


Gene Patents

Problems & Remedies Within the System

OECD Experts Group Meeting on
GENETIC INVENTIONS,
INTELLECTUAL PROPERTY RIGHTS AND
LICENSING PRACTICES

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What are gene patents?

- Patents on nucleic acids that correspond to genes
 - *Human vs. non-human* chemical compound?
- **Should be available only if information regarding function/role/significance of gene is identified by the patent applicant**
 - Sequence alone will not meet PTO requirements
 - Unclear whether discovery of “abnormal” variant is “useful” standing alone



Positive Recent Trends

- **Functional or “results” claiming**
 - Patent standards should limit these types of claims (e.g., prohibition against “single means” claims)
- **Enforcement becoming more “balanced”**
 - *Festo* decision signals shift toward narrower scope of relief

Defining the “clinical” problem

- Limited funds for healthcare, particularly for clinical/diagnostic services
- Perceived ease of “home brew” screening
- Instances of aggressive use of patent exclusivity
- Many “users” -- amplifies conflicts between clinics and patent owners
- Belief that there is no way to limit patent owners actions

A complicating factor ...

- The patents causing concern (i.e., nucleic acid patents) through their use in the clinical sector are the same patents needed by the manufacturing sector to obtain market exclusivity for pharmaceutical products
- Impossible to draw line between appropriate and inappropriate “gene patents”

Some Suggest “Blunt” Options

- Measures that limit patent exclusivity
 - Denial of patents for otherwise patentable nucleic acids inventions
 - Exceptions to patent exclusivity for particular uses (e.g., “public order”, therapy, screening, etc.)
 - Compulsory licensing of patent rights
 - Selective “revocation” of patents

Problems with Blunt Solutions that Erode Patent Exclusivity

- **Patents on nucleic acids essential for product development**
 - Nucleic acid patent often the only “product” that can be protected (i.e., protein already known and cannot be patented)
 - Process claims not typically strong enough to provide market exclusivity and difficult to license/enforce
- **Without product patents that confer market exclusivity to block copying of commercially marketed product, no products!**

Other problems with erosion of patent exclusivity

- **Giving a government agency the authority to selectively and arbitrarily limit or void patent exclusivity is terrifying to investors**
 - Loss of exclusivity subject to political winds and is unpredictable
 - Biotech investments are high risk – patent exclusivity is one of few mitigating factors
- **Allowing early market entry for competitors (before expiration of patent) creates unacceptable risk**

Considerations in identifying solutions

- **Problem must be defined precisely to identify relevant solution**
- **Clinical environment very different from research, development and commercialization settings**
 - Many potential users/licensees
 - Limited commercial impact from each “infringing” use of the patented nucleic acid
 - Do not give “licensee” unintended access to product development and marketing opportunities

Solutions to consider where no “misuse” of patent rights

- Patent “pools” for limited purpose (i.e., use of nucleic acid for testing)
 - More accurate to label as a “clearinghouse”
 - Labs/clinics want to remove transactional costs and hassles of dealing with patent owner
 - Would likely address pricing concerns, either through more leverage or through efficiencies for patent owner
 - Could be acceptable market-based solution?

Solutions where no misuse of patent rights

- Public pressure
 - Pressure applied through negotiations with large providers (e.g., Governments, insurance, healthcare providers) does work most times
 - Public backlash against ill-conceived licensing or enforcement activities
 - Enforcement against research labs not prevalent
 - Limited economic recovery relative to costs of enforcement

Solutions where use of patent rights questionable

- Antitrust solutions
 - Conditioning a patent license on the sale of an unpatented article or service is likely to be an improper “tying” arrangement under most antitrust regimes
 - Asserting rights broader than those granted by claims can be patent misuse and may trigger antitrust liability
 - Patent on intact coding region would not be infringed by “use” of nucleic acids corresponding to an indicative partial sequence (either as substrate or as material being screened)



Conclusions

- Debate is healthy and will produce better system
- Blunt solutions should be avoided
 - Will cause damage to investment climate and commercial development of biotechnology industry
- Explore existing solutions (market, antitrust) if problems exist



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