# Protections from misappropriation and two models for benefit sharing

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### Misappropriation and/or benefit sharing in the context of intellectual property rights or other areas

#### For example, in the context of IGC negotiations:

- Access to biologic resources
- Traditional knowledge
- Traditional cultural expressions

#### More generally:

- Nagoya Protocol on Access to Generic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization:
- Pandemic Influenza Preparedness
   Framework

- WHO Pandemic Treaty
- Rights of patients in clinical trials
- Free software
- Open source science
- Rights of publicity
- Ancillary copyright for press publishers in Europe
- Canada's Online News Act,
- Training data for Artificial Intelligence
- Etc

#### Some concerns

Unfairness as regards who benefits the most

Enclosures of common or public resources

Unequal access

Unfair competition

Inadequate incentives to supply or provide stewardship for unprotected but socially valued inputs

#### The 3 Cs

Consent (permission)

Credit (attribution)

Compensation (remuneration)

#### Consent (exclusive rights)

The granting of an exclusive right to authorize a use is sometimes justified on moral grounds or economic grounds, and can decentralize and privatize the setting of terms for compensation or boundards of the authorization.

The downsides of a system of exclusive rights include potential monopolization, excessive prices, reduced freedom to innovate and high transactions costs.

#### Credit / Attribution

Attribution has an intrinsic value of its own, but is also important for addressing other issues such as the enforcement of licensing conditions in free software and liability or compensation for uses.

In some cases, credit or attribution is controversial and can lead to disputes over the failure to acknowledge contributions or litigation over inventorship or authorship.

Technology can play a role, such as the metadata for digital works, and scale can be an issue, for example, for AI training datasets.

#### Compensation / remuneration

In some areas, compensation set by third parties is preferred to systems of exclusive rights, because it can preserve the benefits of competition and the freedom to use information and biological resources.

It can be challenging and controversial for third parties to set compensation.

By definition compensation imposes costs and discourages uses.

Some proposals for GR-TK would use restrictions on access to information or biologic resources or the use as leverage for benefit sharing.

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

### Model 1: cross licensing proposal

- The European Biotechnology Directive (Directive 98/44/EC) provides a model for enabling advances in agriculture technologies and expanding competition, using mandatory licenses of both patent and *sui generis* plant breeder rights.
- The European Union adopted this approach to address monopolistic power by large seeds companies in the markets for seeds.
- Of particular relevance, is the mandatory cross-licensing provision regarding the patent and plant breeder *sui generis* right.

# 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)

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)

Where the holder of a patent concerning 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)

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 ideas or inventions

Neither right can block the other.

- 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.

Licenses are conditioned on the payment of a reasonable royalty.

# A cross licensing model for a *sui generis* right in GR-TK similar to the EU Biotechnology Directive

- 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 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, perhaps gains some 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.

#### Possible implementation approaches:

- 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.
- The royalty to the patent owner could be lump sum (a one time or annual lump sum payment), allowing zero marginal cost for use.

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 the invention.
- 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 Pack 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.

### 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.

#### 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.

#### Model 2: the Open source dividend proposal

### Motivation: Research is more valuable to society when open:

- Sir John Sulton's conjecture on the relative value of open and closed research
- Openness increases the amount and speed of innovation
- Openness improves data Integrity: subject to Peer review, scrutiny, reproducibility
- Efficient and ethical: Known unknowns! Unnecessary experimentation on animal and humans.
- Lower costs for developers of new products

#### What is the Open Source Dividend (OSD)?

Corrects for an obvious market failure: the lack of economic incentives to share research inputs.

Financial inducement prizes that reward and encourage collaboration and the sharing of knowledge, materials and technologies.

Given to persons or communities (groups or organizations) that openly and freely shared inventions, data, knowledge, biologic resources, or technology that was judged to have been helpful or instrumental in the success of the end product.

#### **Source of funds.** Can be a funded from:

- 1. Share of market entry reward prizes,
- 2. Share of sales revenue
- 3. Share of procurement outlays

#### Implementation of Open Source Dividend

Once a product enters the market, jury is appointed to evaluate claims

Membership in the jury can be randomly assigned from pools for persons with relevant expertise, subject to conflict of interest safeguards

Individuals, communities, firms, organizations, can submit evidence that their freely shared ideas, data, inventions, biologic resources, etc, were useful for the developers of the product.

Jury assigns shares in the open source dividend

#### Benefits of Open Source Dividend

The open source dividend would create a new and needed incentive to share knowledge resource, lower the costs of acquiring rights to intellectual property needed for product development and create the freedom to operate.

Drug developers would both pay and benefit from this system:

- pay by sharing the revenue from the product sales or rewards.
- benefit by the expanded access to royalty free knowledge, materials and data, and fewer transaction costs.