

Old Compound + Known Purpose + Prior Art Concentrations = Obvious Re: IP Litigation

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Galderma Labs L.P., et al v. Tolmar, Inc.

In a split panel decision, the **U.S. Court of Appeals for the Federal Circuit** reversed a district court concluding that the claims at issue were invalid as obvious because they were directed to the use of an old compound for a known purpose in a concentration that falls squarely within a range disclosed in the prior art as preferred for that purpose. The Federal Circuit also concluded that objective considerations of non-obviousness, including teaching away, unexpected results and commercial success, did not overcome the clear and convincing evidence of obviousness based on the prior art. *Galderma Labs L.P., et al v. Tolmar, Inc.*, Case No. 2013-1034 (Fed. Cir., Dec. 11, 2013) (Prost, J.) (Newman, J., dissenting).

Galderma, a manufacturer of topical pharmaceuticals, initiated a Hatch-Waxman patent infringement suit against Tolmar which had previously filed an **Abbreviated New Drug Application (ANDA)** seeking approval from the **U.S. Food and Drug Administration (FDA)** for a 0.3 percent adapalene gel pharmaceutical product for the use in treating acne. Galderma alleged that Tolmar's proposed 0.3 percent adapalene product would infringe numerous claims of several Galderma patents. Galderma had previously marketed a 0.1 percent adapalene gel product for treating acne, Differin® 0.1 percent gel, which had been protected by prior patents that expired in 2010. Tolmar's primary defense challenged the validity of the asserted patent claims, based on obviousness.

Following an eight-day bench trial, the district court ruled that the asserted claims were not obvious and that Tolmar's proposed 0.3 percent adapalene gel product would infringe them. With respect to obviousness, the district court concluded held that Galderma's prior patents, which disclosed the use of adapalene in a preferred range of 0.01 percent to 1 percent in a topical gel for the treatment of acne and other skin diseases did not render obvious the asserted claims, which were all directed to 0.3 percent adapalene topical gel product for treating acne. The district court also found that objective considerations of non-obviousness, specifically, teaching away, unexpected results and commercial success, further supported the validity of the claimed inventions. Tolmar appealed.

Noting that "Tolmar presents an obviousness case that is both straightforward and potent," the Federal Circuit reversed the district court's conclusion that the patent claims were not obvious. The panel majority concluded that Tolmar had proven, through clear and convincing evidence, that the

asserted claims were obvious in view of Galderma's prior expired patents in combination with Galderma's data sheet for its prior Differin 0.1 percent adapalene gel product. The Federal Circuit pointed out that the district court had misapplied the law of obviousness, imposing on Tolmar evidentiary burdens (with regard to motivation to combine) that the law does not require.

The Federal Circuit also rejected the district court's rulings with respect to objective considerations of non-obviousness. In particular, the Federal Circuit found that the prior art did not teach away from using a 0.3 percent adapalene formulation for the treatment of acne, because, although the prior art may have suggested that 0.1 percent adapalene concentration was thought to be optimal at the time of the invention, the prior art did not criticize or discourage using adapalene concentrations greater than 0.1 percent. Rather, the Court concluded that any unexpected results Galderma claimed to have shown with respect to side effects were not probative to rebut the obviousness of the claimed invention because they related to differences in degree rather than differences in kind. Finally, any commercial success was of limited value because, to the extent Galderma's commercial 0.3 percent adapalene gel product was commercially successful, such success was due to Galderma's previous patents, which blocked competitors from marketing any adapalene product for the treatment of acne until they expired in 2010.

In dissent, Judge Newman acknowledged that, "without doubt, the question of obviousness here presented is a close call." Nevertheless, Judge Newman took her colleagues to task for allegedly ignoring several district court findings of fact, applying flawed procedural and substantive law and distorting the burdens and proof and production. The dissent concludes that "[i]n refusing to credit any of the demonstrated 'secondary considerations' my colleagues foreclose patentability to a vast body of improvement patents.

Practice Note: This decision should give pause to pharmaceutical companies who first secure patent protection for pharmaceutical compounds in concentrations falling within a preferred range and then, near the expiration of the patents, subsequently attempt to extend their monopoly by seeking patents for specific concentrations of the pharmaceutical compound within the preferred range.

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