

Genetic inventions, Intellectual property rights and licensing practices

⇒ Impacts on human health and technology uptake

Effects of gene patents and licenses on clinical genetic testing

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Background

- ⇒ Patents are seen as necessary to enhance an inventor's ability to recoup the substantial investments necessary to bring a new drug or device to market.
- ⇒ Are patents an effective incentive for the development of new clinical genetic tests?

Concerns about IP

- ⇒ Concerns about restrictive IP
 - decreased access to testing services
 - increased test costs
 - decreased quality of testing
 - decreased ability to conduct R&D
- ⇒ Concerns about insufficient IP
 - lack of incentive for development of genetic tests

Empirical evidence

↻ Two surveys of laboratory directors in US:

- Effects of gene patents and licenses on the provision of clinical genetic testing services
 - Mildred K. Cho, Samantha Illangasekare, Meredith A. Weaver, Debra G. B. Leonard, Jon F. Merz
- The case of hereditary hemochromatosis
 - Jon F. Merz, Antigone G. Kriss, Debra G. B. Leonard and Mildred K. Cho

Methods

↻ Sample: all laboratories in the US conducting genetic tests

- GeneTests
- Association for Molecular Pathology

↻ Telephone survey

Results: Study 1

↻ 132 respondents of 211 labs contacted (63%)

↻ 122 included who conducted genetic tests

↻ 121/122 conduct testing for clinical purposes

Results: Study 1

- ↻ 79 (65%) had been contacted by a patent- or license holder
- ↻ 30 (25%) said that patent/license holder had prevented lab from continuing a test service
 - 17 for one test, 12 for more than one test
 - Companies more likely to report being prevented than university labs (P=0.001)

Results: Study 1

- ↻ 64 (53%) decided not to develop or perform a clinical genetic test because of a patent
 - No significant difference between companies and university labs (P=0.28)

Discussion: Study 1

- ↻ Patents and licenses have had some negative impacts on ability of labs to conduct and develop genetic tests
- ↻ Laboratory directors in the US believe that patents and licenses have had negative impacts on access, cost, and quality of testing, and on information sharing between researchers

Results: Study 2

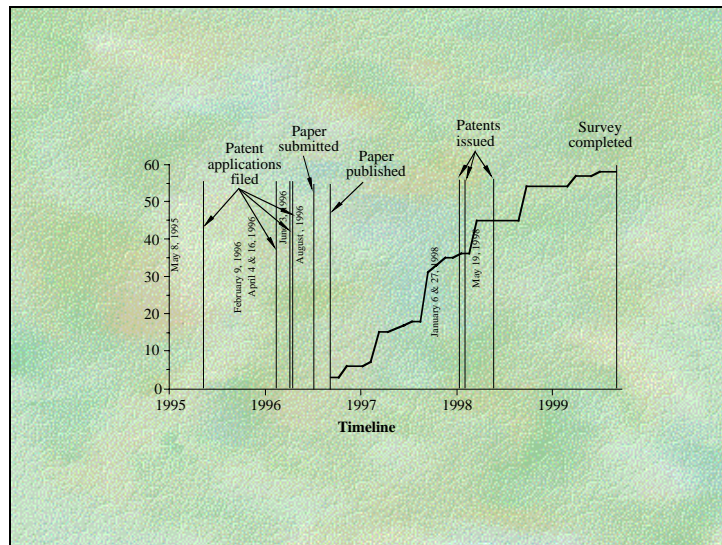
- ↻ 119/128 respondents of labs that conduct hemochromatosis (HFE) testing in US (93%)
- ↻ 58 labs were performing HFE testing

Results: Study 2

- ↻ 31 labs (26%) had not developed and were not performing the HFE test
- ↻ 5 (4%) had stopped performing the test

Results: Study 2

- ↻ 35 labs (60% of 58 performing HFE test) introduced clinical test before first patent issued in Jan. 1998, and after critical paper published in Aug. 1996
- ↻ mean time from publication to adoption = 14 mo.



Conclusions

- Patents and licenses have a significant effect on provision of clinical genetic testing services in the US
- Laboratory directors feel that impacts on cost, quality, access and research are negative for patients

Conclusions

- Labs do not appear to require patents as incentive to develop findings into clinical practice
- Still, patents may provide incentives to conduct research necessary to identify genes associated with disease