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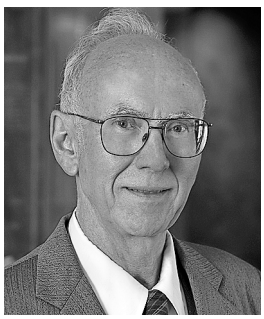
PATENTS

You Got It Wrong! Now What?



BY CHARLES L. GHOLZ AND ALEXANDER B. ENGLEHART

People (including both inventors and patent practitioners) being what they are, a recurrent problem since time immemorial has been the presence of factual errors in patent specifications. Suppose that there is such a factual error in a specification for which you are responsible and that the error has been discovered—either by someone on your side of the table or, more likely, by someone on the other side of the table (that is, by someone working for a prospective licensee or a prospective defendant). What can you do about the factual error?

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What Judge Rich Wrote in *Oda*

In *In re Oda*[1] the claims on appeal from the Patent Office's Board of Appeals recited specific chemical compounds. There were two factual errors in the specification concerning the disclosure of how to make those chemical compounds. However, for the sake of simplicity, this article will focus on only one of those errors.

The original U.S. application had been a translation of a Japanese application, and the errors had occurred in the translation. The error on which this article focusses was that the Japanese word for ''nitric acid'' was mistranslated as ''nitrous acid''—not in the claims, but in the specification's teaching of how to make the compounds recited in the claims.

The application on appeal was a reissue application. The factual error had been discovered before the original U.S. application had matured into a patent, and the U.S. attorney prosecuting the original application had attempted to have it corrected before the patent issued by an amendment under Patent Office Rule 312, 37 C.F.R. § 1.312, allowing amendments after allowance. However, the examiner amazingly refused entry of the amendment after allowance but did not withdraw the application from issue, allowing the application to issue with what presumably were invalid claims.[2]

The U.S. attorney tried again four months after the patent issued, filing an application to reissue the patent

[1] *In re Oda*, 443 F.2d 1200, 170 U.S.P.Q. 268 (C.C.P.A. 1971) (opinion by Associate Judge Rich for a unanimous panel that also consisted of Associate Judges Almond, Baldwin and Lane and Judge Re of the Customs Court, sitting by designation).

[2] Of course the assignee's behavior was equally reprehensible. What it should have done was to file a continuation in order to get the matter cleared up before the patent issued. As Judge Rich noted, 35 U.S.C. § 132, which is applicable to applications for original patents, contains the same prohibition on the insertion of new matter, and, ''Presumably, and we believe desirably, the same term would and should have the same meaning in both contexts.'' 443 F.2d at 1203 n. 2, 170 U.S.P.Q. at 270 n.2. The examiner did not focus on the fact that the applicants could have tried to correct the error before the patent issued, but the board did. However, the court ruled that the assignee's having allowed the patent to issue despite knowing of the factual error therein was irrelevant to the issue of whether the amendments sought to be made in the reissue application contained prohibited new matter.

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correcting the factual error. However, the examiner rejected the claims under 35 U.S.C. § 251, reasoning that:

> The changes of 'nitrous' to 'nitric' . . . are deemed to be drawn to new matter. The specification is considered defective since without the introduction of new matter, the specification is drawn to inoperative embodiments. Applicants are not permitted to add new matter in order to disclose what they intended even though it can be shown that it was part of the original invention and had been inadvertently omitted from the original specification. The fact that the original specification is at variance with the Japanese application *** does not provide the proper basis for such a correction. Ex parte Bondiou et al., 132 USPQ 356 (Pat. Off. Bd. App. 1961). Since both nitrous acid and nitric acid are known to effect the nitration process, the error would not be considered obvious by one of ordinary skill in the art.[3]

Judge Rich's analysis begins with a typically enlightening discussion of the history of the courts' and the commentators' efforts to define the term ''new matter,'' concluding that:

> ''New matter'' is a technical legal term in patent law—a term of art. Its meaning has never been clearly defined for it cannot be. The term is on a par with such terms as infringement, obviousness, priority, abandonment, and the like which express ultimate legal conclusions and are in the nature of labels attached to results after they have been reached by processes of reasoning grounded on analyses of factual situations. In other words, the statute gives us no help in determining what is or is not ''new matter.'' We have to decide on a case-by-case basis what changes are prohibited as ''new matter'' and what changes are not.[4]

In this case, what led the court to decide that the correction of the error was not new matter was the detailed and highly fact-specific ''affidavit evidence from an apparently well-qualified chemist''[5] submitted in support of the application to reissue the error-containing patent. That evidence persuaded the court that the examiner's assertion that ''the error would not be considered obvious by one of ordinary skill in the art'' was clearly incorrect.

Thus, after *Oda*, the bar knew that one way to correct factual errors in a specification was to persuade examiners that those errors would have been obvious to a person of ordinary skill in the art at the time that the application containing the erroneous specification was filed.

What Judge Gajarsa Wrote in *Koito*

Koito Mfg. Co. v. Turn-Key-Tech, LLC[6] involved an accused infringer's appeal of a district court's grant of a motion for judgment as a matter of law by the patentee. The court held that, contrary to the jury's verdict, the claims of the asserted patent were not invalid due to the patentee's allegedly adding new matter to the specification through a certificate of correction. The asserted patent was directed to a method of strengthening injection-molded plastics by cross-laminating layers of plastics—i.e., using two distinct layers of plastics, each with a different flow direction, such that the flow directions overlap and thereby increase the overall strength of the injection-molded plastic. The claimed method involved the use of a ''flow channel'' of a thickness within a defined range.

The patentee had submitted a certificate of correction for the asserted patent that altered the definition of the thickness of the flow channel. In particular, the patent had originally disclosed that the flow channel had to have a thickness no greater than a certain maximum value. The certificate of correction effectively increased this maximum value, thereby allowing the flow channel to be thicker than it had been able to be under the definition in the patent prior to the certificate of correction.

As Judge Gajarsa found:

> The effect of this correction was to redefine the flow channel. Before the correction, the flow channel could have been considered to be only the protrusion from the first-layer-defining mold-cavity section 22. After the correction, however, the flow channel was considered to have the depth of that section and the protrusion.[7]

The jury had found that this change invalidated all of the claims of the asserted patent because it impermissibly added new matter to the specification. The patentee moved for JMOL on this issue, which the district court granted. The accused infringer then appealed the grant of JMOL to the U.S. Court of Appeals for the Federal Circuit.

On appeal, the Federal Circuit affirmed the district court's decision to grant JMOL and found that the certificate of correction did not impermissibly add new matter. In reaching this determination, the Federal Circuit found that the thickness parameter for the flow channel in the original specification would have excluded one of the preferred embodiments disclosed in the specification—as shown in two of the patent's figures—because the claims each required a flow channel that, in that preferred embodiment, would have been thicker and wider than what would have been allowed pursuant to the original maximum value for the thickness of the flow channel as defined in the specification.

The Federal Circuit then found that, because the amended disclosure was inherently contained in the original application (apparently, in the preferred embodiment shown in the two figures), it could not constitute new matter. Accordingly, the Federal Circuit found that the district court did not err in concluding that, as a matter of law, the patentee did not impermissibly broaden the scope of the asserted patent through its certificate of correction.

Thus, after *Koito*, the bar knew that another way to correct factual errors in a specification was to show that correction of the errors would result in bringing within the scope of the claims a preferred embodiment which was disclosed in the specification, but which would otherwise have been excluded from the scope of the claims.

What Judge Bryson Wrote in *Cubist*

Cubist Pharmaceuticals, Inc. v. Hospira, Inc.[8] was a Hatch-Waxman case in which the district court had

[3] 443 F.2d at 1202, 170 U.S.P.Q. at 269-70.
[4] 443 F.2d at 1203, 170 U.S.P.Q. at 270.
[5] 443 F.2d at 1205, 170 U.S.P.Q. at 272.
[6] *Koito Mfg. Co. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 72 U.S.P.Q.2d 1190 (Fed. Cir. 2004) (68 PTCJ 510, 9/3/04) (opinion by Circuit Judge Gajarsa for a unanimous panel that also consisted of Circuit Judges Bryson and Dyk).
[7] 381 F.3d at 1154, 72 U.S.P.Q.2d at 1198.
[8] *Cubist Pharms., Inc. v. Hospira, Inc.*, 805 F.3d 1112, 117 U.S.P.Q.2d 1054 (Fed. Cir. 2015) (91 PTCJ 162, 11/20/15)

held that Hospira infringed claims 18 and 26 in Cubist's '071 patent[9] and that those claims were not invalid. Hospira's appeal focused on a certificate of correction of the '071 patent which corrected a diagram of the chemical structure of a compound described in the specification and recited in those claims. Cubist's problem was that that diagram ''mistakenly identified the stereoisomer of the asparagine amino acid as the 'L' stereoisomer of asparagine, rather than the 'D' stereoisomer [referred to in the opinion as daptomycin].''[10]

Three factors proved important to the court's decision to affirm. First, that error had not been discovered until long after the patent had issued, and, at the time that the application that matured into the patent was filed, it was generally believed that the actual chemical compound incorporated the ''L'' stereoisomer. Second, the specification identified that actual chemical compound in two other ways, so the certificate of correction corrected one identification of the compound to correspond to the other two. And, third, the examiner had approved the issuance of the certificate of correction correcting the error, so Hospira had to argue, not only that the inventors had originally erred in misidentifying the compound, but that the PTO had erred in permitting Cubist to correct the error.

On appeal, Hospira argued that 35 U.S.C. § 255, authorizing certificates of correction of applicants' mistakes, only authorizes correction of ''a mistake of a clerical or typographical nature, or of minor character'' and that the error corrected by Cubist's certificate of correction was none of the above[11] because it expanded the scope of the claims in issue—that is, it made those claims read on subject matter on which the original claims did not read.

In rejecting Hospira's arguments, Judge Bryson relied heavily on the PTO's action:

> Once the PTO has issued a certificate of correction, a court may invalidate the certificate only upon a showing of clear and convincing evidence that it was improperly issued. *Superior Fireplace Co. [v. Majestic Prods. Co.]*, 270 F.3d 1358 (Fed. Cir. 2001)] at 1367.[12]

The district court had held that the certificate of correction did not change the subject matter on which the claims read, but merely corrected the identification of that subject matter, and the Federal Circuit agreed:

> Contrary to Hospira's argument, the original structural diagram in the '071 patent did not establish that the patent was directed to a compound other than daptomycin. As this court has noted, a chemical structure is ''simply a means of describing a compound; it is not the invention itself.'' *Regents of Univ. of N.M. v. Knight*, 321 F.3d 1111, 1122 (Fed. Cir. 2003). In determining what compound the patent claims were directed to, the proper focus is not limited to the chemical structure depicted in the diagram. Instead, the specification as a whole must be considered.[13]

And that's where the fact that the specification had identified the claimed chemical compound in two other ways came in:

> The specification of the '071 patent does not rely exclusively on the structural diagram . . . to describe the subject compound. By reference to a co-pending application . . ., the specification teaches that daptomycin is obtained through fermentation of *Streptomyces roseosporus*. That fermentation process necessarily results in daptomycin, not the variant with the L-isomer of asparagine. * * *
>
> In addition, the specification describes the claimed compound by the code name given to it by Lilly—the designation LY146032. Evidence introduced by Cubist at trial showed that the code name LY146032 refers to daptomycin, not the variant of daptomycin with the L-isomer of asparagine.[14]

Based on all of the foregoing factors, the panel of the Federal Circuit affirmed.

Thus, after *Cubist*, the bar knows that another way to correct factual errors in a specification is to persuade examiners to approve the issuance of a certificate of correction based on inconsistent statements in the same specification or in the specification of a co-pending application referenced in the specification of the application in question.

But Can We Push it Further?

Counsel for Cubist got lucky. There were a plurality of inconsistent statements in the specification, and he could amend the specification to make the statements consistent. But sometimes (perhaps usually) the erroneous factual statement is just there all by itself in the specification in question. Can you correct such an error?

The examiner handling Oda's reissue application clearly thought not, and even Judge Rich's opinion in *Oda* stresses that there are limits:

> This court on previous occasions . . . has observed that the reissue statute is based on fundamental principles of equity and fairness and that, as a remedial provision, intended to bail applicants out of difficult situations into which they get ''without any deceptive intention,'' it should be liberally construed so as to carry out its purpose to the end that justice may be done to both patentees and the public. *In re Willingham*, 48 CCPA 727, 282 F.2d 353, 127 USPQ 211 (1960); *In re Wesseler*, 54 CCPA 735, 367 F.2d 838, 151 USPQ 339 (1966). * * * At the same time we are realistic enough to appreciate that sharp applicants must be watched with a sharp eye. This is nothing new in the legal field.[15]

What Judge Wallach Wrote in *Fox Group*

The opinion that gives us the most hope that the bar's ability to correct factual errors in specifications can be pushed even further is *Fox Group, Inc. v. Cree, Inc.*[16] In that opinion, the majority held that a material that had

(opinion by Circuit Judge Bryson for a unanimous panel that also consisted of Circuit Judges Wallach and Hughes).

[9] The invention was made in Eli Lilly & Co.'s laboratory. The '071 patent was what Judge Bryson called a ''follow-on patent[ ] owned by Cubist.'' 805 F.3d at 1114, 117 U.S.P.Q.2d at 1056.

[10] 805 F.3d at 1116, 117 U.S.P.Q.2d at 1057-58.

[11] Compare *In re Hyman*, 185 U.S.P.Q. 441 (PTO Solicitor 1975).

[12] 805 F.3d at 1118, 117 U.S.P.Q.2d at 1059.

[13] 805 F.3d at 1118, 117 U.S.P.Q.2d at 1059.

[14] 805 F.3d at 1118, 117 U.S.P.Q.2d at 1059. Notably, Judge Bryson does not refer to any evidence suggesting that, as of the effective filing date of the '071 patent, anyone outside the confines of Lilly's laboratory knew that ''the code name LY146032 refer[ed] to daptomycin. . . .''

[15] 443 F.2d at 1203, 170 U.S.P.Q. at 270.

[16] *Fox Group, Inc. v. Cree, Inc.*, 700 F.3d 1300, 105 U.S.P.Q.2d 1097 (Fed. Cir. 2012) (85 PTCJ 178, 12/7/12) (opinion by Circuit Judge Wallach joined by Circuit Judge Newman;

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allegedly been created and the alleged creation of which had been disclosed to the public was available as 35 U.S.C. § 102(g) prior art notwithstanding the facts that Cree (the company that had allegedly created the material) (1) had actively concealed how it had made the material, (2) did not file a patent application disclosing how it had made the material, and (3), when it did commercialize the material (apparently too late for the commercialization to be available as prior art), had done so in a manner that did not allow reverse-engineering.[17]

The senior author of this article criticized Judge Wallach's opinion with uncustomary vehemence in Gholz, *A Critique of Recent Opinions in Patent Interferences*, ''It's OK to Conceal How to Make a Material as Long as You Disclose that You Made the Material!''[18] However, that criticism should not bar either him or any other member of the bar from relying on Judge Wallach's surprising holding.[19]

While Cree was not attempting to correct a patent specification to add a disclosure of how to make the material in question, Judge Wallach's language certainly suggests that he and the other judge who joined his opinion do not think it as important that ''sharp applicants . . . be watched with a sharp eye'' as Judge Rich and his colleagues did.

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opinion dissenting on the relevant point by Circuit Judge O'Malley).

[17] The only opinion that comes to mind as remotely comparable is *In re Argoudelis*, 434 F.2d 1390, 168 U.S.P.Q. 99 (C.C.P.A. 1970). That case held that the pre-effective filing date deposit of a microorganism with the United States Department of Agriculture's depository was adequate 35 U.S.C. § 112 first paragraph support for claims to antibiotic compounds produced by the fermentation of those microorganisms despite the facts (1) that the microorganisms were not accessible by the general public pursuant to a contract between the depository and Argoudelis's assignee and (2) that ''[t]he deposits . . . [were] not a part of the patent application, and the Patent Office exercise[d] no control over them.'' 434 F.2d at 1394, 168 U.S.P.Q. at 103.

[18] 95 Journal of the Patent and Trademark Office Society 24 (2013) § V.A.

[19] Notably, Judge O'Malley's vigorous dissent did not persuade the Supreme Court to grant Fox Group's petition for certiorari.