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WLF Asks Federal Circuit to Keep Burden of Proof on Parties Seeking to Invalidate Patents

(Galderma Labs., L.P. v. Tolmar, Inc.)

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WASHINGTON, DC—The Washington Legal Foundation (WLF) today urged the U.S. Court of Appeals for the Federal Circuit to reconsider an erroneous decision that shifted the burden of proof in certain patent infringement cases from the alleged infringer to the patent holder. In a brief filed in support of a petition for rehearing *en banc* filed by a company holding patents on a skin care medication, WLF argues that the party challenging the validity of a patent should at all times bear the burden of demonstrating invalidity.

In December, a divided Federal Circuit panel overturned a district court decision that had upheld patents on Differin gel, a topical medication approved to treat acne. The panel held the patents invalid because it deemed the purported innovation obvious, and it faulted the district court for imposing the burden of proof on the alleged infringer. Rather, the panel held, in cases in which the alleged infringer demonstrates that “prior art” appeared to disclose the subsequently patented product, the burden must shift to the patent holder to demonstrate that the patents should not be deemed obvious. The panel concluded that the patent holder here failed to meet this burden.

In urging the full Federal Circuit to rehear the case, WLF argues that the panel erred by shifting the burden of proof to the patent holder—a shift that enabled the panel to ignore the district court’s detailed factual findings that the patents were not obvious. WLF further argues that shifting the burden is inconsistent with the well-accepted presumption that a patent issued by the U.S. Patent and Trademark Office is valid. Finally, WLF asserts that the panel decision will decrease financial incentives for improving existing products; would-be inventors will be less likely to incur the costs and risks of research necessary to win FDA approval for important step-improvements if related patents become less likely to withstand legal challenge.

Upon filing its brief, WLF issued the following statement by Chief Counsel Richard Samp: “A patent is presumed to be valid. Unless it reverses course, the Federal Circuit will have undercut that longstanding presumption by ruling that the burden of proof shifts in certain cases to the holder of a challenged patent to show that its patent remains valid, rather than requiring the alleged infringer to demonstrate invalidity.”

WLF is a public interest law and policy center that has appeared in numerous federal courts to defend intellectual property rights, such as the scope and validity of pharmaceutical patents.