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Patents on Molecular Diagnostics:
A Contrarian View

Geoffrey M. Karny

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Overview

- Concerns and criticisms raised
- Social policy underlying patents
- Requirements for obtaining a patent
- Patenting genes
- Impacts of patents: myth vs. reality
- License agreements: key elements
- Conclusions

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Concerns and Criticisms

- How can you patent these tests?
- Why should we allow patents?
- Patents raise costs
- Patents hinder development of improvements and new tests
- Patents limit patient access to health care

Social Policy Underlying Patents

- What is a patent?
  - U.S. government grant to the inventor of a legal right to exclude others
    - From making, using, selling or importing the invention
    - For a limited period of time
    - In return for disclosing the invention to the public
  - This is a property right, even though the property is intangible
    - No more a “monopoly” than your house or car
  - Not a reward, right to sell or guarantee of commercial success

Social Policy Underlying Patents (cont.)

- Why is it granted?
  - To stimulate invention and technological progress
- It takes a lot of time, money and effort to commercialize an invention
  - Average cost to develop a diagnostic: $5M (TriMark Publications, 2005)
    - Caveat: includes $2M for FDA approval
  - Corporate examples
    - Genomic Health prospectus (9/28/05), p. 24: will use $20M of IPO proceeds to fund R&D
    - Third Wave 2005 10-K, p. 29: spent $8.4M for R&D for year ended 12/31/05

Social Policy Underlying Patents (cont.)

- Won't happen if others can "knock-off" the product
- Others can build on the new information
  - Improvements
  - Design-arounds

Requirements for Obtaining a Patent

- Patentable subject matter
  - Statute: process, machine, manufacture or composition of matter
  - Diamond v. Chakrabarty (Supreme Court, 1980): "anything under the sun made by man"
- Utility
  - Specific, substantial and credible; i.e., a real-world use
- Novelty
  - Not known, disclosed in the literature, or used in public. Determined when the application is filed.

Requirements for Obtaining a Patent (cont.)

- Unobviousness
  - Novelty is not trivial
  - Invention was not predictable by a person of ordinary skill in that technology
- Disclosure
  - Describe the invention in sufficient detail to enable a person skilled in that technology to make and use it
- Bottom line: but for the insight and actions of the inventor, the new method or composition would not exist!

Patenting Genes

- How can someone patent a naturally occurring thing like a gene?
- You can't!
  - READ THE CLAIMS! Not the title or abstract
- Examples of claims
  - An isolated DNA molecule encoding protein X
    - Isolated molecules do not occur in nature
    - Patentable if the DNA and protein were not known (before the work of the inventor) and the inventor discovers a practical utility

Patenting Genes (cont.)

- A method of predicting a patient's susceptibility to colon cancer by determining the presence of the following DNA sequences in a tissue sample from the patient:....
  - Not "patenting genes." Patenting the use of the genes.
  - Patentable if new and unobvious
- Remember: but for the inventor, the new invention would not exist

Impacts of Patents: Myths vs. Reality

- There's a thicket of patents on any given gene
  - Yes, but it doesn't matter.
    - Multiple patents for one invention is an artifact of patent prosecution
    - Usually, only 1 owner. E.g., 14 patents (supposedly) for BRCA1, but only 1 company to deal with: Myriad
- There's lots of poor quality patents that shouldn't have been issued
  - Paradise, et al., Science, 307:1566-1567 (2005)
    - 74 patents/1167 total claims reviewed; 667 "problems" (9 "problems" per patent)

Impacts of Patents: Myths vs. Reality (cont.)

- Reality: unsupported conclusions by people (apparently) not trained in patent law.
  - Not 1 of the 74 patents was identified.
  - Most related to scope, which non-patent lawyers don't understand
  - 9 "problems" per patent does not comport with the reality of litigated patents
- Patents are preventing access to health care
  - Cho et al., J. Mol. Diagn., 5:3-8 (2003)
    - Telephone survey of 211molecular lab directors. 122 responses analyzed. 25% discontinued performing patented genetic tests; 53% didn't develop new tests because of patents.

Impacts of Patents: Myths vs. Reality (cont.)

- Reality: They didn't want to pay for a license
  - "People shouldn't be complaining that they can't run tests. They should just pay." P. 5, col. 2, ¶ 2.
- This whole debate comes down to money
  - Are your facilities rent free? Do your employees work for free? Do you get your reagents for free?
  - Why should you get new technology for free?
  - Patent licenses are a cost of doing business

License Agreements: Key Elements

- Grant
  - Exactly what is being licensed
  - What can and cannot be done
- Definitions: critical; tie into grant clause
- Compensation
  - Up-front fee
  - Royalties: based on usage/sales
- Confidentiality
- Indemnification: licensor is usually indemnified
- Term and termination

Conclusions

- How can you patent these tests?
  - Just like any other invention
- Why should we allow patents on them?
  - To stimulate invention and commercialization
- Patents raise costs
  - Lots of things do. They are part of the cost of doing business.

Conclusions (cont.)

- Patents hinder development.
  - If you're unwilling to pay for a license
- Patents limit patient access to tests
  - Is there any test that I can't get?

Thanks!

- Geoff Karny
  - 202-589-2807
  - geoff.karny@bakerd.com