

## Bayer v. Schein Opinion

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

01-1286, -1287

BAYER AG and BAYER CORPORATION,

Plaintiffs/Counterclaim Defendants-Appellees,

v.

SCHEIN PHARMACEUTICALS, INC., DANBURY PHARMACAL, INC.,

and REDDY-CHEMINOR, INC.,

Defendants/Counterclaimants-Appellants,

and

MYLAN PHARMACEUTICALS, INC. and MYLAN LABORATORIES INC.,

Defendants/Counterclaimants-Appellants.

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Appealed from: U.S. District Court for the District of New Jersey

Judge Garrett E. Brown, Jr.

United States Court of Appeals for the Federal Circuit

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DECIDED: August 9, 2002

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Before CLEVINGER, RADER and DYK, Circuit Judges.

Opinion for the court filed by Circuit Judge CLEVINGER. Concurring opinion filed by Circuit Judge RADER.

CLEVINGER, Circuit Judge.

In these four consolidated patent infringement suits,[1] Bayer AG and Bayer Corporation (collectively, "Bayer") sued Schein Pharmaceutical, Inc., Danbury Pharmacal, Inc., Reddy-Cheminor, Inc., Mylan Pharmaceuticals, Inc., and Mylan Laboratories Inc. (collectively, "Schein") for infringement of U.S. Patent No. 4,670,444 and Reexamination Certificate B1 4,670,444 (collectively, the "444 patent"), directed towards a class of chemical compounds that includes the broad-spectrum antibiotic ciprofloxacin, better known as Cipro. Schein raised an affirmative defense of invalidity under 35 U.S.C. § 102(d). On cross-motions for summary judgment, the district court held that the '444 patent was entitled to the filing date of its U.S. parent, Application No. 292,560 (the "'560 application") and thus was not invalid under section 102(d), and therefore the court granted Bayer's motion for summary judgment on validity. Bayer AG v. Schein Pharm., Inc., 129 F. Supp. 2d 705, 725 (D.N.J. 2001).

On appeal, Schein argues that the '444 patent cannot claim the benefit of the parent application because the parent is invalid for failure to satisfy the best mode requirement of 35 U.S.C. § 112. Because we find that the '444 patent is entitled to the filing date of the '560 application under 35 U.S.C. § 120, we affirm.

I

## BACKGROUND

Ciprofloxacin is a relatively simple heterocyclic organic compound developed by Bayer in the 1980s and shown in the figure below, where R<sup>a</sup> is hydrogen.

During the 1970s a group of scientists at Bayer experimented with a group of similar antibiotics, and they discovered that substitution of a cyclopropyl group[2] at the 1-position, *i.e.*, on the nitrogen of the heterocycle ring, greatly increased the potency of the resulting antibiotic. In the fall of 1980, Dr. Klaus Grohe, one of the Bayer scientists, attended a conference at which a Japanese firm disclosed the structure of norfloxacin, a broad-spectrum antibiotic that it had developed. The structure of norfloxacin is identical to that depicted in the figure above for ciprofloxacin, except that norfloxacin has an ethyl rather than a cyclopropyl group on the ring nitrogen. From his earlier research, Dr. Grohe knew that substituting a cyclopropyl group for the ethyl group of norfloxacin would increase antibiotic activity, and he hastened home from the conference determined to make such a compound.

The general synthetic route to Dr. Grohe's desired compound involves construction of the bicyclic ring structure followed by addition of the amino group to provide the final product. An example of the final step—addition of an amine to the previously-constructed bicyclic ring to give the desired antibiotic and a byproduct—is depicted in the figure below. Using generic terms for the types of chemical compounds involved, the final reaction step can be described as follows: starting bicyclic + amine = final product.

Although Dr. Grohe succeeded in making numerous compounds similar in structure to ciprofloxacin, his standard synthetic methodology failed when he attempted to make ciprofloxacin. The problematic part of the synthesis was the construction of the starting bicyclic, 6-fluoroquinolinic acid ("6-FQA"). Dr. Grohe's standard method of making the starting bicyclics used a "cycloaracyclation" reaction that he had previously developed and had disclosed in a published patent application. However, in the case of ciprofloxacin, Dr. Grohe could not make the starting material he needed for the cycloaracyclation reaction. Therefore, he enlisted the help of one of his colleagues at Bayer, Dr. Klauke, who successfully synthesized the precursor 2,4-dichloro-5-fluorobenzoyl chloride, the so-called "Klauke compound," necessary to make 6-FQA via cycloaracyclation. Bayer AG, 129 F. Supp. 2d at 710. While Dr. Grohe concededly had difficulty making the Klauke compound without assistance, it is undisputed that a person of skill in the art could readily obtain the Klauke compound by using commercially-available starting materials and known synthetic methods retrieved through a routine search of the chemical literature.

Using the Klauke compound, Dr. Grohe performed the cycloaracyclation reaction to obtain 6-FQA, which he then converted to ciprofloxacin. The overall reaction sequence Dr. Grohe used to make ciprofloxacin can be regarded as containing three primary steps: (1) synthesis of the Klauke compound; (2) synthesis of 6-FQA via cycloaracyclation of the Klauke compound; and (3) addition of piperazine to 6-FQA to synthesize ciprofloxacin.

Bayer ultimately obtained patents on both the Klauke compound, U.S. Patent No. 4,439,620, and 6-FQA, U.S. Patent No. 4,620,007. It also, of course, sought and obtained a patent on the target compound itself, ciprofloxacin: the '444 patent. The '444 patent claims, as compositions of matter, a class of compounds that includes ciprofloxacin. The parties have stipulated that only claims 1-2, 5, 11-12, 16, 18-21, 25, 27, 29-32, 34, and 36-39 of the '444 patent cover ciprofloxacin.

The application that matured into the '444 patent was not the first filed patent claiming ciprofloxacin; seven other applications preceded it. Bayer filed the first patent application arguably claiming ciprofloxacin in Germany on September 3, 1980. However, that application is not relevant here, because Bayer has stipulated that it does not claim entitlement to its filing date. Thus, for purposes of this appeal, Bayer filed the first relevant patent application in Chile on August 12, 1981. The next day, August 13, 1981, it filed the '560 application in the United States, followed swiftly by applications in South Africa (September 2, 1981), Spain (September 2, 1981), and Argentina (September 3, 1981). It filed a second German application on October 29, 1981. The Chilean, South African, Spanish, and Argentinean patents issued between May and September of 1982. On October 22, 1982, after the issuance of the four foreign patents, Bayer filed a second U.S. application, Application No. 436,112 (the "'112 application"), as a continuation of the '560 application, and then abandoned the '560 application. Bayer filed U.S. application No. 614,923 (the "'923 application") on May 29, 1984, as a continuation-in-part of the '112 application, and then abandoned the '112 application. The '923 application eventually matured into the '444 patent, which issued on June 2, 1987. The parties agree that under 35 U.S.C. § 120, the '444 patent is entitled, at a minimum, to the benefit of the filing date of the '112 application.

The defendants in this case filed Abbreviated New Drug Applications ("ANDAs") with the Food and Drug Administration (FDA) under 21 U.S.C. § 355(j) seeking approval to market generic versions of ciprofloxacin. Bayer AG, 129 F. Supp. 2d at 707. Bayer sued under 35 U.S.C. § 271(e)(2), alleging that filing the ANDAs infringed the '444 patent, and this suit stayed the ANDAs before the FDA. Id. On cross-motions for summary judgment, Schein conceded infringement but argued that the '444 patent is invalid based on the filing and issuance of the Chilean, South African, Spanish and Argentinean patents, because under 35 U.S.C. § 102(d) those foreign patents are prior art that would invalidate the '444 patent. Id. Bayer countered that the '444 patent is entitled to a filing date of August 13, 1981, the filing date of the '560 application, or, in the alternative, that under 35 U.S.C. § 119, it should be entitled to the filing date of the second German application, October 29, 1981. Id. Schein argued that Bayer cannot rely on the '560 application because, in its view, that application does not disclose Dr. Grohe's best mode of making ciprofloxacin as required by section 112. Schein also contended that section 119 should not apply as a matter of law to defeat a section 102(d) bar, and that Bayer was collaterally estopped from arguing the section 119 issue by its failure to appeal an earlier district court decision entering judgment against Bayer on the merits of the section 119 issue.

The district court granted Bayer's motion for summary judgment, holding that the '560 application satisfies the best mode requirement. Id. at 724. After setting forth the two-pronged test for whether a disclosure satisfies the best mode requirement, the court proceeded to analyze the first prong, i.e., whether Dr. Grohe subjectively possessed a preferred mode of practicing his invention. Id. at 719. As to the first prong, the court focused on whether Dr. Grohe preferred a particular method of synthesizing the starting material 6-FQA, and determined that "the undisputed testimony . . . indicates that Dr. Grohe did not have a preference . . . for the Klauke compound or any other particular compound for use as a starting material in the synthesis of 6-FQA." Id. at 720. However, the court determined that Dr. Grohe did have a preference for using the general class of compounds that includes the Klauke compound, because such compounds would allow him to make 6-FQA via cycloaracyclation. Id. The court then turned to whether the '560 application adequately disclosed Dr. Grohe's preference. In answering this question, the court noted that the scope of the claims limits the extent of the required disclosure, and held that because Dr. Grohe's preference pertained to unclaimed subject matter, "the best mode requirement does not compel disclosure of the unclaimed method and the unclaimed starting material beyond enablement." Id. at 721. Because the undisputed evidence indicated that the unclaimed method and starting materials were enabled by the '560 application, id. at 722, the court held that the '444 patent could claim the benefit of the '560 application's filing date under section 120 and thereby overcome Schein's section 102(d) defense, id. at 724.

In light of its disposition of the best mode issue, the district court declined to reach Bayer's arguments regarding the applicability of section 119, id. at 725, and entered judgment for Bayer. Id. Schein appealed, vesting this court with jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

## II

We review a district court's grant of summary judgment de novo. Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 988, 50 USPQ2d 1607, 1609 (Fed. Cir. 1999). Summary judgment is appropriate when "there is no genuine issue as to any material fact and . . . the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). In this case, the parties agree that no genuine issues of material fact remain in dispute regarding Schein's section 102(d) defense, and that the outcome turns purely on legal issues regarding the scope of the best mode requirement and the reach of section 119. Whether an applicant has complied with the best mode requirement of section 112 is a question of fact, Chemcast Corp. v. Arco Indus. Corp., 913 F.2d 923, 928, 16 USPQ2d 1033, 1037 (Fed. Cir. 1990), but the identity of the proper legal standard to apply to the best mode requirement is a question of law, see id. at 925-26, 16 USPQ2d at 1035, which we review de novo. Similarly, whether an applicant can claim the benefit of an earlier-filed foreign application under section 119 in order to defeat a section 102(d) bar presents a pure issue of law, which receives plenary review.

## III

Section 102 provides in relevant part:

A person shall be entitled to a patent unless . . .

(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant . . . in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States. . . .

35 U.S.C. § 102(d) (1994). Three things must occur for a patent to be invalid under section 102(d). First, the applicant must file an application on the invention in another country. Then, more than twelve months later, the applicant must file for a patent on the same invention in this country. Third, the foreign patent must issue before the applicant filed the U.S. patent application. If all three occur, then the U.S. patent is invalid under section 102(d).

In this case, Schein asserts invalidity under section 102(d) based on the following events. First, Bayer filed for a patent on ciprofloxacin in Chile, South Africa, Spain and Argentina. Over one year later, Bayer filed the '923 application that matured into the '444 patent. With respect to the filing date of the '444 patent, Schein concedes that Bayer should receive the benefit of the October 22, 1982, filing date of the '112 application under section 120. Thus, the operative date for section 102(d) purposes, according to Schein, is October 22, 1982, which is over one year after the filing date of the four foreign patent applications, all of which issued well before October 22, 1982. Thus, argues Schein, the '444 patent is invalid under section 102(d).

On these facts alone, Schein is correct. Unless Bayer can rely upon an earlier filing date, the '444 patent must be declared invalid as barred by section 102(d). Bayer, however, argues that the '444 patent is not invalid because it can claim the benefit of the filing date of the '560 application under section 120, and the second German application under section 119. If Bayer prevails on either or both theories, then the '444 patent will not run afoul of section 102(d) because both of the earlier filing dates are within one year of the filing of the Chilean patent application—the earliest-filed of the four potentially-invalidating section 102(d) references. We turn first to the merits of Bayer's arguments regarding the propriety of relying upon the '560 application.

Bayer claims entitlement to the filing date of the '560 application under section 120, which provides in relevant part:

An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, . . . which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment or termination of proceedings on the first application. . . .

35 U.S.C. § 120 (1994). This section allows an application for an invention previously disclosed in a pending United States patent application the benefit of the filing date of the earlier-filed application. In the case at hand, Bayer contends that section 120 entitles the '444 patent to the benefit of the August 13, 1981, filing date of its grandparent, the '560 application. However, by its terms, section 120 applies only if the earlier-filed application, in this case the grandparent, complies with the requirements of section 112. See Dyer v. Field, 386 F.2d 466, 468 n.3, 156 USPQ 85, 86 n.3 (CCPA 1967). Thus, Bayer may defeat the 102(d) bar on this basis only if the '560 application fulfils the disclosure requirements of section 112.

#### IV

Schein argues here, as it did before the district court, that the '560 application does not comply with section 112 because it does not set forth the best mode contemplated by Dr. Grohe for making ciprofloxacin. Specifically, the '560 application does not disclose the synthesis of the Klauke compound or the use of the cycloaracyclation reaction to make 6-FQA. Concededly, both 6-FQA and the Klauke compound are synthetic intermediates not claimed in the '444 patent. However, Schein asserts that 6-FQA and its synthesis via cycloaracyclation of the Klauke compound are novel, and that disclosure of Dr. Grohe's preferred method of making 6-FQA is therefore necessary to adequately describe the best mode of practicing the invention—ciprofloxacin—claimed in the '444 patent. See Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 964, 58 USPQ2d 1869, 1875 (Fed. Cir. 2001). It is undisputed that the disclosure in the '560 application is sufficient to enable one of skill in the art to obtain 6-FQA, even though the compound is otherwise novel and unobvious. See Bayer AG, 129 F. Supp. 2d at 724. Schein claims that the disclosure is insufficient, arguing that for best mode purposes the specification must provide the actual synthetic route that Dr. Grohe preferred to make 6-FQA.

For the reasons given below, we conclude that the '560 application complies with section 112 and therefore may be relied upon by Bayer to defeat Schein's section 102(d) invalidity defense. Given our disposition of the best mode issue, like the district court, we too find it unnecessary to reach the merits of Bayer's section 119 arguments.

#### A

The first paragraph of 35 U.S.C. § 112 provides:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

As we have observed on numerous occasions, section 112 contains both an enablement requirement and a best mode requirement. See Chemcast, 913 F.2d at 926, 8 USPQ2d at 1035; Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1532, 3 USPQ2d 1737, 1742 (Fed. Cir. 1987); In re Karnofsky, 390 F.2d 994, 997, 156 USPQ

682, 685 (CCPA 1968); *In re Gay*, 309 F.2d 769, 772, 135 USPQ 311, 315 (CCPA 1962). The enablement requirement ensures that "that a specification shall disclose an invention in such a manner as will enable one skilled in the art to make and utilize it." *In re Gay*, 309 F.2d at 772, 135 USPQ at 315; accord *Spectra-Physics*, 827 F.2d at 1532, 3 USPQ2d at 1742 ("Enablement looks to placing the subject matter of the claims generally in the possession of the public."). Because an enabling disclosure by definition turns upon the objective understanding of a skilled artisan, the enablement requirement can be met by reference to the knowledge of one of ordinary skill in the relevant art.

The best mode requirement is "separate and distinct" from enablement and "requires an inventor to disclose the best mode contemplated by him, as of the time he executes the application, of carrying out the invention." *In re Gay*, 309 F.2d at 772, 135 USPQ at 315. Unlike enablement, the existence of a best mode is a purely subjective matter depending upon what the inventor actually believed at the time the application was filed. Because of the subjective nature of the best mode inquiry, the best mode disclosure requirement—unlike enablement—cannot be met by mute reference to the knowledge of one of skill in the art. The reason is pragmatic. It is unreasonable if not impossible to require the ordinary artisan to peer into the inventor's mind to discover his or her idiosyncratic preferences as of the filing date. Rather, because the existence of a best mode of carrying out the invention is by definition known only to the inventor, section 112 demands actual disclosure regardless of whether, as an abstract matter, practicing that mode would be within the knowledge of one of ordinary skill in the art. See *Spectra-Physics*, 827 F.2d at 1532, 3 USPQ2d at 1742 (distinguishing best mode disclosure requirement from the disclosure required to satisfy enablement).

But while the best mode requirement cannot be met solely by reference to the knowledge of one of skill in the art, neither does it demand disclosure of every preference an inventor possesses as of the filing date. As is always the case, the text of the statute provides the proper boundaries of the disclosure requirement. Section 112 only demands disclosure of "the best mode contemplated by the inventor of carrying out his invention." 35 U.S.C. § 112 (1994) (emphasis added). Thus, only preferred ways of "carrying out [the] invention" need be disclosed. As we recently noted in *Teleflex, Inc. v. Ficosa North America Corp.*, No. 01-1372, slip op. at 24, (Fed. Cir. June 21, 2002), we stated in *Wahl Instruments, Inc. v. Acvious, Inc.*, 950 F.2d 1575, 1579, 21 USPQ2d 1869, 1126 (Fed. Cir. 1991), that "the term 'mode' and the phrase 'carrying out the invention' are not definable with precision." Nonetheless, before *Wahl* we had referred to the best mode "for making and using" the claimed invention, *Christianson v. Colt. Indus. Operating Corp.*, 822 F.2d 1544, 1563, 3 USPQ2d 1241, 1255 (Fed. Cir. 1987), thus suggesting that the statute is susceptible of interpretation.

Our cases examining the scope of the best mode requirement demonstrate that the best mode disclosure requirement only refers to the invention defined by the claims. The earliest statement on this matter was given by our predecessor court in *In re Brebner*, 455 F.2d 1402, 173 USPQ 169 (CCPA 1972). In that case, the court reversed a Patent Office Board of Appeals decision sustaining a rejection, on best mode grounds, of a patent application claiming a blend of two polymers, polyethylene and an ethylene-methacrylic acid copolymer. *Id.* at 1402-04, 173 USPQ at 170-71. The Board sustained the rejection because the application did not disclose a method of making the two polymers—the starting materials—that comprised the claimed blend. *Id.* at 1403, 173 USPQ at 170. The court reversed because "[a]ppropriate inquiries into the best mode requirement should

pertain to the contemplated mode of carrying out the invention, which in this case is the blend and not the starting materials." Id. at 1404, 173 USPQ at 171. Similarly, in DeGeorge v. Bernier, we reversed the Board of Patent Interference's finding that the inventor failed the best mode requirement by not disclosing the preferred species of an unclaimed word processor. 768 F.2d 1318, 1325, 226 USPQ 758, 763 (Fed. Cir. 1985). DeGeorge is a significant case in our best mode jurisprudence. In that case, we explained that "[b]ecause the properly-construed count does not include a word processor, failure to meet the best mode requirement here should not arise from an absence of information on the word processor." Id. The word processor bore no relationship whatsoever to the claim, and therefore fell wholly outside the best mode requirement. In Zygo Corp. v. Wyko Corp., we rejected a best mode challenge based on a failure to disclose a particular commercial embodiment that enclosed the invention in a box. 79 F.3d 1563, 1567, 38 USPQ2d 1281, 1284 (Fed. Cir. 1996). We declared emphatically that "in keeping with the statutory mandate, our precedent is clear that the parameters of a section 112 inquiry are set by the CLAIMS." Id. Thus, "[b]ecause the claims simply do not require packaging of any sort, the failure to disclose the enclosure is not a violation of section 112." Id.; see also Eli Lilly, 251 F.3d at 963, 58 USPQ2d at 1874 (noting that "[w]ith respect to the second prong of the best mode requirement, the extent of information that an inventor must disclose depends on the scope of the claimed invention"); United States Gypsum Co. v. Nat'l Gypsum Co., 74 F.3d 1209, 1212, 37 USPQ2d 1388, 1390 (Fed. Cir. 1996) (The first prong of the best mode inquiry requires a "determin[ation] whether, at the time the patent application was filed, the inventor had a best mode of practicing the claimed invention" (emphasis added).); Chemcast, 913 F.2d at 927, 16 USPQ2d at 1036 ("The other objective limitation on the extent of the disclosure required to comply with the best mode requirement is, of course, the scope of the claimed invention."); Randomex Inc. v. Scopus Corp., 849 F.2d 585, 588, 7 USPQ2d 1050, 1053 (Fed. Cir. 1988) ("It is concealment of the best mode of practicing the claimed invention that section 112 ¶ 1 is designed to prohibit.").

In accordance with the focus on the claimed subject matter, we have long held that compliance with the best mode requirement requires disclosing the inventor's preferred embodiment of the claimed invention. See, e.g., Dana Corp. v. IPC Ltd. P'ship, 860 F.2d 415, 418, 8 USPQ2d 1692, 1695 (Fed. Cir. 1988) ("The purpose of the best mode requirement is to ensure that the public, in exchange for the rights given the inventor under the patent laws, obtains from the inventor a full disclosure of the preferred embodiment of the invention."); DeGeorge, 768 F.2d at 1324-25, 226 USPQ at 763; In re Gay, 309 F.2d at 722, 135 USPQ at 315 (holding that with respect to the best mode requirement, "an inventor is in compliance therewith if he does not conceal what he feels is a preferred embodiment of his invention"). This result is hardly surprising, for if an inventor has developed a preferred way of practicing the invention, he typically will state that preference in his description of the preferred embodiment. Furthermore, fulfillment of the requirement via disclosure of the preferred embodiment comports with the purpose of the best mode requirement. As our predecessor court held in In re Gay, "[m]anifestly, the sole purpose of [the best mode] requirement is to restrain inventors from applying for patents while at the same time concealing from the public preferred embodiments of their inventions which they have in fact conceived." Id.

Notwithstanding that the best mode requirement keys only on carrying out the claimed invention, "we have found violations of the best mode requirement for failure to disclose subject matter not strictly within the bounds of the claims . . . ." Teleflex, slip op. at 26. In the history of this court and our predecessor courts, we have held

claims invalid for failure to satisfy the best mode requirement on only seven occasions. As we will see, these cases involved either failure to disclose a preferred embodiment, or else failure to disclose a preference that materially affected making or using the invention.

In Spectra-Physics, which concerned patents on a laser and a method of constructing a laser, the inventor preferred to use a TiCuSil active metal brazing process to attach a copper cup to the inside wall of a ceramic tube structure. 827 F.2d at 1530, 3 USPQ2d at 1740. Although the specification disclosed the inventor's preference for using TiCuSil as a brazing material, it did not disclose any of the parameters for performing the six-stage brazing cycle that the inventor had developed for using the TiCuSil brazing material to attach the cup to the tube. Id. at 1536-37, 3 USPQ2d at 1745-46. The patents in suit each stressed the importance of brazing to produce the bond between the copper cups and the ceramic tube, explaining in detail why less than ideal bonding will adversely affect the efficiency and reliability of the claimed lasers. Id. at 1529, 3 USPQ2d at 1740. We affirmed the district court's finding that "[t]he six-stage braze cycle employed by Coherent [the inventor], and developed by it, are [sic, is] necessary to the enjoyment of the invention taught by the patents in suit . . . and are [sic] not sufficiently disclosed." Id. at 1537, 3 USPQ2d at 1746 (second and third alterations in original). Thus, failure to disclose the actual method of brazing preferred by the inventor rendered the patent claims invalid for "fail[ure] to disclose the best mode contemplated by the inventors for practicing their . . . inventions." Id.

Dana involved a patent on a valve stem seal for use in an internal combustion engine. 860 F.2d at 416, 8 USPQ2d at 1694. The seal included a "portion of elastomeric material positioned atop said valve guide. . . ." Id. The inventor conducted a series of tests comparing the effectiveness of various seal designs; each design was tested with and without a 60-second fluoride surface treatment. Id. at 418, 8 USPQ2d at 1695. The inventor concluded that the fluoride surface treatment was "necessary to satisfactory performance of [the] seal," id., because without the treatment, the seal leaked. In other words, the undisclosed fluoride surface treatment had a material effect on the properties of the claimed invention. But although the inventor "believed that the best way of carrying out his invention included fluoride treating the surface of the valve seals," id. at 419-20, 8 USPQ2d at 1696, the specification never "disclose[d] that a fluoride treatment must or even should be applied to the surface of the patented seals" as preferred by the inventor, id. at 420, 8 USPQ2d at 1696. Thus, we held the patent invalid for failure to disclose the best mode of carrying out the invention.

In Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 940, 15 USPQ2d 1321, 1328 (Fed. Cir. 1990), the defendant raised a best mode challenge to claims directed towards capturing data on ordinary magnetic tape cassettes. The inventor preferred audio cassettes "of its own design and specifications and . . . these were different from standard audio tapes in their yield strength and magnetic characteristics." Id. Of all the brands on the market as of the filing date, only a single brand of commercially-available audiotape met the inventor's specifications. We held that failure to disclose either the one conforming brand, or, alternatively, the inventor's specifications for its preferred tape violated the best mode requirement. In effect, the inventor had developed a preferred embodiment of his invention that used a very specific type of audiotape, and failure to disclose that preferred embodiment rendered the claims invalid.

Like Northern Telecom, Chemcast involved an inventor's failure to disclose his preferred embodiment of the claimed invention, a grommet made of a material of a distinct hardness. Chemcast, 913 F.2d at 928, 16 USPQ2d at 1037. The inventor preferred a particular material to make the locking portion of the grommet, but failed to disclose this fact in the specification. Id. at 929, 16 USPQ2d at 1037. We found the patent's disclosure "manifestly deficient." Id. We noted that "[g]iven the specification and the level of skill or understanding in the art, skilled practitioners could neither have known what [the inventor's] contemplated best mode was nor have carried it out. Indeed, on these facts, they would not even have known where to look." Id. at 930, 16 USPQ2d at 1038. Because this amounted to concealment of the inventor's preferred embodiment, we affirmed the judgment of the district court invalidating the claim to the grommet for failure to disclose the inventor's best mode.

In United States Gypsum Co., 74 F.3d at 1213-14, 37 USPQ2d at 1391-92, we confronted yet another example of failure to disclose the inventor's preferred embodiment of a discrete claim limitation—an embodiment preferred because the inventor believed it improved the efficacy of his invention. The claims recited a joint compound that contained, inter alia, "expanded perlite which has been treated with a silicone compound to render it water-insensitive." Id. at 1211 n.5, 37 USPQ2d at 1390 n.5 (quoting U.S. Patent No. 4,454,267) (emphasis omitted). During the course of his investigations, the inventor discovered that a particular perlite, Sil-42, offered numerous advantages in his invention. It obviated the need for screening before use, "eliminated the coarse look of other lightweight fillers, resisted breakdown under vacuum treatment, and yielded a joint compound that was lightweight, easy to sand, and exhibited good non-cracking and adhesion properties." Id. at 1211, 37 USPQ2d at 1389. We rejected the argument that the preference related merely to commercial considerations and thus need not be disclosed as part of the best mode, noting that "[i]n short, [the inventor] believed that Sil-42 perlite was essential to improving the invention; the material was not selected as a matter of commercial expediency." Id. at 1213, 37 USPQ2d at 1391. Failure to disclose the Sil-42 perlite was, therefore, fatal to the validity of the patent.

In Great Northern Corp. v. Henry Molded Products, Inc., 94 F.3d 1569, 1571, 39 USPQ2d 1997, 1999 (Fed. Cir. 1996), we found a best mode violation due to a failure to disclose preferred diamond indentations that were placed on a roll stacker made of papier-mache. The diamond indentations were crucial to producing a usable version of the invention because without diamonds the stacker simply collapsed under the weight of the rolls it was supposed to hold. Id. at 1572, 39 USPQ2d at 1999. Thus, we rejected the patentee's argument that the diamonds were merely a production detail unrelated to the "quality or nature of the invention." Id. On the contrary, because the diamonds materially affected the properties of the claimed invention, they had to be disclosed to comply with the best mode requirement. Because the specification did not disclose the diamonds, we held the claims invalid for failure to disclose the best mode of carrying out the invention.

Finally, Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 46 USPQ2d 1097 (Fed. Cir. 1998), presents a paradigm example of failure to disclose the inventor's preferred mode of making the invention. The patent claimed "an element intended for implantation into bone tissue" and recited that the element contain micropits. Id. at 1062, 46 USPQ2d at 1099. "For whatever reason," the patentee introduced testimony from the inventor that:

(1) "there were some minor details that were not included [in the patent] and which proved to be quite important," (2) other skilled artisans would have to be "lucky" to obtain a piece of suitable micropitted implant "by cutting a piece of titanium at a speed less than twenty meters per minute," the cutting speed disclosed in the patent, and (3) "any of the small detailed recipes that I discussed but did not specify" in the patent "can cause you to fail to get micropitting even though you were cutting the metal at less than twenty meters per minute."

Id. at 1065, 46 USPQ2d at 1101 (alteration in original). We noted that production of the implant depended critically on "a variety of undisclosed machining parameters," and the evidence showed that the inventor knew and preferred these parameters before the filing date. Id. "Thus, the evidence at trial leads to only one reasonable conclusion: [the inventor] possessed a preferred method of making the claimed invention and failed to disclose it sufficiently to enable those skilled in the art to practice that method." Id. at 1065, 46 USPQ2d at 1101-02. The inventor's undisclosed preferences related to manufacture of the claimed implant, and were critical to production of a functional implant, *i.e.*, one that would work correctly. Id. The undisclosed preference thus materially affected the properties of the claimed invention. Hence, we held the patent invalid for failure to disclose the best mode of carrying out the invention.

Thus, we have held a patent invalid for failure to satisfy the best mode requirement in two situations. First, we have invalidated patents when they do not adequately disclose a preferred embodiment of the invention. This is what occurred in Northern Telecom, Chemcast, and United States Gypsum Co. Consequently, if an inventor fails to disclose the preferred embodiment of the invention, the best mode requirement is not satisfied.

Second, we have invalidated patents when the patentee failed to disclose aspects of making or using the claimed invention and the undisclosed matter materially affected the properties of the claimed invention. In Spectra Physics and Nobelpharma, the inventors failed to disclose subjective preferences that related to making the inventions, and the undisclosed information materially affected the properties of the claimed invention. In Dana and Great Northern, the inventors failed to disclose subjective preferences that related to the use of the claimed inventions, and the undisclosed information materially affected the properties of the claimed inventions.

As noted above, DeGeorge is one of the key cases for understanding the best mode requirement. DeGeorge stands for the proposition that the best mode requirement is strictly limited to disclosures that concern preferences for carrying out the claimed invention.[3] In DeGeorge, the interference dealt with a count drawn to certain electrical circuitry designed to obtain automatic indentation of a block of text. The claimed circuitry was designed for use in word processors. The Board of Patent Interferences drew the count to include a word processor with which the claimed circuitry would be used. Absent disclosure of any such word processor, the Board found a best mode violation. We reversed that decision, for the simple reason that the Board had misinterpreted the count. Properly drawn, the count did not claim a word processor. No allegation was made that the choice of any particular word processor would have any effect whatsoever on carrying out the claimed invention, which was the claimed circuitry. In short, a particular word processor had no effect on carrying out the claimed invention.

The instances in which we have held that an inventor failed to disclose the best mode of carrying out his invention are consistent with DeGeorge.<sup>[4]</sup> Each instance in which best mode violations have been found in our precedent deal with the invention itself, and in each of those cases the failure to disclose a preference for carrying out the claimed invention directly impacted the invention itself. In short, we have held that the best mode of making or using the invention need be disclosed if it materially affects the properties of the claimed invention itself.

We now turn to whether Dr. Grohe possessed a best mode of carrying out the invention, and if so, whether the '560 application fails to adequately disclose it.

## B

The general contours of our test for compliance with the best mode requirement are well known: Compliance with best mode is a question of fact composed of two subsidiary factual inquiries. "First, the factfinder must determine whether, at the time of filing the application, the inventor possessed a best mode for practicing the invention." Eli Lilly, 251 F.3d at 963, 58 USPQ2d at 1874. The first prong, we have explained, is highly subjective and focuses on the inventor's state of mind as of the date of filing the application. Id.; see also N. Telecom Ltd. v. Samsung Elec. Co., 215 F.3d 1281, 1286, 55 USPQ2d 1065, 1068 (Fed. Cir. 2000). Second, if the inventor subjectively considered one mode to be preferred over all others, then "[t]he second inquiry is whether the inventor's disclosure is adequate to enable one of ordinary skill in the art to practice the best mode of the invention. This inquiry is objective and depends upon the scope of the claimed invention and the level of skill in the relevant art." N. Telecom, 215 F.3d at 1286, 55 USPQ2d at 1068.

As in enablement, the "invention" referred to in the best mode requirement is the invention defined by the claims. See, e.g., United States Gypsum Co., 74 F.3d at 1212, 37 USPQ2d at 1390 (The first prong of the best mode inquiry requires a "determin[ation] whether, at the time the patent application was filed, the inventor had a best mode of practicing the claimed invention" (emphasis added).); DeGeorge, 768 F.2d at 1325, 226 USPQ at 763 (reversing the Board of Patent Interference's finding that the inventor failed the best mode requirement by not disclosing the preferred species of an unclaimed word processor "[b]ecause the properly-construed count does not include a word processor, failure to meet the best mode requirement here should not arise from an absence of information on the word processor"). Because the scope of the invention obviously impacts what it means to carry out the invention, in Northern Telecom, 215 F.3d at 1286-87, 55 USPQ2d at 1068-69, we held that the first step in a best mode inquiry, before application of the familiar two-part best mode test, must be to define the invention by construing the claims. Definition of the invention "is a legal exercise, wherein the ordinary principles of claim construction apply." Id. Defining the invention by analyzing the claim language is a crucial predicate to the factual portions of the best mode inquiry because it ensures that the finder of fact looks only for preferences pertaining to carrying out the claimed invention.

Once the invention has been defined by examining the claims, the finder of fact—be it the court or a jury—can proceed to determine whether the inventor subjectively possessed a best mode of practicing the claimed invention, and if so whether the specification adequately discloses that mode.

With the proper legal test for compliance with the best mode requirement in hand, we turn to its specific application to the undisputed facts of this case. Under Northern Telecom we first must determine the identity of the invention recited in the claims of the '444 patent at issue: claims 1-2, 5, 11-12, 16, 18-21, 25, 27, 29-32, 34, and 36-39. The claims are directed towards compositions of matter that either comprise or consist solely of the target antibiotic compound—in this case, ciprofloxacin—with the exception of dependent claims 21 and 39, which claim methods of administering the antibiotic compositions recited in other claims. Reexamined claim 1 of the '444 patent is representative of the composition of matter claims:

A compound of the formula

or a pharmaceutically acceptable acid addition salt or an alkali or alkaline earth metal salt thereof,

in which A represents CR<sup>3</sup>,

wherein R<sup>3</sup> denotes a halogen atom,

and

Z represents C—H,

and R<sup>1</sup> and R<sup>2</sup> together with the nitrogen atom which they substitute form a piperazino group.

Reexamination Certificate B1 4,670,444, col. 1, lines 29-67. Like the other composition of matter claims at issue here, reexamined claim 1 recites a specific class of chemical compounds corresponding to the final product of Dr. Grohe's reaction sequence, i.e., to the ciprofloxacin family of compounds. Importantly, the claims do not recite 6-FQA or any other starting bicyclic. The invention, therefore, consists of the final antibiotic product and not the starting materials.

The existence of a subjective preference is not disputed. First, of the various possible synthetic routes to ciprofloxacin, it is undisputed that Dr. Grohe preferred to make his invention by manipulating 6-FQA by reacting it with piperazine. Bayer AG, 129 F. Supp. 2d at 720-21. The patent disclosed this reaction, and it disclosed the structure of the intermediate 6-FQA. Schein does not dispute that Dr. Grohe's preferences regarding the reaction of 6-FQA with piperazine were adequately disclosed.

Second, the district court found, and Bayer does not dispute, "that Dr. Grohe had a preference prior to August 13, 1981 for a starting material comprised of benzoyl halide with leaving groups in the 2- and 4-positions and a fluorine atom in the 5-position [i.e., a class of starting materials including the Klauke compound] so that he could create 6-FQA through the cycloaracyclation method." Bayer AG, 129 F. Supp. 2d at 720. It is also undisputed that the '560 application does not disclose either the Klauke compound or its use in making 6-FQA through cycloaracyclation.

Schein feels that failure to disclose Dr. Grohe's preferred route to 6-FQA is a fatal flaw. We disagree. As we discussed above, not every preference constitutes a best mode of carrying out the invention. Preferences that are reflected in a preferred embodiment or that relate to making or using the invention and have a material effect on the properties of the claimed invention must be disclosed. Schein concedes that Dr. Grohe's preferred way of making the 6-FQA intermediate has no material effect on the properties of the claimed ciprofloxacin end product. Thus, this case is clearly distinguishable from the four cases in which this court has found a best mode violation where an undisclosed preference clearly had a material effect on the properties of the claimed invention.

Nonetheless, and despite its many concessions, Schein argues that disclosure of Dr. Grohe's preferred route to 6-FQA is mandatory in this case because 6-FQA is novel. Schein bases this argument on our recent decision in Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 58 USPQ2d 1869 (Fed. Cir. 2001). We think that Schein's argument is based on a misinterpretation of our best mode jurisprudence in general, and of Eli Lilly in particular.

The patent in Eli Lilly was directed towards the pharmaceutical fluoxetine hydrochloride—the active ingredient in the antidepressant Prozac—and a method of using it to block the uptake of serotonin in the brain. Eli Lilly, 251 F.3d at 964, 58 USPQ2d at 1875. The accused infringer raised a best mode defense based upon the failure to disclose (1) the inventor's preferred method of making a commercially-available starting material for the synthesis of the claimed compound; and (2) the specific solvent preferred by the inventor to purify the fluoxetine hydrochloride by recrystallization following the synthesis. Id. We began our analysis in Eli Lilly by defining the scope of the claimed invention, and then proceeded to determine whether failure to disclose either of these two items amounted to concealment of the best mode of practicing the claimed invention, fluoxetine hydrochloride. Id. We held that it did not. Id. at 964-67, 58 USPQ2d at 1875-77. As to the starting material, we noted that the inventor "disclosed his preference for using p-trifluoromethylphenol [the starting material] when making fluoxetine hydrochloride. What he did not disclose, nor was he required to do so, was the unclaimed method for synthesizing p-trifluoromethylphenol." Id. at 964, 58 USPQ2d at 1875. Disclosure was not required in Eli Lilly because, "[i]n short, the reasons for using [the inventor's] synthesizing method were not linked to the intrinsic quality of fluoxetine hydrochloride, [the claimed invention,] which is the thrust of the best mode requirement." Id. at 965, 58 USPQ2d at 1876 (emphasis added). Eli Lilly thus applied the correct rule: unclaimed subject matter unrelated to the properties of the invention is not subject to the best mode disclosure requirement.

We further observed that "[t]o be sure, if the best mode for carrying out a claimed invention involves novel subject matter, then an inventor must disclose a method for obtaining that subject matter even if it is unclaimed." Id. It is to this statement, together with an earlier statement explaining that "an inventor need not disclose a mode for obtaining unclaimed subject matter unless the subject matter is novel and essential for carrying out the best mode of the invention," id. at 963, 58 USPQ2d at 1874, that Schein looks to support its interpretation of the best mode requirement.

Schein understands Eli Lilly to stand for the proposition that the best mode of obtaining novel subject matter necessary to practice the invention must be disclosed. Schein has misunderstood the import of our statements in Eli Lilly. We merely acknowledged that when a novel compound is necessary to practice the best mode, one of skill in the art must be able to obtain that compound. In other words, our statements regarding "a method for obtaining that subject matter" and "a mode for obtaining unclaimed subject matter" referred only to the requirement that the best mode be enabled. We were not referring to a best mode disclosure itself.<sup>[5]</sup> Here, of course, there is no enablement problem as Schein has conceded that the '560 application contains an enabling disclosure of 6-FQA. Schein merely contends that this is not enough, that the application must disclose Dr. Grohe's preferred method of making 6-FQA. But, because that preference does not materially affect carrying out the invention, ciprofloxacin, it need not be disclosed to comply with the best mode requirement. In short, Bayer did not conceal Dr. Grohe's best mode of carrying out the claimed invention.

V

Because the '560 application complies with the disclosure requirements of section 112, the '444 patent can claim the benefit of the '560 application's August 13, 1981, filing date. Because August 13, 1981, is well within one year of the filing dates of the Chilean, South African, Spanish, and Argentinean patents, the issuance of those foreign patents does not invalidate the '444 patent under section 102(d).

## CONCLUSION

For the reasons given above, Schein has failed to show that the '560 application did not disclose the best mode contemplated by Dr. Grohe of carrying out his invention, ciprofloxacin. Therefore we affirm the district court's judgment that the '444 is not invalid under section 102(d).

## COSTS

No costs.

## AFFIRMED

## UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

01-1286,-1287

BAYER AG and BAYER CORPORATION,

Plaintiffs/Counterclaim Defendants- Appellees,

v.

[www.bartlit-beck.com](http://www.bartlit-beck.com)

SCHEIN PHARMACEUTICALS, INC., DANBURY PHARMACAL, INC.,

and REDDY-CHEMINOR, INC.,

Defendants/Counterclaimants- Appellants,

and

MYLAN PHARMACEUTICALS, INC. and MYLAN LABORATORIES INC.,

Defendants/Counterclaimants- Appellants.

RADER, Circuit Judge, concurring.

Because the alleged best mode in this case was an intermediate, not the claimed invention, the district court correctly concluded that the best mode requirement “does not compel disclosure of the unclaimed method.” Bayer AG, 129 F. Supp. 2d at 721. On this basis, I would affirm. I write to underscore the district court’s correct application of the statutory test for best modes. The alleged best mode in this case does not fall within the scope of the claims. Therefore, this case simply does not require creation of a new test for best modes.

I.

Title 35 requires disclosure of “the best mode contemplated by the inventor of carrying out his invention.” 35 U.S.C. § 112 (1994). The most important words in this phrase are “his invention.” These words invoke the claims. Based on this direct statutory language, the bulk of this court’s precedent states that the disclosure necessary to satisfy the best mode requirement depends on the scope of the claimed invention. Teleflex, slip op. at 22-29; Eli Lilly, 251 F.3d at 963 (“[T]he extent of information that an inventor must disclose depends on the scope of the claimed invention.”); see also ante, at 14-15.

One of these precedents deserves special emphasis as the earliest Federal Circuit case to address the rule for identifying a best mode. DeGeorge was very clear that the Board erred by defining the claim too broadly and identifying an alleged best mode beyond the proper claim scope:

The board found no best mode in the DeGeorge applications. The board’s analysis, however, was influenced by its erroneous claim construction. . . . Because the properly construed count does not include a word processor, failure to meet the best mode requirement here should not arise from an absence of information on the word processor.

DeGeorge, 768 F.2d at 1325. Thus, this court's earliest precedent explains that the claimed invention sets the bounds of the best mode inquiry.

The DeGeorge court certainly did not inquire about a material effect on properties of the invention.

Moreover this emphasis on the claimed invention did not begin with the Federal Circuit. Indeed this court's predecessor followed the same standard:

The claimed invention is a blend of uniformly random ethylene-methacrylic acid copolymer and polyethylene . . . . Appropriate inquiries into the best mode requirement should pertain to the contemplated mode of carrying out the invention, which in this case is the blend and not the starting materials.

In re Brebner, 455 F.2d at 1404 (footnote omitted) (emphases added). The Court of Customs and Patent Appeals limited the scope of "appropriate" best mode inquiries to the scope of the claims. Indeed the present case is very similar to Brebner. In Brebner, the claims did not recite the starting materials; here, the claims do not recite an intermediate. In both cases, "appropriate inquiries" into the best mode need not exceed the scope of the claims.

## II.

With the "scope of the claimed invention" rule governing the identification of best modes, this court should have halted its analysis when the district court correctly applied that rule. Up to the point of acknowledging the claimed invention, this Bayer opinion reflects well the bulk of this court's best mode jurisprudence. Then, inexplicably and without support in the statute or case law, this Bayer opinion widens its best mode net to capture the properties of the claimed invention and further sweeps in any material effect or impact on those properties.[6]

A closer look at the policy and rationale for the best mode requirement discloses the disturbing implications of extending the best mode requirement beyond the reach of the claims. In most instances, the best mode requirement is self-enforcing. If an inventor does not disclose a critical trade secret within the best mode requirement, that nondisclosure puts the value of the entire patented invention at risk -- a risk beyond the requirements of § 112. Competitors in the same technology can, and invariably will, discover the undisclosed trade secret and claim it in a separate patent application. When that application ripens into a patent, the competitor will have a blocking patent that could compromise much of the value of the original patent. Therefore, an informed patent applicant will never withhold a genuine best mode. Informed patent applicants will always either disclose the best mode in the original patent's specification (often as a dependent claim) or, if the trade secret is not part of the claimed invention (as in this case), file a separate patent application on the separate innovation (also as in this case). Because informed patent applicants know to avoid best mode problems, this § 112 requirement is invariably little more than a trap for the uninformed applicant -- usually a university or independent inventor without corporate legal resources. Because the best mode requirement is a

trap for the unwary, the Federal Circuit has wisely followed the statutory “scope of the claimed invention” rule to confine the reach of this snare.

When extended beyond the scope of the claimed invention, the best mode requirement becomes as insidious and destructive as a hidden landmine. One of the cases emphasized by this opinion, Dana, 860 F.2d 415, illustrates those disturbing implications. In Dana, the inventor claimed a seal apparatus, not any method at all, let alone a method of treating elastomeric material to ensure its longevity. Having invented a unique seal apparatus, the inventor could not have guessed that the best mode would reach out to encompass a process to increase the useful life of one component of the invention – a process that was already well known in the prior art to boot. Dana, 860 F.2d at 419. Nonetheless, this court invalidated the patent because the undisclosed method affected the life of the elastomeric material and thus the satisfactory performance of the seal.<sup>[7]</sup>

At the outset, the Dana relationship test could sponsor a potentially boundless inquiry into any undisclosed method or property that could affect the satisfactory performance of the invention. Patent law in general is not concerned with the performance of an invention, let alone its satisfactory performance. Hildreth v. Mastoras, 257 U.S. 27, 34 (1921) (“The machine patented may be imperfect in its operation; but if it embodies the generic principle and works . . . it is enough.”); Decca, Ltd. v. United States, 544 F.2d 1070, 1077, 191 USPQ 439, 444 (Ct. Cl. 1976) (“The mere fact that the system has some drawbacks, or that under certain postulated conditions it may not work . . . does not detract from the operability of the disclosed equipment to perform its described function.”); Nat’l Recovery Tech. v. Magnetic Separation Sys., 166 F.3d 1190, 1196, 49 USPQ2d 1671, 1676 (Fed. Cir. 1999). Notwithstanding this bedrock principle of patent law, Dana would inexplicably make satisfactory performance the critical identifier for best modes.

Sadly this Bayer opinion incorporates Dana within its “material effects” test: “In Dana, . . . the inventors failed to disclose subjective preferences that related to the use of the claimed inventions, and the undisclosed information materially affected the properties of the claimed inventions.” Ante, at 22. Apparently this opinion, like Dana, would include all uses and properties of the invention within the best mode.

Indeed if the rule for identifying a best mode expands to capture potentially innumerable unclaimed “uses” and “properties,” as in Dana, the best mode requirement becomes a minefield for wary and unwary alike. At the outset, one might question the need for a new test. The Federal Circuit has identified best modes for twenty years without a material effect or properties test. Moreover, the Federal Circuit already has a claimed invention rule based on the language of § 112.

In expanding the best mode test to accommodate Dana, this new Bayer test unfortunately creates new conflicts with many cases in which this court found no best mode. Thus this new material effect test contravenes much of the calculus the Federal Circuit has employed in best mode cases. For instance, even this court’s most recent pronouncement on best mode law could not stand under the new test. In Teleflex, the claimed invention was a connector in an automobile shift cable that facilitated easier access for service. Instead of perceiving some new material effect test, Teleflex applied the prior binding Brebner-DeGeorge claimed scope rule to identify best modes:

The claims do not mention any particular material, hardness, or material matching for the clip. The claims do not mention any particular thickness for the clip. Thus, the information alleged to be part of the best mode and alleged to be missing from the disclosure is unclaimed subject matter.

Teleflex, slip op. at 27. Once again, in Teleflex, the claims specified a clip. One property of a clip is hardness. Another is thickness. Another is the metallic material for the clip. Under this new proposed Bayer test, these properties of the claimed clip (each with a material effect on its use and properties) would have triggered a best mode violation. Contrary to this proposed test, however, the Federal Circuit detected no alleged best mode within the scope of the claims and, for that reason alone, rejected the best mode allegations. Moreover this court in Teleflex examined nearly every case catalogued by this present opinion and found no new tests to identify best modes.

Another conflict with the proposed new test arises in Brebner, the earliest best mode case. 455 F.2d 1402. In Brebner, the inventor claimed a chemical compound used to process film. The inventor did not disclose the starting materials necessary to make the claimed compound. No doubt these undisclosed starting materials had a material effect on the properties of the invention because, without these starters, the invention could not be made. Nonetheless, this court's predecessor did not apply a material effect test or examine the compound's properties, but simply determined that the claimed invention is "the blend and not the starting materials." Id. at 1404. Under the material effect test, this necessary starting material would have led to a best mode violation. Again, by expanding the best mode test to accommodate opinions like Dana, this new test creates new conflicts with this court's other precedents.

Another recent case, Eli Lilly, similarly shows the difficulty of expanding the best mode test. While discussing Eli Lilly, this court misses much of its significance. In Eli Lilly, the patents claimed a compound in Prozac and a method of using the compound. The alleged best mode violation was failure to disclose p-trifluoromethylphenol, the starting material necessary to make the claimed compound. The Federal Circuit found no best mode violation:

Neither patent . . . claims p-trifluoromethylphenol . . . or a method for synthesizing it. Thus, while the best mode for developing fluoxetine hydrochloride involves use of p-tri[ ], the claimed inventions do not cover p-tri[ ] . . . . As a result, the best mode requirement does not compel disclosure of [the inventor's] unclaimed method for synthesizing p-tri[ ].

Eli Lilly, 251 F.3d at 964. With those words, the Eli Lilly case followed the "claimed invention" rule. Eli Lilly certainly did not assess the starting material's "effect on the properties" of the invention. As a starting material, the "p-tri" had a direct effect on the claimed invention and certainly its properties and uses as well, but that did not compel a best mode violation.

This Bayer opinion characterizes Eli Lilly as within its new rule based on a few words in Eli Lilly that distinguish the starting material from the "intrinsic quality" of the invention. Of course a starting material differs from the end product, but that is not the proposed test. This Bayer case's bare characterization

does not contend, nor could it, that a starting material does not materially affect the properties of the invention. Under the broad proposed test, Eli Lilly and many other prior cases might have reached a different result. In sum, this Bayer opinion's test for "effects on properties" of the invention seems to have unspecified breadth.

This new test also conflicts with the Federal Circuit's analysis in numerous cases. For instance, Northern Telecom applies the claimed invention rule and eschews a "material effect on properties" test to identify a best mode. In that case, the patent claimed "a process for gaseous etching of aluminum and aluminum oxide that employs a gaseous trihalide." N. Telecom, 215 F.3d at 1287. The district court concluded that the best mode of carrying out the invention was fine line etching. Because aluminum silicon alloy was "necessary" to achieve this etching, "the district court held that disclosure of aluminum silicon alloy was required to satisfy the best mode requirement." Id. at 1286. Judge Clevenger corrected this misapplication of § 112:

As we have repeatedly held, the contours of the best mode requirement are defined by the scope of the claimed invention. . . . Northern Telecom asserts that the district court erred in requiring disclosure of a mode for carrying out something other than the claimed invention. . . . We agree with Northern Telecom . . . What is claimed in claim 1 is a process for plasma etching of aluminum and aluminum oxide in the presence of a gaseous trihalide. Fine line etching is simply not part of the claimed invention.

Id. at 1286-87. Although the district court found that the undisclosed alloy had a necessary effect on the use the invention, this court found no best mode violation because it applied the scope of the invention rule. This court did not apply an effect on properties test.

In sum, a review of the totality of this Circuit's best mode cases, as opposed to a few cases that found a violation, shows that this court does not use an "effect on properties" test to identify best modes, but instead uses a scope of the claimed invention test. Thus, to my eyes, this opinion fails in its effort to erect a new test that is, in any event, beyond the facts of this case.

### III.

As I mentioned at the outset, this district court did its job well. It determined that the scope of the claimed invention did not include any intermediates. Because the defendants could not identify any alleged best mode within the scope of the claimed invention, the trial judge disposed of the best mode allegation as outside the statutory reference to the "invention." In fact, as this court's opinion notes, the inventor fully disclosed the intermediate, but not in this patent's specification. Instead the inventor disclosed the intermediate in a separate patent application. The proposed best mode in this case was so far removed from the scope of the claimed invention that it was itself a separate invention.

Thus, the district court got it exactly right. It applied Federal Circuit law and deserves commendation. Instead, this court purports to use this easy case to erect a new best mode test. Fortunately, both this court's failure to find a best mode in this case and the wealth of prior case law render this Bayer case mostly dicta. Otherwise, the next district judge encountering a best mode case would have to ask several imponderable questions: What is the Federal Circuit rule for the reach of the best mode rule? Even under this case, what is the test to identify a best mode -- scope of the claimed invention, necessary relationship to performance of the claimed invention, or material effect on the properties of the claimed invention? What is a "property?" What is a "material effect?" How "material" is "material?" The district court correctly decided this easy best mode case. This court certainly did not need to plant any new traps in the best mode minefield.

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[1] Bayer filed two actions against each of two groups of defendants: (1) Mylan Pharmaceuticals and Mylan Laboratories; and (2) Schein Pharmaceutical and Danbury Pharmacal. Reddy-Cheminor intervened as defendant in the second group of suits. The district court consolidated the four cases for all purposes, and this opinion will continue to refer to the defendants collectively as "Schein."

[2] A cyclopropyl group is a three-carbon ring. By contrast, methyl and ethyl groups are straight chains of one and two carbons respectively.

[3] The rule stated in In re Brebner and Christianson, *supra*, is no different.

[4] Our decision in this case also does not conflict with Brebner, or Teleflex, or to our knowledge with any other precedent. On its face, Teleflex holds that the best mode requirement does not extend to an inventor's preference for routine or production details, an issue not involved in this case. In Brebner, as in this case, there is no contention that the unclaimed starting material had any effect on carrying out the invention. The decision we reach today, based on holdings of the court that are not dicta, is thus consistent with Brebner.

[5] The unremarkable statement that one must enable novel matter necessary to practice the best mode simply followed from our oft-stated rule that a disclosure of the best mode of practicing the claimed invention is adequate only if it enables one of skill in the art to practice the best mode. *See, e.g., N. Telecom*, 215 F.3d at 1286, 55 USPQ2d at 1068 ("The second inquiry is whether the inventor's disclosure is adequate to enable one of ordinary skill in the art to practice the best mode of the invention."); *Fonar Corp. v. Gen. Elec. Co.*, 107 F.3d 1543, 1548-49, 41 USPQ2d 1801, 1804-05 (Fed. Cir. 1997) (holding that failure to disclose the code for software described by its function does not violate the best mode requirement "because, normally, writing code for such software is within the skill of the art, not requiring undue experimentation, once its functions have been disclosed" and noting that "[i]t is well established that what is within the skill of the art need not be disclosed to satisfy the best mode requirement so long as that mode is described"); Chemcast, 913 F.2d at 928, 16 USPQ2d at 1036 (holding that adequacy of disclosure depends on whether "the disclosure [is] adequate to enable one skilled in the art to practice the best mode").

[6] In dicta, this court has purported to apply the best mode beyond the scope of the claims: “[M]ost of the cases in which we have said that the best mode requirement was violated addressed situations where the inventor failed to disclose non-claimed elements that were nevertheless necessary to practice the best mode.” Chemcast, 913 F.2d at 927. Despite its language about “non-claimed elements,” the Chemcast claim recited a “locking portion . . . more rigid than said base portion.” Id. at 925. Thus, the best mode violation in that case -- a grommet of specified rigidity -- was within the scope of the claims. Chemcast’s comment about “non-claimed elements” was purely dicta. Contrary to the Chemcast dicta, an undisclosed feature only becomes a “best mode” candidate -- by statutory definition -- if it arises within the scope of the claimed invention.

In Chemcast, the inventor’s specification disclosed a grommet of “rigid castable resinous material . . . for example, polyurethane or polyvinyl chloride . . . [with] a durometer hardness reading of 70 Shore A or harder.” Chemcast, 913 F.2d at 929. No doubt the inventor thought that this disclosure was sufficient. After all, the inventor disclosed a preferred embodiment. Moreover, Chemcast Corporation’s actual product, R-4467, was indeed PVC with a hardness reading above Shore A 70 -- consistent with that disclosure.

The Federal Circuit, however, perceived concealment -- the second prong of the best mode requirement. This court noted that R-4467 had a material hardness of 75 on the Shore D scale -- “three hardness scales removed from the 70 Shore A hardness mentioned in the specification.” Id. at 930. This circuit further stressed that the inventors had “expended several months and many hundred man-hours” developing R-4467. Id. at 929. Chemcast is a concealment case, indeed an enthusiastic application of the concealment standard. In its zeal to reach the concealment issue, the Federal Circuit stretched its purported definition of best modes to encompass “unclaimed features,” but that certainly does not override prior binding case law.

[7] On the basis of the inventor’s admission of the merits of the fluoride treatment, the Federal Circuit quickly confined Dana to its peculiar facts. See Wahl Instruments, Inc. v. Acvious, Inc., 950 F.2d 1575, 1580, 21 USPQ2d 1123, 1126 (Fed. Cir. 1991).