Industry opposes genomic legislation

A bill submitted before Congress in late March—the Genomic Research and Diagnostic Accessibility Act of 2002—would exempt from patent infringement medical practitioners (and their respective hospitals and HMOs) who perform genetic diagnostic tests based on patented gene sequences. It would also exempt researchers who use patented genetic sequences for noncommercial purposes and would require the publication of genetic sequences within 30 days of patent filing in cases in which federal funds have been used to develop the invention. The biotech industry argues that such legislation, which would effectively eradicate market exclusivity, would damage the genetic diagnostic market, inhibiting the progress of diagnostic healthcare products.

If passed, the legislation would almost certainly drive down the price of genetic testing without an immediate impact on the development of new tests—in the short term. Genetic labs have demonstrated the ability to quickly develop genetic tests using basic molecular techniques following the publication of gene sequences without the incentive of patents. For example, the genetic test for hereditary hemochromatosis, which causes severe organ damage due to iron overload, was offered by labs several months after the publication of the gene and its common mutations.

In the long term, however, the legislation will have a negative impact on private biotech funding and on the progress of diagnostic healthcare products in the decades to come, according to the Biotechnology Industry Organization (BIO; Washington, DC). According to such companies as Celera Diagnostics (Alameda, CA), Roche Diagnostics (Basel, Switzerland), and Myriad Genetics (Salt Lake City, UT), more advanced genetic diagnostic technologies are unlikely to be developed unless market exclusivity can be secured. BIO contends that the current patent system works extremely well by providing strong incentives to innovate. “Were it not for patents, these technologies would not exist in the first place,” says Lila Feisee, director of intellectual property at BIO. The legislation “is a solution looking for a problem,” she adds.

US Representatives Lynn N. Rivers (D-MI) and Dave Weldon (R-FL) introduced the legislation (HR 3967) in response to growing opposition from academics and clinicians to the exclusivity of genetic test-

ing created by the growing number of gene patents and the licensing practices surrounding them. In support of their claims, they cite Mildred Cho (Stanford University, Stanford, CA) and Jon Merz (University of Pennsylvania, Philadelphia), who have published several articles arguing that patents “have a negative impact on the cost and availability of genetic testing.” Their conclusion is based on a limited number of surveys of clinical laboratory directors who indicated that patents were one reason why certain genetic tests, like the one for hemochromatosis, were not being offered by some laboratories.

But critics argue that their work lacks credible evidence and scientific rigor. “There has been absolutely no data published that anyone wishing to be tested was being denied,” says Feisee. “On the contrary, their survey indicated that the number of

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labs offering the test actually increased following the issuance of the gene patent—suggesting availability increased.” BIO has requested Cho and Merz’s raw data, which it believes was biased by leading questions (among other things) and is in violation of Institutional Review Board guidelines.

Meanwhile, staff at cash-strapped hospitals and clinics maintain that patents increase the cost of genetic testing, making it difficult or impossible for them to offer certain tests. The American College of Medical Genetics (ACMG; Bethesda, MD), which represents nearly all certified clinical and laboratory geneticists in the US, applauds the bills for recognizing “the negative impact of gene patents on the delivery of genetic tests to the public.”

Part of the problem is the practice of exclusive licensing. A vocal supporter of the Rivers bill is pathologist Debra Leonard of the University of Pennsylvania. “Universities are the worst because they grant companies exclusive licenses to genetic testing for genes discovered by researchers at their institutions,” says Leonard. Universities and companies prefer exclusive license arrangements because they provide companies, and hence the universi-

ties, the greatest opportunity to recoup their investment in an industry with very thin profit margins.

The US Health and Human Services Secretary’s Advisory Committee on Genetic Testing is also concerned about patents covering genetic diagnostics and recommends broad non-exclusive licensing and reasonable royalties as a solution. The theory is that broad licensing would drive down the price of genetic testing by creating competition. “Reasonable royalties and mandatory broad licensing would solve the problem,” says Leonard. Although the bill before Congress does not specifically address licensing practices and royalties, the infringement exemption it advocates would effectively nullify these issues.

Although the bill would allow a university to develop a diagnostic based on any gene sequence and the use of such diagnostics freely in hospitals, the cost of developing and performing the tests are still high. Leonard admits that “reimbursement is always a problem” and that laboratories are reimbursed only a fraction of the cost of performing a test. Because royalties typically represent only about 2–10% of the cost of a test, hospitals would still need to subsidize a large percentage of the cost of developing and performing tests in-house.

But companies say that royalties are not the problem and that full reimbursement is possible if health care providers can be convinced that the savings provided by predictive diagnosis offsets the cost of testing. For example, William Hockett, vice president of corporate communications at Myriad Genetics (Salt Lake City, UT), says that by educating health care providers about the predictive benefit of its BRCA1 diagnosis it has been able to achieve a 94% reimbursement rate. This is impressive given that the BRCA1 test costs over \$2,600 owing to the stochastic nature of the mutations, which requires that the entire gene be sequenced.

Meanwhile, to determine whether the first bill is necessary, a second bill (HR 3966) directs the White House Office of Science and Technology to study the effects of genetic patenting on the innovation, cost, and availability of genomic technologies. “There has been almost no thoughtful or scholarly study of the effect of human gene patenting on either scientific progress or the overall health care system,” says Representative Rivers. The Human Genome Project has spent nearly \$100 million studying the “ethical, legal, and social implications” of the project, says Representative Rivers, yet has “funded almost nothing” concerning the implication of patents.

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