Genomics knowledge and equity: a global public goods perspective of the patent system

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Abstract Genomics, the comprehensive examination of an organism's entire set of genes and their interactions, will have a major impact on the way disease is diagnosed, prevented and treated in the new millennium. Despite the tremendous potential it holds for improving global health, genomics challenges policy-makers to ensure that its benefits are harnessed equitably across populations and nations. The classification of genomics as a global public good and the inequity encountered in the development and application of genomics knowledge are outlined in this paper. We examine the effect of the current patent system on the distribution of costs and benefits relating to genomics knowledge between countries of different economic strength. The global public goods concept provides a normative economic rationale for the modification of certain aspects of the current patent system and for the creation of complementary mechanisms to respond to the health needs of low-income and middle-income countries.

Keywords Genomics; Social justice; Patents; Public goods; Resource allocation; Economics; International cooperation; Intersectoral cooperation; Developing countries (*source: MeSH, NLM*).

Mots clés Génomique; Justice sociale; Brevet; Biens publics; Allocation de ressources; Economie; Coopération internationale; Coopération intersectorielle; Pays en développement (*source: MeSH, INSERM*).

Palabras clave Genómica; Justicia social; Patentes; Bienes públicos; Economía; Asignación de recursos; Cooperación internacional; Países en desarrollo (*fuente: DeCS, BIREME*).

Arabic

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Voir page 388 le résumé en français. En la página 388 figura un resumen en español.

Introduction

Genomics is the comprehensive examination of an organism's entire set of genes and their interactions (as distinct from genetics, which is the study of a single gene or a small number of genes to determine specific gene roles in diseases or physical characteristics of an individual). Despite the tremendous potential that genomics holds for improving global health, it presents a challenge to policy-makers to ensure that its benefits are harnessed equitably across populations and nations (*1*). As some of the present authors have previously argued (*2*, *3*), genomics is a global public good but its attributes are not optimized in developing countries, necessitating collective action. In this paper we examine the implications of this insight with respect to the patent system and suggest ways to improve and supplement the patent system in order to better achieve distributive goals.

The patent system

The goal of the patent system is to encourage the creation, dissemination and use of knowledge for the benefit of society (*4*). It does this by creating private "rights" over practical ideas that would, without the patent, be freely available to all. By creating these private rights, the patent system aims to encourage individuals to invest in the creation and dissemination of knowledge, providing them with a mechanism through which to prevent others from using that knowledge at no cost (*5*).

Patent systems are, by their nature, national in scope. A country will adopt a patent system if that system encourages the creation of new knowledge, or of products embodying that knowledge, within the country. National patent systems are not designed to benefit the citizens of other countries. It is at this point that patent systems run up against the global public good nature of genomics knowledge.

Genomics as a global public good

The majority of goods tend to be private in nature, meaning that one person can effectively exclude all others from using a good or benefiting from its use. Private goods are also rival in consumption: once consumed by one, they cannot also be consumed by another. Consider, for example, a cake. The owner of

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the cake can prevent other people from eating it until its price has been paid (i.e., it is excludable) and, once eaten by one person, it cannot be eaten by another (i.e., it is rivalrous) (*6*).

Public goods, in contrast, are both non-excludable and non-rival. The ozone layer, for example, is available to everyone to benefit from it (therefore it is non-excludable) and one person benefiting from it does not prevent another from benefiting also (so it is non-rivalrous). Note that there is a wide range of "impure" public goods, for example where technology can introduce excludability (such as encryption of television broadcast signals) or capacity constraints can lead to rivalry (such as access to clean water in places where rapidly expanding populations cause pollution), but these distinctions do not distract from the main thrust of our argument. In the same way, genomics knowledge belongs to the family of public goods that are both non-excludable and non-rival (*7*). Someone who has genomics knowledge cannot be prevented from using it, and the use of it by one researcher does not prevent the use of it by another.

Global public goods are goods that exhibit a significant degree of public character (non-excludability and non-rivalry) across national boundaries. Global public goods are not merely "international" in the sense of being shared by two or more countries for a particular reason (for example, membership in the same trading block); by their very nature, global public goods can only sensibly be understood to be shared by a group of countries because of the nature of the good itself and not because of some underlying relationship between the countries (*8*). A more technical definition of a global public good is therefore that it is "a good which it is rational, from the perspective of a group of nations collectively, to produce for universal consumption, and for which it is irrational to exclude an individual nation from its consumption, irrespective of whether that nation contributes to its financing" (*8*, p. 9).

As knowledge is commonly regarded as the archetypal public good (*9*), genomics knowledge is an example of a public good. This has been reflected in the manner in which the Human Genome Project has been funded and undertaken: most research upon which genomics discoveries are based was publicly funded (*10*, *11*). The Human Genome Project further demonstrates the global aspects of genomic knowledge as it involves research teams in 20 different countries and arose from the belief that taking a global view of genomics was required to tackle this complex subject and to accelerate biomedical research.

Over all, the innate global public good characteristics of genomics knowledge are significant (*2*, *3*). However, the social and political organization of genomics research has also enhanced its global public good aspect, placing knowledge in the public domain where it can be freely shared (*10*, *11*).

Although genomics knowledge has considerable global public good characteristics in principle, in practice there are constraints on its dissemination and utilization. More specifically, developing countries lag behind the rest of the world in enlarging and harnessing genomics knowledge, causing concern that a "genomics divide" is opening up between rich and poor countries (*12*). The sizeable gap in investment in research and development between developed and developing countries is well documented (*13*, *14*).

The assimilation and utilization of knowledge requires relevant training, equipment, institutions and networks, all of which require investment (*15*, *16*). The absence of this infrastructure generates different degrees of excludability and rivalry between countries. For example, a country without trained scientists is, in practice, excluded from using genomics knowledge to respond to its particular health needs. Because some countries cannot afford to put sizeable resources into building up genomic research capacity, genomics knowledge is far from being a global public good. As a result, genomics risks becoming a "club good": a good that is non-rival but from which some (those without sufficient resources) are excluded. The impact of this is that genomics knowledge will not be used to its full potential around the globe.

Patents and genomics knowledge

Patents provide private rights over public goods, including health research, giving their holders a temporary monopoly (of at least 20 years) in which to commercialize the products of their research and thereby recoup the costs of developing them and make a profit (*17*, *18*). Patents alter the public good character of knowledge by permitting individuals to exclude all others from using the knowledge. This alteration is justified on the basis that the public receives a benefit to compensate it from its loss of access: an encouragement of further knowledge creation. The patent system does this by exacting a price from those who gain private rights to knowledge: disseminating the results of their research to the public. National patent systems are based on the premise that the gain from the dissemination of new knowledge more than compensates for the loss of access during the period of the temporary monopoly.

The difficulty with this logic is that it is based on national economies and national public goods. Genomics knowledge is a global public good, so the argument tends to break down: patents do not distribute their benefits evenly across all nations because of significant differences both in infrastructure (as discussed above) and in markets between countries. In particular, the patent system is designed to provide incentives to develop genomics knowledge in respect of the needs of those countries where there is an active and healthy economy. By relying on market forces, patents cannot work where there is a non-existent or weak market. Thus, the patent system cannot be expected to encourage innovation in areas of study predominantly aimed at low-income countries. The end result is that the patent system may work well to encourage research into the diseases of the wealthy, but will do a poor job of focusing on the needs of low-income countries (*19*–*22*). Thus, while the cost of the patent system — the temporary loss of access to genomics knowledge — is shared by citizens of all countries, the benefit — the development of new health products — accrues overwhelmingly to the few living in high-income countries.

A second feature of patents in respect of genomics knowledge is the scope of coverage. Initially, patents were granted only over genes associated with protein products, but now provide property rights over research tools including expressed sequence tags (ESTs), single nucleotide polymorphisms (SNPs) and the computer programs for the analysis of genomic data (*23*, *24*). As low-income and middle-income countries already lack the scientific infrastructure necessary to carry out genomics research, if these countries follow high-income ones in awarding patent rights over research tools — which they may be obliged to do under the World Trade Organization (WTO) TRIPS Agreement (concerning trade-related aspects of intellectual property rights) — they risk exacerbating their relative disadvantage (*24*).

Value of global public goods in promoting equity

Patents play a complex role in the development of health products and may provide incentives for the discovery of genomics knowledge, which requires expensive research and risk-taking. In this way, they may encourage the development of genomics knowledge and increase the number of products created based on that knowledge.

Nevertheless, patents also make genomics knowledge an excludable good. High levels of patenting (numerous and often overlapping patents, and patents on ESTs or SNPs as noted earlier) can limit knowledge generation in the field of genomics with particular effect on those without resources, such as many in the developing world (*25*). Thus, if we rely on patenting alone the global public good characteristics of genomics knowledge will not be realized.

The value of understanding that genomics knowledge is not only a public good — like all other knowledge subject to patent systems — but a global public good is that we focus better on intercountry effects of patent protection. Instead of assessing the effects of patents on encouraging domestic innovation, we concentrate on the effects of patents on ensuring a fair distribution of genomics knowledge across national boundaries. Such an approach inevitably leads to the conclusion that reliance on the patent system as it currently exists leads to an inequitable distribution of costs and benefits between countries, with low-income countries suffering the most.

None of this leads, however, to the conclusion that we ought to forego the benefits of the patent system. Rather, it argues for a two-pronged approach in which we modify or relax some of the international rules applying to patents over genomics knowledge and, concurrently, develop mechanisms outside traditional patent law to encourage the creation and dissemination of genomics knowledge within low-income and middle-income countries.

An example of the first approach in the WTO Ministerial Conference held in Doha, Qatar, on 9–14 November 2001. At that meeting, the ministers issued a declaration stating that the TRIPS Agreement should not be read so as to prevent measures being taken to protect public health (*26*). This declaration clarified what governments may do under the TRIPS agreement and stressed that each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted (*27*). Compulsory licences permit patented technology to be used freely in specific countries or regions, which could lower the prices of genomic products in developing countries. An assessment of the impact of changes in legislation such as this would benefit from collaboration between, for example, economists, ethicists, lawyers, and science and technology analysts (*4*).

Changing the patent system alone, however, is unlikely to promote genomics knowledge as a global public good. Thus, the second approach to reduce the differing impact of patenting in genomics is through devising supplementary measures to ensure the potential of developing countries to harness genomics knowledge themselves. The realization that we cannot rely solely on the market (i.e., patenting in the context referred to in this paper) to take care of our global collective needs is becoming obvious.

George Soros, for example, stresses that the market is not designed to ensure social justice, and that public goods can thus only be provided by a political process (*28*). He states that far too few resources have been devoted to correcting the deficiencies of globalization and recommends an incentive-based system for the provision of public goods which complements a market-based system for the provision of private goods, such as elements of international financial markets to improve the allocation of resources.

Mechanisms supplementary to the patent system include the creation of research and development funds targeted at diseases of low-income and middle-income countries (*30*, *31*). This is analogous to the US orphan drug legislation and similar laws in other developed countries, which provide firms with incentives to develop treatments for diseases that affect a relatively small number of patients (and hence a small revenue group) (*19*). The development and implementation of legislation for neglected diseases in developing countries, where the issue is not one of a small number of patients but of a low purchasing power across many patients, may therefore result in more affordable drugs.

Another alternative is the establishment of disease-specific partnerships. The International AIDS Vaccine Initiative, the Global Alliance for Tuberculosis Drug Development and the Medicines for Malaria Venture, for example, have resulted in over 70 such global health partnerships (*30*). Such schemes encourage collaboration between public and private institutions. Through these schemes the private sector is provided with promising markets, while the population benefits from a lowering of drug and vaccine costs. Patents exist over the resulting health products but the parties agree to license the use of the products through tiered pricing arrangements — higher costs in industrialized countries to recoup the costs of research and development, and lower costs in developing countries to increase the availability of the health products (*31*).

In order to promote genomics knowledge as a global public good, it must be recognized when to recalibrate the patent system in relation to developing countries to encourage genomics development and dissemination, and when to augment it with supplementary measures. Clearly, this recognition has to be developed. Policies for the patenting of genomics knowledge are indeed required for any of the above approaches, and this is an area where international organizations especially may be useful in lobbying national governments, industry and other key players, and perhaps also in commissioning and designing such policies (*32*). ■

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Résumé

Connaissances en génomique et équité : le système de brevets vu sous l'angle des biens publics mondiaux

La génomique, c'est-à-dire l'examen complet de l'ensemble des gènes d'un organisme et de leurs interactions, est appelée à avoir un impact majeur sur la façon dont les maladies seront diagnostiquées, évitées et traitées au cours de ce millénaire. Malgré son énorme potentiel d'amélioration de la santé à l'échelle mondiale, elle constitue un défi pour les décideurs qui devront assurer que les bénéfices en sont exploités équitablement par les populations et les pays. Le présent article décrit le classement de la génomique parmi les biens publics et les inégalités rencontrées au cours du développement et de l'application des connaissances en la matière. Nous examinons l'effet du système actuel de brevets sur la répartition des coûts et bénéfices relatifs aux connaissances en génomique entre pays de puissance économique inégale. Le concept de biens publics mondiaux fournit une justification économique normative en vue de la modification de certains aspects du système actuel de brevets et de la création de mécanismes complémentaires pour répondre aux besoins sanitaires des pays à faible revenu et à revenu intermédiaire.

Resumen

Información genómica y equidad: el sistema de patentes desde la perspectiva de los «bienes públicos mundiales»

La genómica, el estudio pormenorizado del conjunto de los genes de un organismo y de sus interacciones, repercutirá enormemente en la manera de diagnosticar, prevenir y tratar las enfermedades en el nuevo milenio. Aunque encierra un extraordinario potencial para mejorar la salud mundial, la genómica desafía a los formuladores de políticas a encontrar la manera de asegurar que sus beneficios sean aprovechados equitativamente en todas las poblaciones y las naciones. En este artículo se describen a grandes rasgos la clasificación de la genómica como bien público mundial y las desigualdades surgidas en el desarrollo y aplicación de la información genómica. Examinamos el efecto del actual sistema de patentes en la distribución de los costos y beneficios relacionados con la información genómica entre países de distinta potencia económica. El concepto de bienes públicos mundiales proporciona una justificación económica normativa para modificar algunos aspectos del actual sistema de patentes y para crear mecanismos complementarios que respondan a las necesidades de salud de los países de ingresos bajos y de ingresos medianos.

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