

Appeals court affirms patent infringement rulings against Roche's peg-EPO product

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Amgen announced that the Court of Appeals for the Federal Circuit affirmed the Massachusetts District Court's decision that Roche's peg-EPO product, Mircera, infringes four Amgen patents ('868, '698, '933 and '422) relating to recombinant erythropoietin (EPO) and processes for making it. Regarding a fifth patent ('349), the Federal Circuit reversed the holding of non-infringement by the District Court and remanded that issue for a new trial allowing Amgen to show that Roche's product infringes that patent as well. The Federal Circuit also affirmed the validity of Amgen's patents except for a single issue of obviousness-type double patenting which only impacts Amgen's later expiring patents ('933, '422 and '349). The Federal Circuit remanded this issue to the District Court for further analysis.

"We are pleased with this decision," said David Scott, Amgen's senior vice president and general counsel. "The successful enforcement of intellectual property rights enables Amgen to continue to invest in truly innovative new medicines."

This decision affirms the infringement and validity on all grounds for Amgen's process patents ('868 and '698), affirms the infringement on Amgen's product patents ('933 and '422), affirms all but one validity issue which will be further reviewed by the district court on the '933, '422 and '349 patents, and allows Amgen a new trial to show infringement of the '349 patent.

The Federal Circuit left undisturbed the permanent injunction that prohibits Roche from selling its pegylated EPO product, Mircera in the United States.

Scott added, "Biotechnology innovation is complex, expensive and extremely risky. Companies and investors need appropriate intellectual property protection to justify the risk and to realize an appropriate return on investment."

Amgen discovers, develops, manufactures and delivers innovative human therapeutics. A biotechnology pioneer since 1980, Amgen was one of the first companies to realize the new science's promise by bringing safe and effective medicines from lab, to manufacturing plant, to patient.