Access to Genetic Resources & Traditional Knowledge

The Bellagio compulsory cross-licensing proposal for benefit sharing consistent with more competition and openness.

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14 December 2002

Distributed at the Roundtable on Intellectual Property, Traditional Knowledge and Folklore: Sponsored by the Science and Human Rights Program of the American Association for the Advancement of Science (AAAS) and Franciscans International. Geneva

Many proposals for GR-TK would use restrictions on access to information or the use of such information as leverage for benefit sharing

These restrictions can impede science, raise prices and lead to monopolistic control over new technologies

There may be a better way

- The European Biotechnology Directive provides a model for enabling advances in agriculture technologies and expanding competition, using mandatory licenses of both patent and *sui generis* plant breeder rights.
- Europe is adopting this approach to address monopolistic power by Monsanto and Dupont in the markets for seeds.
- Of particular relevance, is the mandatory cross-licensing provision regarding the patent and plant breeder *sui generis* right.

Article 12 of the EU Directive on Biotechnology provides for compulsory cross-licensing of patents and sui generis rights

DIRECTIVE 98/44/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 July 1998 on the legal protection of biotechnological inventions

Chapter III. Compulsory cross-licensing. Article 12(1)

1. Where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty. Member States shall provide that,where such a licence is granted, the holder of the patent will be entitled to a cross-licence on reasonable terms to use the protected variety.

Chapter III. Compulsory cross-licensing. Article 12(2)

2. Where the holder of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right, he may apply for a compulsory licence for non-exclusive use of the plant variety protected by that right, subject to payment of an appropriate royalty. Member States shall provide that, where such a licence is granted, the holder of the variety right will be entitled to a cross-licence on reasonable terms to use the protected invention.

Chapter III. Compulsory cross-licensing. Article 12(3)

3. Applicants for the licences referred to in paragraphs 1 and 2 must demonstrate that:

(a)they have applied unsuccessfully to the holder of the patent or of the plant variety right to obtain a contractual licence;

(b) the plant variety or the invention constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety.

Follow-on innovators have the right to add value to other ideas or inventions

- Neither right can block the other right.
  - The Plant breeder gets a mandatory non-exclusive license to the patent.
  - The patent owner gets a mandatory non-exclusive license to the plant breeder right.
- The compulsory license to either the patent or the plant breeder right is conditioned on the payment of a reasonable royalty.

Suppose we create a similar situation for sui generis rights in GR-TK?

- The *sui generis* regime would identify an owner (the government, a community, a region, etc) of the GR-TK resource.
- .A property right in the GR-TK resource would be created, that was perpetual, and not dependent upon authorship, invention or novelty.
- .But this sui generis GR-TK right would be limited in scope.

The right would only extend to the efforts to commercialize new patented inventions that were based upon the GR-TK.

- If a patented invention depended in a significant way on the GR-TK resource, it could not be exploited without first obtaining a license to commercialize a patented invention using the GR-TK.
- While the term of the GR-TK sui generis right could be perpetual, the term of the license to exploit a particular invention would be limited to the term of the patent.
- The owner of the patent would have a right to a mandatory license to the GR-TK right, subject to the cross-license of the patent to the owner of the GR-TK resource.

The sui generis GR-TK ownership right would not extend to uses that were not patented

- There would be freedom to do research or use the GR-TK for non-novel uses.
  - Protects consumers and researchers, gaining international support.
- The only time when the GR-TK ownership right becomes an issue is when someone seeks a patent (monopoly) privilege.
  - The cross-license regime has the practical effect of limiting the monopoly power of the patent owner.

The model for licensing the GR-TK right would be the cross-licensing approach in the EU Biotech directive.

- The patent owner would have a mandatory right to a license to the GR-TK sui generis right, and
- The owner of the GR-TK sui generis right would have a mandatory cross license to the patented invention.
- Both licenses would be subject to payment of compensation.

Countries that create the sui generis GR-TK mandatory cross licensing approach could structure it in interesting ways

- One possibility:
  - The royalty to the patent owner could be lump sum (a one time or annual lump sum payment), allowing zero marginal cost for use.
  - The country that has the GR-TK sui generis right could claim royalties from the global sales of the patented invention.
  - The country could license its own industries to compete against the patent owner in the domestic market.
  - Licenses to compete in foreign markets would be possible if foreign countries recognized the cross-license right.

An objective of developing countries will be global recognition of the right.

Scenario # 1

- Merck develops a medicine based upon a biological resource found in Peru.
- The invention meets recognized standards for novelty and utility. Merck obtains patents in Peru, the United States, Europe and other countries.
- Peru declares the invention is based upon its GR-TK resources.

Scenario # 1, con't

- The government of Peru grants Merck a world wide license to use the GR-TK, for the purposes of commercializing the patented drug.
- Merck is required to pay Peru a royalty on its world wide sale of the drug.
- The owner(s) of the GK-TK resource are granted a cross-license in the patented invention.
- The government of Peru can authorize any Peruvian "owner" of the GR-TK to use the patented invention.
- Any use of the patented invention is subject to payment of a royalty to Merck.

Scenario # 1, domestic market

- In Peru, the government could grant anyone a non-exclusive right to use the Merck patent.
  - Compensation to Merck could be a lump sum payment for the entire national use, or structured royalties in more traditional ways.
  - Merck or any firm authorized by the government to commercialize the patented invention would also have to pay royalties to the government/owner of the GR-TK.
  - The net royalties could be positive, negative or equal, depending upon the relative value of the GR-TK or theinvention.
- The cross-licensing approach would facilitate more competition, reduce the monopolistic aspect of the patent, and provide benefit sharing.

Scenario # 1, foreign markets

- Peru would expect Merck to pay worldwide royalties for use of the GR-TK in the commercialization of the patented invention.
- Peru would also assert its right to authorize GR-TK "owners" to cross-license the Merck patents in foreign markets, creating Peruvian competitors to Merck in global markets, if those cross-licenses were recognized by foreign governments.

Scenario #1, regional strategies

- Peru could approach other Andean Pact or Mercosur countries, asking that they recognize the Peruvian *sui generis* GR-TK regime, and in particular, the Peru demand for global royalties on the commercialization of the patented invention, and the cross-licenses.
- Other developing countries could ask Peru to recognize their regimes.

Positive incentives to document, manage and disseminate information about GR-TK

- The benefit sharing model is not based upon trade secrets, restricted access to resources or information, or conditioned upon the signing of contracts.
- Countries would have incentives to document and disseminate information about GR-TK, in order to:
  - Facilitate claims that inventions relied upon the GR-TK
  - To encourage persons to commercialize inventions that generated (sui generis) royalties.

Who benefits?

- The scientific community benefits from greater openness regarding GR-TK.
- Consumers benefit from more competition for patented inventions (less monopoly).
- Countries/owners of GR-TK obtain royalties from the commercialization of the patented inventions.

Who doesn't like this?

- Merck
- Monsanto
- Dupont
- Roche
- GSK
- etc

Please provide comments or suggestions to:

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