

GAO

Briefing Report to Congressional
Requesters

April 1989

BIOTECHNOLOGY

**Backlog of Patent
Applications**





United States
General Accounting Office
Washington, D.C. 20548

Resources, Community, and
Economic Development Division

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The Honorable Robert A. Roe
Chairman, Committee on Science,
Space, and Technology
House of Representatives

The Honorable James H. Scheuer
Chairman, Subcommittee on Natural
Resources, Agriculture Research
and Environment
Committee on Science, Space, and Technology
House of Representatives

In your August 9, 1988, letter, you asked us to examine the large backlog of unprocessed biotechnology patent applications at the U.S. Patent and Trademark Office, an agency of the Department of Commerce. Because of concern that this backlog results in long delays in obtaining patents, which impede the development of important biotechnological inventions, you asked us to answer six questions regarding (1) actions taken to streamline the biotechnology patent application process, (2) the level of technical scrutiny required to process applications in the biotechnology area as compared with other technology areas, (3) the ability of the Patent Office to attract and retain qualified examiners, (4) pendency (i.e., the waiting period from the filing of an application to the date the patent is issued or rejected) for biotechnology patent applications versus other technology applications, (5) a comparison of waiting periods for various types of biotechnology products, and (6) alleged attempts by foreign competitors to overwhelm the patent system with applications.

Our review included obtaining information on the status of the actions taken by the Patent Office to implement a so-called 13-point "catch-up" plan, and an analysis of pendency and work load data generated during 1988 by the Patent Office. We briefed your office on March 7, 1989, on the results of our evaluation and, as requested, have summarized the information presented at that time in this briefing report.

RESULTS IN BRIEF

We found the following:

- Actions are underway to streamline the biotechnology patent application process. The Patent Office has already implemented many parts of its 13-point catch-up plan, which included the creation of a new patent examining group on March 27, 1988, that deals exclusively with the field of biotechnology. However, continued annual increases in the number of filings resulted in the backlog of biotechnology patent applications growing at a rate of 19 percent (5,200 to 6,200) during the first 9 months of the new group's operation (April-December 1988). Because of this large backlog and the inexperience of recently hired patent examiners, the Patent Office estimates that it will take at least 4 years to bring the biotechnology patent waiting period down from its 29-month average to the 18-month average goal for all patent applications. The Patent Office offers accelerated processing for applicants in need of speedy patent protection, but few applicants have taken advantage of it apparently, in part, because of concerns that the required representations create increased risks of challenges by competitors.
- The level of technical scrutiny required to process an application for a biotechnology patent exceeds that required to process patents in most other areas of technology. The learning curve is longer for a biotechnology examiner because of the nature of the technology, its complexity, its newness, and its rapid development. During fiscal year 1988, biotechnology examiners spent about 15 percent more time (an average of 19.3 hours versus 16.7 hours) on biotechnology patent applications than the average time spent on all patent applications. This time represents average time an examiner actually spends on a biotechnology application during the average 29-month pendency time, which is primarily consumed by clerical processing, delays in initiating examinations, waiting for applicant responses to examiner correspondence, and printing.
- To attract and retain qualified biotechnology patent examiners, the Patent Office has obtained from the Office of Personnel Management special engineering pay rates and greater hiring authority to correct prior delays in hiring examiners. The number of biotechnology patent

examiners assigned to the new biotechnology group increased 26 percent (from 72 to 91) during fiscal year 1988. The Patent Office would have hired more biotechnology patent examiners if not for a lack of experienced senior staff in this area to train them. The biotechnology examining group has the lowest ratio of senior to junior staff of any examining group in the Patent Office. Experienced biotechnology experts leave the Patent Office for higher pay, and one of the key sources of replacements is inexperienced college graduates, most with advanced degrees.

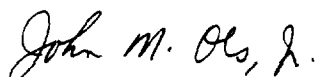
- The total pendency period for biotechnology patent applications continues to be much longer than that of any other technology. During its first 9 months of operation, the biotechnology examining group that was formed in late March 1988, registered an average pendency of 29.4 months from the date of application to the date of issue compared with an average of 21.0 months for all patents issued. A large backlog of applications not yet acted upon that are over 12 months old, along with inexperienced examiners, contributed to the long average waiting period for biotechnology patents issued in 1988. This condition results in long delays in initiating examinations. The biotechnology group average of 14.5 months was the longest waiting period for starting examinations of any examining group--double the average for all technologies. However, the biotechnology group's pendency for starting examinations has shortened and the number of new examinations has increased each quarter since June 1988.
- Longer-than-average delays are typical across the full spectrum of biotechnology developments, but because of smaller backlogs, certain areas, such as biotechnology equipment, are acted upon more quickly by the examiners. Conversely, because of large backlogs of old applications, genetic engineering patent applications take a much longer time to be acted upon. Average pendency for patents issued by the biotechnology areas during the period of April through December 1988 ranged from 25.5 to 39.2 months. But the lowest pendency average was still 4.5 months above the overall Patent Office average.
- On the basis of our analysis of foreign biotechnology patent activity, we did not find that biotechnology patent applications by foreign competitors reflect a

deliberate attempt to overwhelm the patent system with applications and undermine the efficient flow of biotechnology inventions in the United States.

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Our audit work was performed during the period of October 1988 through February 1989 and was done in accordance with generally accepted government auditing standards. Section 1 of this briefing report provides background and information about our objectives, scope, and methodology. Sections 2 through 7 provide detailed information on the six questions you asked us to answer. Appendix I lists and describes the technology covered by the 16 examining groups in the Patent Office. Appendix II lists the six areas in the biotechnology examining group. Appendix III lists the major contributors to this briefing report.

We discussed this report's contents with officials of the Patent Office, who concurred with the facts, and their comments have been included where appropriate. As agreed with your office, however, we did not obtain official agency comments on this report. As arranged with your office, unless you publicly announce its contents earlier, we plan no further distribution of this briefing report until 5 days from the date of this letter. At that time, we will provide copies to the Department of Commerce and to others upon request. If you have any further questions on these matters, please contact me at (202) 275-5525.



John M. Ols, Jr.
Director, Housing and
Community Development Issues

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ABBREVIATIONS

OPM	Office of Personnel Management
PALM	Patent Application, Location, and Monitoring

SECTION 1

INTRODUCTION

The Patent and Trademark Office, an agency of the Department of Commerce, is concerned primarily with encouraging and assisting the development of business and industry in the United States. Its role is to provide patent protection for inventions and trademark registration and to disseminate patent and trademark information to serve the interests of inventors and businesses. It also assists other agencies in matters involving patents, inventions, the transfer of technology, and the promotion of strong intellectual property protection around the world. Finally, it encourages innovation and the scientific and technical advancement of the nation by preserving, classifying, and disseminating patent information.

To carry out its duties, the Patent Office examines applications and grants patents on inventions. It publishes and disseminates patent information, records patent assignments, maintains search files of U.S. and foreign patents and a search room for public use in examining issued patents and records, and supplies copies of patents and official records to the public. It performs similar functions in relation to trademarks.

The examination of utility patent applications is the largest and one of the key functions of the Patent Office. This work is divided among examining groups, each of which has jurisdiction over certain assigned chemical, mechanical, or electrical technologies. At present, there are 16 examining groups (see app. I). Each group includes a number of suborganizations, called art units. Each art unit, so-called because it is responsible for a specific area of technical art, is composed of examiners who review utility patent applications to decide whether the inventions described and claimed there are entitled to patent protection. On the average, there are 13 examiners per art unit and between 6 and 7 art units per examining group.

Although the Patent Office employs a substantial number of administrators, lawyers, scientists and other professionals, the bulk of its professional staff is made up of patent examiners. The Patent Office staff of about 3,400 employees at the end of fiscal year 1988 included about 1,400 patent examiners. The office received over 137,000 patent applications and issued about 78,000 utility patents in fiscal year 1988.

The patent process involves the following three steps:

1. Pre-examination

-- The inventor submits the patent application to the

Commissioner of Patents and Trademarks. Applications are generally reviewed in the order they are received.

- The Patent Office checks formalities; assigns the application a number; mounts it in a folder, which will hold all documentation related to the application; and performs other clerical processing.
- The application is assigned to the appropriate examining group.
- The application is assigned to an examiner with expertise relevant to the subject area of the application.

2. Examination

- An examiner reviews the application for sufficiency of description, compares it with relevant earlier applications, and assesses the patentability of the applicant's claims. This process, known as first action, may require several interactions (usually by mail) between the examiner and the applicant.
- The Patent Office allows or finally rejects the application. The applicant may appeal rejected claims.

3. Post-examination

- Applicants submit the required issuance fee.
- The patent is printed and issued.

THE EXAMINATION PROCESS

The merits of a patent application are decided during the examination. Patent examiners are highly trained individuals who are often specialists in particular fields. The examining process calls for knowledgeable, reasoned judgment and is by no means a clerical function.

The examiner's first step is to understand the concept of the claimed invention. This can be difficult because, while the inventor is obliged to reveal the inventive concepts in the application, the claims are usually stated in terms that permit the widest possible interpretation. (This is to give the patent, if issued, the widest possible coverage.) Once the examiner understands the concept, he or she must depict it in terms that permit access to the relevant collection of "prior art."

Prior art in the U.S. Patent Office search rooms consists of U.S. patents, foreign patents, technical journals, and publications, which total some 29.6 million documents and are

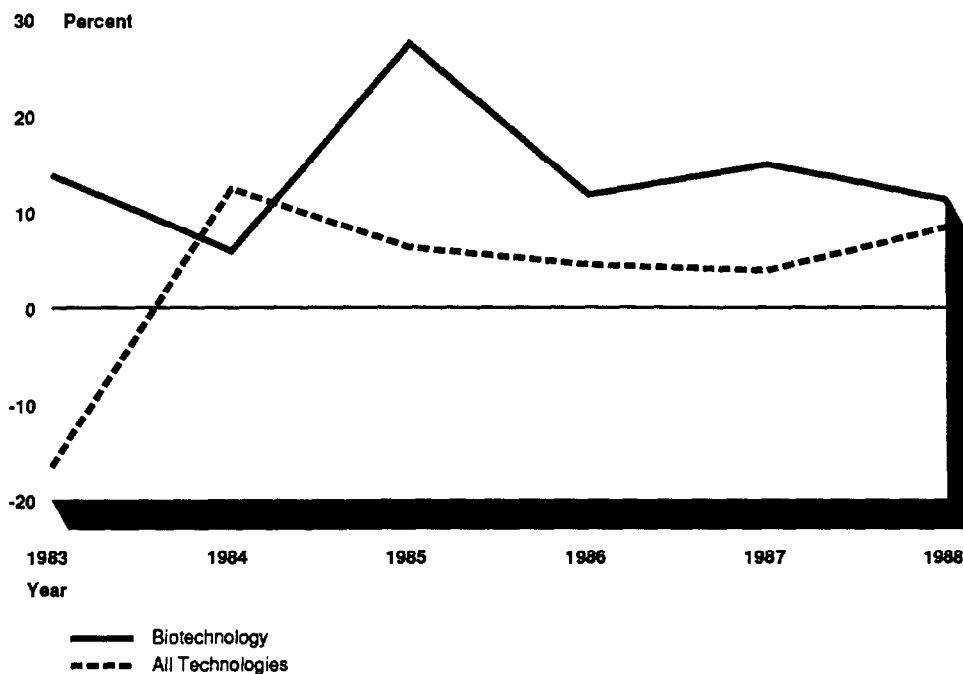
examination steps. Time between receipt of an application and the beginning of examination (i.e., first action) averages 7 months, or about 33 percent of pendency. Another 6 months, or 29 percent of pendency, is spent awaiting receipt of applicants' issuance fees and printing the patent after it has been approved. The remaining 8 months, or 38 percent of pendency, is spent in interactions between the applicant and the Patent Office.

BIOTECHNOLOGY PATENT APPLICATION BACKLOGS

The Patent Office reports that, although efforts have proved successful in reducing time for patent applications in some technologies, the field of biotechnology has not fared as well. On the average, it takes 14 to 15 months before an examiner reviews a biotechnology application and an additional 15 months for final disposition of the application, either through issuance as a patent or abandonment of the application. Thus, the total pendency is 29 to 30 months.

The applications backlog in the biotechnology area continues to increase, despite the addition of examiners and support staff. During calendar year 1988, the number of biotechnology patent applications that were not yet acted upon increased from about 5,200 in April reports to about 6,200 in year-end reports. One contributing factor is that the filing of biotechnology applications (using 1982 as the base year) has grown at a significantly higher average annual rate--20.0 percent--than that for all patent applications--2.9 percent--during fiscal years 1983 through 1988. (See fig. 1.1.)

Figure 1.1: Annual Percentage Increase in Number of Patent Applications, Fiscal Years 1983 Through 1988



Source: U.S. Department of Commerce, U.S. Patent and Trademark Office.

OBJECTIVES, SCOPE, AND METHODOLOGY

In an August 9, 1988, letter, the Chairmen of the House Committee on Science, Space, and Technology and the Subcommittee on Natural Resources, Agriculture Research and Environment, asked us to examine the backlog of biotechnology patent applications at the Patent Office. They expressed concern that this backlog would impede the development of important biotechnological inventions. We were asked to answer the following six questions:

- What actions are being taken to streamline the biotechnology patent application process?
- Does the level of technical scrutiny required to process an application for a biotechnology patent exceed that required to process patents in other areas of technology?
- Given the shortage of biotechnology patent examiners at the Patent Office, how can the office attract and retain qualified individuals to serve as patent examiners in this area?

- How does the waiting period for biotechnology patent applications compare with the pendency period of other technology applications?
- Are long delays typical across the spectrum of biotechnology developments, or do certain areas proceed more quickly through the system?
- Do the biotechnology patent applications by foreign competitors reflect a deliberate attempt to overwhelm the patent system with applications and to undermine the efficient flow of biotechnology inventions in the United States?

To identify ways that the biotechnology patent application process has been streamlined, we obtained updated information on the status of the Patent Office's 13-point catch-up plan. We also obtained information on the number of patent applicants who petitioned for accelerated examination in calendar year 1988. We interviewed several patent attorneys to identify reasons why accelerated examinations are seldom requested.

To determine the level of technical scrutiny required to process biotechnology patent applications, we obtained and analyzed Patent Application, Location, and Monitoring (PALM) Biweekly Time and Activity Corps Summary Reports for calendar year 1988. These reports include time charge summaries for each of the 16 Patent Office examining groups. We compared average examiner time to process biotechnology patent applications with other areas of technology to form some opinions on complexity of biotechnology patents. We also obtained Patent Office correspondence on adjustments made to biotechnology examiner complexity factors to reflect that the patent applications required above-average technical scrutiny.

To examine the shortage of biotechnology patent examiners, we obtained the number of assigned, hired, and terminated patent examiners during fiscal years 1983 through 1988. We also obtained correspondence related to gaining greater hiring authority from the Office of Personnel Management and special engineering pay rates for examiners. In addition, we obtained and analyzed PALM Examiner New Case Action Profile Reports and Biweekly Final Corps Docket Summaries for calendar year 1988. These reports show backlogged patent applications and current receipts of patent applications for each of the 16 Patent Office examining groups. We compared this work load data with numbers of assigned examiners.

To compare the waiting period for biotechnology patent applications with other technologies, we obtained and analyzed PALM Group Patent Case Pendency Reports for calendar year 1988. These monthly reports show, for each of the 16 Patent Office examining groups, the total number of and average months elapsed since the

application date for first actions, allowances, abandonments, and patent issues during the most recent 3-month period.

To address the range of delays in processing patent applications for various types of biotechnology products, we obtained and analyzed PALM backlog, docket, and patent case pendency reports for calendar year 1988 and detailed listings of applications acted upon by biotechnology group examiners during the 3-month period of August through October 1988. These listings included application dates and dates of actions initiated during the period. We computed elapsed months since date of application for each biotechnology patent issued during the period. We also obtained information on prior application dates for those applications that were replacements (continuations) to determine total elapsed months. (The Patent Office calculates elapsed months from the date of the latest application in any chain of replacement applications.)

To determine whether foreign biotechnology competitors have filed an unusually large number of poor quality applications, we obtained listings of applications, coded by origin, acted upon by biotechnology examiners during the 3-month period of August through October 1988. We compared the number of Patent Office actions on foreign applications with actions on domestic applications to determine the relative volume of the foreign applications. A comparison of the origin of all backlogged biotechnology patent applications would have provided more comprehensive analysis, but this information was not readily available from the PALM system. We compared the number of allowances with abandonments for both domestic and foreign applications to determine the relative merits of the foreign applications. We also obtained historical patent issue data for U.S. and foreign origin applicants. In addition, we interviewed the Economics Affairs official who made the charge of attempts by foreign competitors to undermine the system to determine the evidence he had to make the allegation.

Our limited tests of the validity of the data reported in the PALM system identified no errors. However, we did not make an assessment of the internal controls in the computer-based PALM system required to determine the reliability of the data. Our audit work was performed during the period of October 1988 through February 1989, and was done in accordance with generally accepted government auditing standards.

SECTION 2

STREAMLINING THE BIOTECHNOLOGY PATENT APPLICATION PROCESS

The Patent Office has actions underway to streamline the biotechnology patent application process. However, because of the size and age of the backlog and the inexperience of the newly hired patent examiners, Patent Office officials estimate it will take 4 years to reduce biotechnology's average 29-month waiting period to the overall 18-month goal for all patent applications at the Patent Office. To avoid this wait, the Patent Office has developed accelerated examination procedures, which allow applicants who can justify their need for expedited processing to have their applications reviewed before others, regardless of the filing date. However, very few biotechnology patent applicants have taken advantage of this special status, for reasons which are not entirely clear. Patent attorneys told us that applicants are reluctant to use the accelerated procedures because of perceived additional legal risks.

BIOTECHNOLOGY CATCH-UP PLAN

The Patent Office has initiated a plan of action to process biotechnology patent applications more expeditiously. This 13-point catch-up plan included the creation of a new examining group on March 27, 1988, to deal exclusively with the field of biotechnology. Art units and examiners from four groups were consolidated into a new biotechnology group (called "group 180") containing five art units. Effective October 1, 1988, a sixth biotechnology art unit was formed when some of the work load of other art units was redistributed. (See app. II for a list of these six art units and a description of the biotechnology areas covered by each unit.)

Prior to March 1988, most of the biotechnology applications were being examined by the largest examining group in the Patent Office (group 120--organic chemistry), where biotechnology had to compete for management attention with other large and growing areas of technology. The Patent Office reports that this caused conflicting priorities and, ultimately, management problems.

Other parts of the action plan, many of which have already been implemented, include

- adjusting examiner complexity factors (implemented);
- obtaining greater hiring authority from OPM (implemented);
- obtaining special engineering pay rates for new examiners (implemented);

- hiring as many new biotechnology examiners as can be trained by senior examiner staff (in process);
- increasing overtime to the maximum level sustainable for several years (targets set);
- liberalizing and publicizing as necessary the procedure for requesting accelerated examination (implemented);
- identifying examiners in other groups who can be transferred and retrained to examine biotechnology applications in a reasonable period of time (implemented);
- improving communication regarding Patent Office goals and needs and improving morale in the new biotechnology examining group (in process);
- enhancing search tools especially for searching DNA, RNA and protein sequences (in process);
- enhancing technical and legal update training for all examiners (in process);
- stimulating higher productivity in the new biotechnology examining group (targets set); and
- hiring and initially training new examiners for the biotechnology group in other examining groups (in process).

Parts of this action plan relate to steps to attract and retain talented biotechnology patent examiners. (See section 4 for a further discussion of this subject). Other parts of the action plan are designed to correct the biotechnology backlog, while maintaining or even enhancing patent quality. However, because of the size and age of the backlog and the inexperience of the newly hired patent examiners, Patent Office officials believe these actions will not reduce patent pendency in biotechnology in a short time period. The Patent Office goal is to reduce the pendency to 18 months in the biotechnology area by 1992.

REQUESTING ACCELERATED EXAMINATION

Although applications are generally examined in order of their receipt, the Patent Office has a long-standing procedure to ensure that this examination process does not work to the detriment of applicants in need of speedy patent protection. Examination can be obtained out of turn under an accelerated examining procedure if certain requirements are met.

Under this program, applicants must submit (1) a written petition and a \$72 fee, (2) all claims directly to a single invention, (3) a statement that a pre-examination search was made, specifying by whom the search was made and listing the field of search, (4) one copy of each of the references deemed most closely related to the subject matter encompassed by the claims, and (5) a detailed discussion of the references pointing out how the claimed subject matter is distinguished over the references.

Furthermore, to ease the requirements supporting a request for accelerated examination of applications filed by small entities in the biotechnology area, a new program was established in June 1988. To be eligible for the small entity status (500 or fewer employees) program¹, an applicant must file a petition requesting the special status and pay the \$72 petition fee and must (1) state that small entity status has been established or include a verified statement establishing small entity status, (2) state that the subject of the patent application is a major asset of the small entity, and (3) state that the development of the technology will be significantly impaired if examination of the patent application is delayed, including an explanation of the basis for making the statement.

The Patent Office reports that of over 5,000 biotechnology applications filed in 1987, applicants filed only 17 petitions for accelerated examinations, and only 14 petitions, including only 3 claiming small entity status, have been approved during the first 6 months of the new program.

It is not clear what the cause is for the low volume of petitions for special status. A patent attorney told us that the pre-examination search required under the old procedures shifts the responsibility for its completeness from the Patent Office to the applicant and that this increases the risk of patent legality challenges from competitors. Under the new small entity program, this is not applicable because the Patent Office continues to do the prior art search. Patent Office officials told us that they perform complete searches on all special status applications, the same as all others. But another patent attorney told us that the applicant's representations of the significance of the delays on small entity operations could be subject to legal challenges by competitors. Another patent attorney said delays in the public disclosure of technology advances by competitors, rather than delays in obtaining their own patents, is a major concern of some biotechnology patent applicants. A patent application is a confidential document until the patent is issued.

¹According to a National Science Foundation official, of the 690 currently active biotechnology firms, 579 (84 percent) have 500 or fewer employees.

Patent Office officials believe that both the old and the new accelerated examination procedures are well known by either the applicants or their patent attorneys. A notice announcing the new and restating the old program was published on July 19, 1988, in the Patent Office's Official Gazette. This weekly publication includes all amendments to patent regulations as well as information on patents granted. However, special status is not considered unless an applicant petitions for accelerated examination. All applicants receive a filing receipt stating the application's serial number and filing date but are not provided information on the average waiting period caused by backlogs or referred to the accelerated examination procedures.

SECTION 3

LEVELS OF TECHNICAL SCRUTINY REQUIRED TO PROCESS AN APPLICATION FOR A BIOTECHNOLOGY PATENT

The level of technical scrutiny required to process an application for a biotechnology patent exceeds that required to process patents in most other areas of technology. The learning curve is longer for a biotechnology examiner because of the nature of the technology, its complexity, its newness, and its rapid development. During fiscal year 1988, biotechnology examiners spent about 15 percent more time (an average of 19.3 hours versus 16.7 hours) on biotechnology patent applications than the average time spent on all patent applications. This time represents average time an examiner actually spends on a biotechnology application during the average 29-month pendency period.

ADJUSTMENT OF EXAMINER COMPLEXITY FACTORS

The Patent Office reports that biotechnology patent applications differ little from other applications except for their complexity. According to the Patent Office, a long learning curve is necessary for the examiners of biotechnology applications to become proficient and reach peak productivity. The Patent Office reports that the average new patent examiner needs 4 to 5 years to reach full productivity, while new examiners in the biotechnology area take approximately 20 percent longer--about 6 years.

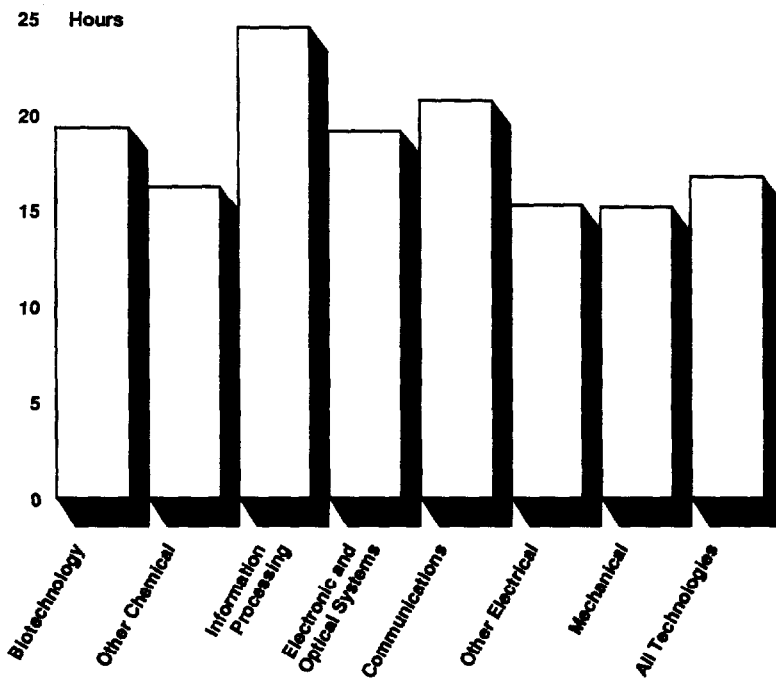
According to the Patent Office, the learning curve is longer for a biotechnology examiner because of the nature of the technology, its complexity, its newness, and its rapid development. Most biotechnology arts have a high degree of difficulty. As a result, biotechnology patent applications need to be directed to examiners possessing broad and in-depth backgrounds in a variety of areas ranging from genetics to microbiology. The rapid growth of information and the explosive development of biotechnology has also led to greater need to understand a variety of interrelated disciplines, such as genetics, immunology, cell biology, biochemistry, microbiology, and bioengineering. Almost two-thirds of the biotechnology examiners hold postgraduate degrees in the field and over one-third hold doctoral degrees.

The Patent Office reviewed the complexity of the biotechnology art and, beginning in fiscal year 1988, gave the examiners 3 more hours to work on those patent applications involving recombinant DNA (deoxyribonucleic acid) and 2 more hours for these involving immunoassay inventions. The office determined that the increased time was necessary because of the difficulty of prior art searches for applications in this area.

AVERAGE TIME SPENT
PER PATENT APPLICATION

During fiscal year 1988, biotechnology examiners spent about 15 percent more time (an average of 19.3 hours versus 16.7 hours) on biotechnology patent applications than the average time spent on all patent applications. Of the 15 other patent examining groups, only the information processing (24.5 hours) and communications (20.7 hours) groups within the electrical technology area required more examiner hours than the biotechnology examining group to process an average patent application.

Figure 3.1: Average Examiner Hours Per Patent Application in Fiscal Year 1988



Source: U.S. Department of Commerce, U.S. Patent and Trademark Office, Biweekly Time and Activity Corps Summary Report.

SECTION 4

ACTIONS TAKEN TO ATTRACT AND RETAIN QUALIFIED BIOTECHNOLOGY PATENT EXAMINERS

The Patent Office hired about 110 entry-level biotechnology patent examiners during fiscal years 1983 through 1988--about 10 percent of the number of new examiners hired for all technologies. As of the end of fiscal year 1988, retention rates for these hires were about the same (40 percent) as those hired in all technologies. The number of assigned biotechnology patent examiners increased 26 percent during fiscal year 1988. The Patent Office would have hired more biotechnology patent examiners if not for a lack of experienced senior staff in this area to train them. The biotechnology examining group has the lowest ratio of senior to junior staff of any examining group in the Patent Office.

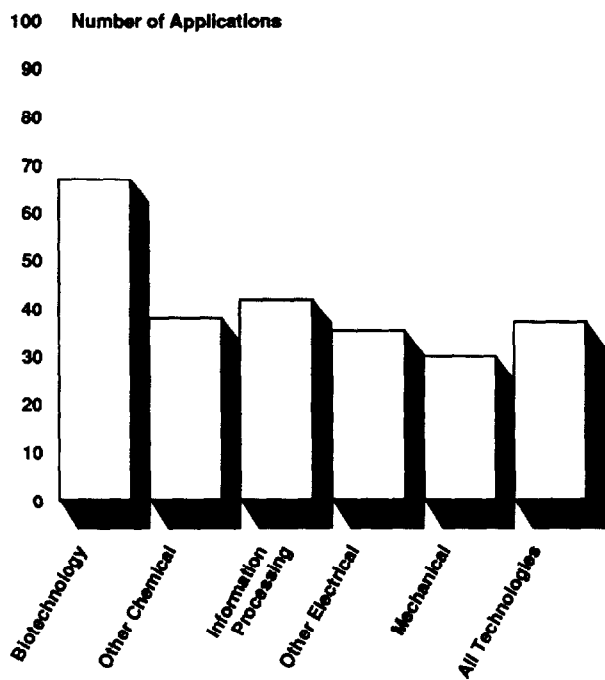
The Patent Office also took other actions related to recruiting and retaining biotechnology examiners, including obtaining special engineering pay rates for examiners and obtaining greater hiring authority from the Office of Personnel Management (OPM).

HIRING AS MANY NEW BIOTECHNOLOGY EXAMINERS AS CAN BE TRAINED BY SENIOR STAFF

Because of the growing number of biotechnology filings, the Patent Office has hired a total of about 110 entry-level examiners from fiscal year 1983 through fiscal year 1988 and plans to hire an additional 100 in the next 5 years. This represents about 10 percent of the total examiners hired and planned to be hired by 1992. According to the Patent Office, one reason more examiners have not been hired is the lack of experienced senior staff in this area to train them. Although all newly recruited patent examiners are formally trained in the Patent Academy, with over 140 hours of classroom time during the first year of employment, they are also closely supervised by either their immediate supervisor or an experienced primary examiner who provides on-the-job training. With only a small pool of experienced primary examiners available, the number of new examiners that can be hired is limited. The Patent Office reports there are now about 20 primary or senior examiners in the biotechnology areas that are capable of training new examiners. According to the Patent Office, creating the proper balance between using experienced examiners for training and using them for examining is difficult and needs constant attention to achieve the highest possible productivity. Some new examiners were recently hired into other examining groups for their initial training and later transfer into the biotechnology group.

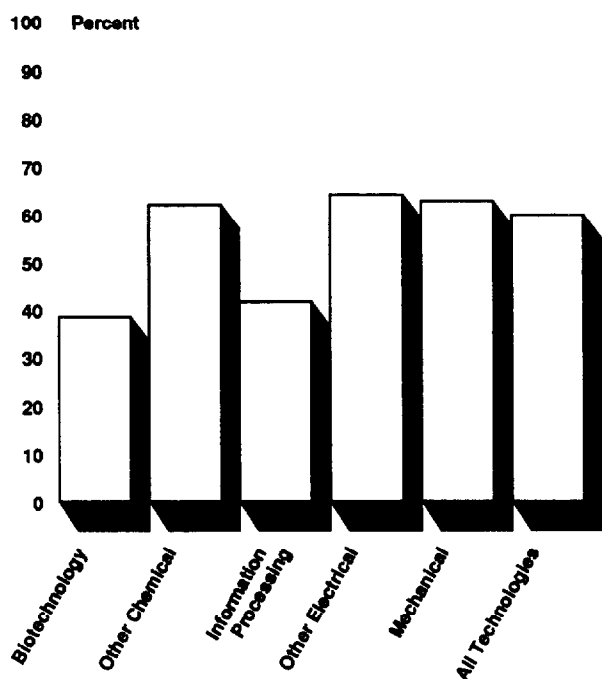
Despite the hiring, the biotechnology group has the highest average number of backlogged patent applications per examiner (66.7) of any technology. (See fig. 4.1.) In addition, the biotechnology group has the lowest ratio of experienced to total assigned examiners of all the examining groups. (See fig. 4.2.) Only 35 of 91 biotechnology examiners (38 percent) had more than 4 years' experience, whereas 827 of the total 1,382 Patent Office examiners (60 percent) had more than 4 years' experience.

Figure 4.1: Average Number of Backlogged Patent Applications Per Assigned Examiner as of December 31, 1988



Source: U.S. Department of Commerce, U.S. Patent and Trademark Office, Biweekly Final Corps Summary Docket Report and Biweekly Time and Activity Corps Summary Report.

Figure 4.2: Ratio of Patent Examiners Hired Prior to Fiscal Year 1985 to the Total Assigned at the End of Fiscal Year 1988



Source: U.S. Department of Commerce, U.S. Patent and Trademark Office, Hiring Analysis.

RETAINING JUNIOR STAFF

The retention rate for biotechnology patent examiners appears to be no greater problem than that for all technical areas. As of the end of fiscal year 1988, 41 percent (45 of 111) of biotechnology patent examiners hired during the 6-year period of fiscal years 1983 through 1988 had subsequently left the Patent Office compared with 40 percent (470 of 1,171) of all examiners hired during this same period. According to a Patent Office survey, of those who indicated why they left, 70 percent said it was to accept positions with higher salaries. Patent Office officials told us that biotechnology examiner attritions over the past 18 months is down substantially. The number of assigned biotechnology patent examiners increased 26 percent (from 72 to 91) during fiscal year 1988, compared with a 5-percent increase for all Patent Office examiners during that same period.

OBTAINING SPECIAL ENGINEERING PAY RATES FOR EXAMINERS

To attract and retain good talent and to put biotechnology examiners, who are life scientists, on a par with other examiners,

who are generally engineers, the Patent Office obtained special pay rates from OPM. Effective in August 1988, entry-level biotechnology examiners began receiving from \$2,500 to \$5,100 more per year. According to the Patent Office, this step will make its pay more competitive with private industry in recruiting top-quality candidates who are in short supply in the rapidly growing field of biotechnology.

OBTAINING GREATER HIRING
AUTHORITY FROM OPM

In 1987 the Patent Office requested and obtained from OPM a delegation of competitive examining authority for patent examiners. The Patent Office believes this action will correct prior delays in hiring new biotechnology examiners from the OPM registry.

SECTION 5

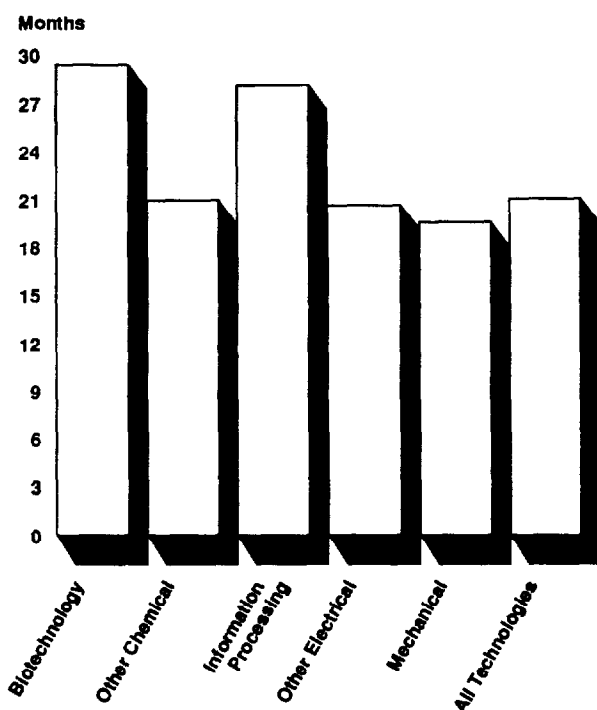
PATENT PENDENCY PERIODS FOR BIOTECHNOLOGY AND OTHER TECHNOLOGY APPLICATIONS

The waiting period for biotechnology patent applications is longer than that for applications in any other technology. During the 9-month period of April through December 1988, the average time from the date of application to the date of issue was 29.4 months. This average remained constant throughout the period. The average waiting period for all patents issued by the Patent Office was 21.0 months. Only the information processing patent waiting period, with an average pendency of 28.1 months, was near the biotechnology average. A large backlog of applications not yet acted upon that are over 12 months old contributed to the long average waiting period for biotechnology patents issued in 1988. This condition results in long delays in making first actions. The biotechnology group has the longest waiting period for first actions of any examining group--14.5 months. However, the biotechnology group's pendency for first actions has shortened, and the number of first actions has increased each quarter since June 1988.

PENDENCY FROM APPLICATION TO ISSUE

During the first 9 months of operation, the newly formed biotechnology group registered the highest average time period from the date of patent application to date of issue. Biotechnology patents were issued an average of 29.4 months after the date of application, whereas patents in all technologies were issued in an average of 21.0 months. Only patents issued within the electrical area by the information processing, storage, and retrieval group had a comparable high average--28.1 months--for patents issued during this period. (See fig. 5.1.) However, the information processing average has been coming down, whereas the biotechnology average has remained relatively constant throughout the period.

Figure 5.1: Average Time Period From Date of Patent Application to Date of Issue, April Through December 1988



Source: U.S. Department of Commerce, U.S. Patent and Trademark Office, Group Patent Case Pendency Reports.

PENDENCY PERIOD FROM APPLICATION TO FIRST ACTION

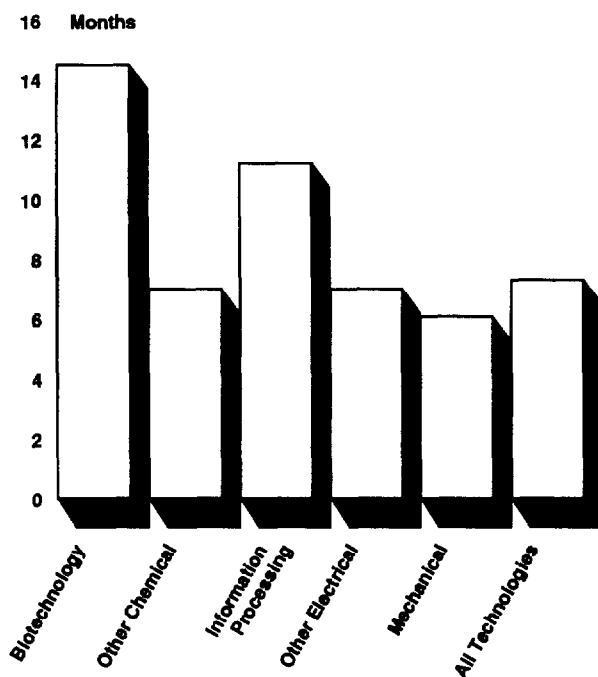
The date of first action is the date at which the patent examiner communicates to the applicant his/her initial conclusions regarding the patent's viability. The first action statement explains why the examiner considers the claimed invention unpatentable and, if that is the case, the communication also contains copies of any relevant prior art found in the search. This communication also points out any formal deficiencies in the application and, if possible, offers suggestions on how the invention can be more precisely defined. It also identifies any problems with the completeness of the description or the ability of one skilled in the art to practice the claimed invention, and suggests how the claim(s) can be amended. A reasonable time period is provided for the applicant to respond.

During its first 9 months of operation, the biotechnology group had the longest average time period from the date of application to the date of first action. First actions in the biotechnology area were made an average of 14.5 months after the

date of application, whereas first actions in all technologies averaged 7.3 months after the date of application.

Only the information processing, storage, and retrieval group, within the electrical area with an average of 11.2 months, had a first action time period comparable to that of the biotechnology group. (See fig. 5.2.) However, the biotechnology examining group has experienced a reduction in its first action pendency period and an increase in the number of its first actions during each of the last two quarters of calendar year 1988. The first action pendency period for the biotechnology examining group decreased at a quarterly average rate of 6 percent, and the total number of first actions increased at a quarterly average rate of 10 percent. (See table 5.1.)

Figure 5.2: Average Elapsed Months From Date of Patent Application to Date of First Action, April Through December 1988



Source: U.S. Department of Commerce, U.S. Patent and Trademark Office, Group Patent Case Pendency Reports.

Table 5.1: Average Time From Date of Biotechnology Patent Application to Date of First Action, April Through December 1988

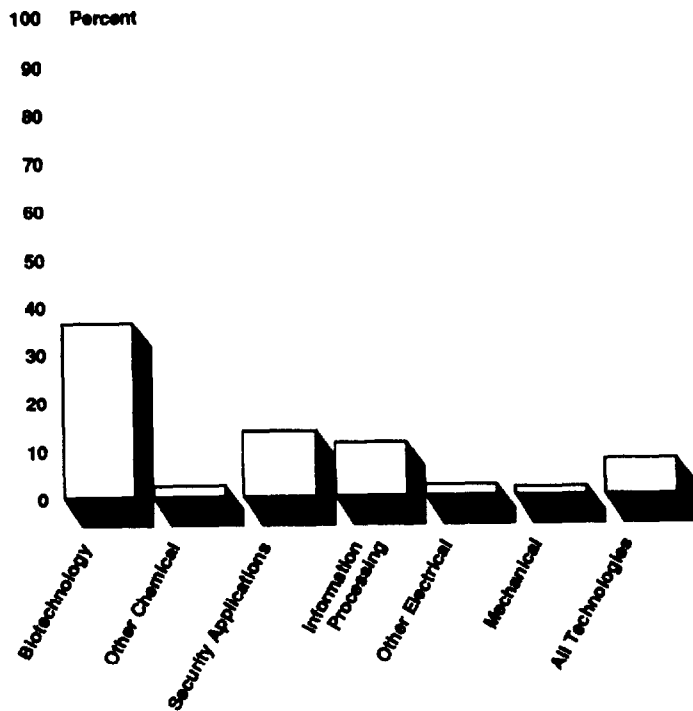
<u>Period</u>	<u>Total first actions</u>	<u>Average months</u>
Apr-Jun	1,540	15.5
Jul-Sep	1,658	14.7
Oct-Dec	<u>1,862</u>	<u>13.6</u>
Total	<u>5,060</u>	14.5

Source: U.S. Department of Commerce, U.S. Patent and Trademark Office, Group Patent Case Pendency Reports.

AGE OF BACKLOGGED APPLICATIONS

The biotechnology group has the highest percentage of applications of any examining group that have not been acted on for over 12 months--36.3 percent. The overall Patent Office average was only 7.5 percent. Only the information processing, storage, and retrieval group (11.2 percent) and the security applications group (13.6 percent) within the electrical area have rates approaching the biotechnology examining group's rates. The sheer size and age of the biotechnology patent application backlog contributed to the long period of time required to take first actions in the biotechnology area. At the end of calendar year 1988, about 2,200 of the total 6,200 backlogged biotechnology patent applications were more than 12 months old. This same ratio has existed during the entire first 9-month existence of the new biotechnology examining group. In contrast, the remaining 15 examining groups had only 1,405 applications over 12 months old out of a total of 42,623 backlogged applications. (See fig. 5.3.)

Figure 5.3: Percentage of Total Backlogged Applications Over 12 Months Old as of December 31, 1988



Source: U.S. Department of Commerce, U.S. Patent and Trademark Office, Examiner New Case Action Profile Corps Summary.

SECTION 6

EXTENT OF DELAYS IN OBTAINING PATENTS, BY TYPE OF BIOTECHNOLOGY DEVELOPMENT

Longer-than-average delays are typical across the spectrum of biotechnology developments, but applications in certain areas, such as biotechnology equipment, proceed more quickly than others. Size and age of the backlog contribute to lower pendency averages for some biotechnology products. The average time from the date of application to the date of issue during the 9-month period of April through December 1988 for each of the biotechnology art units ranged from 25.5 to 39.2 months. The biotechnology art unit with the lowest pendency average was still 4.5 months above the overall Patent Office average.

However, the Patent Office measures pendency only from the most recent application in what may be a chain of additional and replacement applications ("continuations"). We estimate that as many as one-third of all biotechnology patents issued in 1988 resulted from continuations. Factoring in the original application dates for those patents would add about 10 months to the average patent pendency currently reported by the Patent Office. We did not examine the extent of the use of "continuations" by applicants in other technologies, but Patent Office officials told us that this number runs about 22 percent for all technologies.

PENDENCY FROM APPLICATION TO ISSUE

Within the biotechnology examining group, the two art units covering genetic engineering and immunology had the highest average waiting periods from application to patent issue during the period of April through December 1988. (See table 6.1.) During this same period, the average pendency period for all biotechnology patents was 29.4 months. Patent Office officials told us that one of the long-range benefits hoped to be achieved from the formation of the biotechnology group is the ability to more efficiently work toward similar pendency times for all applications in this area. Based on our analysis of activity during August through October 1988, most patents were issued in the 19-to-36-month range. About 19 percent of the patents were issued in 18 or fewer months and about 8 percent of the patents were issued more than 48 months from the date of application. (See fig. 6.1.)

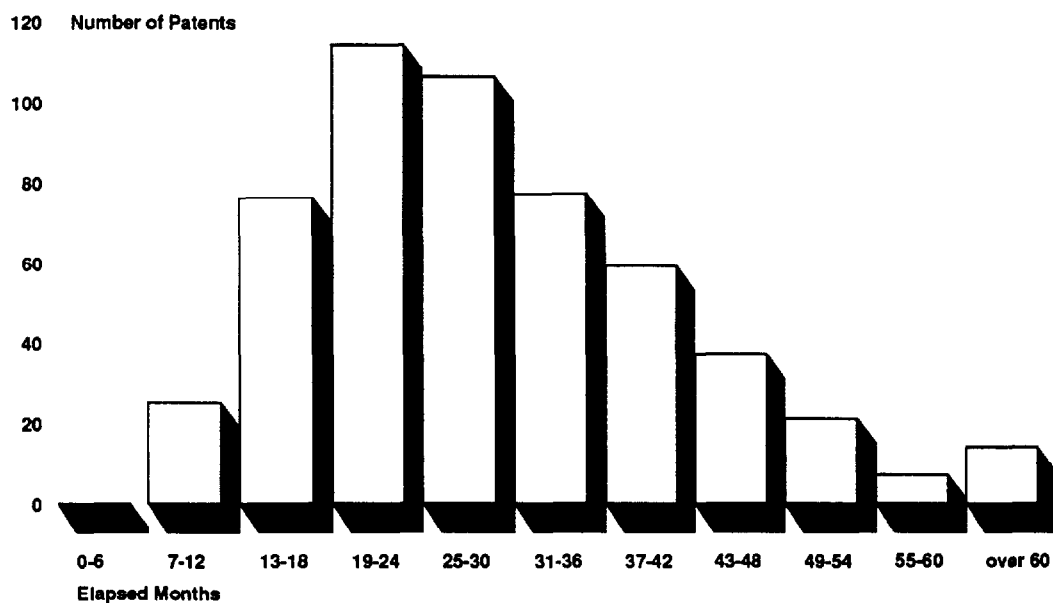
Table 6.1: Average Waiting Period From Application to Issue for Biotechnology Patents, April Through December 1988

<u>Art unit/ description</u>	<u>Total patent issues</u>	<u>Average months</u>
181/equipment	401	26.0
182/immunology	593	34.2
183/biochemicals	384	26.6
184/plants and animals	185	25.5
185/genetic engineering	36	39.2
186/biochemicals	<u>0</u>	<u>—</u> ^a
Biotechnology total	<u>1,599</u>	29.4

^aNot applicable.

Source: U.S. Department of Commerce, U.S. Patent and Trademark Office, Group Patent Case Pendency Reports.

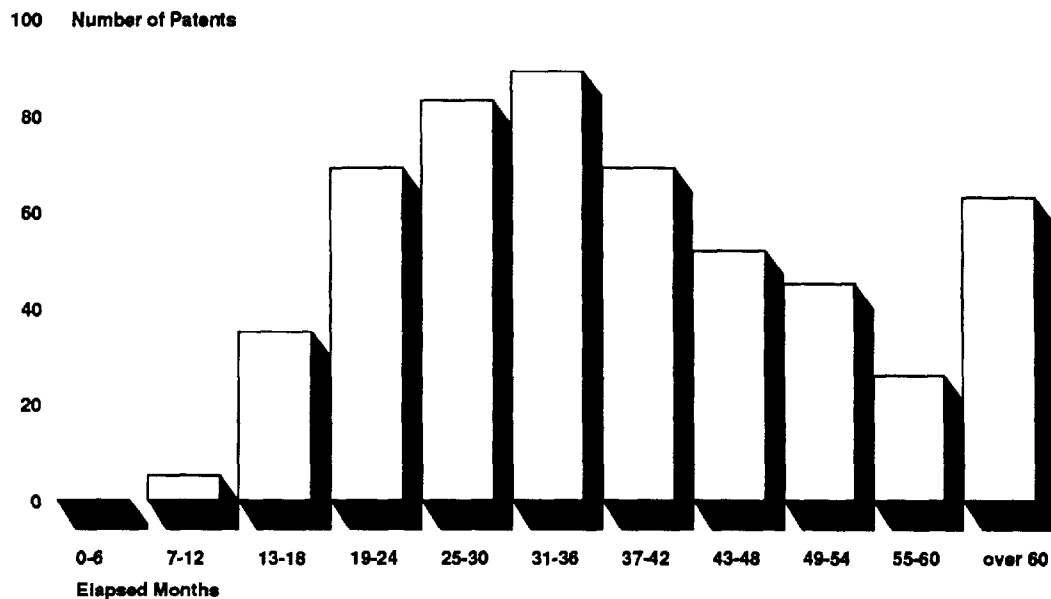
Figure 6.1: Waiting Period and Number of Biotechnology Patents Issued, August Through October 1988



Source: U.S. Department of Commerce, U.S. Patent and Trademark Office, GAO analysis of special pendency run.

However, the Patent Office measures pendency only from the latest application in what may be a chain of replacement applications, or "continuations." For example, if an application is filed in 1980, replaced by a continuation in 1985, and granted in 1986, the issued patent's pendency is 1 year--not 6 years. For the period of August through October 1988, the average waiting period from the original biotechnology patent application to issue was 39.2 months--9.7 more months than the Patent Office's reported average patent pendency. About 7 percent of the patents were issued in 18 or fewer months, and about 25 percent of the patents were issued more than 4 years from the date of the original application. About 36 percent of applications for the patents issued during this period were continuations of prior applications. (See fig. 6.2.) Patent Office officials told us that about 22 percent of applications for patents in all technologies are continuations of prior applications.

Figure 6.2: Waiting Period From Date of Original Application and Number of Biotechnology Patents Issued, August Through October 1988



Source: U.S. Department of Commerce, U.S. Patent and Trademark Office, GAO analysis of special pendency run.

PENDENCY FROM APPLICATION
TO FIRST ACTION

Art unit 185 (genetic engineering) had the longest average period from application to first action for those biotechnology actions initiated during the period of April through December 1988. (See table 6.2.) According to Patent Office officials, this particular art unit, previously known as art unit 127, has shortened its pendency to first action from 28 months to 18.3 months during the past year. During the same period, the average pendency from application to first action for all biotechnology patents was 14.5 months--double the average for all technologies. Old applications contributed to the high pendency averages for biotechnology first actions. Our examination of all biotechnology first actions made during the 3-month period of August through October 1988 showed that over 25 percent of the first actions were made on applications over 18 months old. Art unit 185 (genetic engineering), which has the highest first action pendency average, made first actions on applications of which about 70 percent were over 18 months old.

Table 6.2: Average Waiting Period From Application to First Action for Biotechnology Patents, April Through December 1988

<u>Art unit/ description</u>	<u>Total first actions</u>	<u>Average months</u>
181/equipment	730	11.5
182/immunology	810	15.2
183/biochemicals	1,321	12.1
184/plants and animals	1,052	14.8
185/genetic engineering	920	19.9
186/biochemicals	<u>223</u>	<u>13.0</u>
Biotechnology total	<u>5,056^a</u>	14.5

^aDoes not agree with total shown in table 5.1 because of a difference in report run dates.

Source: U.S. Department of Commerce, U.S. Patent and Trademark Office, Group Patent Case Pendency Reports.

SECTION 7

PATENTABLE IDEAS SUBMITTED BY FOREIGN BIOTECHNOLOGY COMPETITORS

We did not find that the biotechnology patent applications submitted by foreign competitors reflect a deliberate attempt to overwhelm the patent system with applications and to undermine the efficient flow of biotechnology inventions in the United States. Our analysis of biotechnology patent activity and success rates (patent issues versus rejections) did not provide data to support the supposition that either larger relative numbers or lower average quality were associated with foreign biotechnology patent applications.

The Assistant Secretary of Commerce for Productivity, Technology, and Innovation discussed the status of international competitive and trade policy, particularly as they pertain to biotechnology products, before the Subcommittee on Natural Resources, Agriculture Research and Environment and the Subcommittee on Science, Research and Technology of the House Committee on Science, Space, and Technology on July 14, 1988. He stated that "the Patent Office has been inundated with these [biotechnology] patent applications, many of them from Japan" and that "Some people have suggested that is a strategy to create a problem for issuance." He concluded that ". . . basically the Japanese strategy is to blanket a given area with a lot of little picket patents which would never see the light of day in our [the United States'] system, and will not, probably, but they do inundate the system."

We subsequently asked the Assistant Secretary for more specifics on his charges against foreign biotechnology competitors. He said that his statements were based on comments by some of his American friends who are working as consultants to the Japanese in developing trade strategies in technologies such as biotechnology and superconductors. He said he had not received any information pertaining to this issue from the U.S. Patent Office. Patent Office officials told us that they were not aware of any such problems with foreign patent applications.

QUALITY OF FOREIGN APPLICATIONS

We found the success rate (allowances compared with abandonments) similar for both domestic and foreign biotechnology patent applications that were acted upon by the Patent Office during the period of August through October 1988. Applications from foreign countries had a success rate of 51.4 percent, whereas the success rate of applications from the United States was 49.6

percent. Japan, the major foreign applicant, had a success rate of 48.6 percent.

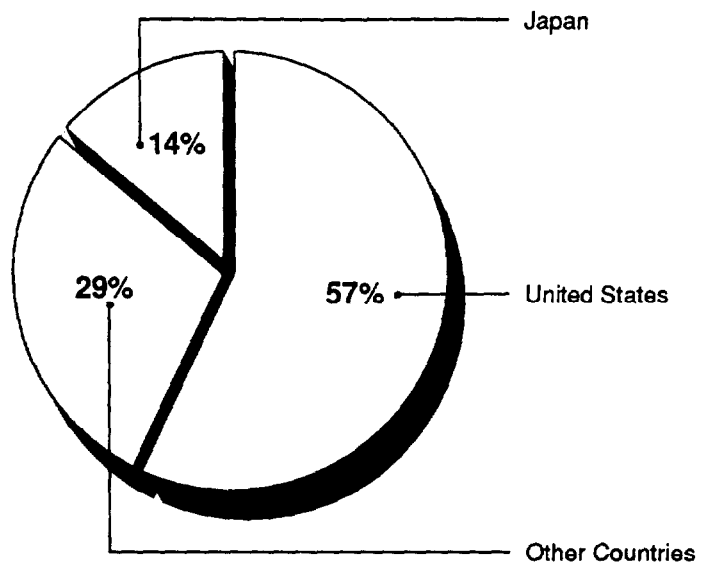
A National Science Board analysis of 1981 patent applications in all technologies showed that foreign applicants' success (resulted in a patent issue) rates ranged from 50.4 percent (United Kingdom) to 70.8 percent (Japan). The success rate for the United States was 58.0 percent.

VOLUME OF FOREIGN APPLICATIONS

About 43 percent of the first actions¹ made during the period of August through October 1988 were on biotechnology patent applications of foreign origin compared with about 57 percent from inventors in the United States. Japan, the major foreign applicant, had about 14 percent of the total applications acted upon. (See fig. 7.1.) Historical data show similar results. During the 10-year period of fiscal years 1978 through 1987, inventors from the United States received 58 percent of all patents awarded by the Patent Office and inventors from foreign countries received 42 percent of all patents--including 15 percent from Japan. In addition, during the 25-year period of fiscal years 1963 through 1987, 43 percent of the patents awarded in the molecular biology and microbiology areas went to foreign country applicants and 57 percent went to inventors from the United States. Japan, the major foreign applicant, was awarded about 18 percent of these patents. (See fig. 7.2.)

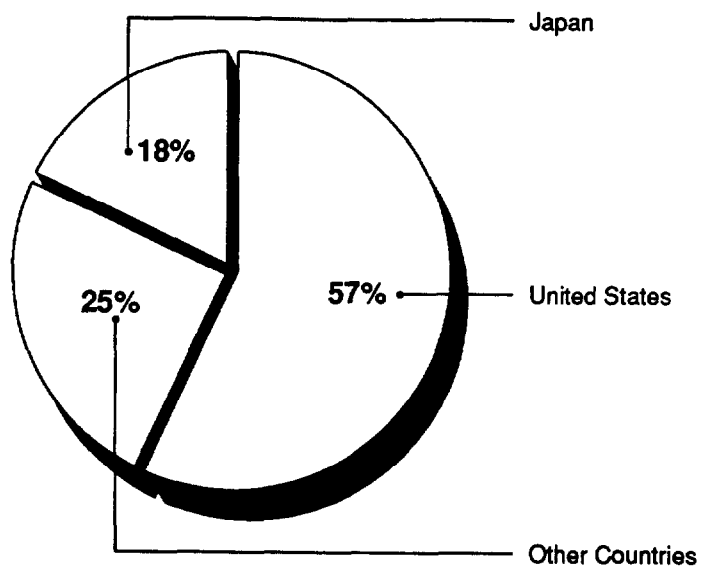
¹A comparison of the origin of all backlogged biotechnology patent applications would have provided more comprehensive analysis, but this information was not readily available from the PALM system.

Figure 7.1: First Actions on U.S.- and Foreign-Origin Biotechnology Patent Applications, August Through October 1988



Source: U.S. Department of Commerce, U.S. Patent and Trademark Office, GAO analysis of special pendency run.

Figure 7.2: Molecular Biology and Microbiology Patent Issues of U.S. and Foreign Origin, Fiscal Years 1963 Through 1987



Source: U.S. Department of Commerce, U.S. Patent and Trademark Office, Technology Assessment and Forecast Report, Technology Profile on Class 435.

CHEMICAL, ELECTRICAL, AND MECHANICAL
PATENT EXAMINING GROUPS

<u>Group number</u>	<u>Category</u>
<hr/> <u>Chemical</u> <hr/>	
110	General, metallurgical, inorganic, petroleum and electrical chemistry, and engineering
120	Organic chemistry
130	Specialized chemical industries and chemical engineering
150	High polymer chemistry, plastics, coating, photography, stock materials, and compositions
180	Biotechnology
<hr/> <u>Electrical</u> <hr/>	
210	Industrial electronics, physics, and related elements
220	Security applications
230	Information processing, storage, and retrieval
240	Packages, cleaning, textiles, and geometrical instruments
250	Electronic and optical systems and devices
260	Communications, measuring, testing, and lamp discharge

Mechanical

- 310 Handling and transporting media
- 320 Material shaping, article manufacturing, and tools
- 330 Mechanical technologies and husbandry, personal treatment information
- 340 Solar, heat, power, and fluid engineering devices
- 350 General constructions, petroleum, and mining engineering

GROUP 180--BIOTECHNOLOGY ART UNITS

<u>Art unit number</u>	<u>Area</u>
181	Chemical apparatus such as analyzers, reactors and sterilizers; processes of chemical and clinical analysis, sterilizing and preserving; immunology and liquid purifications or separation by living organisms
182	Clinical chemistry, microbiology, immunology and enzymology, purification and chemical engineering
183	Carbohydrate chemistry, drug, bio-affecting and body treating compositions containing carbohydrates, animal or plant extracts of undetermined constitution, nucleic acid assays, microbiology, fermentation and chemical engineering
184	Multicellular organisms (animal/plant), molecular genetics, cell culture, immunology, hybridoma, molecular biology, microbiology, fermentation - metabolism and chemical engineering
185	Molecular genetics, catalysis, enzymology, microbiology and chemical engineering
186	Peptide and protein chemistry, drug, bio-affecting and body treating compositions containing peptides, lymphokines other than interferons, antibodies or antigens

MAJOR CONTRIBUTORS TO THIS BRIEFING REPORT

RESOURCES, COMMUNITY, AND ECONOMIC DEVELOPMENT DIVISION,
WASHINGTON, D.C.

John M. Ols, Jr., Director, Housing and
Community Development Issues, (202) 275-5525
Lowell Mininger, Assistant Director
James E. Gwinn, Evaluator-in-Charge

(005753)