

**IN THE UNITED STATES COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT**

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SUN PHARMACEUTICAL INDUSTRIES, LTD.,  
Plaintiff-Appellee,

v.

ELI LILLY AND COMPANY,  
Defendant-Appellant.

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

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**BRIEF OF WASHINGTON LEGAL FOUNDATION  
AS *AMICUS CURIAE* IN SUPPORT OF ELI LILLY AND COMPANY,  
AND SUPPORTING EN BANC REVIEW**

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## CERTIFICATE OF INTEREST

Counsel for *amicus curiae* Washington Legal Foundation certifies the following:

1. The full name of every party or *amicus* represented by me is:

Washington Legal Foundation

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

N/A

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or *amicus curiae* represented by me are:

None

4. The names of all law firms and the partners or associates that appeared for the party or *amicus* now represented by me in the trial court or agency or are expected to appear in this court are:

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## I. INTEREST OF *AMICUS CURIAE*

Washington Legal Foundation (“WLF”) is a non-profit public interest law and policy center that regularly appears before federal and state courts to promote economic liberty, free enterprise, and a limited and accountable government. WLF has participated in numerous court proceedings raising important issues regarding the patenting of pharmaceuticals and the enforcement of pharmaceutical patents. *See, e.g., Allergan, Inc. v. Alcon Laboratories, Inc.*, 324 F.3d 1322, 1330 n.6 (Fed. Cir. 2006) (citing WLF *amicus* brief).

In this case, WLF is concerned with the expansion of the judicially-created doctrine of double patenting. By expanding the grounds on which double patenting may be found, this Court has restricted a patentee’s ability to obtain patent protection for improvements on original inventions and thereby lowered the incentive to innovate. Rather than promoting the “Progress of . . . useful Arts,” U.S. Const. art. 1, § 8, cl. 8, the decision in this case is a call to invent one thing and no more. As explained *infra*, this Court’s precedents now conflict on the question whether a second invention entitles one to a second patent. Ultimately, if the property rights of patent holders can be so easily eliminated, the public may lose faith in the viability of our patent system.

Counsel for Eli Lilly and Company and Sun Pharmaceuticals, Ltd. have both consented to the filing of this *amicus* brief. In addition, pursuant to rule, this brief is accompanied by motion for leave of this Court. Fed. Cir. R. 35(g).

## II. ARGUMENT

### **The Panel Decision Conflicts With The Origins Of The Double Patenting Doctrine And The Prior Panel Decision In *Takeda v. Doll***

The judicially-created double patenting doctrine prevents a patentee from receiving two patents for *one* invention. *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 198 (1894); *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1372 (Fed. Cir. 2005). But the Supreme Court recognized over a hundred years ago that when a “second patent covers matter described in [a] prior patent,” the second patent is still valid so long as the invention claimed is patentably distinct from the invention claimed in the first patent. *Miller*, 151 U.S. at 198. At that time, it was already “settled” that an inventor may obtain “a separate patent” for a “new improvement on his own invention.” *Id.* at 199; *see also* 35 U.S.C. § 101 (patent may be obtained by “whoever” makes an invention “or any new and useful improvement thereof”).

The decision here breaks with *Miller* and limits Eli Lilly to one patent for *two* inventions. In this case, U.S. Patent No. 5,464,826 (“826 patent”), which claims a method of treating cancer by the administration of the pharmaceutical

gemcitabine, was invalidated for double patenting based on U.S. Patent No. 4,808,614 (“’614 patent”). *Sun Pharm. Indus., Ltd., v. Eli Lilly & Co.*, No. 2010-1105, slip op. at 2 (Fed. Cir. July 28, 2010). The ’614 patent described—but did not claim—the method of treating cancer. *Id.* at 3. Instead, the ’614 patent claimed gemcitabine and a method of treating viral infections with gemcitabine, which were both discovered earlier and set forth in a priority application relied on by the ’614 patent. *Id.* Had anyone other than Eli Lilly discovered this method of treating cancer with gemcitabine, quite clearly they would have been entitled to a patent. *See* Petition for Reh’g at 5-6. Eli Lilly has been limited to one patent for two inventions solely because it described the second invention in the first patent family.

*Miller* specifically precludes the possibility that a patent that merely describes a separately patentable invention renders another patent claiming that invention invalid under the doctrine of double patenting. 151 U.S. at 198. But the panel here held that the mere description of the anticancer treatment in the ’614 patent invalidated the claims to the anticancer treatment in the ’826 patent. *Sun*, slip op. at 15. To support its holding, the panel extended *Geneva Pharmaceuticals v. GlaxoSmithKline PLC*, 349 F.3d 1373 (Fed. Cir. 2003), which had held that a compound and its “*single*”—i.e., only—method of use were patentably indistinct. 349 F.3d at 1385 (emphasis added); *see Sun*, slip op. at 7-8. Here, however, the

panel acknowledged that there are two separate methods of use for the compound claimed. *Sun*, slip op. at 15. That fact made this Court's prior decision in *Takeda v. Doll*—not *Geneva*—the most apposite precedent.

In *Takeda*, this Court reviewed a PTO double patenting rejection where one patent claimed a pharmaceutical and a later-filed patent in the same family claimed a method of making the pharmaceutical. *Id.* at 1374. The *Takeda* Court held that the method of making the pharmaceutical would be patentably distinct from the pharmaceutical so long as a second method of making the same pharmaceutical was discovered before the filing of the application that led to the second patent. *Id.* at 1377.

The situation in *Takeda* is analogous to the facts here, but *Takeda's* holding cannot be reconciled with the result in this case. Here, much like *Takeda*, the '614 patent was asserted to invalidate the '826 patent, which claimed a new method of use for the pharmaceutical claimed in the '614 patent. The *Takeda* Court held that a method of manufacture was patentably distinct from the compound if the patentee (or anyone) had discovered at least one other such method before filing its application claiming the method. 561 F.3d at 1377. Yet, here, the panel held that the earlier-filed '614 patent invalidated the '826 patent's claims covering a new method even though the '614 and '826 were filed on the same day, meaning that the new method necessarily was discovered prior to the filing of either patent. Un-

der *Takeda*, discovery of the second method of using the compound should have rendered both the new method and the older method patentably distinct from the compound. But, here, the Court invalidated the patent claiming the second method on the anomalous basis that it was disclosed (but not claimed) in a separate application (for the '614 patent) filed on the same day.

*Takeda* involved methods of manufacture and the instant case deals with methods of use, but there is no significant distinction between *Takeda* and this case. The Patent Act protects new methods of using pharmaceuticals to the same extent that it protects new methods of making pharmaceuticals. *See, e.g.*, 35 U.S.C. § 100(b) (making no distinction); *id.* § 101 (same). And patent applicants must disclose both the method of making and the method of using their claimed invention under the enablement clause. 35 U.S.C. § 112, ¶ 1 (“The specification shall . . . enable any person skilled in the art . . . to make and use the [invention]”). A failure of either requirement would render the patent invalid. *Id.* at § 282, ¶ 2(3).

The panel decision’s departure from *Takeda* is particularly troublesome because—*Takeda* reflects the rules of the Patent and Trademark Office (“PTO”). At the time the two applications at issue here were filed, the PTO rules categorically barred an applicant from presenting claims to a compound and two distinct methods of using that compound. 37 C.F.R. §§ 1.141(a)-(b) (1984). The same rule

prevented applicants from filing claims to a compound and two distinct methods of making the compound. *Id.* And, indeed, if Eli Lilly had violated the rule, it would have been subjected to a restriction requirement, *id.* § 1.142 (1984), forcing its patentably distinct claims into separate patents.

Likewise, today, the Manual of Patent Examination Policy (“MPEP”) authorizes Examiners to restrict an application containing product claims and two methods of use. MPEP §806.05(h) (8th ed., Rev.5, 2006). The MPEP specifies that “[a] product and a process can be shown to be distinct” if “the product as claimed can be used in a materially different process.” *Id.* It even provides a form paragraph to require applicants to do what Eli Lilly did voluntarily. *Id.* at ¶ 8.20 (“Product and Process of Using”). *Takeda* relied on this same section of the MPEP to hold the claims there patentably distinct. 561 F.3d at 1375 (citing MPEP § 806.05). And the PTO there agreed that “product and process claims are patentably distinct if multiple processes for creating a product exist at the time of invention.” *Id.* Ironic, that the panel would bind together claims through the doctrine of double patenting, that the PTO required to be patented separately through the mirror-image doctrine of restriction. The Court should invite the views of the PTO before effectively nullifying its long-standing policy.

Finally, this court’s recent decision in *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010), has amplified the importance of the double patenting doctrine by in-

creasing the amount of patent term adjustment under 35 U.S.C. § 154(b). While the patents in this case had 17-year post-issuance terms and were not subject to patent term adjustment, all modern (20-year post-filing term) patents are eligible for patent term adjustment. And these modern patents are still subject to double patenting. *In re Fallaux*, 564 F.3d 1313, 1318-1319 (Fed. Cir. 2009).

With increased patent term comes the increased likelihood that a terminal disclaimer—incorrectly required as a result of this decision—will cut off patent rights prematurely. When Congress set the patent term (with adjustments), it established a careful balance between providing incentives for innovation and encouraging disclosure and competition. To the extent it prevents inequitable extensions of patent terms, the doctrine of double patenting promotes this balance. But there is no injustice in awarding two patent terms where, as here, there are two inventions. By allowing only one patent term for two inventions the panel decision unjustifiably reduces incentives to innovate. This Court should sit en banc and consider the views of the PTO before taking that step. *Cf. Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 167 (1989) (states precluded from adjusting the “careful balance” between public rights and patent rights as set by Congress).

### III. CONCLUSION

The Washington Legal Foundation urges that the petition for rehearing en banc be granted.

Respectfully submitted this 8th day of September, 2010.

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