GENEVA PHARM., INC. v. GLAXOSMITHKLINE, PLC SHOULD BE OVERRULED![1]

By

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and

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Introduction

Prior to the Federal Circuit's opinion in Geneva Pharm., Inc. v. GlaxoSmithKline, PLC, 349 F.3d 1373, 68 USPQ2d 1865 (Fed. Cir. 2003) (opinion by Circuit Judge Rader for a panel that also consisted of Chief Circuit Judge Mayer and Circuit Judge Bryson) (hereinafter referred to as "Geneva"), it was well-established that obviousness-type double patenting (hereinafter referred to as "OTDP") analysis only considers the subject matter *defined by the claims* and that the content of the specifications of the two cases[4] under consideration may only be used to construe the metes and bounds of those claims.[5] However, contrary to (but without purporting to overrule[6]) precedent, the three-judge Geneva panel held that unclaimed utility, disclosed in the specification of a patent claiming a compound, could be used as if it were prior art and combined with the subject matter defined by a compound claim to invalidate claims to methods of using the compound on OTDP grounds.[7]

The Facts in Geneva

The Geneva panel affirmed the district court's ruling that claims (in "the '720 patent") to methods of using a compound, potassium clavulanate, to inhibit β-lactamase in humans were invalid on OTDP grounds.[8] The court held that claims to methods of using the compound in the '720 patent were not patentably distinct from claims to the compound itself in an OTDP reference ("the Fleming patent") when combined with the reference's unclaimed disclosure of

the compound's utility for inhibiting β-lactamase in humans.[9] In so holding, the court reasoned that, "[t]he '720 patent claims nothing more than Fleming's *disclosed utility* as a method of using the Fleming compound." [10]

Geneva's Progeny

The Federal Circuit has twice relied on the reasoning in Geneva to invalidate claims to methods of using compounds on OTDP grounds.

The first case relying on the holding in Geneva under consideration here is Pfizer, Inc. v. Teva Pharm. USA, Inc., 518 F.3d 1353, 86 USPQ2d 1001 (Fed. Cir. 2008) (opinion by Circuit Judge Dyk for a panel that also consisted of Chief Circuit Judge Michel and District Judge Kennelly of the Northern District of Illinois, sitting by designation) (hereinafter referred to as "Pfizer"). The Pfizer panel invalidated claims (in "the '068 patent") to methods of administering a therapeutically-effective amount of compounds to treat inflammation-related disorders as not patentably distinct from an OTDP reference ("the '165 patent") that claimed the compounds and disclosed the compounds' utility for treating inflammation-related disorders.[11] In addition to relying on the utility disclosed in the specification of the OTDP reference, the Pfizer court based its OTDP holding, at least in part, upon the fact that a composition claim in the OTDP reference included the term "therapeutically-effective amount"[12] which was "stipulated by the parties to mean the same thing in both patents."[13] Thus, the Pfizer panel might have reached the same conclusion without relying on the utility disclosed in the specification of the '165 patent, according to the reasoning in Geneva.

The second case relying on the holding in Geneva under consideration here is Sun Pharm. Indus., Ltd. v. Eli Lilly & Co., 611 F.3d 1381, 95 USPQ2d 1797 (Fed. Cir. 2010) (opinion by Circuit Judge Prost for a panel that also consisted of Circuit Judge Bryson and Circuit Judge

Gajarsa) (hereinafter referred to as "Sun"), rehearing en banc denied, 625 F.3d 719, 96 USPQ2d 1830 (Fed. Cir. 2010). The Sun panel affirmed the district court's ruling that claims to methods of treating cancer (in "the '826 patent") using effective amounts of a compound, gemcitabine, were invalid as not patentably distinct from the claims in an OTDP reference ("the 614 patent") that claimed the compound gemcitabine and disclosed the compound's utility for treating cancer in the specification.[14]

In Sun, Geneva's inconsistency with precedent did not go unnoticed. The court denied both panel rehearing and rehearing en banc by a narrow 5 to 4 vote—and over one of Judge Newman's customarily vigorous dissents. In that dissent (which was joined by Chief Circuit Judge Rader,[15] Circuit Judge Lourie, and Circuit Judge Linn), she argued that the holding in Sun was inconsistent with OTDP precedent (without, however, specifically calling for overruling of Geneva) and that extension of the reasoning from Geneva to the facts of Sun was undesirable because the result was inconsistent with the policies underlying OTDP law.[16]

In her dissent, Judge Newman observed that, "[u]ntil recently it was beyond dispute that the law of double patenting is concerned only with what is patented—that is, what is claimed."[17] She cited to 11 opinions (ranging from an opinion of the Federal Circuit's predecessor court, the CCPA, in 1964 to an opinion of the Federal Circuit in 1992) supporting the proposition that disclosure in the specification of an OTDP reference may not be considered as if it were prior art in an OTDP analysis.[18] Further, she opined that the ruling in Sun "d[id] not further the policy of obviousness-type double patenting" because a finding of no OTDP would not improperly extend the term of any patent in that case, "let alone . . . shock one's sense of justice," as asserted in the Sun panel's opinion.[19] Finally, Judge Newman concluded that the ruling in Sun effected an improper deviation from precedent meriting en banc review, otherwise "leav[ing] the innovation

community without guidance on which the trial courts, and the users of the patent system, can rely."[20]

Geneva Is Inconsistent with the Precedents on Which It Relies and Should be Overruled

We believe that the holding of Geneva should be overruled. Not only is it undesirable for the reasons advanced by Judge Newman, but it is not supported by the authorities on which it relies.

The three-judge Geneva panel relied on In re Byck, 48 F.2d 665, 9 USPQ 205 (CCPA 1931) (hereinafter referred to as "Byck"), and In re Christmann, 128 F.2d 596, 53 USPQ 634 (CCPA 1942) (hereinafter referred to as "Christmann"),[21] to support the proposition 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.[22]

However, the Geneva panel failed to recognize elements necessary to the reasoning in those cases. These necessary elements include the first en banc CCPA panel's reliance on *prior art* in combination with the claimed subject matter of the OTDP reference to support the rejection in Byck and the second en banc CCPA panel's reliance on the appellant's *binding admission of no patentable distinction* to support the rejection in Christmann. Thus, neither Byck nor Christmann affirmed a rejection of claims based only on the unclaimed disclosure of utility in combination with the subject matter claimed in the OTDP reference.

In Byck, the court affirmed a decision of the Board of Patent Appeals affirming a rejection of claims to a method of using an insulating composition as unpatentable over claims to the same insulating composition in the OTDP reference ("the '079 patent") *in view of a prior art patent* ("the Baekeland patent") disclosing the same method but with a different insulating material.[23] Although the '079 patent disclosed the Baekeland patent, presumably in support of

the statutory utility requirement, the court did not affirm rejection of the method claims based on unclaimed disclosure of insulating composition utility in the '079 patent, but rather the prior art Baekeland patent itself.[24] The court expressly clarified that, although "there was no error in [the board's] citing [of] the ['079] patent,"[25] it was not cited as prior art, "but to show that appellant had already received a patent for the only invention that was disclosed in either application."[26]

No one can tell how the Byck court would have decided the case in the absence of the prior art Baekeland patent. Thus, in light of the court's express reliance on prior art, the Byck opinion does not support the holding in Geneva that claims to a method of using a composition are never "patentably distinct from an earlier claim to the identical composition in a patent disclosing the identical use" in the absence of prior art disclosing the "identical use."[27]

In Christmann, the court affirmed a decision of the Board of Patent Appeals which in turn affirmed the rejection of claims to compounds as unpatentable over claims to insecticidal compositions including those compounds in the OTDP reference ("the '789 patent").[28] Although "the application ma[de] no mention that [the compound was] useful for any purpose other than as an insecticide,"[29] the court did not base its decision to affirm rejection of the application claims on the claims of the OTDP reference and the utility disclosed but not recited in the claims of the OTDP reference.[30] Rather, the court based its affirmance of the OTDP rejection on the applicant's "binding admission"[31] that the application claims were not patentably distinct from the claims of the OTDP reference. The court ruled that there was a binding admission of no patentable distinction because the applicant canceled identical claims, without traverse, in response to the PTO's rejection for lack of patentable distinction when earlier presented in a prior copending application which matured into the OTDP reference.[32]

No one can tell how the Christmann court would have ruled in the absence of the

applicant's binding admission of no patentable distinction between the claims at issue and the claims of the OTDP reference. Hence, Christmann also does not support the holding in Geneva that claims to a method of using a composition are never "patentably distinct from an earlier claim to the identical composition in a patent disclosing the identical use" in the absence of a binding admission by the party charged with OTDP that the claims are not patentably distinct.[33]

Conclusion

We believe that that the Geneva court's failure to recognize necessary elements in the reasoning of both Byck and Christmann resulted in an undue and unfortunate extrapolation of the holdings from those cases. We also agree with Judge Newman's dissent from the denial of the petition for rehearing en banc in Sun that the holding in Sun (and, hence, the holding in Geneva) is highly undesirable from the point of view of the policies underlying the doctrine of OTDP.[34]

Accordingly, we respectfully submit that the Federal Circuit should correct the course of OTDP law by overruling Geneva and renewing the focus of OTDP analysis on the *subject matter defined by the reference claims* and not on the disclosure in the reference specifications.

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[4] In this context, "cases" is a generic term that reads on both patents and patent applications.

[5] In re Vogel, 422 F.2d 438, 441, 164 USPQ 619, 622 (CCPA 1970), and see generally 3A Chisum, Patents § 9.03[1][b].

[6] Of course, it is fundamental Federal Circuit jurisprudence that a three-judge panel has no authority to overrule precedent. South Corp. v. United States, 690 F.2d 1368, 215 USPQ 657 (Fed. Cir. 1982) (en banc).

[7] 349 F.3d at 1385–86, 68 USPQ2d at 1875.

[8] 349 F.3d at 1386, 68 USPQ2d at 1875.

[9] Id.

[10] Id. (emphasis added).

[11] 518 F.3d at 1363, 86 USPQ2d at 1008.

[12] This fact diminishes the significance of the Pfizer panel's reliance on the Geneva panel's reasoning. Hence, there is a chance that Pfizer would stand even if Geneva is overruled.

[13] 518 F.3d at 1363, 86 USPQ2d at 1008.

[14] 611 F.3d at 1383, 1389, 95 USPQ2d at 1798, 1803.

[15] Since then Circuit Judge Rader had delivered the opinion in Geneva, it is remarkable that he joined Circuit Judge Newman's dissent in Sun. However, he did not write separately to explain his apparent change of heart.

[16] 625 F.3d at 721–23, 96 USPQ2d at 1832–33.

[17] 625 F.3d at 721, 96 USPQ2d at 1831.

[18] 625 F.3d at 721–22, 96 USPQ2d at 1832.

[19] 625 F.3d at 723, 96 USPQ2d at 1833 (internal quotes omitted).

[20] Id.

[21] Since none of the judges who sat on Byck and Christmann is still sitting, we have not given their names.

[22] 349 F.3d at 1385–86, 68 USPQ2d at 1875 (emphasis added).

[23] 48 F.2d at 665, 667, 9 USPQ at 205, 207.

[24] 48 F.2d at 667, 9 USPQ at 206–07.

[25] 48 F.2d at ___, 9 USPQ at ___.

[26] 48 F.2d at 667, 9 USPQ at 207.

[27] 349 F.3d at 1385–86, 68 USPQ2d at 1875; 48 F.2d at 667, 9 USPQ at 207.

[28] 128 F.2d at 597, 53 USPQ at 635.

[29] 128 F.2d at 598, 53 USPQ at 635.

[30] Id.

[31] 128 F.2d at 599, 53 USPQ2d at 637.

[32] 128 F.2d at 599, 53 USPQ at 636–37.

[33] 349 F.3d at 1385–86, 68 USPQ2d at 1875.

[34] As we previously wrote in Gholz and Hibshman, Is the Respondents Entire Specification "Prior Art" on a Motion for a Judgment of No-Interference-In-Fact?, 17 Intellectual Property Today No. 9 at page 8 (2010), we also believe that the holdings in Sun and Geneva, if extended to interference law, would be equally undesirable for that branch of the law.