3d 1288, 1297 (Fed. Cir. 2002); see also Manual of Patent Examining Procedure ("MPEP") § 201.08 (8th ed., Rev. 5, 2006) ("A continuation-in-part is an application filed during the lifetime of an earlier nonprovisional application, repeating some substantial portion or all of the earlier nonprovisional application and adding matter not disclosed in the said earlier nonprovisional application.") (emphasis in original). A divisional application is defined as "[a] later application for an independent or distinct invention, carved out of a pending application and disclosing and claiming only subject matter disclosed in the earlier or parent application . . . ." MPEP § 201.06.

[5] The district court declined to consider this issue below on the ground that it had been raised too late in the proceedings. We need not address the propriety of the district court's refusal to consider this issue because we may properly decide the issue, even if not raised below, since the issue of whether section 121 applies to CIPs is a predicate legal issue necessary to a resolution of the issues before the court. See Kamen v. Kemper Fin. Servs., Inc., 500 U.S. 90, 99 (1991); Forshey v. Principi, 284 F.3d 1335, 1356 (Fed. Cir. 2002) (en banc) superseded by statute on other grounds, as recognized in Morgan v. Principi, 327 F.3d 1357 (Fed. Cir. 2003).

Also, we see no basis for the claim that Pfizer was somehow prejudiced by Teva's failure to raise this purely legal issue earlier in the proceeding. We also conclude that Teva adequately raised the issue on appeal in its "Statement of Issues."

A divisional application "is often filed as a result of a restriction requirement made by the examiner." Id.

Pfizer argues that the terms "divisional" and "continuation-in-part" are merely labels used for administrative convenience, and that accordingly, although the '068 is termed a CIP, it is in effect a divisional for purposes of section 121. In other words, Pfizer contends that the term "divisional application" as it is used in section 121 refers broadly to any type of continuing application filed as a result of a restriction, regardless of whether it is labeled by the PTO, for administrative purposes, as a divisional, a continuation, or a CIP. We disagree.

Section 121 explicitly refers to "divisional applications." That section provides:

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

35 U.S.C. § 121 (emphases added). As noted above, the third sentence of the statute provides a safe harbor (for patents or applications derived as the result of a restriction requirement) from attack based on the original application (or a patent issued therefrom), or based on applications or patents similarly derived from the same

restriction requirement. That safe harbor, by its literal terms, protects only "divisional application[s]" (or the original application) and patents issued on such applications.

The legislative history of section 121, like section 121 itself, refers specifically to "divisional application[s]." The House Report, referring to section 121, states:

> This section enacts as law existing practice with respect to division, at the same time introducing a number of changes. Division is made discretionary with the Commissioner. The requirements of section 120 are made applicable and neither of the resulting patents can be held invalid over the other merely because of their being divided in several patents. In some cases a divisional application may be filed by the assignee.

H.R. Rep. No. 82-1923, at 20 (1952) (emphasis added).

The "changes" referred to in the legislative history included the safe-harbor provision of section 121. Prior to the 1952 Patent Act, no protection was afforded to patent applications filed as a result of a restriction requirement—referred to at the time as a "requirement for division"—and such applications were often rejected or held invalid on double patenting grounds. See Studiengesellschaft Kohle mbH v. N. Petrochemical Co., 784 F.2d 351, 358 (Fed. Cir. 1986) ("SGK") (Newman, J., concurring); In re Eisler, 203 F.2d 726 (CCPA 1953). Thus, although a requirement for division embodied a determination by the PTO that the patent application contained more than one patentably distinct invention, such a determination did not protect the divisional application from rejection on grounds of double patenting. In re Isherwood, 46 App. D.C. 507, 512 (D.C. Cir. 1917) (holding that an examiner is not estopped from rejecting a divisional application because of an earlier requirement for division). The PTO and the courts were therefore not precluded from rejecting an application filed as a result of a requirement for division based on the very same application from which the subsequent application was divided. See In re Kauffman, 152 F.2d 991, 993 (CCPA

1946). Pursuant to this practice, a patent applicant could appeal an examiner's requirement for division, United States ex rel. Steinmetz v. Allen, 192 U.S. 543 (1904), and "his failure to litigate the question was at his peril." Kauffman, 152 F.2d at 993.

The inequity of this practice was well known by 1952. See In re Ferenci, 83 F.2d 279, 282-83 (CCPA 1936) ("One anomalous result . . . is that after division has been required and the applicant has complied therewith, the divided claims have been rejected on the ground of double patenting, although it is obvious that division was required upon the theory that the original application contained claims for more than one independent invention.").[6] The purpose of section 121 was to eliminate this inequity and thereby allow applicants to reasonably rely on restriction requirements. See SGK, 784 F.2d at 358 (Newman, J., concurring). Given the protection of section 121, applicants would no longer need to appeal a restriction requirement because they would no longer be penalized for acquiescing in an improper restriction requirement. See id. at 359. The enactment of section 121, therefore, brought clarity and fairness to the interaction between restriction and double patenting.

There is no suggestion, however, in the legislative history of section 121 that the safe-harbor provision was, or needed to be, directed at anything but divisional applications. The commentary and materials published since section 121's enactment similarly contain no suggestion that section 121 was meant to cover any applications other than divisionals.[7] Although the legislative history reveals no reason why

[6] See also W. F. Hyer, Note: Divisional Practice and Double Patenting, 17 Geo. Wash. L. Rev. 537 (1949).

[7] See P.J. Federico, Commentary on the New Patent Act, at 35 (1954) (reprinted at 75 J. Pat. & Trademark Off. Soc. 161, 196 (1993)); John C. McIntyre, Jr.,

Congress drafted section 121 only to benefit divisional applications, there are certainly plausible reasons why Congress would have concluded that section 121 should be limited to divisional applications, and not include CIPs. The need for the protection only existed when a divisional application was filed as a result of the restriction. If the section had included CIPs, which by definition contain new matter, the section might be read as providing the earlier priority date even as to the new matter, contrary to the usual rule that new matter is not entitled to the priority date of the original application. See Asseff v. Marzall, 189 F.2d 660, 661 (D.C. Cir. 1951). There was no possible reason for protecting the new matter from double patenting rejections.

The difference between divisional applications and CIPs, moreover, was well known at the time that Congress enacted the 1952 Patent Act. The Manual of Patent Examining Procedure in use at the time included definitions of the different types of applications. A divisional was defined as "[a] later application for a distinct or independent invention, carved out of a pending application and disclosing and claiming nothing not disclosed in the earlier or parent application . . . ." MPEP § 201.06 (1st ed., 1949). And a CIP was defined as "an application filed during the lifetime of an earlier application by the same applicant, repeating some substantial portion or all of the earlier application and adding matter not disclosed in the said earlier case." Id. § 201.08 (emphasis in original). Indeed, these earlier definitions are nearly identical to those in the latest edition of the MPEP (quoted above). Despite this awareness, however, the drafters of section 121 chose to refer specifically and only to divisional (and original)

The Effect of a Restriction Requirement in the Patent and Trademark Office on a Subsequent Double Patenting Adjudication, 4 AIPLA Q.J. 301 (1976).

applications. If the drafters wanted to include CIPs within the protection afforded by section 121, they could have easily done so.

Pfizer's only claimed authority for including CIP applications within the scope of section 121 are three cases where this court, although it did not consider the question, may have assumed that section 121 applied to CIP applications filed in response to a restriction requirement. See Geneva Pharms., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1382 (Fed. Cir. 2003); Gerber, 916 F.2d at 689; SGK, 784 F.2d at 355. But in two of these cases we held that section 121 was inapplicable on other grounds, and thus did not need to, and did not in fact address the divisional question. Geneva, 349 F.3d at 1382 (finding that the patentee did not comply with the consonance requirement); Gerber, 916 F.2d at 689 (same). In the third, we disposed of the double patenting issue on the ground that the claims of the patents were patentably distinct. SGK, 784 F.2d at 355. Since the issue now before us was not decided by those cases, they are not binding authority. See Rhone Poulenc Agro, S.A. v. DeKalb Genetics Corp., 284 F.3d 1323, 1334 (Fed. Cir. 2002).

We conclude that the protection afforded by section 121 to applications (or patents issued therefrom) filed as a result of a restriction requirement is limited to divisional applications. We note that this interpretation of section 121 is consistent with the PTO's understanding of section 121. See Ex parte Granados, No. 2002-2030, 2003 WL 25283825, *11 (B.P.A.I. Sept. 26, 2003) (not selected for publication) ("[T]he instant case is a continuation-in-part, not a divisional . . . . It therefore does not fall within the literal terms of [section 121]."); see also MPEP § 804.01 (similarly referring to "divisional" applications). Here, the '068 patent, though it derived from the application

that led to the '823 patent, was filed as a CIP and not a divisional application. We hold that section 121 does not apply to the '068 patent and that the '165 patent may be used to invalidate the '068 patent. Given our conclusion, we do not consider Teva's alternative argument that section 121 does not apply because the '165 patent is not consonant with the restriction requirement made in the parent application.

B

Because section 121 does not prohibit us from using the '165 patent as a reference against the '068 patent, we must next determine whether the claims of the '068 patent are patentably distinct from the claims of the '165 patent.

Obviousness-type double patenting is a judicially created doctrine that "prohibit[s] a party from obtaining an extension of the right to exclude through claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent." Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 967 (Fed. Cir. 2001). We have identified two steps in an obviousness-type double patenting analysis. First, "a court construes the claim[s] in the earlier patent and the claim[s] in the later patent and determines the differences." Id. at 968. Second, it determines whether those differences render the claims patentably distinct. Id. "A later patent claim is not patentably distinct from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim." Id. We have also held that a "claim to a method of using a composition is not patentably distinct from an earlier claim to the identical composition in a patent disclosing the identical use." Geneva, 349 F.3d at 1385-86. Double patenting is a question of law, which we review without deference. Ga.-Pac. Corp. v. U.S. Gypsum Co., 195 F.3d 1322, 1326 (Fed. Cir. 1999).

Here, although the district court first held that section 121 precluded the use of the '165 patent against the '068 patent, the district court also found that if section 121 did not prevent the '165 patent from being prior art, it would hold that the relevant claims of the two patents were not patentably distinct. We agree that the relevant claims of the two patents are not patentably distinct. The claims at issue of the '068 patent merely recite methods of administering a "therapeutically-effective amount" of the compositions found in claim 5 of the '165 patent. Moreover, the term "therapeutically-effective amount" is found in claim 1 of the '165 patent and was stipulated by the parties to mean the same thing in both patents.[8] Thus, we agree with the district court that the '068 patent merely claims a particular use described in the '165 patent of the claimed compositions of the '165 patent.[9] The asserted claims of the '068 are therefore not patentably distinct over the claims of the '165 patent.

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[8] To the extent that Pfizer contends that we may not rely on the teachings of the specification or claims in the '165 patent to reject the claims of the '068 patent, we disagree. See Geneva, 349 F.3d at 1386. There is nothing that prevents us from looking to the specification to determine the proper scope of the claims. In Geneva, we stated:

> It would shock one's sense of justice if an inventor could receive a patent upon a composition of matter, setting out at length in the specification the useful purposes of such composition, manufacture and sell it to the public, and then prevent the public from making any beneficial use of such product by securing patents upon each of the uses to which it may be adapted.

Id. (internal citation omitted).

[9] Pfizer argues that claims 15-17 must be considered separately because these claims are directed to the particular disorders of arthritis, pain, and fever. We find that these recitations do not claim non-obvious subject matter, since claim 5 of the '165 patent generally claims compounds, which the specification indicates are used to treat "inflammation-related disorders."

We conclude that: (1) Pfizer cannot claim the protection of section 121 with respect to the '068 patent because that patent did not issue on a divisional application, and (2) the asserted claims of the '068 patent are not patentably distinct from the claims of the '165 patent. Accordingly, the '068 patent is invalid for obviousness-type double patenting.[10]

II

We next consider Teva's contention that the '823 compound and '165 composition patents are invalid because they violate the best mode requirement. The best mode requirement is contained in 35 U.S.C. § 112: "The specification shall . . . set forth the best mode contemplated by the inventor of carrying out his invention." The test for compliance with best mode is comprised of two steps: first, whether, "at the time of filing the application, the inventor possessed a best mode for practicing the invention;" and second, whether the inventor's disclosure was "adequate to enable one of ordinary skill in the art to practice the best mode of the invention." Bayer AG v. Schein Pharms., Inc., 301 F.3d 1306, 1320 (Fed. Cir. 2002). The first prong is subjective and focuses on the inventor's state of mind at the time the application is filed; the second prong is "objective and depends upon the scope of the claimed invention and the level of skill in the relevant art." Id. The "invention" referred to in the best mode test is the invention as defined by the claims. Id. Typically, the best mode issue concerns the applicant's failure to disclose a preferred embodiment, but not always. In Bayer, we explained that

[10] The effect of our decision is to require amendment to the district court's judgment to change the effective date of the order preventing approval of Teva's ANDA. Also, our determination requires the elimination of the provisions of the district court's order enjoining Teva from the manufacture or use of celecoxib in violation of the '068 patent.

the best mode requirement does not "demand disclosure of every preference an inventor possesses as of the filing date." Id. at 1314-15. We held that the best mode requirement does demand disclosure of an inventor's preferred embodiment of the claimed invention. Id. at 1316. However, it is not limited to that. We have recognized that best mode requires inventors "to disclose aspects of making or using the claimed invention [when] the undisclosed matter materially affect[s] the properties of the claimed invention." Id. at 1319.

We first consider Teva's best mode challenge to the generic claims of the compound and composition patents: claims 1-3, 7-8, 11, and 13 of the '823 patent, and claims 1-5, 15-16, and 18 of the '165 patent. Teva contends, with respect to those claims, that Pfizer violated the best mode requirement by failing to disclose its preference for COX-2 selectivity. Here, Teva's argument is limited. Teva does not claim that Pfizer had a subjective, undisclosed preference for a particular compound (a preferred embodiment) at the time it filed the patent applications. Rather, Teva argues that the generic claims of the '823 and '165 patents do not teach one of skill in the art how to arrive at the preferred embodiment because they do not reveal Pfizer's preference for compounds that demonstrate COX-2 selectivity. Teva asserts that, without the knowledge of the preference for COX-2 selectivity, one of ordinary skill in the art would not be able to identify a preferred embodiment (compound or composition) in the generic claims.

It is undisputed that, at the time of filing, Pfizer preferred compounds and compositions that were COX-2 selective, and that this preference was not disclosed in either the compound or the composition applications. Moreover, according to Teva,

many of the claimed compounds are not in fact COX-2 selective. Teva contends that, by concealing its preference for COX-2 selectivity, Pfizer was able to keep for itself the crux of the invention. That is, Pfizer effectively hid among the many disclosed compounds and compositions in the generic claims the one or two compounds that were truly valuable by not disclosing how to identify which compounds displayed COX-2 selective characteristics. Without knowing the properties of the compound that Pfizer would later single out, Teva argues, Pfizer could effectively withhold from the public its actual invention—a compound or composition that was COX-2 selective. This preference, Teva argued, was relevant to using the claimed invention. The district court held that, "[a]lthough Teva's argument has some intuitive appeal," J.A. at 181, under this court's precedents, a preference for COX-2 selectivity was "not an aspect of using the claimed compounds or compositions that materially affects the properties of the claimed inventions," because it did not "affect the intrinsic properties of the claimed invention or teach anything that must be done to the compounds or compositions in order to make them work." J.A. at 184.

Pfizer argues that the district court correctly construed our precedent as foreclosing the possibility that the best mode requirement demands the disclosure of such a preference. It argues that, under Bayer, the best mode inquiry is limited to determining whether the patent conceals a preference for making or using the claimed invention. And, according to Pfizer, because there is no dispute that one of ordinary skill in the art would know how to make and use the claimed compositions and compounds themselves, there can be no best mode violation.

These contentions as to the generic claims raise a difficult issue that we need not resolve to decide this case. This is so because we undertake the best mode inquiry on a claim by claim basis, and we conclude that the celecoxib-specific claims are not invalid.

Claim 9 of the '823 patent and claim 17 of the '165 patent are both celecoxib-specific claims; they each disclose only one compound/composition. Here, there is no issue as to these claims about failing to disclose the preferred compound or composition because these claims are directed to a single compound and composition. There is thus no failure to disclose a preferred embodiment or a preference for identifying the preferred embodiment with respect to these claims. Teva's sole argument is that, even after identifying the compound celecoxib, the criteria for selecting the correct dosage requires knowledge of Pfizer's preference for COX-2 selectivity, and that under Bayer there is failure to disclose a preferred way of using the invention. Pfizer does not appear to dispute that dosage range could be a preferred method of use that materially affects the properties of the invention under Bayer. But Pfizer counters that dosages were disclosed in the specification, and that there was no evidence that the inventors preferred another dosage. This appears to be undisputed. Teva's only answer to this is that COX-2 selectivity could affect dosage. Although Teva is correct, there is no evidence that at the time of filing the inventors planned to use the COX-2 selectivity criterion to arrive at a preferred dosage (in contrast to their intent to use COX-2 selectivity to arrive at the right compounds). Thus, there was no evidence that they concealed a preferred method of getting to the right dosage. We thus hold that at least the celecoxib-specific claims in the '823 and '165 patents did not violate the best mode

requirement. We affirm the district court's judgment that these claims are not invalid and are infringed.

Having concluded that these claims are valid, we need not address the generic claims. There is no counterclaim for invalidity in this case, see Cardinal Chem. Co. v. Morton Int'l, Inc., 508 U.S. 83 (1993), and a finding that the other claims were invalid would not change the practical effect of the district court's judgment since the order is directed to the use of celecoxib. In other words, it makes no practical difference whether Teva's ANDA filing infringes other claims in the '823 and '165 patents.

III

Teva next contends that the patents in suit are unenforceable due to inequitable conduct. A patent will not be held unenforceable due to inequitable conduct unless there is clear and convincing evidence that the patent applicant (1) either "made an affirmative misrepresentation of material fact, failed to disclose material information, or submitted false material information, and (2) intended to deceive the [PTO]." Cargill, Inc. v. Canbra Foods, Ltd., 476 F.3d 1359, 1363 (Fed. Cir. 2007). If it finds materiality and intent, a district court must then "balance the equities to determine whether the patentee has committed inequitable conduct that warrants holding the patent unenforceable." Id. at 1365. We review a district court's findings on the threshold issues of materiality and intent for clear error, and the ultimate decision on inequitable conduct for abuse of discretion. Id. at 1364-65.

"Information is material for the purposes of an inequitable conduct determination if a reasonable examiner would have considered such prior art important in deciding whether to allow the parent application." Digital Control, Inc. v. Charles Mach. Works,

437 F.3d 1309, 1314 (Fed. Cir. 2006) (internal citation omitted). We have noted that under the "reasonable examiner" standard, "a misstatement or omission may be material even if disclosure of that misstatement or omission would not have rendered the invention unpatentable." Id. at 1318.

Before the district court, Teva argued that Pfizer had committed inequitable conduct by failing to disclose two Merck publications during the prosecution of the applications that led to the patents in suit. These two publications—the '501 application and the '995 patent—both derive from and claim priority to Merck's U.S. Patent Application 08/082,196 ("the '196 application") filed several months before Pfizer filed its initial application. The '196 application was later abandoned and never published, and could not, therefore, have been used as prior art under 35 U.S.C. § 102 against any of the patents in suit. The '501 application was published before the '823 patent issued; the '995 patent issued and was published after the '823 patent issued but before either the '165 patent or the '068 patent issued. With respect to the '823 patent, Teva argued that Pfizer should have disclosed the '501 application because that would have led a reasonable examiner to the earlier '196 application and therefore to the application for the '995 patent, which was a CIP of the '196 application. With respect to the '165 patent and the '068 patent, Teva argues that Pfizer should have disclosed the '995 patent itself. There was no dispute that Pfizer was in possession of these two references during the pendency of its own patent applications.

The district court held that neither the '501 application nor the '995 patent was material. The district court also held that, even if the Merck references were material, Teva had failed to meet the threshold showing of intent. We conclude that, even if the

Merck references were material, the district court did not clearly err in finding that Teva failed to establish that Pfizer acted with an intent to deceive.

On appeal, Teva contends that the materiality of the references standing alone, in the absence of a credible explanation for withholding them, is sufficient to establish intent. However, the district court held that Pfizer had offered a good faith explanation for failing to disclose the Merck references based on the testimony of Pfizer's witness, Dr. Talley, who was one of the named inventors of celecoxib. Dr. Talley testified that Pfizer had studied the Merck references and concluded that none of the compounds disclosed in the Merck references was similar to the compounds disclosed in Pfizer's own patent applications. This is because, as Dr. Talley explained, the compounds disclosed in the Merck references had a different heterocyclic core than the compounds of the Pfizer applications and that this was a significant distinction. Pfizer notes that the PTO itself recognizes that such differences are significant. Pfizer also presented evidence below of its own highly consistent pattern of disclosing references having the same heterocyclic core in the prosecution of hundreds of its other patent applications. Indeed, Pfizer established that, in connection with the prosecution of a separate patent application that had the same heterocyclic core, it did disclose the '501 reference. The district court credited this "highly consistent pattern" as strong evidence supporting Pfizer's good faith explanation for not disclosing the Merck references. Because the Merck references disclosed compounds having a different core, Pfizer concluded that they were not material. The district court found that Dr. Talley's testimony in this

respect was credible, and we see no basis for overturning that finding.[11] Given the existence of a credible reason for the withholding, the materiality of the references standing alone is not sufficient to establish intent. See Ferring B.V. v. Barr Labs., Inc., 437 F.3d 1181, 1191 (Fed. Cir. 2006) (requiring three conditions where a party relies solely on the materiality of the references: "(1) the applicant knew of the information; (2) the applicant knew or should have known of the materiality of the information; and (3) the applicant has not provided a credible explanation for the withholding"). For these reasons, we conclude that the district court did not clearly err in finding that Teva failed to prove by clear and convincing evidence that Pfizer intended to deceive the PTO by not disclosing the Merck references. There is therefore no basis for finding inequitable conduct.

IV

We find that the asserted claims of the '068 patent are invalid for double patenting and reverse the district court on that aspect of its judgment. We also find that claim 9 of the '823 patent and claim 17 of the '165 patent are not invalid for a best mode violation. Finally, the '823 patent, the '165 patent, and the '068 patent are not unenforceable for inequitable conduct. Accordingly, we affirm the district court's judgment of infringement with respect to claim 9 of the '823 patent and claim 17 of the '165 patent.

[11] Teva argues that the district court improperly restricted its cross-examination of Dr. Talley by not allowing questions regarding Dr. Talley's signing of the oath in the patent application. The district court not only determined that Teva's line of questioning went beyond the scope of direct, but it also concluded that the evidence that Teva wanted to elicit from Dr. Talley was already in the record. We do not find that this was an abuse of discretion.

CONCLUSION

The judgment of the district court is AFFIRMED-IN-PART and REVERSED-IN-PART.

No costs.