The Patent Game: Raising the Ante

Burdened by complex rules, high staff turnover, and a flood of applications, the patent office will soon hit inventors with a new shock: bigger fees

GILBERT P. HYATT, A 53-YEAR-OLD CALIFORnia inventor, hit the jackpot last summer, proving the adage that patience is a virtue. Twenty years before, he had staked a claim before the U.S. Patent and Trademark Office (PTO). His application was rejected, but Hyatt persisted. He filed again, then again, adding new details, year after year. He split the application and came back on numerous refilings, including a court hearing. Each time he left empty handed. But then, in July 1990, without explanation, an examiner gave Hyatt what he'd been seeking and what no electronics company could have anticipated: A patent for a basic microprocessor—a computer on a chip.

No, there's no gimmick. THE BASIC single-chip computer! Hyatt now has priority back to 1970 for one of the key inventions of this century, even though his design was never used in a working device and manufacturers were unaware of it. If Hyatt can enforce this mega-patent, he will have done more than overturn microelectronics history; he may be able to collect royalties from nearly every microprocessor maker in the United States, becoming an instant billionaire.

How did this happen? Hyatt will tell you "justice was done. The little guy does have a chance against corporate America." But others see it as a prime example of how the patent system, bound by its arcane rules and procedures, can render irrational decisions. If Hyatt did indeed make a fundamental discovery in electronics, why was it left to molder for 20 years? Or, if it was not fundamental, why did the patent office validate Hyatt's far-reaching claims?

These questions are now being asked by Texas Instruments (TI). TI claims it invented and manufactured single-chip computers before Hyatt had the idea. Having sold 250 million of the gadgets, TI charged into the patent office in January, arguing that Hyatt hadn't even used the term "single-chip microcomputer" in his papers until 1977, a few months after TI had received a patent on it. Hyatt calls this a "nuance." But it prompted the patent office to hold a confidential in-house trial, called an "interference," to determine who has priority. The legal briefs are already flying in a process that's likely to wrap Hyatt's patent in the coils of the bureaucracy for at least another year. Legal fees for each party could range from hundreds of thousands to millions of dollars.

Not for the fainthearted. *Clearing the patent examination* (bottom right) *is the first step in a legal maze that has been known to preoccupy some applicants for a decade.*

All of which makes the Hyatt case a useful entry point to look at a patent system in distress. The U.S. patent system has been the envy of the industrialized world. "My friends in Europe say they wish they had our system," says renowned inventor Jacob Rabinow, a mechanical engineer at the National Institutes of Standards and Technology with 226 patents to his name. And indeed, despite a decade of criticism for slowness, U.S. patent examiners, for the most part, are regarded as efficient. Under orders to speed up their pace, since 1983 they have brought the average pendency period for an application down from 24 to 18.4 months. Patent Commissioner Harry F. Manbeck Jr. boasts that this is the quickest pace at any patent office in the world. And it is quite an achievement for a bureaucracy of 1600 examiners, responsible for issuing more than 160,000 patents each year. In fact 1991 marked a milestone in productivity for this arm of the Commerce Department, located in Crystal City, Virginia: It was the year of the 5 millionth patent.

However, the statistics on speed don't necessarily indicate good performance. According to U.S. bioengineering companies, for example, if one focuses on patent examinations that involve complex issues on the cutting edge of science, the record is less than encouraging. The biotech industry has been complaining for the past few years that the

system isn't well equipped to handle the subtle issues its members often bring in. As evidence, they cite the long pendency time for biotech applications, which is now at least 26 months, 40% longer than the figure for nonbiotech patent applications. And when major patent decisions do come down, industry leaders say, they are often murky, narrow, and wrapped in an impenetrable legal jargon.

So, while the system may have improved its profile on average, it still faces difficult problems in dealing with hot areas of technology where innovation is coming thick and fast. And many observers, noting the patent office's financial problems, believe things could get worse before they get better. At stake, many argue, is the crucial edge U.S. industry has had over competitors in the global economy—its creativity.

The problems of today's patent office (some would call them chronic) derive in part from an 18th-century principle—unique to the United States—that guides the office. This is the rule that property rights should go to the person who proves that he or she conceived an invention first. All other major patent offices follow a simpler rule, giving priority to the person who first files an application. In the U.S. system, the task of fixing the true moment of conception in disputed cases can be tedious and expensive. This philosophical approach increases the complexity of patent reviews, and therefore the need for special competence.

Dollar doldrums

The biggest single problem facing patent seekers is cost. Not only are legal expenses climbing rapidly, managers of university technology offices complain, so are "user fees"—a form of tax the patent office charges. Hoping to pay for an expensive computer project (see box, p. 22) and a growing staff of examiners, Congress agreed last year to let PTO increase charges across the board by 69%. Then the Administration phased out virtually all federal support in 1992. Where's the money to come from? PTO's fee increase this year is to be focused on "small entities," a group that includes universities, individuals, and companies with fewer than 500 employees. Until now, they have enjoyed a 50% discount; they will soon lose it.

Things have gotten so grim that some companies face a fee increase since last October of 200%. No surprise, then, that many observers fear that the number of patents sought by academics and small businesses will decrease. To inventor Rabinow, the worst change is the increase in "maintenance" fees, due in the third, seventh, and eleventh year after issuance. The price will be a loss of radical ideas. Revolutionary inventions—he rattles off a litany of examples, including xerography, color photography, and FM radio—are produced by lone inventors or small companies with no stake in the status quo. Creative mavericks could "get discouraged" hunting for investors, he says. Howard Bremer, representing the Association of University Technology Managers, agrees: The new fees are "pricing the United States patent system out of the market for many inventors," he says.

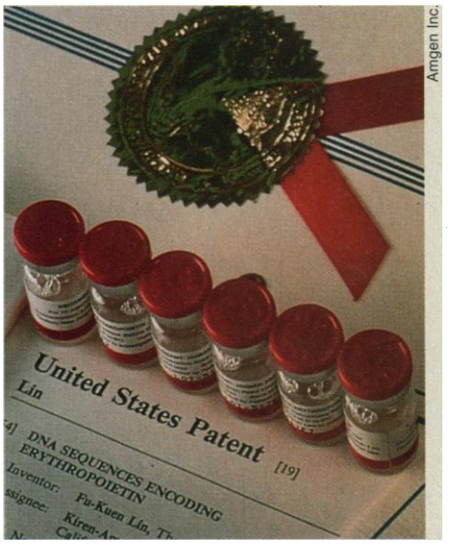
One way universities might counter this trend would be to spend more than they do now to get and enforce patents, but this seems unlikely. Fast-rising attorneys' fees have already got officials trimming their plans. Says Joyce Brinton, director of Harvard's licensing office, her university spent "more than $1 million" on patent lawyers last year, and expenses are rising steadily. Jon Sandelin of Stanford says the legal fees associated with obtaining a patent have doubled in the past 3 years. Stanford is planning a "major study" of the problem this summer. Carl Wootten at the University of California seems to have had the worst experience: The UC system's legal fees doubled in just one year—1990—rising to $3 million. These big universities are wary of increasing their investments in patents; smaller schools are even more risk-averse.

Academic researchers aren't the only ones who may suffer if the fees keep rising. Equally endangered are technological pioneers working for themselves, for small companies, perhaps even for the national laboratories, which pay fees like anyone else. Ronald Barks, who manages technology transfer at the Los Alamos National Laboratory, points out that many new inventions appear "ahead of their time." But, he says, tight budgets and rising fees prompt managers like himself to discard patents before the second maintenance payment, if no company has expressed interest. He thinks of it as throwing away a public investment in technology.

Patent Commissioner Manbeck responded to these complaints in a recent hearing before the House subcommittee on intellectual property, saying the U.S. patent office is still the world's most efficient—charging an inventor on average of about $6,700 to keep a patent for the full 17 years. He claimed this is about one-third the average lifetime cost for a Japanese patent. If higher maintenance fees cause some people to abandon unsold ideas, so much the better, said Manbeck: The system will become more efficient if it clears away dead wood. The main reason for relying on fees, he said, is to guarantee income stability.

Journey to Wonderland

After cost, it's the system's complexity that often frustrates patent seekers. Even experts find the system can be as eccentric as Alice's Red Queen in deciding whom to punish and whom to reward. This unpredictability drives some high-tech companies to desperate acts.



Winner. *$10 million in court battles secured Amgen's patent on erythropoetin.*

Consider a recent, bitter fight between two biotech companies over human erythropoetin (EPO), a protein that stimulates the production of red blood cells—and is already a very profitable pharmaceutical. The initial phase of the battle ended this spring when Amgen, Inc., of Thousand Oaks, California, won a victory over Genetics Institute (GI) of Cambridge, Massachusetts. After 4 years of litigation, costing each combatant around $10 million, the U.S. court of appeals ruled decisively for Amgen. It validated the Amgen patent, which covers EPO produced by inserting a human gene into Chinese hamster ovary cells, and knocked out GI's patent, based on purified human urine.

Today, the ruling is interpreted as a victory for genetic engineers, but before it came down, the experts had no clue as to who might win. Investment analyst Peter Drake of Vector Securities International in Deerfield Park, Illinois, one of the best in the business, declared the match a toss-up in a careful but ambiguous review last December. He said each party had a "30% chance of losing."

Even now, it's not clear that Amgen's big victory will protect its claim to have pioneered the gene-splicing method of producing EPO. The reason: The patent office handles claims for a "product" separately from those on a "process." Until now, the litigation has dealt only with EPO as a product. But both Amgen and GI are also seeking "process" patents for genetically engineered EPO. This part of the fight has just begun in an interference proceeding at the patent office, and will continue for months...or years. The battle in foreign

courts, involving still different issues, is also just getting started and, Drake says, could last "several years."

The confusion over product and process patents has affected the biotechnology industry so much that a few companies have been asking Congress to intervene. Genentech, for one, is cheerleading a reform effort sponsored by Representative Rick Boucher (D–VA) and Senator Dennis DeConcini (D–AZ). Their bills would change the law to state that "process" and "product" patents can cover the same thing, if the product is truly original. The aim is to make it easier to get patents on genetically engineered proteins, even when the natural analogs may have been well characterized in the literature.

Some think it would be a mistake for Congress to intervene on such a fine point, and the big companies in genetic engineering quietly oppose the bill. Says William Duffey, chief patent counsel for Monsanto, "The interests of the small biotech startup companies may differ from the thinking of the large industries." The Boucher bill, he adds, smacks of "special interest legislation." So far, it hasn't made it out of committee.

Questions of competence

Bioengineers can be befuddled when they come face-to-face with the rules of the patent system, but patent examiners can also get confused when they must give an authoritative judgment on a new scientific discovery. Hyatt's microprocessor patent would seem to offer an example, but the problem isn't limited to electronics. Biologists are grumbling that examiners have been at the same time too slow and too "easy" in awarding patents in biotechnology. The complaints seem contradictory, but they may arise from the same problem: a shortage of experienced staff at PTO.

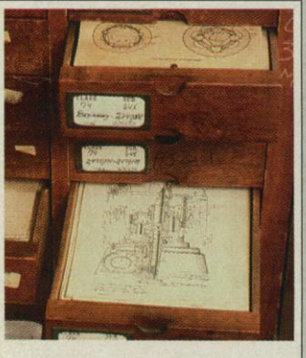
Take the case involving two major suppliers for genetic engineering—New England Biolabs and Life Technologies (then Bethesda Research Labs (BRL)). Executives at the companies claim that the patent system goofed in granting a patent to Harvard recently. "We saw a product we wanted to make [modified T7 DNA polymerase]; there was no patent on it and it looked unpatentable," says one official who did not want to be named. Yet both companies insist that the product was obvious and, as one executive said, it was "foreseen in the literature many years before," although the patent examiner may not have known it.

In early 1990, New England Biolabs and BRL began producing it and offered it for sale. Then both watched in horror as a patent was awarded in August to Harvard researchers, who licensed it to yet another company, U.S. Biochemicals (USB). USB, in turn, promptly forced the two producers out of the market with implied threats of a lawsuit, while actually suing a third, Pharmacia Biosystems, which settled out of court. Despite confidence in their position, though, the losers aren't planning a challenge; they say they can't afford the legal fees. Harvard and USB have no comment, other than to say the patent was thoroughly examined and approved. One executive gave a parting shot: "It's sort of a crapshoot right now in biotechnology."

And that's what drives small companies to distraction: Patent attorneys don't regard the views of one examiner, or even one

Computerizing 28 Million Files

John Doll, a supervisor for the group that checks biotechnology patents, offered to show a visitor how an examination is done. He unlocked a security door and led the way through a maze of rooms that house biotech files. Inside were cabinets containing stacks of small "shoe box" drawers, each about 5 inches deep. In these are old patents, the primary information source for examiners who must check a new application to see whether it is original.



Patents in shoe boxes.

The entire Patent and Trademark Office (PTO) is a maze of such warrens, holding two centuries worth of technical plans. Ideas are divided into categories, subcategories, and, finally, numbered drawers. To check a subject, the examiner pulls out a file and flips through, looking at old patents. Doll took a drawer at random, rifled through, and pointed to a yellowed sheet dated 1906, when all of physics was being shaken by another patent examiner—in Berne, Switzerland.

Dickensian? The shoe-box search method may look antique, but no complete substitute has yet come along. The patent office has learned the hard way that computers don't solve every problem. Since 1983, a massive automation project has been a-borning at PTO, as technicians try to convert its 28 million paper files to digital electronic form. The need for computers is immediate, and growing. As Doll explained, 25% of the paper files may be off the shelf at a given moment, and 7% may be lost or misfiled. An electronic database is beginning to solve that problem—as well as another: to make it easier to include the burgeoning stacks of foreign patents, which have been handled in a haphazard manner so far. But adapting computers to suit the examiners' methods has been a nightmare.

The task proved more complex than anyone predicted, mainly because patents include drawings and other graphic images that can't be stored in text files, but that examiners must see. When PTO dove into the computer market, good image technology was not available. The office forged ahead anyway, wandering astray for a time in the R&D world, running up cost overruns and missing deadlines. PTO then recruited a new automation chief, Thomas Giammo, who overhauled the project in 1988-89. He agrees that "we were having problems before," but says that the project is now meeting both time and money targets. Taxpayers hope so: More than $200 million has been spent since 1983; the budget is now running at $92 million a year; and (here's the bad news) the budget is climbing.

Text files, at least, are now on line for all U.S. patents since 1973. Within another 5 years, Giammo predicts, the system will be fully operational, and many benefits will begin to appear. The in-house paperwork or "wrapper" that goes with each application will be computerized, and so will the publishing of patents. Eventually, Giammo says, applications will be submitted in digital form as well. (PTO already requires that biotechnology sequence data be submitted in digital form.)

Despite Giammo's best efforts, however, the image database is still struggling. It encompasses only a fraction of the paperwork done at PTO and isn't likely to be widely available for public use any time soon. Thus far, only 140 of the 1600 examiners use it for primary searches, because that's all the system can accommodate. They still go to the shoe boxes for backup. Giammo had hoped that electronic data could be neatly compartmentalized for each examining group by type of technology, but it turns out that examiners like to roam into "neighboring" fields. So the architecture of the network must be redesigned to handle a heavier workload. ■ E.M.

judge, as definitive. Says an attorney with a major biotech firm: "People view the system as 1000 patent offices, because the standards can vary from examiner to examiner. You can have cases going on for years that you think are better than others that fly through the patent office."

Working conditions for the examiners don't help the situation, either. The biotech attorney, who asked to remain anonymous, says: "There's still a quota system and [the patent examiners] have to move cases—under pressure—sometimes without really understanding" them. And this makes it harder to recruit and retain an adequate technical staff. PTO loses staff rapidly to the private sector, where salaries and perks are more generous. Even a newly minted patent attorney can make $100,000 a year starting out, says one university official.

John Doll, a supervisor in PTO's group 180, which handles biotech applications, concedes that staff turnover is an ongoing problem. Doll ticks off the number of "attrits" recently—18 in fiscal year 1989 and 31 in 1990, out of a total of slightly more than 100. He estimates that one-third of the group today has spent less than a year at PTO. But, says Doll, the rate of departures is slowing, and he assumes that because of the recession, "things are not as good on the outside this year."

Making the system better

Criticized for the slow pace and uneven quality of examinations, PTO has made improvements in the past few years. Doll says the number of examiners in the biotech group increased from 43 in 1986 to 91 in 1988 and then to 140 today. Even outside critics, like Lisa Raines, executive director of the Industrial Biotechnology Association (IBA), say they have detected a quickening tempo. IBA has helped the patent office set up a Biotechnology Institute to educate the staff and improve the quality of examinations. The institute brings academic and industry researchers in to describe the latest technology. But Raines sees no earthshaking change. The number of pending biotech applications is still high, hovering around 18,600—higher than at the end of fiscal 1990. And because PTO's budget is pinched, plans to expand group 180 are on hold.

Elsewhere in the system, patent officials are trying to stimulate reform, though whether they can make any headway against inertia

Can Electronic Property Be Protected?

Like many biotechnology products, software is difficult to define and even harder to protect as intellectual property. Many programmers rely on copyright law—originally intended to stop plagiarism and art fraud—to prevent illicit copying of their work. But they have also attempted to get patents for software "inventions," which range from small program subroutines to full-scale operating systems. Neither approach has worked very well, according to a recent report by the National Research Council (NRC),* and some knowledgeable observers are deeply concerned about the possible implications of dragging intellectual property lawyers further into the digital world. Says Jerome Reichman, a Vanderbilt University law professor and a participant in two NRC forums: "If we continue to stretch [patent and copyright law] too far...I'm afraid we are going to have a breakdown and a lot more problems than we think we are solving."

One of the worries Reichman and others cite is that the courts may have gone overboard in using copyright laws to protect the rights of software designers. Historically, courts have awarded narrower protection to literary works with "functional" aspects—that is, with practical uses—than to those with artistic purposes. (Narrow protection means that someone must copy a work almost exactly before infringing a copyright.) Software programs, which are clearly functional, should receive narrow protection under that principle. But a 1985 federal district court decision known as *Whelan* expanded the copyright protection software to include its "structure, sequence, and organization," thereby protecting program aspects such as file and data structures or sequences of screen displays as if they were art forms.

This decision opened the door to a number of well-publicized lawsuits, including one filed against Microsoft Corp. by Apple Computer, which claimed that Microsoft's popular "Windows" system infringed the "look and feel" of the desktop environment originally created by Apple for the Macintosh system. University of Pittsburgh law professor Patricia Samuelson, another NRC forum participant, is one of many who think the suit is just the kind of undesirable consequence one would expect from *Whelan*, which she terms a "radical step" based on a flawed analogy between software and literary works. She believes the decision could inhibit software innovation by extending copyright protection too far. "Judges have been blind to the fact...that progress in the field of technological arts may more easily be impeded by strong copyright protection than...in the field of the literary arts," she says.

This view opens the door to a different group of intellectual property experts who believe that patents offer a better way to protect the functional aspects of programs. A patent conveys 17 years of ownership rights in a "nonobvious, novel, and useful" invention in exchange for full disclosure of the working details, and many program writers are now seeking these rights. According to a recent estimate prepared for the State Bar of Texas, the Patent and Trademark Office now issues about 200 software patents each year.

But this avenue is not without its own pitfalls. Many legal experts say that courts are inconsistent in applying the law, making it difficult to predict whether a given program infringes on a patent or not. For instance, while patents are not awarded for algorithms, which are considered "laws of nature," the Patent Office draws a fine distinction between "computer algorithms" (which are patentable) and "mathematical algorithms" (which are not). Furthermore, a proliferation of software patents—which are frequently obtained for "conventional, or even obvious processes," according to Brian Kahin, an adjunct research fellow at Harvard—further hinders the progress of software development by forcing innovators either to risk litigation or to engage in lengthy and expensive research to ensure that they have not independently created a patented design.

To biotechnologists—and perhaps inventors generally—these complaints will sound all too familiar. But if the history of intellectual property litigation is any guide, many of the legal issues are likely to be settled by the courts in a piecemeal fashion that clarifies what the NRC report describes as an "ambiguous" legal environment, even though it pleases no one. In the absence of proposals for intellectual property reform—which can only be enacted through Congress—such a resolution may be the best anyone can hope for. ■ DAVID P. HAMILTON

*"*Intellectual Property Issues in Software,*" National Research Council, May 1991.

is questionable. Secretary of Commerce Robert Mosbacher has created a special Advisory Commission on Patent Law Reform chaired by Manbeck. He and the 14 university leaders, business executives, and lawyers on the panel have a deadline of August 1992 to come up with new ideas. Their mandate is broad, as reflected in an appeal published last month by PTO. It asks for comment on software patents, the clash between U.S. and foreign standards, and the fact that "patent litigation is said to be complex, expensive, unpredictable."

One of the panel's big tasks, says assistant patent commissioner Michael Kirk, is to find out whether U.S. citizens want simplicity enough to "harmonize" with other nations. Goaded by multinational corporations, which do want a change, the patent office has been negotiating a universal patent agreement in the World Intellectual Property Organization since 1984. As part of the deal, the United States might yield on its "first-to-invent" rule, and U.S. officials have offered to move toward the "first-to-file" standard.

But a shift could hurt academia. In the United States, university scientists publish discoveries first and file for a patent later. Under most foreign systems, the inventor loses the right to a patent if he or she publishes first, and must make a first official publication through the patent office. This is why it can be so difficult for U.S. university-based scientists to get patents abroad. Although academics would like to extend their reach overseas, they don't want to reduce their freedom to publish. U.S. officials have been working on a possible compromise that would guarantee a year's "grace period" for filing an application after a discovery. Others have suggested combining the grace period with an amendment that would recognize publication in a peer-reviewed journal as a form of official notice. But but so far the negotiators haven't found a solution that satisfies everyone, and they don't seem close.

Which brings us back to where we began: money. In more generous times, some of these problems would prompt temporary relief from Congress through a larger federal appropriation. This would at least help on the financial and staffing needs. But this solution isn't possible any longer. Just the opposite: The Bush Administration has made it clear that the patent office is to rely less on the Treasury. As Manbeck said recently, PTO "stands at a crossroads" this year, and it remains to be seen whether the path it has chosen—that of becoming a quasi-private agency—will streamline the system, or just make the problems more intractable. ■ ELIOT MARSHALL

Baltimore Case—In Brief

Three months after a widely leaked draft report by the Office of Scientific Integrity (OSI) within the National Institutes of Health accused Tufts immunologist Thereza Imanishi-Kari of fabricating data in a 1986 Cell *paper she had co-authored with Nobel laureate David Baltimore, the controversy has become, if anything, more intense. An unusual series of published statements in* Nature *from the principals in the case has catalyzed a bitter debate within the biomedical community. What follows—for those weary of reading all the statements and counterstatements—are the highlights.*

Imanishi-Kari's Rebuttal

Thereza Imanishi-Kari has not been silent on the OSI draft report. In her 45-page official reply to the OSI, she not only complained that OSI had denied her due process protection (thereby convincing a group of more than 100 biomedical researchers recently to agree with her in a public letter to OSI—*Science*, 21 June, p. 1607), but also denied fabricating data, calling the OSI's reliance on forensic and statistical analysis "the weakest of all possible forms of evidence."

For instance, OSI concluded that Imanishi-Kari had fabricated one set of data after a Secret Service analysis revealed a "full match" between materials (the ribbon ink, paper, and printer) ostensibly used to produce her 1985 radiation counter tapes and those from experiments done in 1981 and 1982—several years before Imanishi-Kari's laboratory had received the mice on which she was allegedly experimenting. The OSI's clear implication is that she fabricated the data by selecting old tapes and pasting them onto new pages.

Imanishi-Kari contested this finding in her reply, arguing that the comparison of tapes in the full match was "utterly lacking in scientific significance" since the two sets of tapes had been produced by different types of radiation counters with different output formats. While one immunologist friend of Imanishi-Kari's says privately that he found this reply compelling, sources familiar with the forensic work note that the two counters easily could have been connected to the same printer. (Unfortunately, those who know for certain—the OSI and the Secret Service—refuse to comment.)

O'Toole Fires Back

A separate firefight broke out when Margot O'Toole—the Imanishi-Kari postdoc who challenged the paper in 1986—published a 4-page statement in which she raised a number of serious allegations against David Baltimore, Imanishi-Kari, and members of the Tufts University and MIT panels charged with investigating her challenge. Her statement was a direct response to Baltimore's earlier public apology (*Science*, 10 May, p. 768), which critics such as Harvard molecular biologist and Nobel laureate Walter Gilbert considered inadequate. Although O'Toole had made many of her charges before, most of them were news to all but the inner circle of aficionados who have been following every twist and turn in the case.

O'Toole not only charged that she had provided Baltimore and the two scientific panels with enough information in 1986 to realize something was wrong with the *Cell* paper, she claimed that in meetings with both the MIT and Tufts panels Imanishi-Kari had admitted to not performing "crucial experiments." And in spite of that evidence, she claimed, the panels had concluded no correction was warranted. O'Toole wrote that she considered it a "disgrace" that the authors had failed to retract the paper back in 1986, and complained that the senior scientists involved considered the protection of Imanishi-Kari's career more important than scientific truth.

Baltimore and the panel members haven't taken O'Toole's latest remarks calmly. In another statement in *Nature*, Baltimore charged O'Toole with creating a "misleading impression" and making numerous "overstatements and errors." Herman Eisen, who undertook the MIT inquiry, wrote that he was "puzzled" by O'Toole's "turn-around." In fact, Eisen says, O'Toole's original memo on the case "contains no suggestion that reported results were based on nonexistent or fraudulent data." As a result, he wrote, the memo hinted at little more than "a typical scientific dispute." And the Tufts panel members denied O'Toole's version of events, writing that Imanishi-Kari had never said she didn't perform important experiments.

Who really knew what when? The latest round of statements does little to answer that question. Take, for example, Eisen's response. Because he is highly thought of in biological circles, many scientists were willing to believe that O'Toole had overstepped the bounds