



## Federal Circuit Affirms Invalidity of Method Species Claims Over Prior Art Genus

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On November 10, 2015, the Federal Circuit issued its opinion in *Prometheus Laboratories, Inc. v. Roxane Laboratories, Inc. et al.*, No. 14-1634, -1635, slip op. (Fed. Cir. Nov. 10, 2015) affirming the district court's decision invalidating U.S. Patent No. 6,284,770 ("the '770 patent"). The district court found that "the elements of the '770 patent were present in the prior art, and the differences between the prior art and the claims of the '770 patent are insubstantial . . . [as] some of the prior art is virtually identical to the claimed inventions." *Id.* at 6. The district court further found that any alleged secondary considerations of non-obviousness did not overcome the *prima facie* case of obviousness. *Id.* at 6-7.

The claims of the '770 patent are directed to a method of treatment for IBS-D (diarrhea-predominant irritable bowel syndrome) utilizing the previously known active pharmaceutical ingredient, alosetron (marketed as Lotronex®). *Id.* at 2. In particular, the '770 patent claims are directed to treating women with IBS-D, who experienced symptoms, including pain, for at least six months. *Id.* at 3-4. The main prior art reference, U.S. Patent No. 5,360,800 ("the '800 patent"), described and claimed a "method of treating a condition [such as IBS] which is ameliorated by antagonism of 5-HT<sub>3</sub> receptors which comprises administering to a patient an effective amount of [alosecron]." *Id.* at 3 (quoting claim 17 of the '800 patent, and noting that claim 27 of the '800 patent specifies the treatment of IBS). The Federal Circuit, the district court, and the parties agreed that the '770 patent claims recite a species of the genus taught in the '800 patent— *i.e.*, the '770 patent recites a method of treating a narrow population suffering from IBS-D with alosetron while the '800 patent generally discloses (and even claims) a method of treating IBS with alosetron. *Id.* at 8-9.

Without getting to the obviousness-type double patenting question, in affirming the obviousness of the '770 patent claims, the Federal Circuit reaffirmed its holdings in *AbbVie Inc. v. Mathilda & Terrence Kennedy Inst. of Rheumatology Tr.*, 764 F.3d 1366 (Fed. Cir. 2014): in the context of an obviousness analysis, "if the later expiring patent is merely an obvious variation of an invention disclosed and claimed in the reference patent, the later expiring patent is invalid." *AbbVie*, 764 F.3d at 1378-79; *Prometheus*, slip op. at 14.

The Federal Circuit also was not persuaded that any alleged secondary considerations of non-obviousness overcame the *prima facie* showing of obviousness. *Id.* at 14-17. For example, the Federal Circuit agreed with the district court's conclusion that Prometheus did not show its commercial success evidence had appropriate nexus to the '770 patent claims because "the growth in revenue [since Lotronex's reintroduction into the market] is due to Prometheus's actions in marketing, increasing the price of Lotronex, and introducing a series of rebates to stimulate sales of the drug, rather than from the treatment method claimed in the '770 patent." *Id.* at 15. Likewise, the Federal Circuit agreed that any alleged long-felt-need or unexpected results were due to the known drug compound itself rather than the '770 patent's method of treatment. *Id.* at 16-17.

The *Prometheus* decision provides support to ANDA filers for invalidating method of treatment patents as obvious when the claimed method is simply a narrower variation of a method described in a prior art reference. *Prometheus* reaffirms, in part, that: (1) a claimed method species can be invalidated by the prior art genus; (2) commercial success does not support



non-obviousness when premised on marketing activities and price increases; and (3) the benefits of using a known drug compound do not support any alleged unexpected results and/or long-felt unmet need when those benefits are attributable to the drug itself and not the claimed methods of treatment.

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