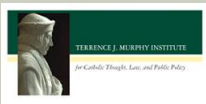


Policy Reports

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TALKING POINTS ON THE PATENTABILITY OF GENETIC MATERIAL

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Which notion of ownership may (should) apply to genetic resources?

1. The term “genetic resources” is used to designate many different subject-matters.¹ For example, Article 2 of the Convention on Biological Diversity (1992) broadly defines the term “genetic resources” as “‘genetic material’ [further defined as ‘any material of plant, animal, microbial or other origin containing functional units of heredity’] of actual or potential value.” Under such a broad definition, genetic resources could refer to the spore of an as yet undiscovered fungus in the rainforests of Brazil, a genetically modified human embryonic stem cell being kept under cryopreservation in a lab in the UK, or anything in between. The notion of ownership that should apply to genetic resources must vary in accordance with the nature of the subject-matter.
2. At the outset it should be recognized that certain “genetic resources” may not be considered property, and that it is unacceptable to subject them to any sort of “ownership.” At the least, this category would include human persons at any stage of development, beginning with the single-celled embryo.² The reason for the institution of any property regime must be the promotion of the common good. It is inconsistent with the dignity and intrinsic inalienable worth of the human person—and therefore contrary to the common good—to make living human persons the direct object of any property right.
3. Rewarding or encouraging the deliberate taking of human life through the granting of property rights in materials that can be obtained only through the destruction of living human persons is also incompatible with human dignity. For this reason, the granting of patents on embryonic stem cells and other subject-matter (including processes) that may be acquired (or carried out) only through intentionally life-ending interventions, or that creates incentives for such destruction in the future must be opposed as contrary to human dignity and the common good.³ This same logic would not apply to materials that can be obtained without serious risk to human life or processes intending to benefit the human subject.⁴ The question of patentability in this latter situation is a matter of prudence, weighing the value to be gained by

proffering such protection as balanced against the challenges and costs of administering the system.

4. In sum, humans at any stage of development must never be subject to ownership, and property interests that depend on, require or incentivize the intentional destruction of human life must also be opposed. Proposed legal protections for the ownership of other genetic resources, on the contrary, must be evaluated using prudential judgment, taking into account considerations of justice, cost, and benefit in light of the unique facts at issue.

Which elements should amount to a “discovery” of genetic resources?

5. Within the realm of genetic resources that may be subject to property rights, there is still a broad spectrum of materials that lie between the two extremes of those still in an unaltered or natural state and those that result from the intensive application of human effort or intervention. The degree of credit allowed for the “discovery” of genetic resources may reasonably depend on the amount of effort that contributed to the discovery and its usefulness to mankind.

6. The cataloguing of biological materials still in their natural state does have value and is laudable as it may lend to efforts to preserve creation and the genetic resources it contains. These materials do have “potential” value, loosely speaking, but that value is limited until it is enhanced by further research, and mere documentation of genetic material hardly amounts to a discovery of genetic resources. These materials are still a part of creation, destined for the common use and benefit of all mankind.⁵ Once man has devoted his intelligence and means to the study of these materials and drawn from them some new and useful application or derivative subject-matter, however, then it may be said that there has been a true discovery of genetic resources. This added requirement makes meaningful the distinction between “genetic materials” and “genetic resources” as defined by the CBD.

7. Generally speaking, the finding of unique biological materials in their natural state is not a discovery of genetic resources. The application of human labor to detect useful attributes or components in those same raw materials may lead to what may properly be termed a “discovery” of genetic resources.

What could amount to a “just remuneration” for the ownership of genetic resources, especially in developing countries?

8. As explained above, naturally occurring biological organisms themselves are a part of creation and destined for the common use of mankind. As such, they should not be the object of absolute and exclusive ownership or control as species. It may be justifiable to give local communities or nations where materials providing genetic resources are discovered some rights to control access and to receive a share of profits from their utilization, however, if it promotes the common good, including the preservation and development of genetic resources, for instance, in poorly developed regions of the world where there is danger of loss through environmental damage.⁶

9. Research seeking to derive beneficial uses and products from genetic materials is praiseworthy, and measures designed to encourage and protect the dedication of time and capital to such research are just and may promote the common good by accelerating the search for solutions to problems in the modern world. This is particularly true in the pursuit of new medical treatments, where special protections are needed to ensure that producers are able to recover their massive expenditures on research—including just wages for scientists and others who carry out such research, as well as compliance with regulations that ensure the safety of their products.⁷

10. Still, such measures to protect property interests must comport with the demands of justice. The duty to provide just compensation, as well as the practical desire to incentivize research, may in certain extenuating circumstances give way to higher duties, in particular the preservation of human life⁸ and access to essential medicines (especially in developing nations).

11. In addition, there is growing recognition that “the knowledge and innovations of indigenous and local communities represent intellectual added value in relation to the natural state” of genetic resources and that “traditional knowledge can lessen major research and development expenditure by identifying, or relating to each other, possible practical solutions to existing problems.”⁹ This traditional knowledge may not fit well into existing paradigms of intellectual property protection. It often lacks scientific precision, its origins may be untraceable, and it may reside in the collective consciousness of an entire community, but its great utility in reducing development costs by providing a fertile starting point for further scientific investigation must be acknowledged. The appropriation of traditional knowledge without remuneration not only constitutes an unjust enrichment of those profiting thereby, but contributes to an unhealthy mistrust that inhibits fruitful cooperation between holders of traditional knowledge and those with the expertise needed to fully develop its potential for the benefit of all mankind.¹⁰ Agreements for access to both genetic resources and traditional knowledge regarding those resources must be shaped by principles of justice, taking into account the relative positions of the various parties to the agreements. These agreements should neither become an opportunity for excessive rent-seeking, nor be tainted by an economic dictatorship of highly developed nations over the developing world.¹¹ Here again, this is the domain of prudential judgments (informed by principle), attending carefully to the particular facts of each individual case.

12. In conclusion, just remuneration for the ownership of genetic resources is highly context dependent. Generally speaking, mere dominion over genetic materials should be given less protection, whereas resource intensive development of beneficial derivative subject-matter should be given stronger protection, but consideration of factors such as environmental preservation, human dignity, access to essential medicines, and the value of traditional knowledge should influence the creation of international policy. Stable and just legal structures that create predictability in relations between various parties will form an essential foundation on which to base ownership rights. Case by case analysis, however, may be required in extraordinary cases when adherence to normal processes will lead to irreparable harm. In such situations solutions should be sought that balance the desire to encourage and compensate beneficial research with the duty to promote the common good and protect human life, especially for the most vulnerable.

¹ See, e.g., Glossary of Key Terms Related to Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions from the Twenty-Fourth Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (WIPO/GRTKF/IC/24/INF/7).

² The European Court of Justice (CJEU) in *Oliver Brüstle v. Greenpeace* correctly reasons that embryos that are produced through NST or stimulated parthenogenesis are equal in status to those obtained through the union of male and female gametes.

³ Cf. *Oliver Brüstle v. Greenpeace*.

⁴ “Scientific and technical progress, whatever it be, must then maintain the greatest respect for the moral values that constitute a safeguard for the dignity of the human person. And because, in the order of medical values, life is the supreme and the most radical good of man, there must be a fundamental principle: *first oppose everything harmful, then seek out and pursue the good.*” Dangers of Genetic Manipulation, Address by Pope John Paul II to members of the World Medical Association (October 29, 1983) (emphasis added).

⁵ Cf. Paul VI, *Populorum Progressio* ¶ 22 (1967).

⁶ Traditional Knowledge and the Need to Give It Adequate Intellectual Property Protection (Document presented to WIPO by GRULAC).

⁷ Cf. Intervention by His Excellency Monsignor Diarmuid Martin to the Plenary Council of the WTO on Trade-Related Aspects of Intellectual Property Rights (Wednesday, 20 June 2001).

⁸ For instance, in the case of an epidemic where rapid access to vaccinations or medication could prevent widespread loss of life.

⁹ *Id.*

¹⁰ *Id.*

¹¹ Cf. Paul VI, *Populorum Progressio* ¶ 59 (1967).