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Biotech in Court: A Legal Lesson on the Unity of Science

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ABSTRACT This paper examines the American legal system's reliance upon the unity of science through a close study of the testimony presented in a biotech patent trial, explicated through the context of the legal practice of patent drafting and the history of the American biotechnology industry. In order to decide whether a key patent related to the polymerase chain reaction (PCR) was invalid, the court needed to decide whether the inventing scientists had made intentional misrepresentations in the process of drafting and prosecuting the patent. I analyze the various images of science presented to the court by scientists testifying about how scientists report their experimental results in scientific publications. By setting this testimony about scientific authorship in the context of the legal understanding of patent authorship, I explain why the court was prepared to accept a universal notion of science and of the scientist that rendered unimportant any distinctions between papers and patents, or between professors and biotech scientists. This image of universal science was opposed at trial by local and specific images of sciences which have been institutionalized in industrial science throughout the 20th century, and which I argue were adopted and adapted by the American biotech industry of the 1970s to the 1990s in ways that contributed both to the trial court's finding against the patent, and to the instability of that ruling.

Keywords author, biotechnology, inventor, law, patent, PCR, unity of science

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In 1976, a postdoctoral fellow at the University of California-San Francisco, traveled across the San Francisco Bay to give a seminar – not an unusual occurrence, but Dr David Gelfand's specific destination was less usual. Rather than heading to a department at the UC-Berkeley, he was going to speak to employees of the five-year-old Cetus Corporation. The seminar was part of Cetus' courtship of Gelfand. Cetus wanted to develop a recombinant DNA division, and sought Gelfand to head this endeavor. When Gelfand, initially unenthusiastic, agreed to make the move, both Gelfand and his recruiters saw him as crossing more than just a body of water. He was making a move out of the world of academic science, and giving up his objective of running a university-based laboratory, in order to join the world of for-profit, commercial science (Rabinow, 1996: 41–44).

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Gelfand's efforts in this new world eventually earned him the only half-joking accolade of 'Biotechnology Folk Hero'.[1] In Gelfand's position at Cetus, his decisions, publications, and laboratory work were embedded in a set of legal and market realities different from those he might have encountered had he instead taken a job as a university professor. While he continued to write papers in peer-reviewed scientific journals such as *Science*, he also signed patent applications that were assigned to his employer. It was as a patentee that Gelfand returned across the bay to San Francisco in February 1999 to take the witness stand in a federal courtroom. Here, Gelfand's activities and written descriptions of his work were subjected to the crucible of high-stakes patent litigation.

In the 1980s, Cetus had been the site of development of the polymerase chain reaction, a technique for manipulation of DNA better known as 'PCR'. As told in Rabinow's (1996) ground-breaking ethnographic study, *Making PCR*, that 'simple little thing' (Mullis, 1994a: x) had spawned a business worth hundreds of millions of dollars and a Nobel Prize. It also inspired two knockdown drag-out patent wars. The first, between DuPont and Cetus,[2] culminated in a victory for Cetus in 1991 (Mullis, 1994b: 427). The second war emerged from a licensing dispute between Hoffman-LaRoche Corporation ('Roche'), the multinational corporation that had purchased PCR from Cetus in 1991 for US$300 million, and the Wisconsin-based biotech supply company Promega Corporation. Roche formally declared war by filing *Roche v. Promega* in 1992.[3] In one battle of this war, Promega claimed that a PCR patent granted jointly to Gelfand and a Cetus laboratory technician, Susanne Stoffel, was invalid.[4] Promega based its argument on allegations that Gelfand and Stoffel had made deliberate errors in the papers they submitted to the US patent office. Within patent law, such an allegation is known as committing 'fraud on the patent office'. In February 1999, Gelfand was testifying as part of Roche's effort to defeat Promega's fraud claim, preserve his patent, and protect Roche's PCR business.

Promega won this particular battle,[5] and it did so partly through denying that Gelfand had chosen a separate world of science in pursuing a professional career as a 'Biotechnology Folk Hero'. Promega presented the testimony of expert scientific witnesses who told the court how scientists behaved with regard to written reports of their research, and who judged Gelfand as a scientist who had authored a scientific publication, that is, the disputed patent. Through such testimony, Promega convinced the court that there was clear and convincing evidence that Gelfand was a fraud, and that the patent he shared with Stoffel was a flawed scientific publication, unworthy of legal recognition. The court accepted a universal notion of science and of the scientist that rendered unimportant any distinctions between papers and patents, or between professors and biotech scientists.

The concept of science and scientist which triumphed in that San Francisco courtroom is recognizable to science studies scholars as a much-derided, but still lively, version of unitary science (Gieryn, 1983: 781; Dupré, 1993: 7–9; and more generally, Rosenberg, 1994: 8–11; Galison, 1996: 3–8; Shapin, 2001: 102–06; Mercer, 2002: 140–44). What Shapin

(2005: 317) has called 'the idea of science as integral, special, even sacred in its integrity', is shown by this patent litigation to be a cherished concept not only of many of the scientists who testified, but also of the American legal system.[6] And not only is the concept of unitary science cherished in law,[7] but the deployment of this concept by a court, a truth-generating machine, highlights the real world consequences of this philosophical debate: *if* science is unitary, and all scientists operate by the same, identifiable rules of behavior, *then* the patent is invalid, and hundreds of millions of dollars of commercial sales are at risk.

The sites of interaction between science and scientists and the law and lawyers have been fruitful locations for analysis of the role of science in the modern world.[8] Shapin (2005: 317) points to science's 'unique and coherent value' as a 'normative resource' as a reason for the persistence of the concept of science as itself unique and coherent. The reliance of law on science as a normative resource has been well explicated (for example, Wynne, 1982; Jasanoff, 1990, 1995). So it is no surprise that the legal system has a stake in supporting a concept of unitary science. While the use of scientific expertise as source of judicial decision-making is part of what occurred in *Roche v. Promega*,[9] the question of the nature of science itself, and the accompanying question of the nature of the scientist, centered in this legal battle around a text, the patent (see also Cambrosio et al., 1990, generally; Miller, 2000: 6–7). A patent can be considered a law–science hybrid (Edmond, 2001: 192), a speech act (Bazerman, 1999: 104–09), a piece of property (35 U.S.C. sec. 271[a]), and finally, in the ruling of this court, a scientific publication (7 December 1999 Order; see also Szybalski, 1982: 228–29). The court applied its concept of unitary science when considering the relationship of Gelfand and Stoffel, the inventors, to the patent text. It did so in the context of the testimony of scientific experts about the practices of scientific publication (see also Biagioli, 2003: 254–55), and in the context of the legal practices of patent production, as discussed below (see also, Myers, 1995).

This particular trial illustrates the participation of the American legal system in the long history of defining and rejecting a universal science, which in part has occurred through explications of a distinction between commercial science and academic science. Boundary drawing between commercial and academic science was not a newly emergent phenomenon in the late 20th century (Gieryn, 1983: 786–87, 790), but it had been given new impetus in the last quarter of that century by the burgeoning American biotechnology industry, which brought the lure of lucre into the biological sciences (Kenney, 1986, 1998; Kevles, 1998; Krimsky, 1991, 1998; Wright, 1998). Just like scientists generally (Shapin, 2001: 102–03), the scientists in this case were not united in their support for unitary science. The warring corporations, of course, were not interested in a random sampling of scientists, but hired, at hefty hourly rates, witnesses who espoused the view favorable to their side. Promega witnesses expressed the unitary line. This view, ultimately adopted by the trial court, was of a unitary science, consisting of a shared pursuit of knowledge by all scientists under common rules, no matter where located. Roche witnesses, less successfully, advocated the disunity

of science. They claimed the significance of distinctions between scientific publications and patent applications, and between 'pure science' and commercial or industrial science. The lack of success of Roche's preferred view of science, scientists, and scientific texts as local and contingent may have been in part due to the muddled nature of its witnesses' assumptions. Gelfand was portrayed as both a new type of scientist, the biotech scientist, and as an old type, the industrial scientist. Roche witnesses and lawyers articulated each type as distinct from the academic scientist (itself a reified type), but in different ways. The biotech scientist, exemplified by the notion of a 'Biotechnology Folk Hero', was something new, distinct from a scientist working at, say, a UC-Berkeley, laboratory, and also doing something distinct from old-style industrial research. As Rabinow (1996: 57) had put it when interviewing a senior Cetus scientist, 'entering Cetus in the late seventies was not really the same thing as going to work for Du Pont'. The industrial scientist was also meaningfully distinct from the not-for-profit, curiosity-driven academic scientist. Instead, the industrial scientist was a commercial scientist, engaged in for-profit science, which could be either old-style science-based industrial research[10] or new-style genetic engineering. Neither of these disunified and localized views of science and scientists won out in this court battle.[11]

After first describing the technology at issue, and the outlines of the legal dispute, I analyze Promega's legal case, using the words of its witnesses to illustrate the notion of authorship, and thus, the image of science and scientists, that Promega chose to advocate. In order to understand the legal context for Promega's proposed image of science and of the inventing scientist, I then discuss how this court and the American patent system viewed science and patent writing both generally and within Cetus. This case study is then given some historical context by a brief consideration of the American biotech industry in the 1970s through the 1990s, including its origins, its foundation myths, and its relation to American industrial science more generally.

A Brief History of PCR

The technology at the heart of *Roche v. Promega*, PCR, was (and is) a technique for selectively amplifying a fragment of DNA from a heterogeneous collection of DNA. In the reaction, the DNA is denatured into single strands, and copied at the desired spot using specific primer fragments of DNA to initiate the creation of complementary new strands through the action of a DNA polymerase, thereby creating new double-stranded copies of the selected region. This process, in which the products of each round of synthesis serve as the templates for the next round, is repeated again, and again, and with each cycle of denaturation and copying, the collection of copies of the desired piece of DNA grows exponentially.[12] As explored by Rabinow (1996: 4–9), the flamboyant surfer-scientist, Dr Kary Mullis, has been credited with the invention of PCR.[13] Mullis received the first patent for this technique as sole inventor,[14] and he shared the Nobel Prize

in chemistry in 1993 for his PCR work. Very rapidly, scientists found uses for PCR in numerous aspects of biotechnology, as well as in forensics, diagnosis, paternity testing, and the recovery of DNA from ancient specimens (Mullis et al., 1994: 233–406; Jordan & Lynch, 1998: 775).

Mullis has repeatedly told the story of what Shapin (1999: 17) has called his 'eureka! moment on the road to Mendocino', when Mullis first conceived of the amplifying technique (for example, Mullis, 1990: 59–61; Mullis, 1994b: 430; Mullis, 1998: 1–8). Rabinow (1996) used extensive interviews with Mullis and others to tell the story of the path from Mullis' eureka moment to the commercial availability of bench-top boxes which perform PCR in silently automated fashion ('thermal cyclers'), and of the industry setting in which that transformation occurred. That story involved the first PCR patent war, *DuPont v. Cetus*. DuPont claimed that Mullis had not invented PCR, but that, in fact, PCR was previously known, and in any case obvious in light of other scientific research. In 1991, the jury rejected this argument, confirming the validity of the Mullis PCR patent, and the status of Mullis as the inventor of PCR (Mullis, 1994b: 427–29; Rabinow, 1996: 8). Soon after the verdict, Cetus, unable to sustain its corporate profitability, sold the PCR technology and patents to Roche for US$300 million, and ceased operations (Rabinow, 1996: 158). Roche not only acquired the PCR technology, but hired many of the scientists who had been working with it, including Gelfand and Stoffel.[15]

Rabinow's story ended here. His story was one of 'a fortuitous space of experimentation', of the making of PCR in the novel space of a biotechnology company in the San Francisco Bay Area in the 1980s (Rabinow, 1996: 159). It certainly appeared that PCR's story ended as well. PCR was 'made' so definitively that the intellectual property in PCR was worth millions, and the award of the Nobel Prize to Mullis was only the final sign of an established, well-recognized, significant scientific discovery. But, as Rabinow had explored, PCR was the product of a biotechnology company. As the product of a biotechnology company, PCR was designed to be profit-making. While Cetus Corporation did not manage to profit by PCR in time to save itself, PCR's success as a scientific discovery has been inseparable from its success as a commercial invention. As a commercial invention, PCR was no longer contained within Mullis' initial patent. Mullis' 'simple little thing' expanded to (according to Roche) 'more than 130 innovative US patents related to the PCR process'.[16] The trade press reported that by the year 2000, Roche was making about US$100 million per year in sales of PCR products.[17] With that kind of money at stake, no sooner did one patent war end than the next began, and the PCR story continued.[18]

A Brief History of *Taq* Polymerase

To understand the second PCR patent war, *Roche v. Promega*, it is necessary to understand that the PCR process claimed in Mullis' patent was not actually the process performed in a thermal cycler sold in the 1990s. For that process, *Taq* polymerase was crucial. *Taq* is short for *Thermus aquaticus*, a

hot springs bacterium from which the polymerase was isolated.[19] *Taq* polymerase, adapted for function in very hot water, can survive the repeated cycles of elevated temperature necessary to denature the template DNA. Without *Taq* polymerase, performing PCR required a human to stand by and add more polymerase after each denaturation step, so that the reaction could continue. As one of the Cetus employees involved in transforming Mullis' idea into a marketable product described it, the use of *Taq* polymerase 'led to the current rapid and automated procedure and transformed the reaction from a method of last resort to one of first choice' (Erlich, 1989: iii). Without *Taq* polymerase, then, there would have been no thermal cyclers, no proliferation of technology, no Nobel Prize. It was DNA polymerase that was *Science* magazine's 'Molecule of the Year' in 1989 for its spectacular use in PCR (Guyer & Koshland, 1989).

The invention of *Taq* polymerase did not consist of an eureka moment, but of the painstaking purification and characterization of native polymerase from *Thermus aquaticus*, and ultimately, the cloning and preparation of recombinant *Taq* polymerase. According to Rabinow's (1996: 128–32) research, this protein isolation chore, a key step in making PCR into a commercial product, finally fell almost by default to Gelfand, who delegated most of the experiments to Stoffel. It was Gelfand and Stoffel who filed for a patent for a 'Purified Thermostable Enzyme', and then published their results in *Science* (Saiki et al., 1988) and in the *Journal of Biological Chemistry* (Lawyer et al., 1989), along with other Cetus employees.

The *Taq* patent resulted from a series of scientific, commercial, and legal steps. As described through the trial testimony, Stoffel performed experiments. Gelfand, supervising and guiding her bench work, had conversations with Stoffel and others within and beyond Cetus about DNA polymerases generally, about thermostable polymerases in particular, and about the Cetus experiments. At Cetus' request, two outside contractors made sample batches of native *Taq* polymerase to demonstrate their readiness to be suppliers of commercial quantities of the molecule. Meanwhile, a Cetus patent attorney wrote an initial patent application, filed 22 August 1986, and then another attorney wrote a continuation-in-part application, filed 17 June 1987, adding the results of later experiments.[20]

At the patent office, the patent examiner rejected all claims in the application as anticipated by and/or obvious from previous literature. The key prior references in this case were two papers about a *Taq* polymerase, one by Chien et al. (1976) and the other by Kaledin et al. (1981). Just as DuPont had argued that earlier papers on *in vitro* DNA synthesis showed that PCR was not a new invention (Mullis, 1994b: 428–29), the examiner asserted that these papers showed that the invention claimed by Gelfand and Stoffel had already been invented by these two groups, or if these prior researchers did not have it exactly, the purified *Taq* polymerase claimed by Cetus would have been obvious to one skilled in the art, looking at these earlier papers.[21] The rejection came in an official patent office document called an 'Office Action', to which the official reply is called a 'Response', Cetus filed its Response on 6 March 1988. The examiner evidently found

the Response persuasive, and issued a 'Notice of Allowance'. The original patent specification became US Patent No. 4,889,818 on 26 December 1989.

The Patent Litigation

Nearly 10 years later, in February 1999, Roche and Promega met in federal court in San Francisco, and asked the judge to decide whether, in the process of obtaining the *Taq* polymerase patent, Gelfand and Stoffel had committed fraud on the patent office. The penalty under US patent law for fraud on the patent office is a declaration that the patent so obtained is invalid. This patent war stemmed from a license Promega had purchased from Cetus to sell *Taq* polymerase for non-PCR purposes. Roche accused Promega of selling *Taq* for PCR purposes, in violation of its license, and filed suit in October 1992. Promega counterclaimed that the *Taq* patent was invalid, which claim, if proven, would prevent Roche from enforcing its license agreement.[22] Based on pretrial motions, the court had found four material misstatements by the inventors to the patent office. The purpose of the February 1999 trial was to determine whether these misstatements, or any others, were intentional, a requisite part of a determination of fraud.[23] At the trial, held without a jury, Promega needed to show intent by the legal standard of 'clear and convincing evidence'. The misstatements that were found to be significant at trial fell into three categories:

> (1) representations regarding the difference in molecular weight between the claimed and prior art Taq enzymes; (2) representations that the inventors had performed Example VI, one of the procedures described in the specification, and that they had achieved the described results; and (3) representations concerning the comparative fidelity and template dependence of the claimed enzyme and the prior art enzymes.[24]

Promega argued that misconduct had occurred through what was said and unsaid in the patent application and the Response. According to Promega, Gelfand and Stoffel concealed experimental results, lied to the patent office, and failed to perform the needed experiments. As part of its showing of intent to defraud, Promega argued that *Taq* polymerase had been previously isolated by the Chien and Kaledin groups, as the examiner had stated in the Office Action, and that the inventors were intending to obscure their lack of inventiveness when they made their misstatements. Roche's scientific experts, and the inventors themselves, not only disputed the existence of any misstatements, but argued that the Chien and Kaledin groups had isolated only a fragment of *Taq* polymerase. The Roche witnesses testified that Gelfand and Stoffel rightfully claimed to be the first to isolate and characterize full-length *Taq* polymerase. Therefore, according to Roche's argument to the court, any misstatements were not intentional attempts to cover up a fatal flaw in the application – there was no such flaw – but simple human errors that did not change the underlying validity of the application.

Promega's Legal Strategy: Casting the Biotech Inventor as Academic Scientist

Promega's winning strategy for turning Gelfand and Stoffel into frauds was straightforward. With regard to each claimed misstatement, Promega made its argument through the testimony of academic scientists with expertise in the particular area of science. Promega sought to convince the court that the patent documents were incorrect or misleading according to the standards used in writing peer-reviewed scientific papers. Because the inventors, as scientists, knew these standards, according to Promega's argument, the violation of these standards could only have been intentional. Speaking as scientists with knowledge of how scientists operate, the experts not only testified as to what was misleading in the patent documents, but as to what standard of truthfulness, precision, and candour should be used to measure these inaccuracies.

Rather than review the scientific arguments in detail, I focus on the second step of Promega's two-step argument, the standards for judging the alleged discrepancies between the patent documents and internal Cetus documents. The expertise of the academic scientist witnesses, in both substantive science, and in standards for scientific truth-telling, was proven to the court by the traditional measures used for giving rewards to academic scientists: grants awarded, prizes received, honorary society memberships, publications, and journal editorships. And for witness after witness, once counsel for Promega had established these credentials, and led the witness through an explanation of the disparity in the patent documents, counsel then asked the witness how he would evaluate the disputed portion of the patent documents if the statement had been made in a scientific publication.

For example, Promega brought Dr Dale Mosbaugh, a professor of environmental and molecular toxicology at Oregon State University, to testify about an argument Cetus had made to the patent office about the specific activity and fidelity of its *Taq* polymerase compared with the activity of the *Taq* polymerase described in the Chien and Kaledin papers.[25] After Mosbaugh explained his opinion that Gelfand had information in his possession that showed that statements made in Cetus' Response about specific activity were incorrect, counsel for Promega asked him the following series of questions about his evaluation of the patent application, considering it as 'a scientist', 'an academic', and, finally, considering the application as a 'major scientific publication':

> *Q:* Among scientists, if a scientist had the information that you have discussed yesterday and today, would – and the statements made in – on March 6th of 1989, were made to that scientist, would that scientist have believed them to be truthful or untruthful?
>
> *Mosbaugh:* Well, I am a scientist and I would have believed that they were untruthful.
>
> *Q:* As an academic, if the information – if that statement were made in an academic context without revealing the information, what would be the conclusion in an academic context concerning Dr Gelfand's conduct?

Mosbaugh: It would be academic dishonesty.

Q: And what would be the consequence of that?

Mosbaugh: Certainly, the NIH [National Institutes of Health] and other governing bodies that oversee science have policies that dictate how scientists must operate. Because if we are going to carry on and move the envelope of science forward, one has to do this truthfully and honestly so that others can depend on the results. This is taken very seriously. I don't know what actions specifically would be taken, but they would be investigated.

Q: And if this statement were made in a publication, a scientific publication, and subsequently it was learned the data and information which you have subsequently learned from those notebooks, what would be the consequence in a major publication, a scientific publication?

Mosbaugh: I believe retraction of the information would probably be in order.[26]

Similarly, Dr Stuart Linn, a professor at UC-Berkeley, and Promega's expert witness on nuclease (as well both a former student of Promega's witness Dr Arthur Kornberg and Mosbaugh's post-doctoral advisor), was asked to use his extensive experience in policing academic misconduct to evaluate Gelfand and Stoffel as authors of statements to the patent office about the purity of the claimed *Taq* polymerase.

Q: [C]ould they [Gelfand and Stoffel] have made those statements truthfully?

Linn: No, they could not truthfully have made those statements.

Q: Now, viewed from a scientific standpoint – by the – how would these be – how would these be interpreted given the information that you now have that they either did not do them or what they did was they verified that they were wrong?

Linn: This would be interpreted under the characterization of misconduct or fraud.

Q: Why do you say that? What background do you have to make such a statement yourself?

Linn: Well, actually in the past few years I've had experience with misconduct situations in three capacities. First of all, as head of the division of biochemistry and molecular biology I'm charged with initiating or responding to claims of fraud or misconduct amongst the various members of our division, which number several hundred.

The Court: Among the what?

Linn: Various members of our division, faculty and other graduate students, post-doctorates and so forth; and we've had several instances of misconduct, which I've had to investigate. Secondly, I am the principal investigator of a training grant from the National Institutes of Health, and that training grant by the mandate of Congress necessitates that we give instruction to the trainees, these would be graduate students or post-doctoral trainees, on how to identify and how to deal with misconduct.

> And so I have the obligation of assuring that some sort of training is provided to these students and post-docs, and also I have taken part in the training myself. And, thirdly, as a journal editor, an executive editor of a journal, I've had several instances of misconduct amongst submitted manuscripts which I have had to deal with.[27]

Again, Linn spoke from 'a scientific standpoint', as a head of an academic group, as a recipient of an NIH grant, and as a journal editor experienced in reviewing manuscripts for publication. Counsel for Promega put this argument in context for the court:

> *The court:* What you're attempting to show is that the misstatements, which the court has previously found, were so far off the mark that no reputable scientist could possibly believe these things.
>
> *Counsel:* Yes, Your Honor. I mean, I would submit to you, Your Honor, there are only two possibilities whether [sic] someone does something. They deliberately intended to do it or they carelessly did it; and I think when a scientist says that another scientist would not be careless at this level, one is allowed to infer that this statement was deliberately made. As the witness has indicated, these statements are not correct.[28]

The court followed this testimony of fraud closely. A later witness, Dr Thomas Kunkel, a scientist at the National Institute for Environmental Health Sciences, evaluated Gelfand and Stoffel as if they were working in his government laboratory. Like Mosbaugh and Linn, he testified about what scientists do in scientific publications. Although he testified that he had no personal experience with scientific misconduct, based on his opinion that Gelfand and Stoffel had submitted incorrect information to the patent office with respect to the fidelity of the *Taq* polymerase, he opined that their conduct would warrant dismissal from his laboratory.[29] At the conclusion of Kunkel's testimony, the judge asked some questions to clarify 'the degree to which you hold the beliefs which you have just expressed'.[30] Finally, the judge asked: 'In your view is Dr Gelfand a fraud?' Kunkel answered, 'Yes. … And he knew better.'[31]

Through the testimony of these witnesses, Promega's attorneys based their case of fraud on the concept of science and scientists as defined by experts in the world of academic and public science, and on the rules of authorship for papers in peer-reviewed journals.[32] None of Promega's scientific witnesses claimed any expertise in the evaluation of statements made to the patent office, or discussed any experience with patenting, but their lack of patent experience was not an issue in the case. By the type of testimony it presented, Promega asked the court to consider the behaviour of academic scientists and of biotech scientists as governed by a common set of rules. Promega's argument also sought to ignore any difference between authoring a scientific paper – which Gelfand had done many times both as an academic scientist and as a biotech scientist – and authoring a patent. Promega, through its expert witnesses, described a universal notion of science, scientists, and scientific authorship that transcended

these differences.[33] To understand the favourable reception of Promega's universalizing argument by the court, it is necessary to understand the patent law's perspective on the scientist as inventor and on the process of creating the patent.

When the Biotech Scientist Becomes Inventor: Patent Law and Scientists

Throughout the 20th century, the process of obtaining a patent has forced lawyers and scientists into unusual proximity. Patent lawyers have been expected to straddle what were seen by the patent system as two separate worlds. By the 1980s, they were required to pass a patent bar examination, the only national subject-matter-specific bar examination in the USA. Before an applicant could even sit for the patent bar examination, he or she was required to have earned a bachelor's degree in science or engineering, or the equivalent.[34] As biotechnology developed as an industry, and thus into a source of clients, it became customary for patent attorneys specializing in biotech to have doctorates, as the science in this area was considered unusually complex. Roche and Promega each had at least one lawyer with a doctorate on their trial team.[35]

Even though the patent attorney was expected to be conversant with the world of the scientist, the legal system did not expect the scientist to be familiar, or even comfortable, with the patent system or the courtroom. This expected incompatibility led to books such as *Patenting in the Biological Sciences: A Practical Guide for Research Scientists in Biotechnology and the Pharmaceutical and Agrochemical Industries* (Crespi, 1982), which was published in 1982, just a few years before Gelfand and Stoffel applied for their patent. Its author, R.S. Crespi, himself a PhD and a self-described patent consultant, saw a special need to 'introduce research workers in the biological sciences to the subject of patents so that they may communicate more readily with those professionally engaged in the law and practice of patents' (Crespi, 1982: 1). Crespi noted that 'the more academically inclined researchers', including some in industry, were 'uncomfortable' with even the word 'inventor' (Crespi, 1982: 1). This discomfort, according to Crespi, was well-founded. While scientists may 'prefer to think of themselves as good scientists proceeding according to the accepted canons of science … we shall see that invention and good plain science are not the same thing' (Crespi, 1982: 1). Further, unlike the scientist, '[t]he patent is firmly based in the economic rather than the intellectual world' (Crespi, 1982: 31).[36]

This notion on the part of patent practitioners that biotech scientists are only reluctant inventors, more interested in the 'canons of science' than the commercialization of invention, was shared by the patent office, which was inclined to see all scientists, no matter where employed, as focused on 'good, plain science' and not well-suited for transforming that science into an invention through a patent. Just as Crespi assumed that biotech inventors would apply for patents through patent practitioners, and that the legal

professional would do the bulk of the work, aided by the inventor, the US patent office 'strongly recommend[ed]' that patent seekers retain the services of a patent attorney or agent.[37] As Myers' (1995) case studies exemplified, this advice was generally followed by scientists who realized their skills were not the same as those needed to draft a strong patent. This separation between patent professionals and scientists assumed a boundary. The assumed boundary divided what Crespi termed the scientific/intellectual world from the legal/economic world. Even when employed in industry, 'academically inclined researchers' concerned with the 'canons of science' were in the former realm, and their inventions and resulting patents were in the latter. According to this intellectual geography, there was a boundary between academic science and commercial invention, but the boundary did not divide science or scientists into separate categories. The person of the scientist did not cross the boundary – only his or her work did, with the help of the patent attorney to manage the passage. The scientist, a universal figure, engaged in the unitary task of 'good, plain science' guided by universal 'canons', remained always in the scientific/intellectual world, even when becoming a patentee.

Tension about Tense: Authoring a Patent

The testimony and arguments in *Roche v. Promega* underscored the contradictory notions of the patent that were embedded within this legal view of the relationship among the scientist, the invention, and the text of the patent. The patent was both an artifact of the legal/economic world, as a product of a patent attorney's translation, and a text of the scientific/intellectual world, as a document attributed to an inventing scientist. The relationship among the patent attorney, the inventor, and the patent text was particularly crucial to Promega's argument in support of two of the alleged instances of fraudulent misrepresentation. Promega pointed out two examples in the patent specification: Example V, 'Expression of Taq Polymerase', and Example VI, 'Purification'. These examples were written in the past tense. Gelfand and Stoffel, however, admitted that neither procedure had been performed by anyone at Cetus exactly as described before the examples were submitted to the patent office.[38] While Roche did its best to keep the record unclear on these points, it appeared from the testimony that even viewing the evidence in the light kindest to the Cetus scientists, Example V was a description of the best way to express recombinant *Taq* polymerase, but not the method Cetus actually had used, and Example VI was a combination of two Stoffel experiments to purify native *Taq* polymerase.

Promega, through its experts, argued that by using the past tense, Gelfand and Stoffel were stating to the patent office that they had performed these steps, which was literally untrue. Gelfand and Stoffel themselves agreed in testimony that 'scientists' only use the past tense to indicate work they had done. For example, Gelfand testified in response to questioning by Promega's counsel and the Court as follows:

> *Q:* I'm simply asking you: when you used those terms, 'was', 'were', or the like, you mean you actually did it; don't you? When you used those terms as a scientist, that's what you mean, you did it?
>
> …
>
> *The court:* The question is, Dr Gelfand, when you used the past tense as a scientist or when you use the past tense as a scientist, you mean what occurred in the past; correct? I think that's the gist of your question.
>
> …
>
> *Gelfand:* Yes, Your Honor.
>
> *The court:* Okay. That, I assume, is the way that you understand 'past tense' in your scientific work; correct?
>
> *Gelfand:* Yes, Your Honor.
>
> *The Court:* All right.
>
> …
>
> *Q:* You used the tense, the past tense, in Example 6 indicating you had done it and in a scientific publication that means you did it, it doesn't mean you hoped for it, it means you did it; doesn't it, Dr Gelfand?
>
> *Gelfand:* In a scientific publication, yes.[39]

Just as Promega's experts had testified about what scientists do in 'scientific publications', Gelfand testified about himself as a 'scientist' and about a 'scientific publication'. In order to combine use of the past tense in the patent text with Gelfand's testimony to show fraud on the patent office, Promega needed to erase the role of the patent attorney in the translation of an invention into a patent. For Gelfand's testimony about scientists and scientific publications to be damning, the court simply had to consider Gelfand and Stoffel as the scientific authors of the disputed patent examples. Patentees, yes, but scientists still. As scientific authors, writing in the past tense, and knowing these steps had not been performed as written, Gelfand and Stoffel became deliberate liars, whose actions could be categorized by the law as fraudulent.

This concept of scientists and patent authorship would appear to be contradicted by both the legal practice of drafting patents and the scientific practice of drafting papers, which were clearly different. Both Crespi (1982: 6) and Myers (1995: 58, 84, 92) pointed to the different types of professional expertise embodied in the two types of documents. Consider the 1988 *Science* paper about *Taq* polymerase, which Gelfand and Stoffel co-authored with other Cetus employees (Saiki et al., 1988). Some combination of Gelfand, Stoffel, and the other listed authors presumably wrote the paper for *Science*, and all listed scientists have been publicly credited as authors.[40] The process of writing the patent application was unclear from the trial transcript, but just as in Myers' case studies, the writing process involved patent practitioners, in addition to any participation by Gelfand and Stoffel.[41]

Unlike a scientific publication which credits only one type of contribution in the list of authors, the *Taq* patent, like any late-20th-century US patent, had a series of status identifiers on its front page. There were the 'inventors', listed in the order the applicants chose. There was the 'assignee', in this case, Cetus Corporation. A US patent of this period also named the examiner, in this case, both a primary examiner and an assistant examiner. These were the government employees who had responsibility for determining whether the application met the legal requirements of novelty, utility, and non-obviousness. Finally, the patent listed the 'attorney, agent or firm' responsible for the prosecution, and in this case, Cetus chose to list three in-house attorneys, Janet Hasak (who wrote the application), Kevin Kaster (who wrote the Response and testified at trial), and Albert Halluin (their supervisor). None of these people were referred to in the law as 'author'. Authorship thus was a very shaky category as applied to the *Taq* patent.

The details of 20th-century patent application procedure in the USA, the legal equivalent of a journal's 'instructions for authors', were contained within a mammoth and oft-revised government publication, the *Manual of Patent Examining Procedure* (MPEP). First published by the patent office in 1949, the MPEP was originally an internal document directed to patent examiners to guide them in their jobs, but became a basic guide for prosecuting attorneys and agents as well, to guide them in drafting patent applications and responding to the patent office. As Promega's expert on patent office procedures testified, the MPEP is *not* directed toward inventors.[42] The MPEP specifically provided for what were called 'prophetic examples', descriptions of methods which could be practiced, complete with the predicted results, but which had not been performed by the applicant.[43] Cetus' Examples V and VI could have been considered such prophetic examples. As prophetic examples, the examples were within the acceptable realm of behavior for patent drafting. The notion of a prophetic example, part of the legal/commercial world of the patent, had no counterpart in a scientific publication of the type described by Gelfand, Linn, Mosbaugh, and Kunkel. What did it mean, therefore, that Gelfand and Stoffel agreed that they would never use the past tense to describe an unperformed experiment in a scientific publication, or that Linn, Mosbaugh, and Kunkel felt that extreme sanctions should flow from such a misuse of tense in a scientific publication?

In the legal practice of patent authorship, as defined by the MPEP, the use of the past tense in a prophetic example is not advised. But as even Promega's patent expert testified, because the MPEP does not have the force of law, violations of its provisions are not necessarily even misconduct.[44] Promega needed to show not only misconduct, but clear and convincing evidence of intentional misconduct, resulting from material omissions or misstatements in communications with the patent office. Such use of the past tense, then, might be a minor peccadillo by a patent attorney, a violation of instructions never intended for the inventor. Or in the words of one of the Roche attorneys, 'this case can't possibly turn on the past tense'.[45] But by the rules of authorship of scientific publications, as defined by Promega's witnesses and accepted by Gelfand, describing an

experiment as performed when in fact it was not performed was impermissible, perhaps even fraudulent.

What did happen in the drafting of the *Taq* patent? While the transcripts of the trial tell us little about how the Cetus patent attorneys and scientists worked to draft the patent documents,[46] we do have an account of how an earlier Cetus inventor worked with a Cetus patent attorney. After the Mullis patent was upheld by a jury in *DuPont v. Cetus*, Mullis (1994b) wrote an account of the trial. He included a discussion of the drafting of the Mullis patent, which he described as very much a joint effort between himself and the junior Cetus patent attorney, Janet Hasak, the same attorney who later wrote the *Taq* patent application. Mullis explained that Hasak initially told him to leave the claim drafting to her, but 'as we batted sections of the draft back and forth on the computer, I prevailed in bringing a sense of my own esthetics into the document'. Mullis claimed that eventually, through his superior debating and typing skills, he wrested drafting control from Hasak, and in the process, 'I naively left the patent open to attack.' Mullis linked his aesthetic sense which he brought to authoring a patent to his experience of authoring a scientific publication: 'I was playing without a full deck, emulating an academic publication' (Mullis, 1994b: 433–34). In retrospect, after having experienced a trial over the validity of his patent, Mullis determined that his initial conflation of academic publication and patent application was a serious error (Mullis, 1994b: 434–435).

Although we do not have the inventors' account of the generation of the *Taq* patent application, Gelfand provided this general account of his interactions with Kevin Kaster, a Cetus patent attorney, with regard to the Response, making it clear that Gelfand was not the primary author:

> *Q:* And following that rejection, you attempted to – with Mr. Kaster – prepare a response to that rejection; is that right?
>
> *Gelfand:* I believe Mr. Kaster – Mr. Kaster prepared a response to the examiner's rejection.
>
> *Q:* And you aided in that because you provided data and other information to him; isn't that true?
>
> *Gelfand:* I provided input.
>
> *Q:* Yes. And you reviewed drafts of that letter as well, did you not?
>
> *Gelfand:* I don't recall reviewing drafts, but I have no reason to doubt that I may have reviewed a draft.
>
> *Q:* You are not saying today, are you, that the response of Mr. Kaster to the rejection went unreviewed by you, are you?
>
> *Gelfand:* I don't believe that I ever reviewed the final response that Mr. Kaster submitted to the patent office.
>
> *Q:* But you participated in the process from the time of the rejection until that letter went; isn't that right?

> *Gelfand:* I certainly provided input. I don't know over what period of time that was.[47]

Stoffel was even more blunt in her characterization of her participation: 'I was not involved in the writing of this document [the Response]. … I read it in the end and I signed it. But I was not participating.'[48]

The only Roche witness who testified in the authorial voice was Kaster, drafter of the Response. He called it 'my response'[49] and repeatedly used the first person singular in describing its content: 'I am reviewing', 'I point out', 'I am amending the claims'.[50] He testified as to his strategy in bringing up different matters in the Response that were not included in the amended claims, based on his understanding of patent office practice.[51] Here, he discussed a paragraph of the Response which begins 'Applicants utterly reject … ':

> *Kaster:* Basically, I'm now laying a foundation for the next point in the argument; and what I point out here is, you know, I reiterate the examiner seemed to believe that our molecular weight determination reported in the application was an anomalous molecular weight. I utterly reject that belief.
>
> I point out that – I next go to the two prior art references, and I report that Chien reports a molecular weight of 63,000 to 68,000. I report that Kaledin, et al. reports a molecular weight of 60,000 to 62,000. I then remind the examiner of the amino acid determination by analysis of DNA sequence performed by the inventors, that that indeed gave a molecular weight of over 90,000.[52]

While Kaster was drafting in the voice of the applicants (Gelfand and Stoffel), he reported that it was he himself who utterly rejected the examiner's statement. Kaster went on to testify that he added an additional argument about the Chien reference at the last minute, without showing the changes to the inventors.[53]

Roche's counsel attempted to reinsert the patent attorney into the picture, in order to make the difference between legal and scientific practice matter:

> *Counsel:* … Who wrote Example 6? You know, who put it in the past tense? Was it put in by accident? Did someone do it deliberately? Why would anybody put something in the past tense deliberately when you're trying to set forth your best mode, when you're trying to tell – set forth your best mode and protocols were sent out. There was no intent to deceive. There was no intent to hide anything. The fact that it was put in the past tense by some patent lawyer who misunderstood something? Who knows? We don't know. You know, we – that's the point. We don't know. What happened? Where is the evidence of intent? Where is it? Who did it? You know, did the patent attorney do it by accident? We don't know. They never called the patent attorney who wrote that. They had Dr. Gelfand. You know, he didn't write it. Who did?[54]

To Roche's counsel and to Gelfand, remembering his communications with Kaster, it was obvious that Gelfand was not the author of the examples at issue as he was an author of the *Science* paper, and it was also obvious

that Gelfand's acknowledgement that scientists do not describe experiments not performed in the past tense in 'scientific publications' was beside the point. A clear boundary existed in the world-view of these actors that made the declarations of Promega's experts irrelevant, and Promega's argument absurd. Yet, Promega succeeded at trial in using the standard of scientists authoring scientific publications to judge the text of the *Taq* patent, and Gelfand and Stoffel as its authors. The evidence before the court of the drafting process, the legal system's own understanding of the patent attorney as translator, the attempt by Gelfand and other Roche witnesses to separate the scientific practice of paper writing from the legal practice of patent prosecution – all this evidence was declared, not false, but legally insignificant.[55]

Promega's success in this particular instance was possible due to the deep commitment of the legal system to the notion of a unified, universal science. Like Crespi and the patent office, the court categorized all inventing scientists as scientists first and foremost, even as they became patentees. As scientists, then, they could be seen as scientific authors, and the resulting document, as a scientific publication. The patent attorney was only a translator – the truth was still a matter of science, linked to the scientist in the scientific/intellectual world, and the content of the patent document was therefore judged by those standards, rather than by the legal/commercial standards of the MPEP. Drawing upon the image of universal science, Promega was able to conjure a universal scientific author who came complete with unchanging rules of behavior to judge his or her words, whether in a peer-reviewed journal or in a patent application. The court, relying on this concept of universal author within a universal science, refused to recognize as meaningful any distinction between patent author and scientific author, as inconsistent with its conception of the unity of science. There could be no distinction between the biotechnologist, the scientist in industry, and the professor, the scientist at a university, when it came to fundamental notions of truth.

While Promega's success was possible because of the judge's comfort with and commitment to a concept of universal science, a familiar notion within American jurisprudence, it was not inevitable. As Edmond (2000) has pointed out, different judges characterize and deploy a concept of universal science differently. In the hands of another judge, the court's legal analysis might have begun by focusing on the patent document, rather than on its authors. The court might have characterized the patent as a legal/commercial document, distinct from scientific publications that existed on the other side of the boundary as scientific/intellectual documents. In this scenario, the court, while maintaining a concept of the universality of the scientist and of science, might have rejected the inclusion of a patent within the category of scientific publications, leading to the opposite outcome. Despite the continuing attempts of judges to use the unity of science as the rock upon which to build legal truth, a unitary conception of science remains as 'sand', refusing to reliably cohere over time and across courtrooms and cases.

The Industrial Scientist, the Professor, and Founding Myths of Biotechnology

The way in which the *Roche v. Promega* court chose to deploy a conception of the unity of science in this case was influenced by the type of commercial science under consideration. The conflation of authors of scientific papers and commercial patents may have ignored a boundary that Cetus' scientists took for granted, but it was aided by Cetus itself, as part of the general culture of the American biotech industry. Rabinow's (1996) description of the 'fortuitous space of experimentation' in which Cetus and its employees operated is in part a description of the way the new biotech companies positioned themselves with respect to preexisting notions of industrial science and longstanding ideas of 'pure' academic science. The legal system was not the only site of conflation of biotech and academic scientists. The American biotech companies of the 1970s to 1990s and their hires considered themselves part of a universal science that included the academy.

This position, part of the founding mythology of contemporary biotech, was well explained in a 1995 book about biotechnology, *The Golden Helix: Inside Biotech Ventures* (Kornberg, (2002) [1995]). Its author, Dr Arthur Kornberg, a Nobel-Prize-winning enzymologist and founder of the biochemistry department at Stanford University, was called as Promega's first witness at trial to provide a tutorial on DNA polymerases for the court, and to lend his considerable prestige as a Nobel laureate and prominent polymerase researcher to Promega's case.[56] In *The Golden Helix*, he describes in detail how he and other academic scientists at first 'shunned all commercial connections', but when they became convinced that certain companies could permit them to do 'basic research' and 'maintain adherence to academic standards', they were willing to cross what he portrays as the clear and longstanding boundary between the academy and industry to take advantage of industry resources and assist in the disease-fighting work of drug development (Kornberg, 2002 [1995]: ix, 3).

The advantages of biotech, according to Kornberg's account, as well as Rabinow's interviewees, were that biotech offered an environment which was like the university, only more so. The participants defined the characteristics of 'real' science as those that were shared by both environments. More time was available for benchwork, with the work of teaching and committees left behind. More collaborative work was possible, without the balkanization of departments and the individualistic approach forced on academic scientists by the grant awarding system and the tenure process (Rabinow, 1996: 26–31; 107). The biotech industry in this period consciously relied upon the conflation of its research employees with academic scientists, linked by similar modes of research – what Kornberg called 'academic standards' – in order to recruit its researchers. In this universalized image of science, there were not separate industrial, commercial, private sciences and academic, non-commercial, public sciences, but something transcendent, 'science', which was assumed to occur both at universities and in biotech.

Just as, then, the legal system supported Promega's universalization of the academic scientist, the biotech industry, Cetus included, supported this move with its characterization of itself as a 'space of experimentation' in which 'academic standards' were maintained and academic prestige was valued. Yet while this image of science was firmly embedded in the founding mythology of late-20th-century American biotech, it was not the only image of science maintained by participants in this industry. Roche lawyers and witnesses articulated a different image of science to the court. While Cetus may have benefited from a belief that 'academic standards' applied to its scientists, in this trial, Roche needed to claim the meaningful, real distinctions between Promega's academic witnesses and Cetus employees. Roche strove to show that when Gelfand and Stoffel picked up the *Taq* polymerase project, they were not interested first and foremost in what Kornberg saw as the hallmark of the scientist: 'the pursuit of curiosity about the basic facts of nature' (Kornberg, 2002 [1995]: 7). Instead, they wanted to get PCR to work in a commercially viable manner. If the purified *Taq* polymerase worked in PCR, then *Taq* polymerase could become a vital piece of PCR as a product. The next goal was getting *Taq* polymerase production up to commercial quantities as quickly as possible, which they approached by cloning the gene, expressing it in *E. coli*, and developing a purification process for the now recombinant enzyme. The process by which this science was being done at Cetus, Roche therefore argued, was different than the process by which it would have proceeded in a university laboratory, where the goal might have been articulated as getting enough data to write a paper or finish a dissertation (see Rabinow, 1996: 25–26).

There was a whole group of scientists at Cetus who were doing product development, some of whom were trying to get PCR working in a reliable benchtop way. One testified: 'What happened was that I started to do optimization on PCR because they wanted to sell this product; and at the point I got involved with it, it was having a lot of problems.'[57] Cetus needed to 'get it to start working'.[58] Thus, when Gelfand was asked at trial why he did not replicate earlier experiments, he answered from a product development perspective:

> *Gelfand:* Nothing prevented us [from replicating earlier work] other than the desire to move ahead, move along, develop – learn about the enzyme and make a lot more of it rather than, in my view at the time, reproduce an artifact.[59]

Cetus, the for-profit corporation, needed customers and sales. As Cetus' then-president, Ron Cape, had said in 1981: '[B]y far the most important thing to us is how to commercialize the science. … It is delightful for us to have businesses based on science that is truly of Nobel Prize-winning caliber. But that is not enough' (Cape, 1982: 141).

Before this trial, Gelfand had described himself to Rabinow as quite a different animal than an academic scientist: 'I have great admiration and

respect for academic science. The things that I was interested in doing, I would not be able to do as well in an academic setting as I would in a corporate position. … It's very difficult, as an academic scientist, to do interactionist, collaborative science' (Rabinow, 1996: 44). In his own mind, Gelfand was no longer an academic scientist. He was a different sort of scientist, engaged in a distinct type of science. In so designating themselves and their work as specific to a commercial environment, Gelfand and his colleagues drew upon an image of 'industrial science' that preceded the founding myths of biotech.

Industrial science in the USA has existed since at least the turn of the 20th century (Reich, 1985; Dennis, 1987; Hounshell & Smith, 1988). The formation of the role of the industrial scientist coincided with line-drawing pronouncements of academic scientists separating themselves from these new scientists, most famously that of Professor Henry Rowland. Rowland, a physicist at the recently established Johns Hopkins University, gave an address to the American Association for the Advancement of Science in 1883 titled 'A Plea for Pure Science', in which he argued for the virtues of academic science as distinct from industrial science, describing a world in which these separate sciences should both exist.[60] This plea was being repeated by both academic scientists and biotech scientists in the 1980s (for example, Carey, 1982: 151–53; Yamamoto, 1982: 195–96).

Gelfand, both in interviews with Rabinow and at trial, was engaged in this type of separation of sciences, which has not been limited to the 20th century, to bioscience, nor to the USA.[61] In this intellectual geography, science and scientists do exist in both the scientific/intellectual world, now recast as the 'pure' or academic world, and in the legal/commercial world, now recast as also industrial and private. Perhaps unique to American biotech of this period, however, Gelfand and other participants did not definitely choose one geography over another. Gelfand in 1986, when he was inventing *Taq* polymerase, was participating in two imaginings of science, the universal and the particular. As a biotech scientist, he continued his engagement in real, universal science in this new location, able to do and publish basic research in the most prestigious peer-reviewed journals. Certainly, the editors of *Science* could identify 'real' science when it was offered to them in manuscript. Yet, as a biotech scientist, Gelfand was also an industrial scientist, an inventor committed to commercially successful production of commercially successful enzymes, engaged in locally specific, distinctly practiced, industrial research.

Conclusion

The trial court's decision in *Roche v. Promega* did not travel easily beyond the San Francisco courtroom. It was overturned in part on appeal,[62] it was contradicted by European patent law decisions,[63] and it was never accepted by Roche or the Cetus participants.[64] Promega continued to sell *Taq* polymerase, and the parties battled on before finally announcing a confidential settlement of all cases worldwide in September 2005.[65] While arguing that

the trial judge's opinion was coherent given the legal system's and particularly, the patent system's, view of science and scientists, I do not claim that his decision was correct or incorrect in any absolute sense, nor that it was evidence of any coherent legal concept of the unity of science.[66] The weakness of the decision is also correlated with the strength of the alternative images of science and scientists which Roche lawyers presented at trial.[67]

The historical context for this litigation includes both more than a century of boundary-work between the academy and industry, institutionalizing a notion of disunified science, and what I have termed a founding mythology of biotech, as so akin in its science to academic science that scientists in both locations are engaged in an identifiable universal activity, 'science', The American biotech industry of this period uniquely based itself on these two sets of images of science, with incompatible consequences for the *Taq* polymerase patent, a text designed to move science from the bench to the retail catalogue. Despite this particular judge's refusal to acknowledge any taken-for-granted boundary between scientific publications and patents, or between professors and industrial scientists, both aspects of this history continue, expressed in the individual biographies and self-definitions of biological (and other high tech) scientists (Shapin, forthcoming).

The articulation of boundaries between types of science will continue to be useful, even as it remains unresolvable whether such boundaries can or should be declared natural and real, in the truth-telling systems of either the law or science. Consider Promega Corporation. Promega, as a for-profit company, made strategic decisions in this trial. It built on the founding mythology of biotech, and universal images of science and scientists in the patent law, to carry the notion of 'academic standards' to a logical conclusion, aiding its business goals with regard to *Taq* polymerase. But Promega presumably does not want its own scientists to author patents unaided as if they were authoring papers. The simple syllogism by which biotech scientists are considered indistinguishable from academic scientists, and therefore, authors of patents who are to be judged by the same rules as authors of scientific papers, was helpful to Promega in this case, and also may be generally helpful in recruiting highly qualified scientists, but it is potentially disastrous in the courtroom the next time Promega is defending one of its own patents.

As Gieryn (1983: 787) has noted, the tension between basic and applied research is 'unyielding'. I would add that in American biotech start-ups in the 1970s to 1990s, the tension between universal and local notions of science was also unyielding. Choosing an image of science within which to define the biotech scientist was a local, constantly changing way of presenting a particular industry at a particular moment in time, and of justifying career decisions amidst a newly forming set of options. It also was a choice with worldly consequences. Both sets of tensions were exposed when the creation of a patent, the sine qua non of profitable biotech, became a legal matter, revealing in the courtroom the continuing strengths and weaknesses of unitary science.

Notes

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1. *Hoffman-La Roche, Inc. et al. v. Promega Corporation*, N.D. Cal., No. C 93-1748 VRW Transcript (hereafter 'Transcript'): 550–1.
2. *E.I. du Pont de Nemours & Co. v. Cetus Corporation*, N.D. Cal., No. C 89-2860 MHP (hereafter *DuPont v. Cetus)*.
3. *Hoffman-La Roche, Inc. et al. v. Promega Corporation,* N.D. Cal., No. C 93-1748 VRW (hereafter '*Roche v. Promega*').
4. David H. Gelfand and Susanne Stoffel, 'Purified Thermostable Enzyme', U.S. Patent No. 4,889,818, issued 26 December 1989 (the '*Taq* patent').
5. Promega's victory was announced in the court's 7 December 1999 Order, 1999 WL 1797330 (N.D. Cal.).
6. For a discussion of the recent iteration of universal science by the US Supreme Court in the context of certifying scientific experts, see Edmond & Mercer (2002: 310–16, 331–32).
7. While the American legal system cherishes this concept, judges are unable to choose a single definition of a unitary, universal science (Edmond 2000: 216–17). In this embrace of multiple versions of universality, legal professionals are similar to scientists themselves (Shapin, 2001: 104–05).
8. These same sites have been equally fruitful for explicating the '"seamless web" between scientific and nonscientific forms of knowledge' (Edmond, 2001: 192).
9. For science studies scholarship on the use of scientific expertise by the law, see, for example, Wynne (1989), Jasanoff (1995), Edmond (2000), Edmond & Mercer (2004).
10. For descriptions of this 'old-style', see Reich (1985) and Hounshell & Smith (1988), the latter of which addresses DuPont research explicitly.
11. For an articulation of the distinction between academic science and commercial science in the early 20th century, see Veblen ([1918]: 3–5), and for its appearance in an earlier biotech patent litigation, see Cambrosio et al. (1990: 281).
12. For a more technical description see Mullis et al. (1986) and Erlich (1989: 1).
13. See Mullis (1998) for the self-image Mullis presented, and Shapin (1999) for an analysis of that image.
14. Kary B. Mullis, 'Process for Amplifying Nucleic Acid Sequences', U.S. Patent No. 4,683,202, issued 29 July 1987.
15. The actions described at the *Roche v. Promega* trial occurred at Cetus, and involved Cetus employees. The images of the biotech scientist at issue were those of the Cetus employees, and thus of biotech scientists. At the time of trial, however, many of those same people were Roche employees, and the legal strategy was directed by Roche. Roche, as a multinational pharmaceutical company, is not a biotech company in the sense that Cetus was in the 1980s. For a discussion of the relationship between biotech start-ups and multinationals in the 1980s, see Kenney (1986: 190–216). Roche's corporate structure and its move into biotechnology are discussed by Chandler (2005: 242–45). Note that after the sale of PCR to Roche, Chiron Corporation bought the remainder of Cetus (Rabinow, 1996: 158).
16. Roche website, at <www.roche-diagnostics.com/ba_rmd/pcr_jounalists_vs.html>, accessed on 20 May 2004.
17. Contans (2001: 21). Dr Thomas White of Celera Corporation, formerly of Roche and Cetus, estimates that this number is closer to US$500 million when both diagnostic and research products are included (personal communication with the author).

18. For other ways the PCR story continued, see Jordan & Lynch (1998).
19. *Thermus aquaticus* was originally identified based on a sample taken from Yellowstone National Park, causing some controversy about the corporate use of national resources (Robbins, 1997: F3).
20. *Taq* patent.
21. The content of the Office Action is described in *Hoffman-LaRoche, Inc v. Promega Corp.*, 323 F.3d 1354, 1358 (Fed. Cir. 2003).
22. *Hoffman-LaRoche, Inc v. Promega Corp.*, 33 U.S.P.Q.2d 1641, 1642, 1649 (N.D. Cal. 1994).
23. 323 F.3d at 1359.
24. 323 F. 3d at 1359–60. Note that it was never suggested at trial that there were any misstatements in Gelfand and Stoffel's reporting of their experimental results in Lawyer et al. (1989) or Saiki et al. (1988). The question of fraud was limited to the legal category of 'fraud on the patent office', and did not include general allegations of scientific fraud such as discussed in Kevles (1995).
25. See 323 F. 3d at 1365 for a summary of part of Mosbaugh's testimony. On this point, as on each other point at issue, Roche produced testimony from its own academically credentialed scientist-witnesses supporting the statements made in the patent as correct and accurate based on the data known to the inventors at the time. This paper by no means reviews the complete testimony on either side, nor do I claim to give equal time to the arguments of each side.
26. Transcript: 587–88. Note that court reporters follow a convention for recording testimony that generally uses 'Q' and 'A' without identifying the speaker. In this paper, I include the speaker's name or role when useful for understanding.
27. Transcript: 976–77.
28. Transcript: 871–72.
29. Transcript: 1400.
30. Transcript: 1401.
31. Transcript: 1403.
32. Promega's attorneys were by no means the first attorneys to import standards from one place of science to another. As shown in Lynch (1998: 848–49), in the early PCR criminal cases and in the O.J. Simpson trial, the same move was imposed on laboratory technicians in forensic laboratories, who were measured against standards of scientific behaviour imported from other contexts by lawyers eager to dispute their data. Forensic engineers have also objected to the application by courts of universalized images of engineering to their industrial practices (Edmond, 2002: 386).
33. Cambrosio et al. (1990: 279–81) describe a similar struggle between litigating parties over the characterization, not of the patent text, but of an assay, which may or may not have been different in academic and commercial settings.
34. An applicant who successfully takes the patent bar, yet does not have a law degree, becomes a patent agent, and can prosecute patents, representing clients before the patent office, but not in any court.
35. Roche's team included Jennifer Gordon, who has a PhD in biochemical engineering, and Promega's team included Peter Carroll, who has a PhD in immunology. See *Hoffman-LaRoche, Inc. v. Promega Corp.*, 319 F.Supp. 2d 1011, 1013 (N.D. Cal. 2004) for the list of the attorneys appearing for each party, and *Martindale-Hubbell Law Directory* for the attorneys' professional biographies.
36. Crespi's words are an echo of mid-20th-century sociological descriptions of the industrial scientist described, and critiqued, in Shapin (2004: 344–45).
37. US Patent and Trademark Office website, Frequently Asked Questions, answer to 'Do I need an attorney or agent to file my patent application?' While the legal answer is 'no', the PTO says instead: 'The U.S. Patent and Trademark Office (USPTO) strongly recommends that all prospective applicants retain the services of a registered patent attorney or patent agent to prepare and prosecute their applications' <www.uspto.gov/main/faq/> (accessed 8 February 2006).
38. Transcript: 1060, 1173–75.

39. Transcript: 1177–79, 1182. Stoffel faced the same catechism. Transcript: 1038–40. This legal stratagem of using counter-factuals, and their interplay with actual past actions, is also explored in Lynch (1998: 846–48) and Lynch (2001: 143–46), and has been advised as a tactic to deconstruct science in the courtroom in Oteri et al. (1982).
40. The norms of assigning authorship credit in scientific papers, which may be unlinked to drafting the document, or even to performing the described experiments, are discussed in Kevles (1998b: 31–46) and Biagioli (2003: 261–73).
41. Transcript: 2066–68.
42. Transcript: 1553. The MPEP is frequently issued in new editions. At trial, the parties referred to the 1983 edition, as revised in 1988, as the version applicable to the prosecution of the *Taq* patent.
43. Transcript: 1543–45.
44. Transcript: 1553–55.
45. Transcript: 1632.
46. As Roche was unwilling to waive the attorney–client privilege that prevented outside parties from discovering communications between Cetus employees and their attorneys, the actions of patent attorneys in the generation of the patent documents were mostly left undiscussed in the courtroom.
47. Transcript: 1158–59.
48. Transcript: 1106.
49. Transcript: 2078.
50. Transcripts: 2078, 2081.
51. Transcript: 2082–83.
52. Transcript: 2090.
53. Transcript: 2123.
54. Transcript: 1633.
55. In its 7 December 1999 Order, the trial court called Kaster the 'principal author' of the Response (1999 WL 1797330 at 4), but held Gelfand accountable for its wording and truthfulness (1999 WL 1797330 at 6).
56. Kornberg also testified for DuPont in the *DuPont v. Cetus* trial, claiming that the discovery of PCR was obvious, in part in light of his own work on polymerases, and thus was not a patentable invention (Kornberg, 2002 [1995]: 236–41). Note that Linn, whose testimony was quoted above, also agreed to testify for DuPont in that earlier trial, but was not permitted to do so (Kornberg, 2002 [1995]: 240).
57. Transcript: 74.
58. Transcript: 80.
59. Transcript: 1171.
60. Rowland's address is discussed in Dennis (1987: 494–502).
61. For example, engineers have laid claim to 'applied science' as part of their professional territory (Kline, 1995) and the courtroom has been the locus of boundary-work between science and engineering (Edmond, 2002). Gieryn (1983, 1999) has identified the historical persistence and utility of boundary-work by practising scientists. For example, Gieryn (1983: 784–91; 1999: 37–114) has shown how scientists, both in Victorian England and 20th-century America, have worked to demarcate the boundary of their science, in order to consolidate power and resources.
62. 323 F.3d. 1354 (Fed. Cir. 2003).
63. European Patent Office Board of Appeal Decision, 24 October 2003, T 1080/01 – 3.3.8.
64. Personal communication with Thomas J. White; White (2000); Sninsky & White (2000).
65. The settlement was announced in a Roche press release, dated 12 September 2005 (in possession of author).
66. See Edmond (2000), as discussed in note 7.
67. I do not intend to suggest that at any given historical moment, industrial and academic or commercial and non-commercial science are naturally distinguishable. Their intertwining and overlapping nature have been explored by many scholars including Kenney (1986), McMeekin & Harvey (2002), and Shapin (2006).

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