

First to Invent vs. First to File: The Impact of an Old Dilemma on the Future of Biotechnology and Pharmaceutical Discoveries



Mojdeh Bahar, J.D., M.A.
Technology Licensing Specialist
Office of Technology Transfer
The National Institutes of Health



Road Map

- Definitions
- A brief history of the debate
- The current patent landscape in Pharma and Biotechnology
- Unique attributes of Biotech/Pharma
- Arguments in support of first-to-file
- Arguments in support of first-to-invent
- Possible impact of the change

First to Invent

- First-to-invent is based on Article I section 8 of the Constitution:

“Congress shall have power... to promote the progress of science & the useful arts by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.

- Currently the U.S. is the only first-to-invent patent system.

First-to-file

- Called first-inventor-to-file in more recent patent literature
- Serves as the basis of granting patents in all foreign jurisdictions
- Codified in Articles 4, 11(a) and 11(b) of PCT

A Brief History

- 1966- Report of the President's Commission on the Patent System recommending a first-to-file system to President Johnson
- 1983-Trilateral Co-operation between EPO, JPO and USPTO was set up
- 1992-The Advisory Commission on Patent Law Reform, Report to the Secretary of Commerce, includes a similar recommendation to President Bush
- Patent Reform Act of 2007, Section 3.

Two Different Points of View

- The Patent Reform Act of 2007 has been passed by the House (H.R.1908) and is currently before the Senate (S.1145)
- There are two camps as to many of the provisions.
- Principally, both camps agree on move to first-to-file.
- Two Distinct Camps
 - Coalition for Patent Fairness, backed by Microsoft, Intel, Dell, High Tech and Wall Street firms
 - Coalition for 21st Century Patent Reform, pharmaceutical companies, multinationals such as GE and Motorola

The Current Patent Landscape in Pharma and Biotechnology

- In these sectors, R & D expenditures have increased ten fold between 1981 and 2001.
- A purely numerical comparison of issued patents in two classes, 424 and 514:
 - 1981 2,017
 - 2000 6,751 (7,806)
 - 2007 3,944
 - These numbers are as accurate as the examiner's classification
 - The decline in 2007 numbers, might be partially due to QA efforts

Unique Attributes of Biotech/Pharma.

- Increase in R & D expenditure
- Increase in number of strategic alliances, mergers and acquisitions
- One patent and/or one patent family can provide the foundation for years of R & D
- Obtaining a patent is not the only obstacle to marketing, FDA is also a player
- Taking the invention from bench to bedside takes many years and millions of dollars
- Enablement and Written Description are frequently problematic (35 USC 112)

Arguments in support of first-to-file

- Harmonization with other jurisdictions
- Inventors will file on/describe/disclose their inventions earlier (The *quid pro quo* of the patent system)
- Elimination of interference proceedings
- Elimination of potential of fraud in swearing behind references
- One of the only provisions in the Patent Reform Act that brings the various industries together

Arguments in support of first-to-invent

- Small entities will be disadvantaged by the first-to-file system (some contend that this is not the case)
- Some credit the current first-to-invent system for U.S.'s “innovation based economy”
- The constitutional provision clearly sets out the first-to-invent requirement
- Elimination of interferences also eliminates deciding on other non-priority related matters
- Derivative proceedings may have a new set of issues
- Can and should be used as a bargaining chip in international negotiations

Possible Impact of the Change

- More provisional and cover sheet provisional applications will be filed
- The USPTO would need to review future disclosures more closely and award priority appropriately
- Derivation litigation will replace interference practice
- U.S. loses its “bargaining chip” in international negotiations
- Harmonization of (at least one aspect of) patent practice throughout the world

Sources

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Any Questions?

Thank you for your kind attention