

Patenting Human DNA: What Flexibilities Does the TRIPS Agreement Allow?

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The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) requires World Trade Organization (WTO) members to grant patents in all fields of technology. A large number of patents covering genes, including of human origin, have been issued in developed countries. In some cases, patents granted cover any possible use of the gene, even if not disclosed in the application. However, WTO members enjoy a significant flexibility to determine their policy regarding gene patents. The TRIPS Agreement does not define what an “invention” is; it does not determine either how the novelty and other patentability requirements are to be applied. Hence, national laws may exclude genes, even if claimed as isolated, altogether from patent protection. If gene patents were issued, they may nonetheless apply limitations to the scope of claims, such as circumscribing protection to the uses specifically claimed by the applicant. An exception based on moral considerations is also viable, particularly in the case of human genes. In view of this flexibility, countries may adopt the policies on this subject that best suit their cultural and moral values and their technological or industrial policies.

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The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) defined, for the first time in a multilateral treaty, certain requirements regarding the subject matter eligible for patent protection.¹ Article 27.1 stipulated that “patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application”. While this provision was an outstanding victory for the established pharmaceutical industry (see, e.g., Perez Pugatch, 2004), as long as it ensured an almost worldwide protection for pharmaceutical products² by January 2005,³ the rules of relevance to the emerging biotechnology industry were more limited and provided a less clear legal framework. This was a reflection, to a great extent, of the divergences existing among developed countries about the protection of biotechnological inventions (see, e.g., United Nations Conference on Trade and Development—International Centre for Trade and Sustainable Development [UNCTAD-ICTSD], 2005, p. 388). These divergences have persisted. In a report issued in 2002, the World Health Organization (WHO) noted that “[C]urrently, the situation regarding the patenting of discoveries arising from genomics is little less than chaotic and has come under fierce criticism from many quarters” (WHO, 2002, p. 135).

Article 27.1 of the TRIPS Agreement obligates members to protect “inventions” provided that they meet the requirements of novelty, inventive step (or