

ENZO AGAIN: THE FEDERAL CIRCUIT'S ABOUT-FACE

By Ari Kaplan

My grandmother once told me that I should admit when I am wrong and move on with my life. Apparently, two of the judges on the U.S. Court of Appeals for the Federal Circuit have also heard this advice. In a stunning July decision a three-judge panel unanimously reversed its own 2-to-1 April ruling in *Enzo Biochem v. Gen-Probe*. This time around Judges Alan Lourie and Sharon Prost agreed with dissenter Judge Timothy Dyk.

Gen-Probe Incorporated and a number of other companies were sued by Enzo Biochem, Inc., for patent infringement. Gen-Probe and the others countersued, claiming that Enzo's patent on a method of detecting gonorrhea was invalid because it failed to meet the written description requirement. Typically, an inventor must adequately describe an innovation in writing to demonstrate that he or she has full possession of it.

In the biotech field the written description requirement tends to cross paths with the enablement requirement, which compels an inventor to provide specific instructions on how to reproduce the invention. The instructions need to be adequate for a person "skilled in the art" to understand.

The trouble is, it is not simple to describe a genetic sequence or protein in writing. So biotech patent applicants have

sought protection based on a description of the invention's purpose along with a deposit of the material at issue in a public storage lab. This practice is consistent with past holdings of the Federal Circuit and the government's own *Manual of Patent Examining Procedure*.

Back in April, though, the three-judge panel, attempting to follow a 1997 case that established more stringent requirements for patents involving genetic material, held that depositing virtually indescribable material in a public lab did not satisfy the written description requirement. The ruling shook the IP community [see "What A Bind!" June].

Enzo filed for rehearing with the support of amicus curiae briefs from Fish & Richardson and the U.S. Department of Justice. The government argued that *Enzo* should be reconsidered because it "had the serious potential of undermining a large number of issued patents," says former U.S. patent commissioner Q. Todd Dickinson.

Upon rehearing the panel reversed itself, deciding that the written description and enablement requirements can be met by depositing vital material in a public lab. The case is now back with the district court on remand.

How often does the Federal Circuit reverse itself? According to unofficial statistics compiled by the Federal Circuit Bar Association, rehearing is only granted, either by a panel or by the entire court en banc, in only 2 percent of cases. As for reversal by a panel, "this is a complete first for the Federal Circuit in patent law," says Harold Wegner a partner at Washington, D.C.'s Foley & Lardner. He notes that the last reversal of this sort was decided by the Federal Circuit's predecessor, the Court of Customs and Patent Appeals.

Is the circuit likely to revisit cases more often? Fish & Richardson's Frank Porcelli, counsel of record for his firm's amicus brief, thinks a trend may be emerging based upon the Federal

Circuit's 1998 decision in *Nobelpharma AB v. Implant Innovations, Inc.* and its 2001 decision in *Eli Lilly v. Barr Laboratories, Inc.*

In the first case, a panel reconsidered its initial holding and modified it, vacating the original decision. In the second case, the circuit, sitting en banc, vacated a decision and sent it back to the panel, which reached the same conclusion on different grounds. These sorts of reconsiderations are more efficient than convening the entire court for oral arguments and a ruling, Porcelli says, and may become more common.

In the *Enzo* case, many biotech practitioners are pleased by the court's about-face. Says Robert Sullivan, a partner at New York's Darby & Darby: "*Enzo II* will have much less impact on biotech patent practice than *Enzo I* would have, had it not been vacated."