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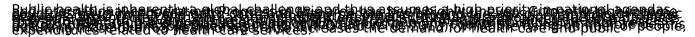
IP to address social challenges

IP can help to address social challenges, including health care, poverty and food security, and environmental sustainability. Innovation is a critical part of the solution when tackling important societal challenges, and IP rights provide businesses with incentives to invest in relevant inventions so as to produce needed innovations. Creating this knowledge and facilitating access and transfer to these innovations should be joint objectives of policies.

What are social challenges?

Social challenges—some of which are global in nature such as climate change—include notably health, poverty and food security, and environmental sustainability.

Health



As confirmation of the importance of good health for development, three of the eight United Nations (UN) Millennium Development Goals (MDG) focus on health: child health, maternal health, and fighting HIV/AIDS. Moreover, improved health outcomes are a prerequisite for developing countries to break out of poverty.

Poverty and food security

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Moreover, malnutrition is a major cause of mortality, especially for children under 15. A complex of factors is responsible for food insecurity in low- and middle-income countries, but poverty and deficiencies in access to food are major contributors. To meet the food security needs of the next 30 years and to create wealth in poor communities, there is a need to increase agricultural productivity on the presently available land, while conserving the natural resource biodiversity (Blakeney, 2002).

Environmental sustainability

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Climate change due to global warming, manifested in more frequent droughts and higher temperatures, has adverse effects on agricultural productivity, biodiversity, and also health. Not only are infectious diseases spread more easily, accounting for roughly 15 million deaths annually, but the quantity and quality of drinking water and food stocks are also threatened (OECD, 2009). The global community now widely accepts the urgency of coordinated and concerted actions needed to combat the problem of climate change resulting from the increasing accumulation of greenhouse gases (GHGs), and particularly of carbon dioxide (CO2). There is an increased need for new technologies to help in this battle (Barton, 2007; Maskus, 2010).

How does IP contribute toward addressing social challenges?

Innovation is a critical part of the solution to societal challenges, both at the global or the local level. Specifically, by promoting innovation in technological areas relevant to social challenges, IP rights



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can significantly contribute to fostering such innovations. IP can provide businesses with incentives to invest in relevant inventions that will produce innovations. Moreover, the protection of knowledge needs to be combined with policies and mechanisms that facilitate access, transfer and wide implementation of such innovations. The following sections cover specific aspects of innovation for health, food security and environmental challenges.

Health

Bringing a medicine to market is a long and complex process that is very costly and takes many years to complete, pharmaceutical companies need incentives to invest money to develop and produce new and better medicines (EC, 2013). Because medical technologies are expensive to develop but relatively cheap to reproduce, it would be unsustainable for companies to invest in product development and regulatory approval if their competitors were in a position to immediately introduce replica products. Thus the IP rights can play a critical role to incentivise investments (WHO, WIPO and WTO, 2013).

Indeed, the pharmaceutical sector stands out in terms of its dependence on patents to capture returns to research and development (R&D) (see IP and innovation in biotechnology and pharmaceuticals [1]). Moreover, the patent system's requirement to make inventions accessible through public disclosure creates an extensive information base that serves as a tool for charting freedom to operate, potential technology partnerships and procurement options, as well as giving policy makers insights into patterns of innovation in the medical sector (WHO, WIPO and WTO, 2013).

In practice, patents are also used as a means for concluding many technology partnerships and R&D collaborations, with multiple licensing arrangements made in order to deliver a new medical technology to the public (WHO, WIPO and WTO, 2013). In this sense, appropriate licensing of patents can help build partnerships and enable innovation through cooperation in bringing new medical technologies to market. For example, new models of socially responsible licensing help to ensure that new medical technologies are available and affordable for underserved communities. Public-private partnerships (PPPs) have resulted in creative licensing agreements that forego profit maximization in favour of providing essential technologies to poorer countries at affordable prices. Voluntary licenses also form part of corporate social responsibility programmes (e.g. for HIV/AIDS treatments). In addition, models like the Medicines Patent Pool have reinforced the trend towards voluntary licensing programmes that increase access to medicines (WHO, WIPO and WTO, 2013).

In addition to patent rights, the protection of clinical trial data against "unfair commercial use" is also important, given the considerable efforts made to generate these data and bring new medicines to the market, although certain forms of test data protection potentially delay the entry of generic medicines and should be reviewed accordingly (WHO, WIPO and WTO, 2013).

Other relevant aspects of IP to health care innovation include the following:

- The relationship between trademarks and International Non-proprietary Names (INNs), which are generic names for active pharmaceutical ingredients that are important for the accurate identification of products, and thus for the safety of patients (WHO, WIPO and WTO, 2013).
- Copyright questions regarding whether IP protection covers the package inserts or
 information leaflets that accompany pharmaceutical products. Given that copyright generally
 extends to making copies of original works on a commercial scale, courts have sometimes
 found that generic pharmaceutical producers cannot reproduce for their own products direct
 copies of the original expressions contained in package inserts of the original producer of the
 product (WHO, WIPO and WTO, 2013).

Affordable prices are a critical determinant of access to medicines, and generic competition is a key



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factor in driving prices down. Yet, even low-priced generic medicines are often still unaffordable for large parts of the population in many low- and middle- income countries, and availability of essential medicines in the public sector is still insufficient, which raises issues of access to medicines, economic and commercial factors, and industrial policy (WHO WIPO and WTO, 2013).

A number of IP instruments facilitate access to medicines for both communicable and non-communicable diseases:

- Patent rights are temporary and only last for a limited period of time (usually 20 years, plus up to five years extension for drugs in certain countries).
- Exclusions from patentable subject matter and exceptions and limitations to patent rights are permitted in order to ensure harmony with broader public policy goals.
- Patent application, examination and grant procedures, as well as opposition, appeal, and other review procedures allow courts and other review bodies to correct erroneous decisions and give relief where necessary, in order to ensure that the patent system as a whole functions as a public interest policy tool.
- Countries can also make use of the flexibilities available under the international IP regime like the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) (WHO WIPO and WTO, 2013), notably those regarding health-related national emergencies.

Food security

It has been argued that modern agriculture's use of genetic resources (GR) and traditional knowledge in biotechnology—for example, for the creation of genetically modified organisms (GMOs) and breeding of new varieties of plants—can contribute to food security (EP, 2011). Among the promises of transgenic crops are increases in productivity.

The IP system plays an important role in the agricultural sector (see IP and innovation in agriculture [2]), particularly in agricultural innovation and food security. IP protection for agricultural or green biotechnology has spurred investment in the engineering of desirable genetic traits and their introduction into useful local species. These technologies include pest control traits as well as herbicide tolerance; postharvest traits, such as delayed ripening of spoilage-prone fruits; agronomic traits, such as nitrogen fixation and utilisation, restricted branching and environmental stress tolerance; male and/or seed sterility for hybrid systems; and output traits such as plant colour and vitamin enrichment (Blakeney, 2002).

One issue raised by patented seeds is the right of farmers to save and replant, which is accepted under the plant variety protection (PVP) regime but not under the patent regimes. This needs to be examined from different angles: the need for economic incentives to invent; the vital importance of food for millions of small farmers in developing countries; a market structure with millions of competing buyers on the one side, and a few sellers with strong market power on the other side.

The 2010 Nagoya Protocol to the Convention on Biological Diversity is designed to advance fair benefit sharing and to prevent biopiracy. Existing arrangements for multilateral access and benefit sharing in the area of agriculture include the 2002 International Treaty on Plant Genetic Resources for Food and Agriculture.

Environmental challenges

IP protection is important to enhance the pace of innovation of environmentally sound technologies



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(ESTs), but also to improve their effective diffusion and adaptation into locations where they are most needed, often countries in the developing world (Maskus, 2010). Several technologies for reducing emissions need adaptation and calibration to local conditions and therefore cannot be transferred between regions without significant costs. IP rights are important to support transfer activities of private firms since possessing a monopoly right increases the returns to product development and adaptive investments (Thomson and Webster, 2010).

In addition to patents, the following IP rights are most relevant to ESTs: trade secrets (firms sometimes choose to keep their inventions secret in this type of technology), copyright, new plant varieties, and design protection (Maskus, 2010). Because many of these technologies include computer programs within their technological implementa¬tion, it is important to consider copyright policy among those that may encourage innovation (Abbott, 2009). Plant variety protection is relevant because new varieties of plants may be developed for use in generating energy and to mitigate the impact of climate change (such as plants that exhibit improved drought-resistant characteristics) (Abbott, 2009). With regard to design protection, technologies such as a wind turbine might embody a new ornamental (but not functional) design and therefore be protectable (Abbott, 2009).

It is generally assumed that the pharmaceutical sector is highly dependent on strong patent protection, mainly because of the high cost involved in developing new drugs and the low cost of reverse engineering these new drugs. Preliminary research suggests that most ESTs—such as alternative energy resources (AERs) and climate change mitigation technologies (MTs) industries—may be less dependent on strong patent protection or that patents are less likely to cause significant bottlenecks in the development and transfer of such technologies (Abbott, 2009). However, there are still concerns that patents and other IP rights may pose barriers to accessing technologies that are important for environmental sustainability (Barton, 2007; Maskus, 2010). IP rights are perceived to be a barrier for "scaling up" the transfer of ESTs and the "affordable" access to these technologies in a rapid time frame (Abdel Latif et al., 2011).

It should be noted that the creation of new plant varieties by agricultural biotechnology (as explained earlier) also has positive environmental effects. The development of new plant varieties increases the actual diversity of species, and if genetic barriers can be eliminated through genetic engineering, there will arguably be an increase of botanical diversity as well (McManis, 1998).

What are the policy implications regarding IP and social challenges?

Health

ஈட்டு இந்தி Level Forum on Medicines for Neglected and Emerging Infectious Diseases in 2007

"Supporting developing countries-led efforts in strengthening their own health, local production and research systems.... In particular: ...Taking steps to strengthen the capability of developing countries to manage issues of intellectual property, including using available flexibilities to the fullest extent, and to build sustainable networks and capacity for global research." (OECD, 2007).

In this regard, countries have adopted several measures for addressing IP issues in health care including the following:

- Promoting the transfer of technology, knowledge, data and technical skills to strengthen innovation systems in developing countries (OECD, 2009).
- Exploring collaborative mechanisms for IP licensing and models of socially responsible licensing (WHO, WIPO and WTO, 2013).
- Imposing strict guidelines to prevent strategies employed to delay the entry of generic competition, such as "evergreening" (WHO, WIPO and WTO, 2013).



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 This would help respond to health needs and avoid delays in access to medicines.
- Creating mechanisms to encourage research on medicines for diseases that mainly affect poor countries where buying power is severely limited (OECD, 2009).
- Ensuring that the IP provisions included in trade agreements with developing countries are compatible with the Doha Declaration (EC, 2013).
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Food security

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It is important to improve access to relevant technologies by developing certain policy tools such as patent landscapes (data on the type of technologies that are patented and by whom) on technology relating to crops that are of particular interest to developing countries and LDCs with problems of food security and malnutrition.

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