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INTERNATIONAL PATENTING OF HUMAN DNA SEQUENCES

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National governments grant property rights to inventors in the form of patents. With a patent, the inventor (or the owner of the patent) has the legal right to license others to make, use, or sell that invention. When inventions result in new or improved products or processes, patent owners can reap economic benefits that typically spill over to associated users and consumers. But inventions that lead to the creation of entire new industries have more profound impact on national economies and on international relations. Patents of human DNA (deoxyribonucleic acid) sequences are a recent example of industry-creating inventions.

Shadowing the widely anticipated economic and medical benefits associated with this technology area is a great deal of controversy. Proponents argue that patents on human DNA sequences are necessary to make diagnostic and therapeutic products commercially available. Others voice concerns about the patenting of naturally occurring elements and more general concerns that giving companies monopoly rights over specific DNA sequences will hinder scientific progress. Ethical issues surrounding cloning for reproductive and therapeutic purposes also cloud the debate.

Despite the ongoing controversies, patent offices worldwide have issued thousands of patents on human DNA sequences. As researchers move from mapping sequences to decoding their functions and manipulating them for diagnostic and therapeutic purposes, their work will likely transform the way many diseases are treated. And the companies and countries that own key patents in this technology area will benefit most from these developments.

This InfoBrief explores the relative strength of America's inventive activity in this technology area through an examination of international patenting patterns by U.S. inventors. It compares the position of the United States with that of more than 40 countries, including Japan, European countries, and other major industrialized and industrializing countries.

U.S. inventors filed for more international patents in this technology area than inventors in any other nation and more than the combined total of inventors in the 15-nation European Union.

The analysis is built around the concept of a *patent family,* which consists of all patent documents published in a country associated with a single invention.[1]

[1]Information presented in this report was developed by Mogee Research & Analysis Associates under contract to the National Science Foundation. Data on patents covering human DNA sequences were drawn from GENESEQ and the Derwent World Patents Index (DWPI), two online databases published by Derwent Publications. GENESEQ is the world's most comprehensive database exclusively devoted to patented sequence information, and each patent record in GENESEQ is reviewed and coded by molecular biologists at Derwent. Patents are included that claim DNA sequences or that refer to DNA sequences in their claims. A search was conducted in GENESEQ for all gene sequence patents that had been coded by the experts as relating to humans. GENESEQ records go back to 1981.

Each GENESEQ record corresponds to a patented sequence, rather than a patent, and gives only the basic patent number covering each sequence. Therefore, the basic patent numbers were mapped from the GENESEQ search into the DWPI, which covers patenting from over 40 different countries and patent-granting authorities, to retrieve more complete information. Each DWPI record is a summary of all countries of application for each single invention. This record is called the patent family for the invention, which avoids the problem of double-counting inventions patented in more than one country. Using this procedure, 10,759 Derwent records were obtained, with 1980 as the earliest priority year.

Inventions for which patent protection has been sought in more than one country are called *international patent families* and are the subject of this paper. Counting international patent families makes international comparisons more accurate by mitigating the bias introduced by national patent systems that encourage large numbers of patent applications. They also serve to identify those inventions intended for international use. The first application filed anywhere in the world is the *priority application:* it is assumed that the country in which the priority application was filed is the country in which the invention was developed. Similarly, the *priority year* is the year the priority application was filed.

The three indicators used in this assessment are overall trends of international inventive (patenting) activity, the number of organizations assigned patents, and the number of highly cited inventions.

Number of International Patent Families

This first indicator is a measure of the extent and growth of inventive activity considered important enough to be patented outside the country of origin. These data are tabulated by priority year.[2]

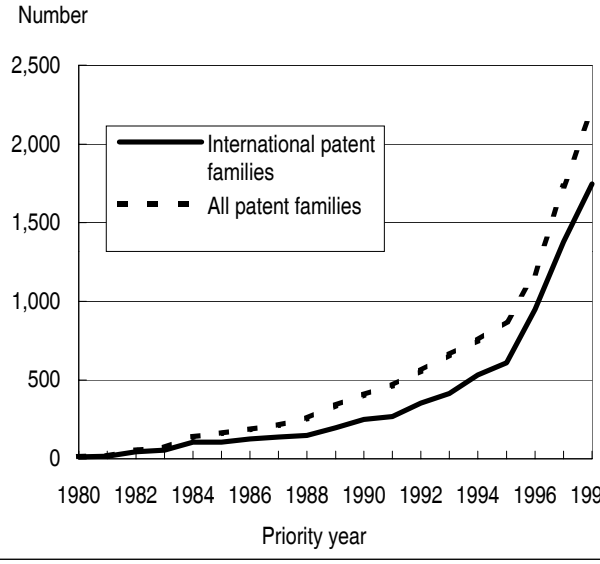
The number of international patent families formed in this technology grew rapidly during the period examined.[3] The total number of patent families formed tripled from the early to late 1980s (1980-84 versus 1985-89) and nearly tripled again during the early and late 1990s (figure 1 and table 1). Throughout this 20-year period, the United States led all other nations and the 15-nation European Union with 72 percent of total international patent families formed. The U.S. share increased from 57 percent during 1980-84 to 59 percent during 1985-89 and then jumped to 71 percent in the early 1990s and 74 percent by the late 1990s. By contrast, Europe's share trended downward from period to period. From a high of 19 percent achieved throughout much of the 1980s, Europe's share dropped to 16 percent during 1990-94 and to 15 percent for the later half of the 1990s. Overall, Europe accounted for just under 16 percent of total international families formed during the 1980-99 period. Great Britain (with a 6 percent share) and Germany (3 percent) were the leaders among the European countries.

Japan's share of total international patent activity in this technology area was 10 percent, a share greater than any other single country except the United States. But like Europe, Japan's share was highest in the early 1980s (20 percent) turning mostly downward thereafter. By the second half of the 1990s, Japan accounted for just about 8 percent of total international patenting in this technology.

Number of Patenting Organizations

The number of organizations in a country that are active in a technology may indicate a country's ability to innovate and its potential for innovative activity in that technology area. Research by Michael Porter (1990) suggests that the growth of clusters of innovative organizations is associated with national competitiveness. The Council on Competitiveness (2001) also associates clusters of innovation with higher

Figure 1. **New human DNA sequence patent families by priority year: 1980-98**



SOURCE: "International Analysis of Human DNA Sequence Patenting," submitted to the National Science Foundation by Mogee Research and Analysis Associates (Reston, VA, April 10, 2001).

[2]The priority year is the year that the priority application was filed. The first application filed anywhere in the world is the priority application: it is assumed that the country in which the priority application was filed is the country in which the invention was developed.

[3]Due to the time lag between patent application and publication, data for 1999 should be regarded as incomplete.

Table 1. **International patent families of human DNA sequence patents, by priority country and priority year: 1980-99**

Priority country	Priority period				
	All years	1980-84	1985-89	1990-94	1995-99
Total	7,810	233	715	1,817	5,045
United States	5,610	132	423	1,295	3,760
Japan	747	47	131	173	396
Great Britain	474	30	47	110	287
European Patent Office	240	2	24	40	174
Germany	231	6	20	53	152
France	143	5	22	47	69
Australia	59	4	7	15	33
Israel	54	2	9	18	25
Denmark	48	0	10	19	19
Canada	40	2	2	8	28
Sweden	34	0	3	10	21
Italy	29	0	1	18	10
South Korea	19	0	0	3	16
China	17	0	0	1	16
Netherlands	9	0	6	1	2
Switzerland	8	0	4	1	3
New Zealand	7	0	0	1	6
Austria	6	0	0	2	4
Patent Cooperation Treaty	5	0	0	0	5
Spain	4	0	0	0	4
Finland	4	0	0	0	4
Ireland	4	0	2	0	2
Norway	4	0	1	0	3
Belgium	3	2	0	0	1
India	2	0	0	0	2
Soviet Union	2	1	1	0	0
Argentina	1	0	0	0	1
Brazil	1	0	0	0	1
Czech Republic	1	0	0	1	0
Cuba	1	0	1	0	0
Honduras	1	0	0	1	0
Mexico	1	0	0	0	1
Yugoslavia	1	0	1	0	0

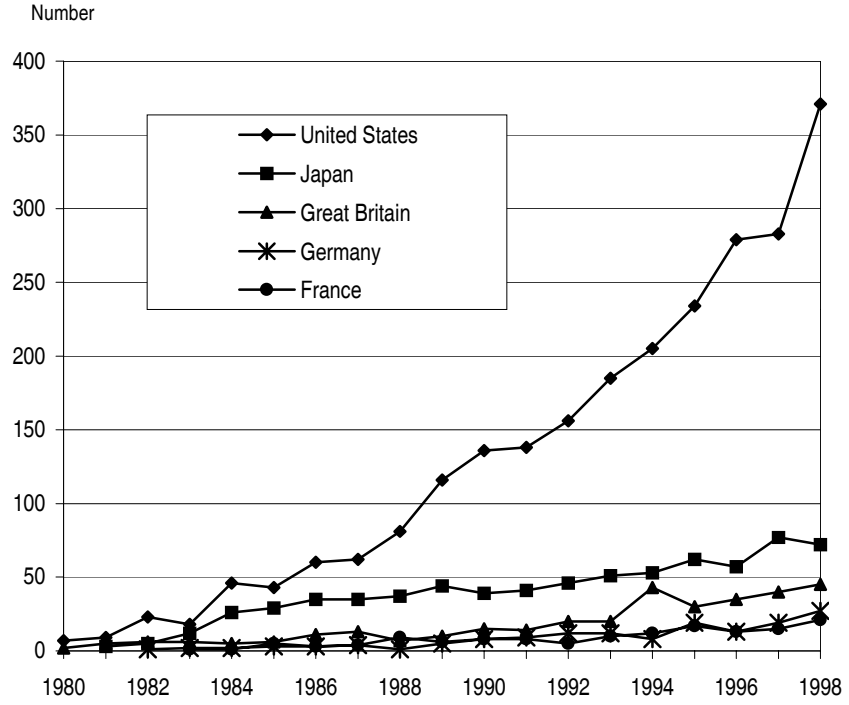
NOTES: Patents in a family are linked together through "priority" details. Priority is established by the original patent application date in the first country where the application is filed. Due to the time lag between patent application and publication, data for 1999 should be regarded as incomplete.

SOURCE: "International Analysis of Human DNA Sequence Patenting," submitted to the National Science Foundation by Mogee Research and Analysis Associates (Reston, VA, April 10, 2001).

rates of innovation, productivity growth, and new business formation.

The United States has had the most organizations filing patent applications for human DNA sequences and, since the late 1980s, fueled by the Human Genome Project, the number of organizations has generally increased at a rate faster than the other major countries patenting in this technology area (figure 2). Japan has ranked second every year since 1983 and Great Britain has ranked third every year except for 1988. Although still quite low, the number of patenting organizations in several countries, including Australia, China, Israel, Sweden, and South Korea, has increased significantly in the past few years. Although corporations dominate human DNA patenting overall, the types

Figure 2. **Organizations filing at least one human DNA sequence patent family: 1980-98**



NOTE: Nations presented were the top 5 in 1998. Excludes patent families owned by individuals.

SOURCE: "International Analysis of Human DNA Sequence Patenting," submitted to the National Science Foundation by Mogee Research and Analysis Associates (Reston, VA, April 10, 2001).

of organizations actively patenting human DNA sequences vary among priority countries, reflecting in part differences in the structure of their research systems[4] (table 2). The United States and Great Britain have a large number of universities seeking patents for human DNA sequences, although far more corporations than universities are active in these countries. Corporations dominate patenting of human DNA sequences in France, Israel, and Japan. Unlike the other major patenting countries, Australia, Canada, and China tend to have as many or more universities than corporations seeking patents for human DNA sequences.

[4]Table 2 shows the number of unique organizations filing patent applications, not the number of applications filed. In this table, individuals are included if no other type of organization was assigned the patent. If a company was assigned a patent and it was coassigned to the individual, the individual was assumed to be an employee of the company. If two organizations (e.g., a company and a university) were coassigned a patent, both were counted.

Number of Highly Cited Patents

Interpatent citations provided by the patent examiner indicate the "prior art," the technology in related fields of invention, that was taken into account in judging the novelty of the present invention.[5] The number of citations a patent receives from later patents can serve as an indicator of its technical importance or value.[6] The indicator used here attempts to measure a country's contribution toward advancing this technology field by determining the number of highly cited patent families

[5]The citations counted are those placed on European Patent Office (EPO) patents by EPO examiners. EPO citations are believed to be a less biased and broader source of citations than those of the U.S. Patent and Trademark Office. See Claus and Higham (1982).

[6]A country's share of the most highly cited patent families is expressed here as a ratio of its representation among highly cited patent families to its representation among the total families in this particular technology.

Table 2. **Organizations filing patent families of human DNA sequences, by organization type and priority country: 1980-99**

Country	1980-84	1985-89	1990-94	1995-99
Australia	4	11	13	42
Corporations	1	5	4	16
Universities	3	4	6	16
Not-for-profits	0	2	2	6
Government agencies	0	0	1	3
Individuals	0	0	0	1
Canada	2	5	10	28
Corporations	1	3	2	8
Universities	1	2	4	13
Not-for-profits	0	0	0	0
Government agencies	0	0	1	0
Individuals	0	0	3	7
China	0	0	1	22
Corporations	0	0	1	4
Universities	0	0	0	6
Not-for-profits	0	0	0	2
Government agencies	0	0	0	5
Individuals	0	0	0	5
Germany	4	9	25	93
Corporations	4	9	14	33
Universities	0	0	3	9
Not-for-profits	0	0	4	8
Government agencies	0	0	1	5
Individuals	0	0	3	38
European Patent Office	3	19	21	79
Corporations	1	12	12	40
Universities	1	2	1	16
Not-for-profits	1	1	2	11
Government agencies	0	1	3	3
Individuals	0	3	3	9
France	1	14	26	35
Corporations	1	6	16	20
Universities	0	3	2	3
Not-for-profits	0	2	3	7
Government agencies	0	3	4	5
Individuals	0	0	1	0
Great Britain	15	32	80	107
Corporations	10	29	45	63
Universities	2	0	18	27
Not-for-profits	3	1	7	9
Government agencies	0	1	8	4
Individuals	0	1	2	4
Israel	2	3	6	15
Corporations	1	2	5	12
Universities	0	0	1	2
Not-for-profits	0	1	0	0
Government agencies	1	0	0	1
Individuals	0	0	0	0
Japan	31	88	130	150
Corporations	27	65	93	117
Universities	0	3	6	2
Not-for-profits	2	4	6	7
Government agencies	1	5	6	9
Individuals	1	11	19	15
United States	77	215	441	736
Corporations	52	116	241	412
Universities	13	53	108	163
Not-for-profits	7	23	48	59
Government agencies	1	7	13	20
Individuals	4	16	31	82

SOURCE: "International Analysis of Human DNA Sequence Patenting," report submitted to the National Science Foundation by Mogee Research and Analysis Associates (Reston, VA, April 10, 2001).

from each priority country[7] (table 3). A value of 1.0 indicates that a country's share of the highly cited families is identical to its share of total families; a value greater than 1.0 in the ratio column indicates that a country is overrepresented, while a score of less than 1.0 indicates that a country's patent families are undercited.

Although during the past 20 years the United States has had the largest number by far of highly cited patents in this technology, its total number of highly cited patents has been about what would be expected based on its overall level of patenting. Japan had few highly cited patents from the early 1980s but improved in each of the next three periods. Nevertheless, even in the most recent period, 1995-99, Japan remained slightly underrepresented among the most highly cited patents. One possible explanation is that about half of Japan's patent families are protected only in Japan, and examiners at the European Patent Office (EPO) may be less likely to cite such patents.

Great Britain was significantly overrepresented among the most highly cited patents in the 1985–89 time period, but in the last two time periods Great Britain's share of the most highly cited patents has been about what would be expected based on its level of activity. Germany had about twice as many highly cited patents as expected in the 1985–89 and 1990–94 time periods but had fewer than expected in the last time period. Because these citations come from EPO, one might expect that EPO patents would be overrepresented; however, this effect occurred only in the 1990–94 time period. EPO priority patents were underrepresented among the most highly cited patents in the 1985–89 time period and are about what would be expected in the 1995–99 time period. Care should be taken not to read too much into the ratios for countries with very low levels of activity, where one or two highly cited patents from these countries may make them overrepresented among the highly cited families.

Summary of U.S. Position

Based on this examination of selected variables of international patenting of human DNA sequences, the U.S. science and technology enterprise is a leader in this key technology area. During the period examined, the United States had filed more patent applications for human DNA sequences than all other nations combined; most U.S. patents (75 percent) became international patents (patented in more than one country); and the United States had the most organizations actively filing patent applications for human DNA sequences. The United States also had the largest number of highly cited patents of all the countries active in this technology area, but based on its overall level of patenting, its share did not exceed what would be expected.

Similar in economic size to the United States, the 15-nation European Union has not shown the same international patent activity in this technology area and has far fewer organizations participating. Great Britain and Germany were the leaders among the European Union countries. Whereas the number of highly cited U.S. patent families was consistent with its level of overall patent activity, Great Britain and Germany's patents were generally overrepresenteded among the most highly cited patents—an indication of the important work taking place in these two European Union countries.

Japan's share of total international patent activity in this technology area was greater than any other single country except the United States. But like Europe, its share was highest in the early 1980s turning mostly downward thereafter. Japan has a large number of organizations patenting in this technology area but did not produce the number of highly cited patent families expected based on its level of patent activity.

[7]Those considered highly cited were determined using a distribution definition.

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Table 3. **Priority countries ranked by share of top-cited human DNA sequence patent families**

Priority country and period	Share of top cited (percent)	Share of total families (percent)	Ratio top cited to total families
1980–84			
United States	80.0	56.8	1.4
Great Britain	10.0	10.1	1.0
Japan	10.0	23.6	0.4
1985–89			
United States	62.3	61.6	1.0
Japan	16.4	23.2	0.7
Great Britain	8.2	4.8	1.7
Germany	3.3	1.8	1.8
Denmark	2.5	0.9	2.8
France	2.5	2.1	1.2
European Patent Office	1.6	2.1	0.8
Israel	1.6	0.8	2.0
Netherlands	0.8	0.5	1.6
Sweden	0.8	0.3	2.7
1990–94			
United States	69.8	71.9	1.0
Japan	10.8	14.1	0.8
Great Britain	4.7	4.2	1.1
Germany	4.3	2.2	2.0
European Patent Office	2.6	1.4	1.9
France	2.6	1.9	1.4
Australia	1.3	0.7	1.9
Denmark	1.3	0.7	1.9
Israel	1.3	2.0	0.7
Canada	0.9	2.6	0.3
Italy	0.4	1.0	0.4
1995–99			
United States	76.8	70.3	1.1
Japan	9.8	11.0	0.9
Great Britain	4.8	5.0	1.0
European Patent Office	2.7	2.8	1.0
Germany	2.1	3.2	0.7
Australia	1.8	1.2	1.5
France	1.2	1.3	0.9
Canada	0.3	0.8	0.4
Denmark	0.3	0.3	1.0
Israel	0.3	0.4	0.8

NOTES: Priority country is established by the location of the original patent application. The European Patent Office (EPO) and the Patent Cooperation Treaty (PCT) represent two alternatives to filing multiple applications at individual patent country offices. For these two filing routes, an applicant makes an initial single filing at the responsible office (i.e., the European Patent Office for EPO applications and the World Intellectual Property Office (WIPO) for PCT applications) rather than through their home countries.

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