District Court Power to Enjoin Improper Use Code Is Limited

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Addressing for the first time the role of a district court to remedy an improper use code submitted to the U.S. Food and Drug Administration (FDA), the U.S. Court of Appeals for the Federal Circuit held that a federal court’s powers are limited to enjoining an improper use code and that the party is “given the opportunity to propose the specific language of the use code.” Novo Nordisk A/S et al. v. Caraco Pharmaceutical Laboratories, et. al., Case No. 10-1001 (Fed. Cir., July 30, 2012) (Rader, C.J.) (Dyk, J., concurring-in-part and dissenting in part). The decision was rendered on remand following the Supreme Court’s decision in Caraco Pharmaceutical Laboratories v. Novo Nordisk. (See IP Update, Vol. 15, No. 5.)

By way of background, the Supreme Court’s Caraco decision held that generic drug manufacturers have the right to counterclaim against a branded company to force a correction of a “use code” provided to the FDA. Use codes are submitted by the brand company to describe the scope of method claims for patents listed in the Orange Book. The FDA relies on such use codes to assess whether the generic’s proposed label would overlap with the method claims of the listed Orange Book patents.

On remand to the Federal Circuit, the Court assessed whether Novo’s current use code was correct and whether the district court erred in issuing a mandatory injunction requiring Novo to reinstate its prior use code. On the first question, the Court held that Novo’s current use code inaccurately described Novo’s patent as covering two FDA-approved methods that the patent in question admittedly did not cover.

Having so determined, the Court then examined whether the district court erred by mandating Novo to resubmit the use code and to include specific language in the prior use code to describe a specific claim of one of the patents at issue. The Federal Circuit held that the district court properly ordered Novo to correct the use code listing for the patent in question. However, the Federal Circuit held that the district court abused its discretion “in dictating the precise terms of the use code to be submitted” to the FDA. As the Court explained, it is the branded company that is “given the opportunity to propose the specific language of the use code” within the parameters of the patent’s scope as defined by the court. If the revised use code is overbroad, the district court has the power to correct the error.

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