Litigation Departments of the Year: Hale and Dorr - Navigating the Narrows

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Biogen Inc., a pioneering biotechnology company started in 1978, is fortunate to have one of the best-selling biotech-based medicines on the market, AVONEX. Introduced in 1996, the multiple sclerosis (MS) drug had sales of $760 million in 2000. The Food and Drug Administration granted it so-called orphan drug status, which gives Biogen a monopoly until 2003.

Except that another company also lays claim to that monopoly. Berlex Laboratories Inc., the American arm of Schering AG, insists that its patent broadly covers the transformation of cells from Chinese hamster ovaries to produce human interferon, which helps fill in the scleroses in the spinal nerves.

To produce the drugs, Biogen and Berlex use similar technologies. Both companies insert modified DNA molecules (one out of 166 amino acids is switched) into the hamster cell, which then makes the core ingredient, interferon. The difference between their processes rests in the delivery: Berlex inserts its DNA into the cell all at once, while Biogen sends DNA molecules in one by one to modify the cell nucleus.

Boston-based Hale and Dorr convinced a federal district court judge in Biogen's hometown, also in Boston, that it wasn't trampling on Berlex's turf. Last August, after four years of litigation, the judge cleared Biogen, contending that Berlex should have better specified the fence where its turf ended.

Biogen sighed in relief. AVONEX is the company's sole product on the market, and it accounts for the bulk of its revenue. Because the MS patient population is relatively small -- 2 million people around the world -- the disease qualifies for orphan status, a grant of special treatment for companies that are willing to make such ostensibly unprofitable drugs. Strictly speaking, AVONEX has never enjoyed a monopoly -- it has competed against Berlex's similar product, Betaseron, which the FDA had granted orphan status in 1993. The FDA deemed AVONEX substantially different from Betaseron in 1996, and approved it for sale. Unwilling to wait for administrative appeals to run their course, Berlex immediately sued Biogen for patent infringement.

The MS medication market is worth fighting over. MS patients taking either of these two treatments will likely use them for the remainder of their lives. MS also strikes more young adults than does any other orphan disease. In its suit, Berlex asked for lost profits from 1996 on, and to prevent AVONEX's sale in the future.

The clock is ticking for Biogen. After 2003, Serono S.A., which makes the leading European MS medicine, will be able to pursue AVONEX's sales.

Meanwhile, on Nov. 7, Berlex continued its challenge in the U.S. Court of Appeals for the Federal Circuit. To argue the case, Biogen again enlisted Hale and Dorr, which handles patent litigation. This session, firm lawyers will argue four cases in the Federal Circuit. Indeed, patent cases now make up 45 percent of its total litigation docket, says William Lee, who argued this one.

Lee says this case reflects the growing inclination of judges to read biotechnology patents narrowly, in response to the difficulties presented by granting rock-solid rights based on ambiguous biological science. During the oral argument, the judges seemed to suggest that Berlex would need to have done lab experiments to claim rights to more than the one DNA method that it describes in the patent's specification. "You have a system of so many unknowns and uncertainties until the work is done," said Judge Pauline Newman from the bench. "How far into the future, how broadly one can look based on the experiments that one does, is quite a troublesome issue." Lee will be paying attention. He has another biotechnology case coming up in New York federal court soon.