



Moving From Everyday Dosing to Less Frequent Dosing is Obvious

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Plaintiffs were the holders of a New Drug Application for the administration of 40 mg/ml glatiramer acetate (GA) three times per week to treat patients with relapsing forms of multiple sclerosis. They marketed their product under the brand name COPAXONE®. Plaintiffs filed suit alleging patent infringement after several defendants submitted Abbreviated New Drug Applications seeking approval to market generic versions of COPAXONE®. After conducting a seven-day bench trial, the court held that all of the asserted patent claims were invalid as obvious.

In conducting its analysis, the court explained that obviousness “hinges on the core elements of the asserted claims: (1) a 40 mg dose of GA that is (2) administered in three subcutaneous injections over seven days with at least one day between injections.” Regarding the first element, the court found that a 40 mg dosage form of GA was explicitly disclosed in the prior art and that the prior art did not teach away from that dose. For the second element, the court noted that persons of skill in the art knew that daily GA injections were difficult to tolerate and would have been motivated to pursue less frequent dosing schedules. The court also found that the prior art taught that GA administered every other day may be as effective as daily administration. The court ultimately held that the claimed 40 mg dose amount and dosing schedule would have been “obvious to try” because “[t]he 40 mg dose...was one of two doses studied extensively” in the prior art and that “[t]here were also a finite number of days on which to administer injections considering there are only seven days in a week.” The court also considered long-felt need, failure of others, unexpected results and commercial success, but determined that none of these secondary considerations warrant a finding of nonobviousness. As to commercial success, the court acknowledged that, while there is no

dispute that COPAXONE® is a successful drug, its success was due to “aggressive pricing, promotion, and COPAXONE® brand loyalty.” The Court’s finding with respect to dosing schedule is consistent with recent precedent holding that claims directed to a once-daily treatment, as opposed to a more frequent schedule, would have been obvious. *See AstraZeneca LP v. Breath Ltd.*, 542 Fed. Appx. 971 at 979-81 (Fed. Cir. 2013); *see also Purdue Pharma Prods. L.P. v. Par Pharm. Inc.*, 377 Fed. Appx. 978 at 982-83 (Fed. Cir. 2010).

In re Copaxone Consolidated Cases, 14-cv-01171 (D. Del. Jan. 30, 2017)

Categories

Non-Obviousness

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