NIH May Own Gilead’s Blockbuster Hepatitis Drug Due to Misstep

Every year, the National Institutes of Health (NIH) spends billions of federal dollars on research and development of new drugs and therapies for treating and preventing serious illnesses. Drugs to combat everything from pandemic flu to cancer, pain management and chronic, debilitating diseases like hepatitis have resulted, at least in part, from NIH funding. Funding is often awarded in the form of contracts and grants to universities, pharmaceutical companies and cutting-edge life sciences companies.

NIH funding can mean the difference between success and failure for many companies. However, there can be a dark side to the federal funding rainbow: failing to comply with NIH regulations. NIH, like all other agencies, is subject to the Bayh-Dole Act (BDA), Pub.
L. 96-517, 35 U.S.C. 202, which imposes affirmative duties on funding recipients to (1) report the development of “subject inventions,” (2) formally elect to retain title to such inventions, and (3) file for patent protection of those inventions. When recipients file patent application(s), they are obligated to disclose whether their invention was federally funded. Virtually all NIH R&D grants and contracts include these obligations, and overlooking them can have disastrous consequences.

From time to time, NIH-funded R&D gives rise to blockbuster treatments like sofosbuvir, the active ingredient in Harvoni, Sovaldi, Epclusa and Vosevi – revolutionary hepatitis C drugs. Sofosbuvir-based drugs have few side effects and have so far achieved a nearly 100 percent cure rate in affected patients. Of course, that cure comes at a steep price; Harvoni, for example, costs $100,000 per patient for several rounds of treatment. These drugs, in turn, have drawn billions of dollars annually in combined sales. In 2017, Gilead reportedly earned $9.1 billion on its four products to treat hepatitis C, including Harvoni and Sovaldi.

On March 14, 2018, Knowledge Ecology International (KEI), a nonprofit organization, asked the Secretary of the Department of Health and Human Services (HHS) to investigate a failure to report NIH funding in U.S. Patent No. 7,964,580, which is listed in the FDA Orange Book for all Gilead sofosbuvir-based hepatitis C drugs. If HHS finds a failure to disclose NIH funding in the patent, KEI has further requested that the government take ownership of the patent based on the BDA’s reporting and disclosure provisions. Gilead, therefore, could be forced to forfeit its title to the patents — a boon for patients and insurance companies, and a bust for Gilead. Of course, with billions at stake, Gilead is likely to defend itself aggressively.

This is not the first time NIH has considered taking ownership of patents due to noncompliance with the BDA requirements. In Campbell Plastics v. Brownlee, 389 F.3d 1243 (Fed. Cir. 2004), the Court of Appeals for the Federal Circuit held that failure to meet the BDA’s obligations can cause a federal funding recipient to lose its patent rights, even absent any particularized harm to either the funding agency or the public. In Campbell, the federal contractor failed to disclose the “subject invention” within the requisite two-month timeframe. Campbell Plastics did not disclose its patent application to the U.S. Army until after the patent was issued and long after the specified time periods had passed. After learning of the patent, the Army determined that Campbell Plastics had forfeited title to
the patent by failing to elect title using the forms and timing the contract specified. The Federal Circuit upheld the decision, and the contractor forfeited the patent. The *Campbell* outcome cost the company dearly, and the potential for loss in Gilead’s case is much larger.

The new Gilead controversy is an important reminder that inventions resulting from federal R&D funding have significant strings attached. Many recipients assume, without confirming, that they are compliant. That high-risk assumption carries with it the very real prospect that the company could later be stripped of its patent ownership and suffer a host of associated legal and business setbacks.

Instead, each funding recipient should develop and rigorously adhere to internal policies and procedures — with appropriate training — to ensure that it timely (1) identifies subject inventions internally, (2) discloses those inventions to the funding agency, (3) formally communicates its election to retain title, and (4) discloses the source of federal funding in any patent application, all while generating the necessary written records to prove that it timely complied with the applicable BDA requirements. Internal policies and procedures should be reviewed periodically to ensure continued compliance.

Recipients should also periodically review the status of government-funded inventions, even after the funding agreement has been completed. Any identified issues should be reported at once to the funding agency to mitigate any forfeiture risk. The subsequent sale of the patent assets and inventions to a third party may not prevent the government from taking title to the invention. Accordingly, third parties interested in acquiring a government contractor should thoroughly investigate the contractor’s compliance with BDA mandates.

Internal compliance measures and periodic reviews can greatly reduce a recipient’s exposure, and companies should consult with legal counsel to ensure their policies are comprehensive and up to date. The Gilead issue illustrates the importance of implementing such measures — they may mean the difference between success and failure for federal R&D funding recipients.
Endnotes

1 The ‘580 Patent has been the subject of other battles as well. In February 2018, a federal judge in Delaware reversed a previous $2.54 billion jury verdict that resulted from a finding that Gilead’s sofosbuvir-based drugs infringed a patent owned by Idenix Pharmaceuticals Inc., a Merck subsidiary. Additionally, another nonprofit group, Initiative for Medicines, Access & Knowledge, has filed petitions with the U.S. Patent Trial and Appeal Board seeking to challenge Gilead’s Orange Book-listed patents covering Sovaldi.

2 Once notified, the government must elect to take title within 60 days. See 37 C.F.R. § 401.14(d)(1). However, proposed changes to the BDA were published in the Federal Register in November 2016 with a request for public comment. One important proposed change is the removal of the 60-day time during which the government can request title after learning of an unreported or unelected invention. Under this proposed change, if the initial disclosure and election of title requirements are not timely met, the government has the opportunity to request, at any time, title to the invention and any associated patent rights. Consequently, the title to the patent rights may be permanently clouded if the initial disclosure or election was not timely made. This proposed rule change has not yet been made final.

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