Gilead May Have Forfeited Ownership of Its Blockbuster Hepatitis Drug Patents

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The Patent and Trademark Law Amendments Act of 1980, known as the Bayh-Dole Act (BDA), Pub. L. 96-517, 35 U.S.C. 202, enables universities, nonprofit institutions and small businesses to own, patent and commercialize inventions developed with federal funding. Before the BDA, federally funded inventions had to be assigned to the federal government, which resulted in hundreds of valuable patents sitting idle as the government struggled to effectively commercialize technologies derived from federally funded research. Before the BDA’s enactment, fewer than 5 percent of the approximately 28,000 patents assigned to U.S. government agencies had been commercially licensed—the rest were left sitting on the shelf.

Since the BDA, the number of patents awarded to universities has increased substantially. A recent Biotechnology Industry Organization (BIO) study found that between 1996 and 2013, university patent licenses (to third parties) contributed $1.18 trillion to the U.S. economy and supported nearly 4 million well-paying jobs. Today, federal funding comes in many forms and can mean the difference between success and failure for many companies.

The National Institutes of Health (NIH), for example, spends billions of federal dollars annually on research and development of new drugs and therapies for treating and preventing serious illnesses. Drugs to combat everything from pandemic flu to cancer and chronic, debilitating diseases like hepatitis have resulted, at least in part, from NIH funding. From time to time, NIH-funded R&D gives rise to blockbuster treatments like sofosbuvir, the active ingredient in Harvoni®, Sovaldi®, Epclusa® and Vosevi®—Gilead’s 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 in combined sales annually—in 2017, Gilead reportedly earned $9.1 billion on its four hepatitis C products.

NIH funding is often awarded in the form of contracts and grants to universities, pharmaceutical companies and cutting-edge life sciences companies. However, there can be a dark side to the federal funding rainbow: failing to comply with the funding agency’s regulations. The NIH, like all other agencies, is subject to the BDA, 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. A subject invention is one that has been developed while performing the research activities required under the contract or grant. Importantly, when recipi-
ents file patent applications, they are obligated to disclose whether their invention was federally funded and identify the funding agency. In other words, the recipient must give developmental attribution to the federal government. Virtually all NIH R&D grants and contracts include the BDA’s obligations, and overlooking them can have potentially disastrous consequences. Recently, Gilead’s hepatitis products have become the target of an inquiry that highlights the pitfalls of the BDA’s disclosure, election and attribution obligations, and the importance of timely compliance.

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 an alleged failure to report NIH funding in U.S. Patent No. 7,964,580, which is listed in the Food and Drug Administration’s Orange Book for all Gilead sofosbuvir-based hepatitis C drugs. If HHS finds that the original funding recipient failed to provide attribution of the NIH developmental funding in the underlying patent application, KEI has further requested that the government take ownership of the patent based on the BDA’s reporting and disclosure provisions and conclude that Gilead forfeited its title to the patents—a boon for patients and insurance companies, and a bust to Gilead. Of course, with billions at stake, Gilead is likely to defend itself aggressively, as it has in other high-profile battles surrounding the ‘580 Patent.

This is not the first time a federal agency has considered taking ownership of patents due to BDA noncompliance. In Campbell Plastics v. Brownlee, 389 F.3d 1243 (Fed. Cir. 2004), the U.S. 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. Campbell Plastics received funding from the U.S. Army to develop components of an aircrew protective mask. The funding contract specified that if Campbell Plastics failed to disclose any invention developed under the contract within two months, the Army could obtain title to that invention. Campbell Plastics subsequently invented a new type of gas mask but failed to disclose the invention to the Army within the requisite timeframe. Campbell Plastics also did not disclose its patent application covering the new gas mask to the Army until after the patent was issued and long after any specified time periods in the contract 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 even greater.

Since Campbell, few courts have had occasion to consider this issue. In L-3 Communications Corp. v. Jaxon Engineering & Maintenance, Inc., 125 F. Supp. 3d 1155 (D. Colo. 2015), the defendants sought summary judgment on the grounds that the plaintiff, L-3, did not have any ownership interest in the asserted patent because the government had exercised its right to appropriate title to the patent due to the plaintiff’s failure to disclose the subject inventions in a timely manner. In that case, the Army Corps of Engineers, which provided funding that led to the patented invention, sent a letter to the plaintiff to activate “the Government’s right to appropriate title” to the patent-at-issue. The court held that the government appropriated the plaintiff’s rights in the asserted patent by sending the letter, and thus the plaintiff no longer possessed standing to bring the patent infringement claim.

It is important to note, however, that in cases in which the government has taken title to an invention, it has done so under the BDA regulations as they are embodied in the federal funding contract, not through any self-executing force of the BDA or the regulations themselves. See Bd. of Trs. of the Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc., 487 F. Supp. 2d 1099 (N.D. Cal. 2007). Accordingly, the BDA does not alter the general rule that title to a patent vests in the inventor or the designated assignee. The government must affirmatively act to establish its title and invoke forfeiture. See Cent. Admixture Pharmacy Servs., Inc. v. Advanced Cardiac Solutions, P.C., 482 F.3d 1347 (Fed. Cir. Apr. 3, 2007).

Under the current rules, the government must elect to take title within 60 days of being notified. 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 change, if the initial disclosure and election of title requirements are not timely met, the government could 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.

The latest Gilead controversy is an important reminder that inventions resulting from federal R&D funding have significant strings attached. The government’s march-in rights stemming from a recipient’s failure to commercialize a subject invention are commonly confused with the loss of title rights resulting from a recipient’s failure to comply with the BDA’s reporting, election and attribution obligations. The two are distinct and arise from different causes, but both are rooted in the recipient’s failure to meet its contractual duties related to subject inventions. 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 procedures should be reviewed periodically to ensure continued compliance. With that in mind, recipients might start with the following activities to strengthen their existing policies:

1. Subject Invention Designation: What is the internal reporting mechanism for identifying inventions developed on each federally funded project and for deter-
2. Title Election Notifications to Agency: From the date of subject invention disclosure, is there a written procedure to notify the agency of your election to retain title to the subject invention within two years?

3. Funding Disclosure in Patent Applications: Do you have a written procedure to notify patent counsel of each subject invention’s funding history?

4. Outsourcing Arrangements: For R&D efforts outsourced to small businesses, nonprofits, universities and others, do you ensure your lower-tier team members are also following the requirements of the Patent Rights clause (FAR 52.227-11)?

This list is by no means exhaustive, but it may provide a good starting point for funding recipients to ensure compliance with the BDA’s requirements. Recipients should periodically review the status of government-funded inventions, even after the funding agreement has been completed. Internal compliance measures, training 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. In addition, companies should note that 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 or a patent portfolio should thoroughly investigate the contractor’s compliance with BDA mandates.

Any questions concerning compliance with the BDA should be thoroughly examined by the recipient, with assistance from legal counsel, and if circumstances warrant, a plan should be developed to address any issues. 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.