EDITORIAL

INCENTIVE TO BE INVENTIVE

This year sees the twenty-fifth anniversary of the Bayh–Dole act in the United States, which was passed with the intention of stimulating the industrial application of academic research. That the act has had a major impact is unquestionable, but a thorough assessment of the balance of its benefits and costs, and of the role of other factors, has been lacking.

In 1980, following years of debate about the ownership of patents resulting from publicly funded research, the Bayh–Dole act was passed in the United States. Motivated in part by the belief that the lack of clearly defined property rights for academic inventions made with the aid of federal funds impeded the commercialization of these inventions, this act contained several key provisions intended to encourage technology transfer from academia to industry.

First, it was clearly stated that universities could retain title to inventions developed with the aid of federal funding. Second, a uniform federal patent policy was established, simplifying the previous complex procedures by which US universities obtained patents related to such inventions. And third, universities were encouraged to collaborate with companies to promote the utilization of inventions arising from federal funding.

By giving academic inventors a stake in the commercial success of early-stage inventions, the act created incentives for them to become involved in their development and commercialization, and thereby facilitated technology transfer. And so successful has the act been in this respect that it is widely viewed as the crucial catalyst to unlocking the potential of inventions made in academia with the help of federal funds.

However, although it is indisputable that many major US universities have prioritized licensing intellectual property and technology, and in some cases made it a significant source of revenue, hard evidence on the extent to which the Bayh–Dole act is directly responsible for these changes is thin on the ground. Furthermore, while extolling the necessity of patenting and licensing to facilitate academia–industry interactions and technology transfer, proponents of the Bayh–Dole act have tended to overlook the potential risks it poses for US universities and the academic research enterprise as a whole.

A major risk highlighted by critics of the act is that university patenting and licensing have led to greater levels of secrecy and less sharing of early results. Indeed, the lack of distinction in the Bayh–Dole act between inventions that are likely to lead directly to commercial applications and those that just represent scientific advances that enable further studies may have encouraged the patenting of research tools to keep open the possibility of future profits, which could potentially impede research in the long-term. In addition, cases in which institutions have obtained broad patents derived from the Bayh–Dole act — in particular on fundamental discoveries in the life sciences — have led to attempts to obtain substantial compensation after a product has been marketed.

A well-known case is the dispute about a patent on the NF-κb signalling pathway based on discoveries made through federally funded research at the Massachusetts Institute of Technology. Under the provisions of the Bayh–Dole act, the technology was licensed exclusively to Ariad Pharmaceuticals and, when the patent issued, Ariad filed a suit against Eli Lilly claiming that two Lilly drugs that work by inhibiting NF-κb activity infringed the patent, even though these had been developed without the benefit of the patent. Critics of the act cite this as an example of the sort of broad technology that would have been best left unpatented or licensed non-exclusively.

Despite such problems, the successes of the Bayh–Dole act have led to more and more countries seeking to emulate it. However, such attempts are being made without a full understanding of the importance of the influence of the act on the surge in university patenting and licensing in the United States in the past quarter century. Other factors, including the long-standing relationship between US universities and industry, the general shift towards stronger intellectual property rights in the United States over this period, and the major advances in biomedical science, have also had a role, but to what extent? Future decisions related to the appropriate design of licensing policies for universities engaged in patenting of inventions would benefit greatly from a thorough analysis of the contribution of such factors to the benefits of the Bayh–Dole act, and also of the costs to academic research, in order to maximize societial benefits from publicly funded research.