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Drugmakers Argue Double Patenting Ruling Defies Congress

By **Dani Kass**

Law360 (November 28, 2023, 9:58 PM EST) -- AbbVie, Merck, Johnson & Johnson, AstraZeneca, Novartis and other big-name pharmaceutical companies are urging the full Federal Circuit to reconsider a patent invalidation that they say placed a judicially made rule above law set by Congress.

The drugmakers asked the appeals court to grant a **rehearing petition** filed by Cellect LLC, which is hoping for another shot to prove that its patents shouldn't have been invalidated through the obviousness-type double patenting doctrine. That doctrine bars patent owners from getting follow-on patents that aren't "patentably distinct."

In amicus briefs submitted Monday and Tuesday, the drug company amici claimed the Federal Circuit's ODP holding undermines a section of federal patent law that allows patent terms to be lengthened based on agency hold-ups during prosecution, referred to as patent term adjustments.

"The panel's decision may mean that because a parent patent is adjusted for Patent Office delay, the expiration of child continuation applications can be used as an ODP reference against the originally-filed parent, resulting in holding the parent invalid over its later-filed child," stated an **amicus brief** led by Merck Sharp & Dohme LLC.

Merck is joined in its brief by AstraZeneca Pharmaceuticals LP, Amgen, Inc., Johnson & Johnson, Novo Nordisk Inc. and the Association of University Technology Managers Inc.

A Federal Circuit **panel in August** said that when a patent term adjustment causes two patents to expire at different times, they can still be invalidated for double patenting. For Cellect, that meant the invalidation of image sensor patents challenged by Samsung.

"This decision violates long-standing precedent in holding that ODP, a judge-made equitable doctrine, can nullify a statutory right, PTA, and does so based on a fundamental misconstruction of the PTA statute that contradicts its plain text," the Merck brief states.

The Pharmaceutical Research and Manufacturers of America — a trade group representing branded-drug companies — **wrote in a separate brief** that the Federal Circuit's ruling would undermine the right to a full patent term, which the law governing PTAs claims must be at least 17 years.

"The Patent Term Guarantee Act's text is clear and mandatory: when the Patent Office fails to meet certain statutory deadlines in examination, the 'term of the patent shall be extended 1 day for each day' of Patent-Office delay," the organization's brief states. "Applying double patenting because of patent-term adjustments awarded to compensate the patent owner for Patent-Office delays would, for many patents, result in effective patent terms far shorter than 17 years, contrary to the very purpose of the statute."

The Intellectual Property Owners Association **said in its own brief** that the Federal Circuit erred by reviewing the double patenting first, and then considering patent term adjustments.

"Instead, the panel should have started (and ended) its analysis with the statute," IPO said. "Had the panel done so, it would have concluded that appellant was entitled to the patent term adjustments it received."

AbbVie Inc. and Innovation Alliance claim Congress has made clear when ODP is allowed to shorten PTA, and those circumstances involve a disclaimer that patent applicants can make during prosecution to override a double-patenting rejection. That disclaimer was not present here.

"Congress has repeatedly considered ODP in the context of PTA and set out specific provisions addressing when ODP would cut short PTA," **their brief states**. "Had Congress intended to extend ODP to additional scenarios, it would have enacted different statutory language."

AbbVie and Innovation Alliance added: "A court may not rewrite Congress' statutory language based on its own policy preference."

Innovation Alliance's members include AbbVie, Interdigital and Qualcomm Inc.

Additional briefs in support of the rehearing petition were filed by the Biotechnology Innovation Organization **and** Biocom California, **Novartis Pharmaceuticals Corp**., Language Technologies Inc., Parus Holdings Inc. **and** Robocast Inc.

The American Intellectual Property Law Association, New York Intellectual Property Law Association and a former Eli Lilly general counsel **filed briefs supporting Cellect** a few days earlier.

The USPTO has until Dec. 14 to respond to the rehearing petition.

A representative for the USPTO declined to comment Tuesday. Counsel for Cellect did not immediately respond to a request for comment.

The patents-at-issue are U.S. Patent Nos. 6,982,742; 6,424,369; 6,452,626; and 7,002,621.

AbbVie and the Innovation Alliance are represented by Jonathan S. Massey, Chiseul Kylie Kim and Kenneth M. Goldman of Massey & Gail LLP.

BIO and Biocom are represented by Kevin E. Noonan, Donald L. Zuhn Jr., Aaron V. Gin, James C. Gumina, Andrew H. Velzen and Ashley Hatzenbihler of McDonnell Boehnen Hulbert & Berghoff LLP and Hansjorg Sauer of BIO.

IPO is represented by Paul H. Berghoff of McDonnell Boehnen Hulbert & Berghoff LLP, Henry Hadad of Bristol-Myers Squibb and IPO's Samantha J. Aguayo.

Language Technologies, Parus and Robocast are represented by Steven J. Rizzi of McKool Smith.

Merck, AstraZeneca, Amgen, AUTM, J&J and Novo Nordisk are represented by Howard W. Levine and Jennifer S. Swan of Hogan Lovells.

Novartis is represented by Jane M. Love of Gibson Dunn & Crutcher LLP.

PhRMA is represented by Steven J. Horowitz and Jeffrey P. Kushan of Sidley Austin LLP and by its own David E. Korn.

Cellect is represented by Paul J. Andre, Lisa Kobialka, James R. Hannah, Jonathan Caplan and Jeffrey Price of Kramer Levin Naftalis & Frankel LLP.

The federal government is represented by Farheena Y. Rasheed, Amy J. Nelson, Kakoli Caprihan and Brian Racilla of the U.S. Patent and Trademark Office.

The case is In re: Cellect LLC, case number 22-1293, in the U.S. Court of Appeals for the Federal Circuit.

--Additional reporting by Ryan Davis. Editing by Jeremy Abrams.