

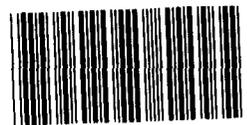
GAO

Report to the Chairman, Subcommittee  
on Regulation, Business Opportunities,  
and Energy, Committee on Small  
Business, House of Representatives

September 1990

# BIOTECHNOLOGY

## Processing Delays Continue for Growing Backlog of Patent Applications



142349

RELEASED

**RESTRICTED**—Not to be released outside the  
General Accounting Office unless specifically  
approved by the Office of Congressional  
Relations.

549301

---

---

**Resources, Community, and  
Economic Development Division**

B-234556

September 28, 1990

The Honorable Ron Wyden  
Chairman, Subcommittee on Regulation,  
Business Opportunities, and Energy  
Committee on Small Business  
House of Representatives

Dear Mr. Chairman:

As requested in your April 4, 1990, letter, and subsequently agreed with your office, we updated our report on the large backlog of unprocessed biotechnology patent applications at the U.S. Patent and Trademark Office (PTO), an agency of the Department of Commerce.<sup>1</sup> That report dealt with several issues, including: the level of scrutiny required to process these applications compared to others; actions taken to streamline the process for these applications; and the ability of PTO to attract and retain qualified examiners.

In this update, we determined (1) the extent of the current backlog, (2) the current impact of PTO actions to accelerate decisions on biotechnology patents, and (3) the impact of continuations on reported patent pendency time in 1989. We briefed your staff on the results of our work on July 13, 1990, and, as requested, have summarized the information in this report.

---

## Results in Brief

The swift granting of a patent encourages both investment in biotechnology research and the commercialization of related inventions. Unfortunately, despite PTO actions designed to accelerate decisions on biotechnology patents, processing delays continue for a growing backlog of biotechnology patent applications.

During calendar year 1989 and the first half of 1990, the inventory of unexamined biotechnology patent applications increased by about 33 percent, from about 6,200 to about 8,200. This increase reflects about a 15-percent average annual increase in the number of filings during the past 6 years. Over 40 percent of the about 8,200 backlogged patent applications were over 12 months old.

---

<sup>1</sup>Biotechnology: Backlog of Patent Applications (GAO/RCED-89-120BR, Apr. 12, 1989).

PTO's efforts to accelerate the award of biotechnology patents have been less effective than anticipated. The average waiting time for processing biotechnology patent applications was about 26 months in 1989 compared with the about 19-month average for all other technologies. Because of the large growth in filings and the shortage of experienced senior biotechnology patent examiners, PTO is no longer projecting that by 1992 it will reduce the pendency period for biotechnology patents from its current 26-month average to the targeted 18-month average goal for all patent applications. As of August 1990, PTO had not established a new date to replace the 1992 target date.

The actual time required to process inventions contained in patent applications is longer than the pendency reported by the PTO because the PTO measures pendency of applications, not inventions. A patent granted on an invention may be the result of a chain of replacement applications, or continuing applications. For example, during 1989, about one-third of the 25,615 inventory of unexamined (backlogged) and in process biotechnology patent applications resulted from chains of continuing applications. Factoring in the original application date for the 7,079 patent applications issued or abandoned in 1989 would add 9.0 months to PTO's reported average patent pendency of 26.3 months.

---

## Background

Patent applications are assigned to the appropriate examining group—1 of 16 such groups. Each group includes a number of suborganizations, art units, responsible for a specific area of technology. Examiners in the art units review patent applications to decide whether the inventions described are entitled to patent protection.

The examination process includes a search through United States patents, prior foreign patent documents that are available in PTO, and available nonpatent literature, to see if the invention is new, useful and nonobvious (significantly different from prior inventions). The examiner decides whether to grant a patent based on a review of the application and search results.

An Office "action" notifies the applicant of the examiner's decision. It states reasons for any adverse decision or any objection or requirement and provides information that may assist the applicant in judging whether to pursue the application. If the invention is not considered patentable subject matter, the claims will be rejected. Some or all of the claims may be rejected on the first action by the examiner; relatively few applications result in patents as originally filed.

---

If the application is rejected or objected to, the applicant must request reconsideration in writing, responding to every rejection in the Office action. The application is then reconsidered, and the applicant is again notified of the Office's decision. If the applicant elects not to further pursue the issuance of a patent under the existing application, PTO considers the application as no longer pending and classifies it as abandoned. In order to control the time frame of patent applications, PTO normally makes the second Office action final. The applicant is then limited to: (1) appeal to the PTO Board of Patent Appeals and Interferences and to the courts in the case of rejection of any claim; (2) presentation of a further amendment for consideration by the examiner (although the applicant does not have a right to have the amendment entered by the examiner); or (3) filing a continuing application.

As an alternative to appeal, when applicants desire consideration of different claims or of further evidence, continuation applications are often filed. Each continuing application also needs to include the claims and evidence for which consideration is desired. If the continuing application is filed before expiration of the appeal period and it refers specifically to an earlier application, the applicant is entitled under 35 U.S.C. 120 to the date of the earliest filed application for subject matter common to both applications.

An earlier filing date is important because occasionally two or more applications are filed by different inventors claiming substantially the same patentable invention. The earlier filing date determines patent rights, absent any other evidence. Furthermore, in the examining group, applications are examined in the order in which they have been filed. Thus, continuing applications are scheduled for examination based on the date of an earlier filed application on which they rely for common subject matter.

---

## Backlog Continues to Grow

The number of unexamined biotechnology patent applications continues to increase. Between January 8, 1989, and July 3, 1990, the number of biotechnology patent applications not yet acted upon increased from 6,163 to 8,213 (41.3 percent of which were over 12 months old). One contributing factor is that the filing of biotechnology applications has grown at a significantly higher average annual rate—14.9 percent—than have all patent applications—7.5 percent—during fiscal years 1984 through 1989.

## Long Delays Continue Despite New Efforts

As we reported in April 1989, PTO instituted a 13-point plan in 1988 to accelerate the award of biotechnology patents. The plan includes hiring 100 new biotechnology patent examiners over 5 years, consolidating all biotechnology examining responsibilities into a new group (called "Group 180"), which currently contains eight art units, enhancing search tools by using personal computers to access PTO and commercial data bases, improving training for examiners by joining with the biotechnology industry to create the Biotechnology Institute, and liberalizing the procedure for requesting accelerated examination.

Through June 30, 1990, the number of biotechnology patent examiners assigned to Group 180 increased by 23 percent (from 91 to 112) from October 1, 1988. According to the PTO, more biotechnology patent examiners would have been hired, but it had an insufficient number of experienced senior staff to train them. Only 16 of the current 112 biotechnology examiners (14 percent) have more than the 6 years' experience required to become a senior examiner.

The large number of patent applications not yet acted upon, along with the relatively small number of experienced senior examiners, have continued to cause long waiting periods for PTO first actions. During calendar year 1989 and the first half of 1990, first actions in the biotechnology area were made an average of 13.1 months after the filing date of the application, whereas first actions in all technologies averaged 7.1 months after the filing date of the application.

To avoid the wait created by the backlog, PTO 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. Our analysis of Patent Application, Location, and Monitoring (PALM) computerized data showed that of 25,615 biotechnology patent applications pending during 1989, only 144 had petitions for accelerated examination. (See table I.9.) In April 1989, we reported that applicants are reluctant to use the accelerated procedures because of perceived legal risks.

---

Because of the size and age of the backlog created by the large growth in filings and the shortage of experienced senior biotechnology patent examiners, PTO no longer believes it can meet its goal of reducing the average biotechnology patent processing time from its 26-month average to 18 months by 1992, bringing the pendency for these patents in line with the PTO average for all technologies. No new target date had been established as of August 1990.

---

## Extensive Use of Continuations Masks Actual Pendency Time

As we previously reported, PTO measures pendency of each application in a chain of replacement applications, or continuing applications. PTO officials believe that measuring pendency of applications rather than of inventions is a better management control over patent processing efficiency because patent examiners cannot control the use of continuations. Only the patent applicant decides whether and when to file a continuing application, so long as it is filed during the pendency of the prior application.

A continuing application is often filed in situations where an applicant desires consideration of different claims or of further evidence related to an application for an invention considered unpatentable and rejected by a PTO examiner. With a continuing application that meets the conditions of 35 U.S.C. 120, the applicant is entitled to the benefits of the earlier filing date of the prior application. This earlier date may be important in determining patentability or who owns an invention, although pendency is measured from the latest filing.

Using PALM data, we determined that about 32 percent of the 25,615 biotechnology patent applications pending during 1989 resulted from continuations. (See tables I.1 through I.4.) We did not examine the extent of the use of continuations by applicants in other technologies, but PTO officials told us that continuations for all technologies is 24 percent.

We used the date of the original application rather than the date of the most recent continuation application for the 7,079 patents issued or abandoned in 1989 and calculated pendency of 35.3 months—9.0 months more than the PTO-reported average patent pendency of 26.3 months. (See tables I.5 and I.6.) Using this same approach, we calculated that the 18,534 applications pending at the end of 1989 had, on average, been in process for 26.7 months since their original application date.

---

These 18,534 applications included 7,529 unexamined (backlogged) applications (examiners had not yet made a first Office action). (See table I.7.) A total of 1,627 of the patent applications pending at the end of 1989 had been in process for more than 5 years since the date of the original application.

The PTO pendency goal for patent applications is 18 months. Thus, if the original application date was considered, the 18,534 patent applications pending at year-end had already been in process, on average, about 50 percent more than the pendency goal. However, according to PTO officials, the pendency goal would be more than 18 months if PTO measured pendency of inventions rather than of applications.

Our analysis of the recorded processing steps for 926 biotechnology patent applications (with a first Office action) abandoned and refiled as continuation applications in calendar year 1989 showed that an average of 2.5 Office actions and 31.2 months elapsed during the life of the original application. About 25 percent were abandoned after the first Office action, and an additional 50 percent received a final rejection after the initial response from the applicant. A final rejection after the applicant's first response is counted as the second Office action by PTO. About three-quarters of the 595 final rejections were second Office actions. This rejection rate is consistent with PTO's policy of normally making the second Office action final. Only about a fifth of the 926 applications had more than 2 Office actions. (See table I.8.)

---

Our audit work was performed between April and July 1990 in accordance with generally accepted government auditing standards. Our review included an analysis of PALM data contained in PTO computer tapes for all biotechnology patent applications on hand during 1989. We also examined work load reports generated during 1989 and the first 6 months of 1990 by PTO. Appendix I contains tables of data generated from our analysis of PALM computer tapes.

We discussed this report's contents with PTO officials, 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 report until 14 days from the date of this letter. At that time, we will provide copies of this report 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. Major contributors to this report are listed in appendix II.

Sincerely yours,

A handwritten signature in cursive script that reads "John M. Ols, Jr.".

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

---

# Contents

---

Letter	1
Appendix I GAO Analysis of PALM Computer Tapes	10
Appendix II Major Contributors to This Report	14
Tables	
Table I.1: Percent of Continuations Included in All Biotechnology Patents Issued During 1989	10
Table I.2: Percent of Continuations Included in All Biotechnology Patent Applications Abandoned During 1989	10
Table I.3: Percent of Biotechnology Patent Applications Abandoned and Simultaneously Refiled as Continuations During 1989	10
Table I.4: Percent of Continuations Included in All Biotechnology Patent Applications Pending at the End of 1989	11
Table I.5: Average Waiting Period From Date of Original Application for All Biotechnology Patents Issued in 1989	11
Table I.6: Average Waiting Period From Date of Original Application for All Biotechnology Patent Applications Abandoned During 1989	11
Table I.7: Average Waiting Period From Date of Original Application for All Biotechnology Patent Applications Pending at the End of 1989	12
Table I.8: Average Processing Time for Selected Steps for All Original Applications With a First Office Action and Abandoned and Refiled as Continuation Applications in 1989	12
Table I.9: Percent of Accelerated Examinations Included in All Biotechnology Patent Applications Pending During 1989	13

---

**Contents**

---

---

**Abbreviations**

<b>FAOM</b>	<b>First Action on the Merits of the Case</b>
<b>PALM</b>	<b>Patent Application, Location, and Monitoring</b>
<b>PTO</b>	<b>Patent and Trademark Office</b>

# GAO Analysis of PALM Computer Tapes

**Table 1.1: Percent of Continuations Included in All Biotechnology Patents Issued During 1989**

Art unit/description	Total patents issued	Total continuations	Percent
181/equipment	723	219	30
182/immunology	417	134	32
183/biochemicals	665	230	35
184/plants and animals	754	84	11
185/genetic engineering	307	124	40
186/biochemicals	268	106	40
187/equipment and immunology	1	0	0
188/microbiology	0	0	0
<b>Biotechnology total</b>	<b>3,135</b>	<b>897</b>	<b>29</b>

**Table 1.2: Percent of Continuations Included in All Biotechnology Patent Applications Abandoned During 1989**

Art unit/description	Total abandonments	Total continuations	Percent
181/equipment	510	187	37
182/immunology	646	213	33
183/biochemicals	647	206	32
184/plants and animals	653	218	33
185/genetic engineering	684	228	33
186/biochemicals	580	195	34
187/equipment and immunology	119	36	30
188/microbiology	106	44	42
<b>Biotechnology total</b>	<b>3,945</b>	<b>1,327</b>	<b>34</b>

**Table 1.3: Percent of Biotechnology Patent Applications Abandoned and Simultaneously Refiled as Continuations During 1989**

Art unit/description	Total abandonments	Refiled continuations	Percent
181/equipment	510	189	37
182/immunology	646	255	39
183/biochemicals	647	234	36
184/plants and animals	653	272	42
185/genetic engineering	684	311	45
186/biochemicals	580	247	43
187/equipment and immunology	119	35	29
188/microbiology	106	33	31
<b>Biotechnology total</b>	<b>3,945</b>	<b>1,576</b>	<b>40</b>

**Appendix I**  
**GAO Analysis of PALM Computer Tapes**

**Table I.4: Percent of Continuations Included in All Biotechnology Patent Applications Pending at the End of 1989**

<b>Art unit/description</b>	<b>Total applications</b>	<b>Total continuations</b>	<b>Percent</b>
181/equipment	2,318	660	28
182/immunology	2,496	815	33
183/biochemicals	2,946	915	31
184/plants and animals	2,268	650	29
185/genetic engineering	2,334	907	39
186/biochemicals	2,655	944	36
187/equipment and immunology	1,702	547	32
188/microbiology	1,816	652	36
<b>Biotechnology total</b>	<b>18,535</b>	<b>6,090</b>	<b>33</b>

**Table I.5: Average Waiting Period From Date of Original Application for All Biotechnology Patents Issued in 1989**

<b>Art unit/description</b>	<b>Total patents issued</b>	<b>Average months</b>
181/equipment	723	37.2
182/immunology	417	44.1
183/biochemicals	665	36.7
184/plants and animals	754	24.9
185/genetic engineering	307	47.4
186/biochemicals	268	37.7
187/equipment and immunology	1	33.4
188/microbiology	0	0.0
<b>Biotechnology total</b>	<b>3,135</b>	<b>36.1<sup>a</sup></b>

<sup>a</sup>Patent Office reported average was 27.4.

**Table I.6: Average Waiting Period From Date of Original Application for All Biotechnology Patent Applications Abandoned During 1989**

<b>Art unit/description</b>	<b>Total abandonments</b>	<b>Average months</b>
181/equipment	510	33.1
182/immunology	646	37.3
183/biochemicals	647	29.2
184/plants and animals	653	37.0
185/genetic engineering	684	40.0
186/biochemicals	579	30.8
187/equipment and immunology	119	33.5
188/microbiology	106	35.8
<b>Biotechnology total</b>	<b>3,944</b>	<b>34.7<sup>a</sup></b>

<sup>a</sup>Patent Office reported average was 25.4.

Appendix I  
GAO Analysis of PALM Computer Tapes

**Table I.7: Average Waiting Period From Date of Original Application for All Biotechnology Patent Applications Pending at the End of 1989**

Art unit/description	Total applications	Average months
181/equipment	2,318	23.4
182/immunology	2,496	27.7
183/biochemicals	2,946	23.2
184/plants and animals	2,268	25.7
185/genetic engineering	2,333	33.0
186/biochemicals	2,655	26.9
187/equipment and immunology	1,702	25.8
188/microbiology	1,816	28.6
<b>Biotechnology total</b>	<b>18,534</b>	<b>26.7<sup>a</sup></b>

<sup>a</sup>Includes elapsed months for 1,576 applications abandoned and simultaneously refilled as continuations in 1989.

**Table I.8: Average Processing Time for Selected Steps for All Original Applications With a First Office Action and Abandoned and Refilled as Continuation Applications in 1989**

Processing step	Total time (months)	Total number	Average time (months)
Filing to docketing	4,579	923	5.0
Docketing to first action on the merits of the case (FAOM)	10,489	907	11.6
FAOM to first response	3,606	680	5.3
Abandonment after first action	1,226	226	5.4
First response to final rejection	1,040	446	2.3
First response to second action	600	228	2.6
Second action to second response	883	165	5.4
Abandonment after second action	344	63	5.5
Second response to final rejection	290	108	2.7
Second response to third action	168	57	3.0
Third action to third response	216	43	5.0
Third action to abandonment	121	20	6.0
Third response to final rejection	165	39	4.2
Final rejection to abandonment	4,940	595	8.3
Filing to abandonment	28,856	925	31.2

**Table I.9: Percent of Accelerated Examinations Included in All Biotechnology Patent Applications Pending During 1989**

<b>Art unit/description</b>	<b>Total applications</b>	<b>Total accelerations</b>	<b>Percent</b>
181/equipment	3,551	35	1.0
182/immunology	3,559	13	0.4
183/biochemicals	4,258	18	0.4
184/plants and animals	3,675	24	0.7
185/genetic engineering	3,325	23	0.7
186/biochemicals	3,503	7	0.2
187/equipment and immunology	1,822	16	0.9
188/microbiology	1,922	8	0.4
<b>Biotechnology total</b>	<b>25,615</b>	<b>144</b>	<b>0.6</b>

---

# Major Contributors to This Report

---

Resources,  
Community, and  
Economic  
Development Division,  
Washington, D.C.

Paul J. O'Neill, Assistant Director  
James E. Gwinn, Evaluator-in-Charge  
Sara-Ann W. Moessbauer, Operations Research Analyst

---

### **Ordering Information**

**The first five copies of each GAO report are free. Additional copies are \$2 each. Orders should be sent to the following address, accompanied by a check or money order made out to the Superintendent of Documents, when necessary. Orders for 100 or more copies to be mailed to a single address are discounted 25 percent.**

**U.S. General Accounting Office  
P. O. Box 6015  
Gaithersburg, MD 20877**

**Orders may also be placed by calling (202) 275-6241.**

---

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

Official Business  
Penalty for Private Use \$300

First-Class Mail  
Postage & Fees Paid  
GAO  
Permit No. G100

---