

Patenting in the Emerging Genetic Information and Medical Treatment Industry: Access and Anticommons

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- **Modern gene sequencing can lead to large numbers of patents for gene fragments, tools and related knowledge**
 - Referred to as the Anticommons or blocking of access to new knowledge
- **Early calls for scrutinizing patent policy to avoid an anticommons**
 - Heller and Eisenberg sound warning – proliferation of patent rights may reduce access
 - Patent officials see no difficulties
- **Aggressive private sector R&D effort to sequence base genome**
 - Patents for gene fragments require multiple licenses
 - Reach-through rights drain off incentives for downstream R&D
 - Could lead to under use of genetic information or blocking of access
- **With sequencing of base genome complete**
 - Firms find expected profits for access to base genome less than expected
 - Firms drop base genome business
- **With passage of time**
 - Little evidence of anticommons behavior or blocking of access
 - Some concern over small business provisions of Bayh-Dole proving incentives for exclusive licensing
- **Future events less certain**
 - At present, rewards are few and markets for genetic information are thin
 - With greater profit potential will come greater incentives to seek personal gain
 - More aggressive behavior likely by patent holders

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In May 1998, two events played pivotal roles for the emerging market for genetic information and related medical treatments. The first was a series of articles in *Science* magazine. These articles articulated the issues facing the U.S. Patent and Trademark Office (USPTO) in determining which patents should issue among the then-rapidly growing backlog of applications for gene sequence discoveries and related information.

The second event of significance that May was the formation of Celera Corporation. Celera's mission was to sequence the human genome at breakneck pace using new technologies. In doing so, Celera challenged the Federal program to a "race" wherein the finish line would demarcate the complete identification of the base genome—the genetic code of the "representative human." Fueled by the hubris of the late 1990s, the emergence of new gene sequencing technology, and the potential for immense corporate gains, Celera confronted the fundamental basis for public support of basic research—the belief that private dollars would not support basic inquiry because investments could not be recovered in the market place. Celera was wagering that, through a combination of patents and data base tools, it could profit from what was previously considered basic research.

This paper traces the development of patenting and other public policy issues accompanying the build-up in biotechnology research. It first reviews the interplay between patent policy and genomic technology between 1998 and 2001, when the base genome was published. Following this review, it examines results from several studies that seek to identify instances where anticommons behavior is evident or when access to needed information has been blocked. The studies report that there is little evidence that intellectual property rights restrictions have seriously inhibited the ability of companies or university to carry out planned research. However, we believe that the evidence is far too thin to support a general conclusion that patenting issues have been overcome because the potential profits from biomedical practices have been limited to date. As these potential profits grow, we conclude that patenting issues will also grow in importance.

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