

## Federal Circuit Patent Bulletin: *Prometheus Labs., Inc. v. Roxane Labs., Inc.*

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November 12, 2015

*“The genus-species distinction may have particular relevance in the field of personalized medicine, where, for example, a particular treatment may be effective with respect to one subset of patients and ineffective (and even harmful) to another subset of patients.”*

On November 10, 2015, in *Prometheus Labs., Inc. v. Roxane Labs., Inc.*, the U.S. Court of Appeals for the Federal Circuit (Dyk,\* Taranto, Hughes) affirmed the district court’s judgment that U.S. Patent No. 6,284,770, which related to a method of treatment for diarrhea-predominant irritable bowel syndrome (IBS-D) with alosetron marketed as Lotronex, was invalid for obviousness. The Federal Circuit stated:

We conclude that the asserted claims of the ‘770 patent are invalid as obvious under 35 U.S.C. § 103. A patent would have been obvious “if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.” Obviousness is based on underlying factual findings, including: (1) the level of ordinary skill in the art; (2) the scope and content of the prior art; (3) the differences between the claims and the prior art; and (4) secondary considerations of nonobviousness, such as commercial success, long-felt but unmet needs, failure of others, and unexpected results.

The primary prior art reference relied on by the district court was [U.S. Patent No.5,360,800]. In addition to the ‘800 patent, the district court relied on a number of research publications that predated the October 7, 1997, priority date of the ‘770 patent as prior art references. The district court determined, and the parties agreed, that the relevant person of ordinary skill in the art is a gastroenterologist with three years of experience. The district court also found, and Prometheus and defendants agreed, that the claims of the ‘770 patent recite a species of the genus method claimed in the ‘800 prior art patent.

The ‘800 patent claims the use of alosetron to treat patients suffering from IBS. The ‘770 patent claims treating a subset of those IBS patients—those who (1) are women (2) with IBS-D (3) who have experienced symptoms for at least six months and (4) who have had moderate pain. While the parties dispute whether the claims of the ‘770 patent operate as exclusions defining patient categories that should not be treated with alosetron, we need not decide this question. Even treating the limitations of the ‘770 claims as exclusions, we conclude

that before October 7, 1997, it would have been obvious to a person of ordinary skill to treat those sub-species claimed here.

To be sure, “[i]t is well-settled that a narrow species can be non-obvious and patent eligible despite a patent on its genus.” An “earlier disclosure of a genus does not necessarily prevent patenting a species member of the genus.” The genus-species distinction may have particular relevance in the field of personalized medicine, where, for example, a particular treatment may be effective with respect to one subset of patients and ineffective (and even harmful) to another subset of patients. Singling out a particular subset of patients for treatment (for example, patients with a particular gene) may reflect a new and useful invention that is patent eligible despite the existence of prior art or a prior art patent disclosing the treatment method to patients generally. An obviousness rejection likely would not be appropriate where the new patient subset displayed unexpected results.

But that is not the situation here. In this case, the district court’s factual findings make clear that, at the time of the ’770 patent, it would have been obvious for a person skilled in the art to have separately treated the limited subset claimed in the ’770 patent with alosetron, and that any unexpected results were attributable to factors exogenous to the ’770 patent. . . .

Here, it would have been obvious for a person having ordinary skill in the art reading the ’800 patent to treat female patients with IBS who had symptoms for at least six months and who had experienced at least moderate pain. [T]hese limitations are directed to a known type of IBS, to treating the gender that predominantly experiences IBS, to treating patients with a characteristic that is always or almost always evaluated in establishing IBS, and to assessing symptoms for a duration of time that was common in diagnosing patients with IBS. . . . The record contains abundant evidence that there was a limited number of known parameters and it would have been obvious to combine the teachings as to each parameter.