New Chapter in Decade Long Patent Fight Among DNA Diagnostics Leaders

By Jonathan Loeb on February 16, 2012

Enzo Life Science's U.S. Patent No. 6,992,180 entitled "Oligo- or Polynucleotides Comprising Phosphate-Moiety Labeled Nucleotides" ("the '180 patent") issued in January of 2006. The patent traces back to an application filed in June 1982. After a series of continuation applications, a June 7, 1995 filing ultimately gave rise to the '180 patent. Because it was filed just before the GATT treaty effective date, the '180 patent will expire in 2023 — 17 years from the day the patent issued and 41 years after the original patent filing.

On January 30 of this year, Enzo sued Roche, Life Sciences, and Gen-Probe in the federal district court of Delaware, alleging that certain diagnostic probe products infringe the '180 patent. In particular, Enzo asserts that Roche's HIV and hepatitis C diagnostic tests, Life Technologies' TaqMan® line of assays, and Gen-Probe's APTIMA® assays for chlamydia, gonorrhea, trichomoniasis, HPV, HIV, and hepatitis C all infringe the '180 patent.

Patent litigation among these parties is nothing new. Enzo and Roche are involved a patent suit in New York that has been ongoing since 2002. Enzo and Life Technologies are involved in a similar case that began in 2004. The New York litigation involves multiple patents, including a patent that traces back to the same June 1982 filing that the '180 patent is based on. Some of the patents asserted in both the New York and Connecticut litigations were also the focus of a 2010 Federal Circuit appellate decision, *Enzo Biochem, Inc. v. Applera Corp* (Applera is now Life Technologies). In this case, the Connecticut district court had held that certain Enzo patent claims were invalid because they were indefinite in that they described a linkage group functionally, by stating that it "does not substantially interfere" with hybridization, instead of claiming that linkage group with reference to its structure. The Federal Circuit reversed the Connecticut ruling, upholding the validity of the patents and remanding the case to the lower court. Back in Connecticut, Life Technologies has recently argued that its products do not infringe the asserted claims because its labelled linkage group ***does*** "substantially interfere" with hybridization.

The '180 patent uses the same disputed language as the patents analyzed by the Federal Circuit, requiring a purine analog or deazapurine analog that "does not substantially interfere" with hybridization. In asserting the '180 patent, Enzo may be able to avoid one validity challenge as a result of the Federal Circuit's decision; but in the end, the Delaware, New York, and Connecticut cases could all stand or fall based on whether the accused probes include a linkage group that "does not substantially interfere" with hybridization.

Thanks to Carl Gismervig for his assistance researching and drafting this post.