2010-1105

United States Court of Appeals for the Federal Circuit

SUN PHARMACEUTICAL INDUSTRIES, LTD.,

Plaintiff-Appellee,

v.

ELI LILLY AND COMPANY,

Defendant-Appellant.

Appeal from the United States District Court for the Eastern District of Michigan in case no. 07-CV-15087, Judge George Caram Steeh.

BRIEF OF *AMICUS CURIAE* BIOTECHNOLOGY INDUSTRY ORGANIZATION IN SUPPORT OF DEFENDANT-APPELLANT ELI LILLY AND COMPANY'S COMBINED PETITION FOR PANEL REHEARING AND REHEARING *EN BANC*

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IDENTITY OF THE AMICUS AND AUTHORITY TO FILE

Biotechnology Industry Organization ("BIO") is a trade association of over 1,150 corporate, academic, and non-profit members who research, develop, and produce significant agricultural, environmental, and biomedical products. BIO's members routinely engage in continuing research on basic biotechnology inventions even after initial patent applications have been filed. Often, such research reveals something new about a basic invention, including better and unexpected new ways of using it that require patent protection for their commercial development. BIO appears as *amicus* out of concern that this Court seems poised to expand the judicially-created doctrine of nonstatutory double patenting in ways that negatively impact the patentability of important later-discovered uses. Appellant Lilly is a member of BIO. The parties to this appeal have consented to the filing of this brief but have not contributed to its preparation or filing.

PRELIMINARY STATEMENT

Lilly's Petition for Rehearing presents a clear opportunity for the Court to clarify inconsistencies in the law regarding the use of a patent's specification for a nonstatutory double patenting analysis. The factual predicate that permits a *Geneva*-type analysis does not exist here. Instead, *Gen. Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272 (Fed. Cir. 1992), and its line of cases, must be the controlling authority.

In determining whether a later set of claims is patentably indistinguishable from an earlier set of claims under a nonstatutory double patenting analysis, it is critical for a court to exclude the disclosure of the patent specification to support a finding of double-patenting. To do otherwise would be to open up the inventor's own disclosure, necessary to support earlier patent claims under §112, to render obvious a later set of claims to separate subject matter as if the specification were prior art that operates only against the patentee. Accordingly, double patenting has always focused on the claims, and it has long been the law that courts cannot use a patent's specification in determining whether a later set of claims should be held invalid for being simply an obvious variation of an earlier set of claims. *E.g., Gen. Foods Corp.*, 972 F.2d at 1281.

This Court in *Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373 (Fed. Cir. 2003), accessed an earlier patent's specification only in the special situation where the utility of a claimed compound needed to be ascertained in order to determine whether a later claimed method of using the compound was patentably distinct. In the instant case, however, the utility of Lilly's antiviral compounds is apparent on the face of the claims. Accordingly, the Panel had no need to turn to the specification and use it, as if it were prior art, to invalidate later issued claims. In doing so, the Panel decision extends the doctrine of double patenting beyond its policy roots, departs from the authority of *Geneva* and *General Foods*, and conflicts with the express provisions of the statutory law.

ARGUMENT

I. The Panel Decision Provides No Justification for Use of the Specification as Prior Art for a Nonstatutory Double Patenting Analysis

Long-standing precedent of this Court and its predecessor generally prohibits the use of a patent specification to support a holding of nonstatutory double patenting because a comparison of the claims is the *sine qua non* of such an analysis. *See, e.g.*, *Gen. Foods*, 972 F.2d at 1277 ("Double patenting is altogether a matter of what is claimed"). In particular, the law of this Court is that a patent's disclosure shall not be used "in support of a double patenting rejection…as though it were prior art…." *Id.* at 1281, *citing In re Braat*, 937 F.2d 589, 594 (Fed. Cir. 1991) ("patent disclosure must not be used as prior art"); *In re Vogel*, 422 F.2d 438, 442 (C.C.P.A. 1970) (same). In *Geneva,* the Court acknowledged that *General Foods* constitutes the standard: "Because nonstatutory double patenting compares earlier and later claims, an earlier patent's disclosure is not available to show nonstatutory double patenting." *Geneva*, 349 F.3d at 1385.

Under the specific facts of the patents being compared, however, the *Geneva* Court recognized that a court may need to rely on the specification of the earlier issued patent for the utility of a claimed compound. There, the earlier issued Fleming patent contained a single claim to a compound as shown by its chemical structural formula and a physical property. *Id.* The Fleming patent contained no other claims such as a claim to a method of use by which utility could be

ascertained. The Court therefore turned to the specification to understand the utility of the claimed compound. *Id.*

Similarly, in *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 518 F.3d 1353 (Fed. Cir. 2008), the earlier issued US 5,563,165 (the "'165 patent") contained only claims covering pharmaceutical compositions comprising certain compounds. No claim was directed to, or otherwise recited, a method of using the compounds. Relying on *Geneva*, the *Pfizer* Court turned to the specification for the disclosure of the antiinflammatory utility of the claimed compounds in determining that the later issued US 5,760,068 patent claiming methods of treating inflammation and associated disorders was invalid for nonstatutory double patenting.

In contrast to *Geneva* and *Pfizer*, the Lilly referenced patent, US 4,808,614 (the "'614 patent"), contains compound, method of use, and pharmaceutical composition claims. *Sun Pharm. Indus. Ltd. v. Eli Lilly & Co.*, 611 F.3d 1381 (Fed. Cir. 2010). To understand what is claimed for double patenting purposes, all the claims must be considered. *See, e.g., Gen. Foods*, 972 F.2d at 1283; *see also In re Braat*, 937 F.2d at 593-594. In contrast to the Panel's finding, *Sun*, 611 F.3d at 1387-1388, the '614 patent does not contain a compound claim "standing alone," as in *Geneva*, 349 F.3d at 1385. In claim 13 the '614 patent claims a method of treating Herpes viral infections using the claimed compounds, *Sun*, 611 F.3d. at 1383, thus reciting the compounds' utility within the claims. There is therefore no reason, as in *Geneva*, to turn to the specification of the '614 patent to understand

the utility of any of the claimed compounds. The same utility is recited in claim 14, drawn to an antiviral pharmaceutical composition containing the compound. *Id.* Lilly's patents should therefore be analyzed for nonstatutory double patenting under the *General Foods* line of cases and provide no basis for turning to the relatively narrow authority constituting *Geneva* and *Pfizer*. Those cases require specific predicate facts to warrant their application to a nonstatutory double patenting analysis, and those facts are simply not met here.[1]

The Panel decision here appears to have adopted a new standard allowing courts to freely compare later issued claims to the specification of an earlier issued patent, thereby creating a conflict with decades of nonstatutory double patenting jurisprudence. To avoid further erosion of the long-standing *General Foods* precedent or, in the alternative, merging of the *General Foods* and *Geneva* lines of cases, the Court should grant Lilly's Petition for Rehearing *en banc* to clarify the law and provide clear guidance as to the proper application of *General Foods* and *Geneva*.

[1] The Panel justified its departure from the rule in *General Foods* by stating that "a court considering a claim to a compound must examine the patent's specification to ascertain the coverage of the claim because a claim to a compound, standing alone, does not adequately disclose the patentable bounds of the invention." *Sun*, 611 F.3d at 1387. The Panel cites *Geneva* for this broad proposition. But this justification does not withstand serious scrutiny, especially if taken out of Geneva's specific context. Not all compound claims, "standing alone," fail to adequately define their "patentable bounds," and the Panel nowhere explains why or how the scope of the instant claims was deemed unclear or how it is affected by the disclosed utility. Claims to chemical compounds are not, as a general proposition, limited to their disclosed utility. If that were the case, a compound claim could never dominate another party's later claim to a new and specific use.

II. The Panel Decision Conflicts with the Patent Statute § 120

As explained above, there was no need for the Panel to consult the specification to ascertain the utility of the claimed compounds. But even if the Panel needed to consult a specification for disclosure of the compounds' utility, the Panel should have consulted the specification as originally filed. To do otherwise would expand *Geneva* in ways that conflict with 35 U.S.C. § 120.

In *Geneva*, this Court justified the use of the earlier patent's disclosure by explaining that a patent on a chemical composition "can only be obtained" by disclosing the composition's utility. *Geneva*, at 1386. Accordingly, the utility disclosed to support patentability of the earlier compound claim was deemed to be "an essential part of a single invention" and could not be deemed patentably distinct if later claimed in the form of a method. *Id*.

If the *Geneva* reasoning were to apply to the instant case, it would be appropriate to ask whether Lilly's '614 patent could have been obtained by disclosing only gemcitabine's anticancer utility. Lilly's scientists, however, discovered and first disclosed gemcitabine's anticancer activity only *after* the underlying Serial No. 473,833 (the "'883 application") had been filed. Thus, if the claims of the '614 patent were adequately supported under Section 112 as of the '883 application's filing date, Lilly's later added anticancer disclosure could not be deemed a condition for the grant of the claims – or, in *Geneva's* words, "an

essential part" of a single chemical invention – and should therefore not fall under *Geneva*-type double patenting.

Under Section 120, the '614 patent claims are entitled to the benefit of the '883 patent application, provided that the '883 specification provides sufficient support under 35 U.S.C. § 112 ¶ 1. *See Trading Techs. Int'l, Inc. v. eSpeed, Inc.*, 595 F.3d 1340 , 1359-60 (Fed. Cir. 2010). Here, the parties do not dispute that the '614 patent is entitled to the benefit of the '883 patent application filing date. Indeed, the fact that the PTO issued the '614 patent's claim 13, drawn to a method of treating Herpes viral infections, creates a presumption that the original antiviral activity of the compounds constitutes sufficient utility. Thus, this Court should accord Lilly the full benefit of that original disclosure for all purposes relevant here, and the later-added disclosure should be deemed immaterial.

The Panel did not accord Lilly that benefit. By giving no regard to the different dates of invention, it effectively not only accessed the earlier patent's disclosure in a way that departs from *Geneva* and raises questions about the future applicability of *General Foods*, but it also treated the later invented new use as it were present in the priority application for the purpose of a purported double patenting analysis that collides with 35 USC § 120. In effect, the Panel has rendered unpatentable a new use that was discovered after the priority date of the earlier patent.

This Court should grant Lilly's Petition for *en banc* Rehearing to provide clear guidance as to the proper application of *Geneva*, its interplay with Section 120, and its delineation against *General Foods*.

III. By Changing a Rule of Patentability, the Panel Decision Changes Public Policy and Disincentivizes New Discoveries

BIO submits that courts should be particularly circumspect when expanding law that is not rooted in the statute. Any such expansion should be consistent with the statute as whole, and be supported by a public policy rationale that creates proper incentives for continuing research and timely public disclosure. Biotechnology applicants are particularly likely to continue to study their basic biotechnology inventions and to discover new things about them, new modifications of them, and new uses for them.[2] Such patentees are now on notice that their patent specifications can be used for double patenting attacks without regard to whether new matter was added and when, as well as the choice of application format. In the instant case, for example, the simple ministerial act of filing a continuation application would have allowed Lilly to claim the active

[2]For example, drug products which were developed for later-discovered uses include: sildenafil, changed from a candidate for hypertension to erectile dysfunction; finasteride, expanded from prostate cancer to hair loss; raloxifene, repositioned from birth control to osteoporosis; minoxidil, switched from a hypertension candidate to hair loss; thalidomide, changed from a discontinued antiemetic drug to a successful cancer therapeutic; hydroxychloroquine, expanded use from an antiparasitic to an approved antiarthritic agent; doxepin, expanded from an antidepressant to a antipruritic agent; naltrexone, expanded use from an opioid addiction therapeutic to alcohol withdrawal therapy; bimatoprost, expanded from glaucoma treatment to eyelid hypotrichosis.

ingredient in a patent specification that did not disclose its anticancer activity. The very simplicity with which double patenting could have been avoided underscores how the Panel decision elevates form over substance.

Notably, the Panel provides no policy rationale for its expansion from the holding in *Geneva* and opens the door to future expansion of the use of the patent specification in a double patenting analysis. This concern is not academic; the impact of the Panel decision is in no way limited to patents that were prosecuted under the 17-year patent term provisions that were in effect prior to the effective date of the 1994 Uruguay Round Agreements Act.

The Panel decision furthers no public policy. Indeed, it incentivizes applicants to minimize their application disclosures. Lilly suffers the detriment of expanding the disclosure of its patent specification with the results of its follow-on research and of erring on the side of disclosure. But the requirements of patentability, especially if not set forth in the statute but created by the courts, should incentivize desirable conduct, or at least should not punish innovators for engaging in desirable conduct that violated no rule at the time, and that is wrong only in retrospect.

The Supreme Court has on more than one occasion cautioned against altering the patent law in a manner that risks "destroying the legitimate expectations of inventors in their property." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002). In *Festo*, for example, the Supreme Court noted

that patent prosecution decisions are made based on case law as it is understood at the time, and that any retrospective change can unfairly disrupt the settled expectations of the inventing community. *Id*. Not only do such changes undercut the incentive for future investment in innovation, but they "could very well subvert the various balances the PTO sought to strike when issuing the [patents]." *Id*.

It is critical that when patent law evolves in the courts, it does so in a way that does not disrupt the investment-backed expectations of the inventive community, and does not punish patentees for decisions made during patent prosecution that were reasonably based on the law at that time. Not only is this unfair to settled expectations of inventors, but the biotechnology community needs to understand the ramifications of disclosure in patent specifications. Such understanding will determine the timing in which applications are filed, the timing of research and dsiclosure thereof, and ultimately investment decisions that result in socially beneficial products. While the judicial doctrine of double patenting serves a useful purpose, it should be limited and not expanded to invalidate legitimate patent rights otherwise in full compliance with the patent statutes.

CONCLUSION

For the reasons set forth above, this Court should grant Lilly's Petition for Rehearing *en banc*.

Respectfully submitted,

Dated: September 8, 2010 WHITE & CASE LLP

By:_____

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DECLARATION OF AUTHORITY PURSUANT TO 28 U.S.C. § 1746 AND FEDERAL CIRCUIT RULE 47.3(d)

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September 8, 2010

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John C. Kruesi, Jr.

United States Court of Appeals
for the Federal Circuit

SUN PHARMACEUTICAL v ELI LILLY, No. 2010-1105

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