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# The prevalence of patent interferences in gene technology

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# The prevalence of patent interferences in gene technology

## **Abstract**

Unlike all other countries in the world, the United States awards patents to the first to invent, not to the first to file an application for a patent. In cases where two or more inventors submit patent applications claiming the same invention, an interference may be declared. Interference is the process by which the US Patent & Trademark Office (USPTO; Washington, DC, USA) determines which of the applicants was the first to invent and diligently reduce the invention to practice. More than half of these are resolved in favor of the inventor who was the first-to-file, raising questions about whether this unique system is worth retaining. Interferences are relatively rare. For the period 1998-2002, an average of four interferences were declared for every 10,000 patent applications filed. Data we have gathered suggest that interference proceedings in gene discovery and biotechnology are much more prevalent than other areas of technology. The resulting legal fees are costing the biotechnology industry millions of dollars each year.

## **Comments**

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## **Competition in gene discovery research**

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Unlike all other countries in the world, the US awards patents to the first to invent, not to the first to file an application for a patent. In cases where 2 or more inventors submit patent applications claiming the same invention, an interference may be declared. Interference is the process by which the US Patent & Trademark Office (USPTO) determines which of the applicants was the first to invent and diligently reduce the invention to practice.

Interferences are relatively rare. For the period 1998-2002, there were an average of 4 interferences declared for every 10,000 patent applications filed. More than half of these are resolved in favor of the inventor who was the first to file, raising questions about whether this unique system is worth retaining.<sup>1</sup> Despite their rarity, interferences may provide useful insights about scientific and technological competition.

We are performing interview-based case studies on the discovery, patenting, and commercialization of genetic inventions for a set of 7 diseases having genetic causes (Canavan disease (CD), Chronic Myelogenous Leukemia (CML), Colon Cancers (CC), Cystic Fibrosis (CF), Factor V Leiden (FVL), Hereditary Hemochromatosis (HH), and Spinal Muscular Atrophy (SMA)). Our cases were chosen to capture a range of genetic diseases, encompassing rare (CD), common (HH and CF), single gene (CD, CF, HH, FVL), multigenic (SMA, CC), and somatic (CML) diseases. Except for CML, all of these diseases have at least one patent on a gene in which mutations are known to be associated with disease. One has several patents on one gene (CF), and two have patents on multiple genes (CC, SMA). Given the rarity of interferences, we were surprised to find in this small sample that patents on the genes in 2 of these cases (CF and FVL) had been involved in interferences.

To examine whether we were seeing evidence of a pattern, we secured from the USPTO data on the number of interferences declared and the number of patent applications filed each

year for FY 1998 through 2002. The data is broken down by Technology Centers (TC), which are competency groupings within the USPTO. The number of interferences declared in each technology field and the rate of interference declarations per 1,000 patent applications filed are summarized in the table.

These data show that, in any one year, the rate of interference declaration involving TC 1600 (biotechnology and organic chemistry) was at least 2.5 times the rate of declaration in any other technology area, and was about 6.5 times the average rate of all other technologies for the 5 year period ( $F^*=63.6$  with 1,7 *df*,  $p<0.0001$ ). TC 1600 encompasses drugs, herbicides, pesticides, cosmetics, bioinformatics and other organic compounds, so this rate is not purely attributable to biotechnologies, much less human genetics. Detailed data that would permit greater discrimination of technology involved or historical comparisons is unavailable. Nonetheless, staff in TC 1600 estimated that about 75% of interferences declared in the center involve biotechnologies (George Elliott, personal communication).

These data are consistent with our observations of very high levels of competition and, in some cases, outright races for genetic discoveries.<sup>2</sup> Notable examples of competition in molecular biology include the discovery of the Y chromosome in males first made by Stevens in 1905;<sup>3</sup> the characterization of the structure of DNA;<sup>4</sup> the hunt for HIV;<sup>5</sup> and most recently the quest for the sequence of the SARS virus.<sup>6</sup> Less well-known are the close competitions for discovery of genes for CF and familial breast and ovarian cancers, both of which involved numerous groups. In the latter case, in the mid-1990s, multiple patents on closely related discoveries issued to Oncormed and Myriad Genetics on BRCA1.<sup>7</sup> Myriad and their collaborators at the Universities of Utah and Pennsylvania similarly raced against a British and Duke University group on BRCA2, with US patents issuing to both and potentially overlapping

patents pending in Europe. More recently, the 2001 discovery of the gene associated with the rare Familial Dysautonomia by 2 different research groups also may well result in an interference, since each group filed a patent application on the gene.<sup>8,9</sup>

The high level of competition in these cases suggests several things about the nature of the research. First, without taking any credit away from the scientists so engaged, gene discovery has become ordinary. Necessary intellectual knowhow is shared by many, and success is predicated upon the ability and luck in identifying, soliciting, and studying the “right” families and groups. Second, as in other scientific fields, these discoveries build upon knowledge contributed by others, reflecting the codependent but competitive environment of science.<sup>10</sup> Molecular biology is data intensive, requiring the development of technologies (e.g., faster sequencers and gene chips) and sharing of large databases. The field is relatively young, and the rate of discovery may still be increasing. Given the large body of expertise in molecular biology and the large volume of information now available, there may be a flood of downstream discoveries and developments resulting from the sequencing of the human genome and a concomitant increase in competition and the volume of interferences in the near future.

Interferences are expensive, costing an estimated \$100,000 to \$500,000 to resolve.<sup>1</sup> The biotechnology industry is strongly dependent upon patents, and the high costs of resolving interferences are clearly seen as justified. In the 2 cases we studied, there were 3 nonprofit research institutions and 1 firm involved, and 2 of the nonprofit institutions licensed the patent applications to firms that bore the costs of the interferences. This is consistent with an earlier survey of licensing and technology transfer executives in which we found that nonprofit research institutions often seek at a minimum to cover the costs of patent prosecution in their licensing of gene sequence patents.<sup>11</sup>

There are several limitations to this study. First, our raw data provide no information about the type of invention involved, and we have no ability to discriminate between cases involving genetic discoveries (i.e., sequences and their use) compared to other biotechnology inventions (e.g., devices). Second, our finding of a high rate of interference declaration involving biotechnologies could be an artifact of the accuracy of computer searches by the PTO in discovering overlapping claims for genes, but how much this might contribute to the observed rate is unknown.

Competition in research

| TC     | TC subject matter  | FY 1998    | FY 1999   | FY 2000    | FY 2001    | FY 2002    | totals     |
|--------|--|------------|-----------|------------|------------|------------|------------|
| 1600   | Biotechnology and organic chemistry                          | 56 (2.1)   | 46 (1.5)  | 60 (1.8)   | 52 (1.4)   | 62 (1.5)   | 276 (1.6)  |
| 1700   | Chemical and materials engineering                           | 34 (0.82)  | 21 (0.49) | 24 (0.53)  | 31 (0.63)  | 22 (0.44)  | 132 (0.58) |
| 2100   | Computer architecture, software & information security       |            |           |            | 3 (0.076)  | 1 (0.034)  | 4 (0.058)  |
| 2600   | Communications   |            |           |            | 6 (0.14)   | 1 (0.024)  | 7 (0.082)  |
| 2700   | Communications and information processing                    | 7 (0.14)   | 3 (0.052) | 12 (0.16)  |            |            | 22 (0.12)  |
| 2800   | Semiconductors, electrical & optical systems and components  | 23 (0.45)  | 6 (0.11)  | 6 (0.098)  | 12 (0.17)  | 10 (0.14)  | 57 (0.18)  |
| 2900   | Designs for articles of manufacture                          | 0 (0.0)    | 1 (0.058) | 8 (0.43)   | 2 (0.11)   | 0 (0.0)    | 11 (0.12)  |
| 3600   | Transportation, construction, agriculture, national security | 9 (0.30)   | 4 (0.13)  | 17 (0.51)  | 8 (0.23)   | 6 (0.13)   | 44 (0.25)  |
| 3700   | Mechanical engineering, manufacturing, and products          | 34 (0.81)  | 10 (0.23) | 9 (0.19)   | 10 (0.20)  | 7 (0.13)   | 70 (0.30)  |
| totals |  | 163 (0.64) | 91 (0.33) | 136 (0.44) | 124 (0.36) | 109 (0.31) | 623 (0.40) |

Legend: Annual number of patent interferences declared in each Technology Center field, and rate of interference declarations per 1,000 filed applications. Source: USPTO.

Note: TC 2700 was divided into Centers 2100 and 2600 at the beginning of FY2001.



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