Open Society Foundations and Intellectual Property Rights

-- Position paper presented to the Global Advisory Board in June 2011 --

Intellectual Property (IP) rights represent a societal contract. They award a time-limited monopoly to inventors and creators to exploit their work commercially, providing a financial reward for innovation and creativity. In return, IP rights provide for disclosure and access so that the public can enjoy the fruits of innovation and creativity and can build upon and improve them. OSF strives to safeguard this balance between rewarding discoveries and creativity, and ensuring that the public—especially poor and marginalized populations—can benefit from the ensuing innovation. OSF also aims to ensure that the public interest is represented in IP policy-making and practices worldwide. OSF is committed to the principle that research literature which is the result of publicly funded research is a public good and should be available freely online.[1] *With respect to medicines and public health, OSF additionally promotes novel models for innovation to more adequately address the health needs of people in developing countries.*

Intellectual Property Rights in Open Societies

Intellectual property rights are an important open society issue because they govern the ownership and control of knowledge. In our increasingly knowledge-based world, IP rights can serve to enable affordable access to information and ensure continued creativity and innovation or, alternatively, deny, delay, or distort access to knowledge and knowledge-based goods. IP rules determine the availability and price of vaccines, diagnostics, and medicines, as well as access to textbooks, research journals, tools, and data. They affect the openness of communications via the Internet as well as patterns of economic growth.

OSF's interest in IP rights is motivated by concerns about the direction in which the global IP regime has evolved over the last two decades, in particular:

1. A growing imbalance between the rights of IP holders and the public interest
2. IP policies that do not adequately address the interests of poorer countries
3. Deficiencies in transparent and democratic decision-making.

(1) A growing imbalance between the rights of IP holders and the public interest

In recent decades, the balance of power underlying the societal contract of IP has increasingly skewed towards the interests of rights-holders at the expense of the public interest.

A. Copyright

In some countries, the duration of copyright protection has increased from 28 years following the date of publication to 70 years after the death of the copyright holder. As a result, our public domain today is less than half of what it would be if we returned to the copyright rules of 80 years ago. And while mandatory standards of copyright protection have spread globally, fair use rights to counterbalance those protections are rarely put in place, especially in poorer countries. As a result, for example, 120 countries, most of them in

1 Open access to peer-reviewed research is an important part of the Information Program's work, but is not discussed in this paper, because it is based not on the reform of copyright but on the adoption of open licenses, especially those mandated by research funders. A major milestone in our campaign for Open Access has been a mandate adopted by U.S. Congress which stipulates that all research funded by the National Institutes of Health (about $30 billion annually) be made freely available online.

the developing world, currently do not have a fair use provision that protects the access rights of the blind and visually impaired. The world's largest digital library for the blind, bookshare.org, is able to make its catalog of 60,000 books available to people within the United States who have "certified" disabilities, thanks to an exemption in U.S. copyright law. Outside of the U.S., however, this resource is unavailable because of the absence of such exemptions. As the founder of bookshare.org points out: "Today's piecemeal national approach leads to a few countries with incompatible exemptions for the disabled without an effective approach to cross-border sharing, forcing us to go back to asking permission of the publisher or author to serve anybody outside our country."[2] While new technologies make it possible to imagine a world where visually impaired persons have access to a broad variety of knowledge, the out-of-date legal environment is the most critical barrier. Libraries for sighted people face similar problems. In many countries, libraries lack the simple right to make digital back-up copies of their materials. Even in the US, with some of the strongest fair use provisions in the world, a recent gathering of experts at Harvard concluded that restrictive copyright is the biggest barrier to the creation of a national digital public library.

The public interest is also threatened by overly aggressive copyright enforcement proposals promoted through new instruments such as the Anti-Counterfeiting Trade Agreement (ACTA). Proposed "three-strikes laws" in some countries introduce an administrative process for terminating citizens' access to the Internet for up to twelve months when repeated copyright infringement is alleged. Such laws mandate invasive surveillance of user traffic, violate the principle of due process, and, potentially, curtail free expression. When reviewing the French "three-strikes law," the French Constitutional Court ruled that: "Parliament was not at liberty […] to vest an administrative authority with such powers [i.e. 'the power to restrict or deny access to the internet'] for the purpose of protecting holders of copyright and related rights. Furthermore, […] Parliament cannot […] introduce a principle of presumption of guilt in criminal matters."[3] In line with this aggressive copyright enforcement agenda, we are observing a wave of similar measures being undertaken to outsource policing activities to private Internet companies—mostly Internet service providers. This environment of extra-judicial sanctions against citizens and consumers is posing a serious threat to fundamental rights, transparency, and openness on the Internet.[4]

B. Patents

Since the WTO TRIPS[5] Agreement came into force in 1995, all WTO member states have had to extend the duration and scope of patent protection to the standards requested by industrialized nations. As a result, the capacity of developing countries to locally produce and make available more affordable generic versions of medicines to respond to their public health needs has been eroded. Today, more than 80 percent of the 6 million people who are being treated with AIDS medicines in developing countries are dependent on Indian generics, which were developed before India adopted the TRIPS obligations. Vigorous generic competition resulted in a price drop from more than US$10,000 in 2000 to less than US$70 today. However for all newer medicines, generic production will only be possible after expiry of a 20-year patent or upon explicit authorization of the originator company. In practice this means prohibitively high prices for newer medicines, and many people dying because of a lack of access to medicines. This is the current situation for people living with HIV in developing countries who have developed resistance to the primary AIDS medicines, and

2 Private email communication, October 2008.

3 The decision is available at: http://www.conseil-constitutionnel.fr/conseil-constitutionnel/root/bank/download/2009-580DC-2009_580dc.pdf

4 See http://www.edri.org/files/EDRI_selfreg_final_20110124.pdf

5 World Trade Organization's (WTO) Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement. TRIPS was negotiated at the end of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) in 1994. It sets and globalizes the minimum standards for IP protection and enforcement for all WTO member states.

for most people outside Europe and the U.S. who need treatments for hepatitis C or cancer.

In order to balance IP holders' rights and the public interest, the TRIPS Agreement includes a number of *flexibilities* that countries can use to enable access to patented inventions. In addition, the 2001 Doha Declaration on TRIPS and Public Health states explicitly that the TRIPS Agreement does not and should not prevent member states from taking measures to protect public health, and specifically reaffirmed the right of all members to use the flexibilities contained in the TRIPS Agreement, including compulsory licenses[6]. Yet, these flexibilities are seldom used. Most developing countries lack the knowledge, capacity, and negotiating power to use them. In fact, when Thailand and Brazil chose to use compulsory licenses to make available life-saving medicines for AIDS and cancer for their people, they met strong resistance and political pressure from the U.S. and the E.U., which defended the interests of American and European pharmaceutical industries. Both countries were placed on the US Trade Representative Office "301 Watchlist", which the US uses to monitor other countries' domestic IP policies, and were threatened with commercial retaliation.

Meanwhile, North American and European countries commonly use TRIPS flexibilities to further their own domestic policy objectives. For instance the U.S. government has issued compulsory licenses on satellite technology, night-vision glasses, and medical devices for performing artery surgery. Fearing a bioterrorism attack with anthrax, Canada issued a compulsory license on the antibiotic ciprofloxacin. Italy has issued a compulsory license on the broad spectrum antibiotic combination imipenem-cilastatin, while France has adapted its patent law to broaden the possible government use of patented medicines and diagnostics for public health reasons.[7]

Moreover, both the U.S. and the E.U. (who together with Japan are the source of 75 percent of all patents) routinely exhort other countries to accept IP provisions that go beyond what is required by TRIPS (referred to as "TRIPS-plus") in economic partnership or investment agreements. The current negotiations for a free trade agreement (FTA) between the E.U. and India, as well as the Trans-Pacific Partnership (TPP) agreement between the U.S. and eight other countries are cases in point. Both agreements contain TRIPS-plus provisions that could have a negative impact on access to medicines. For instance in Jordan, the introduction of TRIPS-plus provisions through an FTA with the U.S. has led to a 20 percent increase in medicine prices and delays in generic entry costing at least US$6 million to the country's health system.[8] Peru's Ministry of Health calculated that the introduction of the proposed FTA between the U.S. and the Andean countries would cause medicine prices to increase by 10 percent within a year and 50 percent over 5 years. This would mean an additional cost of US$34 million for medicines in the first year, of which US$29 million would be borne by patients.[9] Many patients would not be able to afford these price increases.

Access to medicines is further threatened by anti-counterfeiting measures that (deliberately) confuse generic medicines with trademark infringements and false medicines, and put police and customs officials in charge of controlling the veracity of medicines. In 2010, this led to at least 19 unjustified seizures of medicines in transit in Europe on their way from India to countries in Africa and Latin America, with treatment interruptions as a result. In Kenya, an anti-counterfeiting bill is being challenged in court by AIDS patient groups for being unconstitutional on the grounds that it endangers lives by arbitrarily denying access to affordable generic medicines.

---

6 By issuing a compulsory license, countries authorize use of a patent-protected invention by the government or third parties without the consent of the patent-holder, usually in return for compensation in the form of royalties.

7 Recent examples of the use of compulsory licenses on patents. KEI Research Note 2007:2, http://www.keionline.org/misc-docs/recent_cls.pdf

8 Oxfam Briefing Paper. All costs, no benefits: How TRIPS-plus intellectual property rules in the US-Jordan FTA affect access to medicines, March 2007.

9 Civil Society Briefing Paper. US-Andean FTA: Access to medicines, 2005. Available at: http://www.citizen.org/documents/perufrentealtlc_accesstomedsoverview%5B1%5D.pdf

Several governments, including the E.U. and U.S., are currently in negotiations to establish the Anti-Counterfeiting Trade Agreement (ACTA), which would establish an international legal framework for enforcing IP rights. This focus on new legislative initiatives to counter the commerce in counterfeit goods marks a shift in responsibility and burden for the protection and enforcement of IP from the private IP holder to governments, and is accompanied by a shift towards criminalization of (even minor or involuntary) IP infringements.

(2) IP policies are not adequately addressing the interests of poorer countries

The WTO TRIPS Agreement first made minimum standards of IP protection mandatory for WTO members. In the past, copyright and patent rules were differentiated according to levels of economic development; under the new regime, poorer countries are forced to accept a one-size-fits-all paradigm that is often incompatible with their interests and needs. As the UK Government's Commission on IP Rights concluded, the main effect of the new IP regime is to benefit those who have knowledge and inventive power, and to increase the costs of access to those without. Thus the costs and benefits of the system are unfairly distributed and in fact increase the gap between rich and poor.[10]

Developing countries are particularly hard hit by restrictive copyright laws. They are net importers of copyrighted materials and have weaker fair use protections than in Western countries. For example, as Consumers International found in a study in 2006,[11] ten out of eleven developing countries surveyed in the Asia-Pacific region had not incorporated fair use provisions for educational purposes to the extent allowed by the international copyright treaties. This means that in most developing countries, schools are forced to act outside the law on a daily basis in order to use copyrighted materials for teaching.

The persistent strengthening of IP protections is often justified as a prerequisite to ensure innovation. The current IP-driven innovation model, however, fails to deliver diagnostics, vaccines, and medicines that address the needs of developing countries. AIDS in children, tuberculosis (TB), and tropical diseases are just a few examples of major health problems in many poor countries that remain largely neglected by the pharmaceutical industry. And for diseases that affect both rich and poor countries, new medicines or vaccines are typically priced out of range for most people living in low and middle-income countries. Examples include life-saving hepatitis C medicines, the HPV vaccine preventing cervical cancer, or the recently launched *Xpert* TB diagnostic test.[12] It should be noted that despite a steady increase in IP protection and research and development (R&D) investments worldwide, medical innovation has actually decreased in the past decades. Out of almost 1,000 new medicinal products that came on the market between 1996 and 2006, only 4 percent represented a therapeutic innovation and another 11 percent offered a clear therapeutic advantage, while 53 percent had no therapeutic benefit or were inferior to products already available.[13] In the IP-driven innovation model, pharmaceutical companies prioritize R&D in function of market opportunities, rather than medical needs. Moreover, many medicines developed by pharmaceutical

---

10 UK Commission on Intellectual Property Rights. Integrating IP rights and development policy (2002). Available at: http://www.iprcommission.org/home.html.

11 Consumers International. Copyright and access to knowledge: Policy recommendations on flexibilities in copyright law (2006), pp. 29–31. Available online at http://www.consumersinternational.org/Shared_ASP_Files/UploadedFiles/C50257F3-A4A3-4C41-86D9-74CABA4CBCB1_COPYRIGHTFinal16.02.06.pdf.

12 While variable between countries, the price range of a 12 months course of hepatitis C medicines (pegylated interferon-alfa plus ribavirin) is US$15,000-30,000; the HPV vaccine costs around US$300-400; the *Xpert* TB diagnostic equipment costs US$16,000 (special price for developing countries), plus an additional cost of at least US$20 per test for the consumables.

13 A look back at pharmaceuticals in 2006: Aggressive advertising cannot hide the absence of therapeutic advances. Prescrire International 2007; 16: 80–86

companies are based on publicly funded university research and discoveries, which were subsequently patented by universities.[14] However the licensing deals granted by universities generally do not specifically recognize this public investment, for instance by requiring affordable access to the resulting medicines.

In recent years, a variety of new mechanisms to promote R&D based on health needs are being discussed at various policy forums, such as the WHO Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property (GSPoA). These include setting up a “Global Fund for R&D,” prizes, advanced market commitments, patent pools, and other mechanisms designed to overcome the limitations of the current system. The emergence of multiple nonprofit product development partnerships (PDPs) to overcome the pharmaceutical market failure for certain diseases is another example. While certain ideas are worthwhile to explore in more detail (and pilot in practice), most fail to fundamentally question the patent-driven innovation model. Moreover, the research community, the pharmaceutical industry, civil society and governments in developing countries have largely been absent from these conversations.

(3) Deficiencies in transparent and democratic decision-making

Increasingly, decisions about substantive IP norms and policies are made behind closed doors.

The Anti-Counterfeiting Trade Agreement is a case in point: negotiators and participating lobbyists had to sign nondisclosure agreements and civil society was presented with a draft negotiating text long after the negotiations had started. When in 2009 the public interest group Knowledge Ecology International (KEI) filed a request under the Freedom of Information Act to access the draft ACTA text, the Office of the U.S. Trade Representative denied the request "in the interest of national security."[15]

Similarly, the E.U.-India FTA is being negotiated behind close doors, although business groups are apparently actively being consulted on their interests in opening up Indian markets. The public interest group Corporate Europe Observatory has filed a case with the E.U. General Court, accusing the European Commission of discriminating in favor of corporate lobby groups and violating the E.U.’s transparency rules.[16]

A third example relates to the ongoing discussions on health innovation that are taking place under the aegis of the World Health Organization (WHO), in particular the GSPoA expert working group on new financing mechanisms to fund health innovation. In addition to various proposals about new sources of money, it is exploring proposals from civil society groups to promote needs-driven innovation by de-linking the cost of R&D from drug prices. Undisclosed and unmanaged conflicts of interests with pharmaceutical interests in the expert working group have, however, given rise to partiality or an appearance thereof that is tainting the work of the group.

14 The 1980 U.S. Bayh-Dole Act encouraged American universities to take out patents on inventions that resulted from federally funded research, and to issue exclusive licenses to private firms on the assumption that exclusive licensing creates incentives to commercialize these inventions. Similar legislations were later adopted by many industrialized countries, but the outcome in terms of public benefit has been controversial.

15 See http://keionline.org/blogs/2009/03/12/acta-state-secret

16 See http://www.corporateeurope.org/global-europe/content/2011/03/eu-reporter-eu-india-court-case

OSF's Work

Responding to the outlined threats, the Open Society Foundations have developed funding initiatives and advocacy efforts that have two over-arching goals:

(1) Support the participation and capacity of civil society and developing countries in IP policy-making at all levels of government;

(2) Promote balanced IP norms that protect the societal contract enshrined in IP law.

The Open Society Information Program: Promoting Access to Knowledge

The Open Society Information Program established a Project on Intellectual Property and Knowledge Governance in 2003, building on a long-standing commitment and successful funding record in the area of access to knowledge. In 1999 it initiated EIFL, a library consortium that serves more than five million users through several thousand university and research libraries in close to 50 countries across the developing world. In 2002, it launched the movement for open access to scholarly research publications. Today, more than 150 open access publication mandates have been adopted by research funders and universities worldwide, including the largest research funder in the world, the U.S. National Institutes of Health. However, unbalanced global copyright rules continue to be a critical barrier to access to knowledge, in particular by disadvantaged groups such as the blind and libraries in poorer countries.

The Information Program aims to bring global IP rules back into balance. Initially, we concentrated on reforming the World Intellectual Property Organization (WIPO), where advocacy supported by the program led to the adoption of an official "development agenda" and a much more public-facing model of rule-making. Going forward, the Information Program will:

- Advocate for fair use rights as they are essential to enabling access to knowledge, especially for disadvantaged groups such as the blind. We will be supporting (a) advocacy for the adoption of a WIPO Treaty for the Visually Impaired; (b) exploration of the need for international norms for other fair use rights such as those affecting digital and distance education; (c) advocacy for strong fair use rights in domestic legislation in developing countries.
- Push back against overly aggressive IP enforcement regimes. Recently, powerful copyright industry interests have begun to lobby for the institution of copyright enforcement techniques to be implemented by Internet service providers, relying on intrusive surveillance mechanisms and punitive termination of personal Internet access without due process protections. This is a threat to free expression and privacy against which the Information Program will continue to advocate by supporting policy analysis, campaigning, and media coverage.

These reform efforts are driven by the Access to Knowledge (A2K) movement, a global coalition of NGOs and experts fostered by the Information Program.

The Open Society Public Health Program: Securing Access to Essential Medicines

The Open Society Public Health Program established the Access to Essential Medicines Initiative (AEMI) in 2007. The magnitude of the AIDS crisis had drawn the world's attention to the high cost of AIDS drugs and other life-saving medicines, and the non-availability of adapted diagnostics, vaccines, and medicines for diseases that primarily affect the poor and marginalized in developing countries. This emergency highlighted the relation between IP rights, drug prices, access to medicines, and priority-setting in medical innovation, as

well as the policy frameworks and power balances that determine these relations. For developing countries and marginalized populations, IP rights have by and large been an outright barrier to access—often with fatal consequences—without substantial benefits in terms of health innovation to address their specific needs.

The Access to Essential Medicines Initiative aims to empower civil society through capacity building, grantmaking for policy-advocacy work, and fostering of leadership to:

- Urge governments to make better use of the existing legal and policy frameworks to improve access to essential medicines, in particular to implement the TRIPS Agreement in full, and make use of the TRIPS flexibilities to increase access to medicines and protect public health.
- Advocate against the implementation of TRIPS-plus measures that increase patent protection and IP enforcement beyond what is required under TRIPS.
- Support civil society to demand transparency and accountability regarding trade and other negotiations that affect health and access to medicines.
- Represent developing countries and marginalized populations in international IP policy debates, such as those happening at the WTO TRIPS council, WIPO, the WHO, the E.U., East African Community (EAC), and other forums to ensure their voice is heard and the balance between private patent rights and the public interest in access to medicines is protected.
- Actively engage in new thinking on alternative models of medical innovation that meet the needs of developing countries, such as de-linking the cost of research and development from the price of medicines, nonprofit drug development, open source drug discovery and development models, or drug development as a social good. This will specifically include creating opportunities for researchers, drug companies, civil society, and governments from the developing world to shape and drive innovations.

Underlying these specific objectives, the Public Health Program aims to nurture a global movement that fosters access to medicines as a public responsibility, and challenges the current commoditization of essential medicines.

Annexes:

UK Commission on Intellectual Property Rights (2002). Integrating IP Rights and Development Policy

UNAIDS, WHO and UNDP Policy Brief (March 2011). Using TRIPS flexibilities to improve access to HIV treatment