Lessons from the Commercialization of the Cohen-Boyer Patents: The Stanford University Licensing Program

MARYANN P. FELDMAN, *Miller Distinguished Professor in Higher Education, Institute of Higher Education, University of Georgia, U.S.A.*
ALESSANDRA COLAIANNI, *Center for Genome Ethics, Law, and Policy, Duke University, U.S.A.*
CONNIE KANG LIU, *Joseph L. Rotman School of Management, University of Toronto, Canada*

ABSTRACT

The Cohen-Boyer licensing program, by any variety of metrics, was widely successful. Recombinant DNA (rDNA) products provided a new technology platform for a range of industries, resulting in over US$35 billion in sales for an estimated 2,442 new products. Over the duration of the life of the patents (they expired in December 1997), the technology was licensed to 468 companies, many of them fledgling biotech companies who used the licenses to establish their legitimacy. Over the 25 years of the licensing program, Stanford and the University of California system accrued US$255 million in licensing revenues (to the end of 2001), much of which was subsequently invested in research and research infrastructure. In many ways, Stanford's management of the Cohen-Boyer patents has become the gold standard for university technology licensing. Stanford made pragmatic decisions and was flexible, adapting its licensing strategies as circumstances changed.

1. INTRODUCTION

The licensing of the Cohen-Boyer patents by Stanford University represents one of the most successful university technology licenses. The discovery covers the technique of recombinant DNA and allows for the useful manipulation of genetic material. Examining Stanford's licensing of the intellectual property is best understood in context and as part of the university's larger strategy. Moreover, designing and setting up the licensing program involved uncharted territory at that time. The first patent issued on December 2, 1980, after 6 years under review at the U.S. Patent and Trademark Office: the original application was filed in November 1974. This date was two weeks before the effective date of the Bayh-Dole Act, which assigned intellectual property (IP) rights over faculty discoveries from federally funded research to universities and emphasized the university's responsibility for commercialization.[1] The intention was to provide a means for economic growth, technological change, and enhanced U.S. competitiveness.

The Cohen and Boyer's discovery provided tools for genetic engineering and was the subject of controversy that led to a lively public debate during the decade of the 1970s. Sally Smith Hughes documents Cohen and Boyer's scientific discovery, Stanford's decision to pursue patents, and the public controversies surrounding recombinant DNA.[2] The debate was symbolically resolved with the June 1980 U.S. Supreme Court ruling on *Diamond v Chakrabarty*, a landmark 5–4 decision, which made the patenting of life forms possible with the Court's oft-quoted clause, "*anything under the sun, that is made by man*." This decision cleared the way for the Cohen-Boyer application, which covered a fundamental technique, with the potential to become a platform technology that essentially led to a new paradigm in biotech research.

Feldman MP, A Colaianni and C Liu. 2007. Lessons from the Commercialization of the Cohen-Boyer Patents: The Stanford University Licensing Program. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

Of course, once the patent was granted, Stanford University, as the assignee, was required to design a licensing program that would be consistent with the public-service mission of the university and provide sufficient incentives for private industry to invest the requisite resources to bring products to market while producing revenue for the university. Feldman, Colaianni and Liu[3] detail the history of Stanford's licensing program, focusing on the process and the logic that guided the commercialization regime. Given the early controversy surrounding the Cohen-Boyer patent, the eventual success required a great deal of creativity, strategy, and persistence. Certainly, the professionals involved all contributed to the success, from Donald Kennedy, then president of Stanford, Robert Rosenzweig, then vice president for public affairs, Nils Reimer, founding director of the Stanford Office of Technology Licensing (OTL) to Katherine Ku, then licensing associate and current director of the OTL.

The purpose of this chapter is to summarize lessons learned from Stanford's design and implementation of the Cohen-Boyer licensing program. Many universities attempt to emulate Stanford University's success at technology transfer; however, there is a limited appreciation for the high degree of creativity and adaptability of the Stanford Office of Technology and Licensing (OTL) in setting up its licensing program and making the myriad decisions that guided the ultimate outcome. In spite of many obstacles, Stanford University pursued the recombinant DNA patents and designed a strategy that met the public-service goals of the university by broadly licensing the technology; provided incentives for private companies to commercialize derivative products; and contributed to the creation of an innovation system that benefited Silicon Valley and reached across the American economy.

2. A LIST OF LESSONS LEARNED FROM COHEN-BOYER

2.1 *Keep wider university goals in mind*

Despite the economic success of the licensing program, profit was not the primary motive. Stanford University had four goals that guided the development of the Cohen-Boyer license:

- to be consistent with the public-service ideals of the university
- to provide the appropriate incentives in order that genetic engineering technology could be commercialized for public benefit in an adequate and timely manner
- to manage the technology in order to minimize the potential for biohazard
- to provide income for educational and research purposes

Robert Rosenzweig, vice president for public affairs at Stanford, in a 1976 open letter addressed to "*Those Interested in Recombinant DNA,*" wrote "*It is a fact that the financing of private universities is more difficult now than at any time in recent memory and that the most likely prediction for the future is that a hard struggle will be required to maintain their quality.*" As a result of these financial concerns, he concluded, "*we cannot lightly discard the possibility of significant income that is derived from activity that is legal, ethical, and not destructive of the values of the institution.*"

The balance of financial objectives against other goals is further demonstrated when Stanford decided not to pursue extending the patent life. The original 1974 patent application had claimed both the process of making recombinant DNA and any products that resulted from using that method. These applications were subsequently divided into the process patent and two divisional product applications: one claimed recombinant DNA products produced in prokaryotic cells and the other claimed the products in eukaryotic cells. Stanford filed a terminal disclaimer, which meant that all subsequent applications claiming recombinant DNA, regardless of how long the patent prosecution process took, would expire on December 2, 1997—the same date as the original 1980 patent.[4] In effect, Stanford agreed to give up royalty rights on the life of the subsequent patents (issued in 1984 and 1988) that would have extended past the original patent's expiration date. This limited Stanford's collection of royalties because of the time delay inherent in commercialization, especially of pharmaceutical

products. Stanford honored its obligation to the licensees with the realization that, as Kathy Ku wrote at the time "*...it would not be good public policy or public relations if we were to ask for or even get such an extension.*"

Stanford did not require other nonprofit research institutions to take a license in order to use the technology. Niels Reimers and Kathy Ku report that the thought of licensing the technology out to other nonprofit research institutions had never entered into discussions about the licensing program. This licensing practice established a research exemption, or research-use exemption, which is consistent with the norms of open science,[5] and stands in contrast to recent developments in research-use exemption policies, such as *Duke v. Madey* and the WARF stem-cell licensing program.[6]

To summarize, engaging in commercial activity encourages higher education institutions to act like for-profit entities. Intellectual property has no value unless it is defended. Stanford set up a litigation reserve fund that provides a credible threat of enforcement of the license. Despite several attempts to withhold payments from a variety of large and small companies plus one attorney who made challenges to the patents a "hobby," Stanford was able to settle these disputes informally and without formal litigation. This stands in contrast to the recent upswing in litigation by U.S. universities, including a recent law suit filed by the University of Alabama to prevent an artist from using the universities athletic colors.

2.2 *Consult widely to build consensus*

While intellectual property typically involves limited disclosure, Stanford University engaged in a pattern of consulting widely across various stakeholders to achieve consensus and to ensure that its actions were supported. For example, Rosenzweig worked to achieve consensus with both the faculty and the National Institutes of Health (NIH) as the sponsoring agency. In a 1976 open letter, he asked the faculty to comment on whether the university should proceed with the patent process. Rosenzweig also sent a letter to Donald Fredrickson, NIH director, asking his opinion on patenting the Cohen-Boyer discovery and enclosed a copy of the memorandum sent to faculty. Fredrickson responded by sending a mass mailing to "a broad range of individuals and institutions," asking them for their comments on the patent question.[7] Fredrickson's letter laid out five possible alternatives that NIH could take regarding recombinant DNA patenting and subsequent licensing: In response, Fredrickson received approximately 50 letters.

A compromise consensus emerged from among a list that Frederickson generated that Stanford should be able to patent recombinant DNA research but with nonexclusive licensing. A nonexclusive license ran counter to economic logic, contrary to the subsequent preferences articulated in the Bayh-Dole, Act and ignored petitions from Genentech and Cetus who stood to gain from exclusive licenses. The logic was that rDNA was a platform technology and that any one company could not exploit all the possible applications. Broad nonexclusive licensing not only contributed to the economic success of the patents but also created a population of companies who drove the technology forward.

There are other instances when Stanford sought transparency that was consistent with the actions of a university. While applicants generally keep patent applications secret from the date they are filed until they are granted and therefore protected, Stanford opened the patent prosecution file to the public. This was an unusual move that was consistent with reducing subsequent questions about the technology and was also consistent with the public mission of the university.

Stanford engaged in an open process that attempted to build consensus across a wide range of stakeholders. While the university did stand to profit from the licensing program, their actions were consistent with the university's larger and more traditional societal goals.

2.3 *Don't behave opportunistically*

The most successful university technology transfer involves relationships that develop over time. Signing a licensing agreement represents a transaction that is a first step in a relationship that requires maintenance and oversight. Each licensee received an annual letter from the Stanford OTL.

That went a long way in establishing long-term relationships and encouraging dialogue.

When Stanford initiated its licensing program, no precedent existed for specific licensing terms of the IP. Keeping with its practice of consulting widely and building consensus, Stanford interviewed a variety of companies representing different markets when the license terms, particularly the royalty rates on end products, were being formulated. Through this effort, licenses were pre-sold and unrealistic terms were avoided. To make the licensing process easier, the OTL took great pains to categorize the different potential recombinant DNA products and to offer appropriate royalty rates. In the end, the OTL settled on four different product categories: basic genetic products, bulk products, end products, and process improvement products. By scaling the rates to reflect the visibility of the licensee's product and the expected revenue from each license, the OTL encouraged compliance. A graduated royalty system ensured that smaller companies weren't penalized with low sales volume.

Stanford made pragmatic decisions about pricing its intellectual property and kept the annual fees and royalty rates reasonable. While this might have reflected a strategy to deal with some of the weaknesses with the patent, the university could have been greedy and pursued higher rates. Nils Reimers recalled at least one alumnus writing, "*You've got a patent; you can dominate everything here. Why are you charging such a low royalty? You know Stanford could use the money. Charge a higher royalty.*"[8] This advice was not taken. The rates that were chosen were selected after consultation with industry about accepted practices and did not exploit the university's monopoly position.

Furthermore, Stanford created special provisions for lower licensing fees and royalty rates for small firms in 1989. At this time, 209 fledging biotech firms, most of them in the San Francisco Bay Area, signed licensing agreements.

2.4 *Be flexible and experiment*

Over the 17 years of the licensing program Stanford experimented with five versions of the standard license agreements and provided three special licensing agreements. A total of 468 companies licensed the Cohen-Boyer technology. Licensing the patents was very much a learning process that balanced the capabilities of companies, especially in the embryonic biotech industry, with the economic potential of the technology. Ku later noted, "*Stanford was trying to license an invention for which products had never been sold and which would apply to many diverse, established industries, in addition to the newly emerging biotechnology industry.*"[9] Table 1 summarizes the various licensing regimes and the number of companies that signed up under each version. Certainly the economic impact would have been less without this flexibility and adjustments.

The first version of the license provided two incentives to encourage companies to sign up. Remember that the technology was already in the public domain through publication and that the open patent files and companies were already using rDNA. It was not clear that companies would comply with the terms. The first incentive for companies to take a license in 1981 was a credit toward future royalties over the first five years, up to a total of US$300,000. The second incentive came when companies were advised that the licensing terms would change and encouraged them to sign up early. In response to this news, 82 companies signed up. The largest share of earned royalties from product sales accrued to these firms.[10]

The first license's terms were a US$10,000 up-front fee with a minimum annual advance (MAA) of US$10,000. Earned royalty rates on products were provided on a graduated basis for bulk products, end product sales, and process improvements on existing products based on production cost savings. Under the licensing agreements, Stanford received unprecedented royalties on downstream drug sales in a stipulation known as *reach-through* licensing: Stanford received end-product royalties based on a percentage of final product sales. The Cohen-Boyer IP rights extended to all products developed using the technology. If companies did not sign a license agreement, any end products they developed that used rDNA could potentially be contested.

Table 1: Cohen-Boyer Standard Licensing Agreements History (in U.S. dollars)

Version	Effective date	Sign-up fee & minimum annual advance (MAA)	Earned-royalty rates			Number of companies signed	Revenue (share)
			End products	Bulk products	Basic genetic products and process improvements		
1	12/2/1980	Each $10,000; with special five times credit	Graduated rate: 1% (first $5M); 0.75% (next $5M); 0.5% (over $10M)	Graduated rate: 3% (first $5M); 2% (next $5M); 1% (over $10M)	10% for basic products sales; 10% of cost savings and economic benefits	73	$215,663,697 (84.66%)
2	1/1/1982	Each $10,000	Graduated rate: 1% (first $5M); 0.75% (next $5M); 0.5% (over $10M)	Graduated rate: 3% (first $5M); 2% (next $5M); 1% (over $10M)		15	$14,229,566 (5.59%)
3	8/1/1985	Each $10,000	Same as above, but started write-in	Same as above, but started write-in		10	$3,338,347 (1.31%)
4	11/1/1986	Each $10,000	1%	3%		21	$5,355,889 (2.1%)
5	9/1/1989	Each $10,000 if < 125 employees; Each $50,000 if > 125 employees	2%	6%		209	$12,120,719 (4.76%)
Alternative license	Mid-1991	No MAA	4%	6%	N/A	12	$2,630,195 (1.03%)

CONTINUED ON NEXT PAGE

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.