

RISKS AND OPPORTUNITIES FOR ACCESS TO KNOWLEDGE

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Introduction

The development of the Internet and other information technologies (IT) has led to a dramatic increase in the importance of knowledge goods and services, in the realms of economic, political, cultural and personal life. In parallel, the research agenda for the development and use of new medical inventions has gained more attention among the public and policy makers and, despite the current relatively modest productivity in terms of new treatments, has raised expectations regarding the potential for dramatic advances in health. These raising expectations are contrasted with the increasingly aggressive pricing of new medicines and a growing awareness of the global disparities in access to them, based in part upon the high prices that are a consequence of intellectual property (IP) protection systems.¹ At the same time, a number of new methods of creating and disseminating knowledge goods have emerged, with great promise in terms of expanding access to knowledge, and reducing disparities of such access.

The changes in technology are partly driving a deep and far reaching reassessment of the rules under which knowledge will be controlled or shared.

None of these developments are taking place in a social or political vacuum. Commercial interests are organized to influence governments and global intergovernmental bodies and the broader public is increasingly being empowered by the new IT to play a more important role in such policy discussions.

What type of access to knowledge (A2K) issues are likely to be addressed in global norm setting?

Public policy is in play in a large number of areas, touching upon virtually every aspect of the knowledge economy. There are many proposed and adopted measures to vastly increase the degree to which knowledge can be owned and controlled, as there also are many proposals, initiatives and experiments to expand access to knowledge. Some of the proposals and initiatives involve intellectual property rights (IPRs), while others involve policies that would support or undermine new methods of collaboration or new business models for creating and disseminating knowledge goods.

For purposes of this analysis the IP issues will be presented first, beginning with non-patent issues, including both copyright and “neighboring” IP regimes, particularly those that are based upon investments in knowledge goods.

¹ Including patents and exclusive rights to rely upon publicly available scientific data on safety and efficacy of medicines.

Copyright

Modern copyright regimes involve government grants of certain commercial and non-commercial rights to the owners of particular forms or manners in which information is expressed, which are typically referred to as “works.” These might include literary works - which today would include nearly any novels, reference works, newspapers, letters, poems, plays, articles, books, blogs, or even unpublished emails between friends - as well as a variety of other forms, such as musical compositions and choreography, sound recordings, motion pictures, paintings, photographs, software, drawings, designs, maps, arrangements of information in databases or advertisements.

The nature of the rights varies from country to country within a global framework of treaties and trade agreements that set global norms. The two most important global agreements concerning copyright are the Berne Convention for the Protection of Literary and Artistic Works² and the 1994 World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (the TRIPS Agreement). Taken together these agreements set out the core national obligations regarding copyright protection that most nations must follow - or risk trade sanctions in a WTO dispute resolution proceeding.³

Copyright owners are seeking new global norms that go far beyond the Berne/TRIPS standards. The efforts have led to a 1996 World Intellectual Property Organization (WIPO) Copyright Treaty, which has been formally accepted by more than 50 countries, and a number of regional and bilateral trade agreements that have extensive provisions on copyright, which greatly exceed the Berne/TRIPS requirements. Among the objectives of the newer treaties and trade agreement are extensions of the term of protections, newer and broader economic rights, such as the right to make a work available to the public, obligations to enforce restrictions against the circumvention of technological protection measures and digital rights management information and, in some cases, restrictions on traditional limitations and exceptions, such as the use of compulsory licensing or various forms of the first sale doctrine (the exhaustion of rights after the sale of a work). New obligations regarding enforcement are also featured in agreements involving the United States (US) or the European Union (EU).

Related (neighboring) rights

There are also a set of “related” or “neighboring” rights, some of which are similar to copyright, such as the rights for performing or producing a sound recording, and some that have little in common with copyright, which normally requires a least a modicum of creativity to qualify for protection.

In some countries, broadcasting organizations receive certain rights in material they broadcast, which is independent of copyright. The basis for the rights for broadcasting organizations is not based upon a creative act but rather upon the act of transmitting information. The broadcasting right can extend to materials that are otherwise in the public domain or it can be an additional layer of rights on top of that which is awarded to a copyright owner for a creative work.

² Of 9 September 1886, completed at Paris on 4 May 1896, revised at Berlin on 13 November 1908, completed at Berne on 20 March 1914, revised at Rome on 2 June 1928, at Brussels on 26 June 1948, at Stockholm on 14 July 1967, and at Paris on 24 July 1971, and amended on 28 September 1979.

³ According to Article 9 of the TRIPS, “Members shall comply with Articles 1 through 21 of the Berne Convention (1971) and the Appendix thereto. However, Members shall not have rights or obligations under this Agreement in respect of the rights conferred under Article *6bis* of that Convention or of the rights derived there from.”

The 1961 International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations, known as the “Rome Convention,” sets out global standards for these rights - but it is not as widely accepted as the Berne Convention standards are for copyrighted works. The US has never signed the Rome Convention, for example. The rights of these parties are also addressed in Article 14 of the TRIPS, which is the more important global instrument.

The term *sui generis* - Latin for “one of a kind” - is a term used to describe special IPRs that do not fit into the traditions established for copyrights, patents, trademarks or trade secrets. Examples of *sui generis* regimes are those created to give special protections for plant breeders, semi conductor chips or data used in the registration medicines or agricultural chemicals. Some countries now provide a *sui generis* right for databases. This *sui generis* database regime is relatively new, following the adoption of an EU Directive which requires members of the EU to protect the underlying elements of databases, even when those elements do not qualify for copyright protection - for example, when the elements contain data, rather than creative works. The criteria to qualify for protection focus on the effort and investment undertaken by the owner of the database, rather than the creative nature of the work. The *sui generis* database right has many similarities to the broadcasters’ right. They convene a property right on information on the basis of the act of transmission and it does not require the broadcaster - or database owner - to demonstrate any creative effort. Both the broadcaster right and the database right create a layer of ownership in the information, in addition to the rights of the copyrighter owner - if any - of the underling information that is transmitted.

Sui generis regimes for databases are controversial. An attempt in 1996 to adopt a WIPO treaty on non-original database components failed, and the US continues to reject such approaches — due, in part, to opposition from a diverse coalition of librarians, academic researchers, consumer groups, database businesses and the US Chamber of Commerce. Some scholars have called upon the EU to reconsider its directive in light of evidence that it may have retarded the development of new databases and knowledge services.⁴ However at present the EU is aggressively seeking to extend the *sui generis* database regime to its trading partners as part of its larger bilateral trade agenda.

Limitations and exceptions to copyright and related rights

In the strongest form, copyright provides an exclusive right to authorize uses of a work. But nowhere are these rights unlimited and, in many jurisdictions and for certain works or uses, the limitations and exceptions to rights are extensive.

The first limitations concern *what* is to be protected under copyright. The TRIPS provides that “copyright protection shall extend to expressions and not to ideas, procedures, and methods of operation or mathematical concepts as such.” Some governments exclude copyright protection for works of government employees or official texts of a legislative, administrative and legal nature. The Berne Convention states that protection does not extend to “news of the day or to miscellaneous facts having the character of mere items of press information.” Some jurisdictions, including the US, are fairly rigorous in excluding from copyright protection information that is mere compilation of factual data, such as books listing names, addresses and telephone numbers.

There are also time limits on rights referred to as *the term of protection* - an important distinction between IP and rights in physical goods and real property. The terms of protection vary in

⁴ Boyle, James. “A natural experiment,” Financial Times, 22 November 2004. <http://news.ft.com/cms/s/4cd4941e-3cab-11d9-bb7b-00000e2511c8.html>

different agreements - and are generally longer in the more recent ones, particularly those involving bilateral or regional agreements that include the US or the EU.

Even when works are protected, certain uses without the permission of the right owner can be authorized by governments, consistent with various rules, including standards for fair practices, the payment of remuneration or the need to remedy anticompetitive practices. As noted by Professor Sam Ricketson:⁵ “It has long been recognized that restrictions or limitations upon authors, and related rights may be justified in particular cases. Thus, at the outset of the negotiations that led to the formation of the Berne Convention in 1884, the distinguished Swiss delegate Numa Droz stated that it should be remembered that ‘limits to absolute protection are rightly set by the public interest.’ In consequence, from the original Berne Act of 1886, the Berne Convention has contained provisions granting latitude to member states to limit the rights of authors in certain circumstances.”

Nations have implemented, with such public interest, exceptions in a number of important areas. As noted in the UN Conference on Trade and Development (UNCTAD) and the International Centre for Trade and Sustainable Development (ICTSD) Resource Book on TRIPS and Development:⁶ “[...] limitations to facilitate private use, teaching, research and other socially valuable purposes are generally considered to be an important aspect of copyright regulations. In continental law jurisdictions, national copyright laws provide case-specific exceptions to copyright in the above areas. Common law jurisdictions follow the fair use or the fair dealing doctrines, on the basis of which similar exceptions have been developed through case law.”⁷

According to Ruth Okediji in a forthcoming article, “The international copyright system: Limitations, exceptions and public interest considerations for developing countries in the digital environment”, “There have been a few studies on the question of limitations and exceptions within the international copyright system [...] the effective diffusion of knowledge goods is directly related to the limitations placed on the proprietary rights of owners of such goods. Specifically with regards to education and basic scientific knowledge limitations and exceptions are an important component in creating an environment in which domestic initiatives and development policies can take root. A well-informed, educated and skilled citizenry is indispensable to the development process.” Okediji writes: “Although the importance of A2K goods has been emphasized with respect to developing countries, it must not be overlooked that access is also a significant part of the copyright balance in developed countries.” Libraries and educational institutions, for instance, provide access in developed countries, too, and depend on limitations and exceptions in developed and developing countries.

The Berne Convention has a mandatory exception allowing the use of quotations from a work that has already been lawfully made available to the public⁸ - an exception strongly supported by scholarly works. The Berne Convention also specifically references some free uses of works in connection with teaching or in the reporting of current events and notes other cases where non-voluntary uses of works can be authorized, subject to equitable remuneration to the authors. On top of specific mentions such as these, there are more general exceptions clauses in treaties and

⁵ Standing Committee on Copyright and Related Rights, Ninth Session, Geneva, June 23 to 27, 2003. “WIPO Study on Limitations and Exceptions of Copyright and Related Rights in the Digital Environment” prepared by Mr. Sam Ricketson, Professor of Law, University of Melbourne and Barrister, Victoria, Australia.

⁶ Resource Book on TRIPS and Development, UNCTAD-ICTSD Project on IPRs and Sustainable Development, Cambridge University Press, 2005, p. 186. www.cambridge.org/9780521850445.

⁷ See Correa, Carlos. “Fair use in Digital era”, *International Review of Industrial Property and Copyright Law (IIC)*, Vol. 33, No. 5/2002. For an analysis of this doctrine in the US legal system, see Okediji, R. “Toward an International Fair Use Doctrine”, *Columbia Journal of Transnational Law*, Vol. 39, 2000-2001, pp.75 et seq.

⁸ Provided the use is “compatible with fair practice,” and “does not exceed that justified by the purpose.”

trade agreements, which embody various “three-step” tests that regulate further exceptions. In the Berne Convention countries can permit reproduction of works (1) in certain special cases, provided that such reproduction (2) does not conflict with a normal exploitation of the work, and (3) does not unreasonably prejudice the legitimate interests of the author. The same provision is restated somewhat differently in Article 13 of the TRIPS. The context in the TRIPS is broader - it applies to any limitations or exceptions to exclusive rights (not just the reproduction right), and it refers to the legitimate interests of the “right owner,” rather than the “author.” A number of regional or bilateral trade agreements also have provisions that are similar to the TRIPS language.

The three-step test is ultimately political - a judgment call regarding ambiguous terms such as “special”, “normal”, “unreasonably” and “legitimate”. Under the Berne Convention, member countries are largely free to make those judgments themselves.

Dispute resolution and the three-step test

With the TRIPS, the evaluation of the three step tests is subject to multilateral dispute resolution proceedings and enforceable by tough trade sanctions. The dispute resolution approach is now being used in a number of bilateral and regional trade agreements, which creates the possibility of forum shopping and inconsistent global norms. Developing countries are expected to fare better in multilateral dispute resolution proceedings, where the number of countries providing submissions is larger and consumer interests are likely to be better represented.

The types of issues that could be resolved in dispute resolution proceedings include the gamut of free and remunerative exceptions to exclusive rights - for example, compulsory licensing schemes; the extent to which certain personal, non-profit and commercial uses of works are free; as well as the degree to which governments undertake effort to enforce laws against infringement or the anti-circumvention of technological protection measures and digital rights management schemes.

The outcomes of dispute resolution proceedings will be influenced greatly by global norms, including state practice, new multilateral and regional trade agreements and treaties and various “soft law” from forums such as the World Summit on the Information Society (WSIS) or bodies concerned with development or human rights.

The 1996 WIPO Copyright Treaty (WCT) is not currently referenced in the TRIPS but it is often included in bilateral trade agreements. It also provides a modern expression of multilateral norms. The preamble of the WCT notes “the need to maintain a balance between the rights of authors and the larger public interest, particularly education, research and access to information, as reflected in the Berne Convention” and includes a TRIPS-like three step test in the WCT Article 10, and an agreed statement regarding copyright limitations and exceptions that reads as follows:

“It is understood that the provisions of Article 10 permit Contracting Parties to carry forward and appropriately extend into the digital environment limitations and exceptions in their national laws which have been considered acceptable under the Berne Convention. Similarly, these provisions should be understood to permit Contracting Parties to devise new exceptions and limitations that are appropriate in the digital network environment.

It is also understood that Article 10(2) neither reduces nor extends the scope of applicability of the limitations and exceptions permitted by the Berne Convention.”

Exhaustion of rights (The first sale doctrine)

One area of particular controversy in the area of copyrighted goods concerns the exhaustion of the seller's rights once a good is placed on the market in a legal sale. The issue can be referred to as "the first sale doctrine" or as "the exhaustion of rights" (both terms are used below). National policies vary considerably, both between countries and between different types of copyrighted works.

Policies regarding the domestic first sale doctrine determine how much freedom a buyer of a work has to resell, lend, rent or give away the work to others, or to it in a different context. Before computers were an important means of distributing works, this was largely a concern for such entities as sellers of second-hand books or recorded music, video rental stores, or libraries. With the expanded use of digital IT, the issues have become much more complex. Publishers of software, data, music, films, video games and other digital works increasingly seek to limit not only the resale, rental, lending or giving away of works, but also the ways works are used by a person - for example, by restricting a work so it can be used on a single device, or for a limited period of time. The degree to which restrictions on the purchaser of a work are enforced by national copyright laws varies from country to country.

In a system of international exhaustion of rights it is possible to have parallel trade in copyrighted goods - the practice of buying goods in a country where prices are lower and importing them into a country where prices are higher. Parallel trade mitigates against high domestic prices for copyrighted goods. In some jurisdictions, seller restrictions on parallel trade have been found to be violations of competition laws. In other cases, they are permitted or enforced by governments.

Under Article 6 of the TRIPS Agreement, governments are generally free to enact laws that recognize the exhaustion of the seller's rights to prevent the resale, rental, lending or sharing of a work and countries also have the flexibility to recognize either national or international exhaustion - or in some limited cases, including the EU, regional exhaustion.

Copyright owners are seeking measures in regional and bilateral trade agreements that would undermine the flexibility in the TRIPS Agreement to recognize international exhaustion of rights for copyright goods - following the success of the pharmaceutical industry in obtaining restrictions against parallel trade in patented goods, in several US free trade agreements.

Civil society groups, including the Consumer Project on Technology (CP Tech), have called for a rethinking of TRIPS rules to permit recognition of exhaustion of rights among countries of similar or higher incomes for certain goods - including those relating to medicines and most copyrighted goods. Such a policy would permit the use of parallel trade to overcome pricing abuses in countries with inefficient or monopolistic distribution systems, while recognizing the public interest in market segmentation between countries of very different incomes. This would require changes in the TRIPS Agreement and the bilateral and regional trade agreements that address the issue of exhaustion of rights.

Technical protection measures - Digital rights management

The development of new digital technologies to store, copy and distribute information has created vast new opportunities to share information. Even before the Internet was widely used by the general public, publishers of music recordings, motion pictures and databases anticipated possible widespread copying of works. They were concerned that software programmers could routinely circumvent technological protection measures that they were developing to control

unauthorized copying of works. At the same time, academic experts and library, consumer and digital rights groups and high-tech consumer firms expressed concern that technological protection measures and digital rights management systems would undermine the ability of users to take advantage of traditional limitations and exceptions to copyrighted works - including those relating to personal, non-profit and commercial uses, stifle innovation in new technologies, and undermine privacy and freedom.

Even before national governments had acted, four new treaties were considered at WIPO to set global norms for new measures that would give copyright owners and others, including performers and producers of copyrighted works and publishers of databases, new powers to control and monitor copying and sharing of information. Two of the treaties were adopted. Their final texts were considerably influenced by the organized opposition from consumer interests and reflected a number of compromises and balancing provisions that were designed to address the legitimate concerns of users.

These two 1996 WIPO treaties⁹ - the WIPO Copyright Treaty (WCT) and the WIPO Performances and Phonographs Treaty (WPPT) - created global obligations to prohibit the anti-circumvention of technological protection measures (TPMs) and digital rights management (DRM) information.

The US implementation of these obligations included passage of the Digital Millennium Copyright Act (DMCA)¹⁰ in 1998. The DMCA contains a number of controversial restrictions on the development of new technologies, as well as a set of exceptions that are specifically designed to preserve some user rights in areas such as education or the development of interoperable products.

While most members of the EU have not formally joined the WCT or WPPT, the EU has adopted several directives that address these issues, the most important of which is the 2001 directive on the protection for anti-circumvention technologies and rights management technologies.¹¹

The obligation to include anti-circumvention/TPM/DRM language is featured in many new bilateral trade agreements, including every one of the recent free trade agreements involving the US.

Many academic experts, library, education, consumer, civil liberties, free software, and development groups have called upon WIPO and others to evaluate the risks that TPM/DRM measures present to access to knowledge - particularly in areas where public policy has traditionally favored more access. When effective, the TPM/DRM measures vastly expand the powers of publishers to control uses of works - dramatically change the balance between consumers and publisher rights.

There is increasing attention not only to the negative impact of TPM/DRM measures on traditional limitations and exceptions to copyright, but to the problems of preserving access to works no longer commercially exploited (orphan works) and on the ways that consumers can use works. The new DRM technologies for music and software frequently restrict the devices that can be used by a person, for example, as well as the number of times or period when work can be used.

⁹ www.wipo.int/treaties/en/

¹⁰ www.copyright.gov/legislation/dmca.pdf

¹¹ http://en.wikipedia.org/wiki/EU_Copyright_Directive

TPM/DRM measures are also introducing enormous new risks to privacy and freedom, as it becomes more and more feasible to track users of data. This extends to the issue of identifying persons who leak documents from governments or corporations engaged in violations of human rights or domestic laws, or which run counter to social norms.

The WIPO Broadcasting/Webcasting Treaty proposal

The WIPO Secretariat and some member States are seeking a new diplomatic conference to consider a new treaty that would provide protections to broadcasting, cablecasting and webcasting organizations. The treaty is highly controversial among organizations that represent consumer and civil society interests, as well as by many copyright owners. The treaty proposal would expand the protections available to broadcasting organization far beyond what is now provided for in the WTO TRIPS Agreement, providing new commercial rights that extend to works that “casters” do not create and which they do not own under copyright laws.

The minimum term of protection for broadcasting organizations would be expanded from the 20 years of the TRIPS to 50 years, even though the IPR is justified on the rationale of protecting investments by the broadcasting organizations, rather than creative contributions to the works. This expanded IPR, which is obtained by transmitting information, would then be extended far beyond traditional television or radio broadcasting to the Internet, where the impact is far more troublesome. No country has ever tried to implement a property right for webcasting organizations, so there is no experience with such a regime when applied to the Internet.

Contracts

An area of rapidly evolving global norms concerns the status of contracts. Particularly those involving non-negotiated contracts for copyrighted works, databases, and other knowledge goods. Publishers are seeking to vastly expand the legal status and use of contracts to restrict access to copyrighted works and data. There are several aspects of such efforts. One involves the issue of contract formulation. Publishers are seeking wide recognition that digital presentations of contracts, embedded in works, should be considered legally binding instruments. In some cases the contracts are approved as click-on agreements that are required before works can be used. But in the future publishers will seek to automatic the contractual approval between the work and the device that uses the work. Some of this work is taking place within the work program of the United Nations Commission on International Trade Law (UNCITRAL). Publishers are also seeking stronger measures on cross-border enforcement of such contracts, through such instruments as the newly negotiated Hague Convention on Jurisdiction and Enforcement of Foreign Judgments, and similar provisions in regional or bilateral trade agreements.

The acceptance of non-negotiated contracts to govern the use of copyrighted works will make copyright laws irrelevant and will allow publishers to essentially privatize policy making. In order to address the problems that this presents, civil society must insist on the development of new norms that address the problems of non-negotiated contracts, which is particularly problematic in a world of cross border transactions.

Control of anticompetitive practices

Article 40 of the TRIPS Agreement is a very important but largely underutilized provision to protect the public interest. It states that “Members agree that some licensing practices or conditions pertaining to IPRs which restrain competition may have adverse effects on trade and

may impede the transfer and dissemination of technology...” and “Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of IPRs having an adverse effect on competition in the relevant market.”

From the point of view of WTO dispute resolution proceedings, Article 40 is extremely important, because it lies outside of the three-step test in Article 13 or 30 of the TRIPS and it provides a different mechanism to address a wide range of issues - including, for example, failures to license IP on reasonable terms, excessive pricing or restricts that frustrate interoperability or technology transfer. Among recent bilateral trade agreements involving the US, only the US/Chile contains a similar provision.

An agenda for A2K

On 4 October 2004, the General Assembly of the WIPO agreed to adopt a proposal offered by Argentina and Brazil, the Proposal for the Establishment of a Development Agenda for WIPO.¹²

This proposal was strongly supported by developing countries, as well as by a large contingent of civil society. Prior to the General Assembly meeting, hundreds of non-profit organizations, scientists, academics and other individuals had signed the Geneva Declaration on the Future of WIPO,¹³ which calls on WIPO to focus more on the needs of developing countries, and to view IP as one of many tools for development - not as an end in itself.¹⁴

A2K Treaty project

Following the “Development Agenda” proposal at WIPO, civil society and academic organizations - including CPTEch - have lead an initiative to promote a new A2K Treaty, which would protect access to knowledge and facilitate the transfer of technology to developing countries.¹⁵ This proposal addresses many of the issues detailed in this document, which pose a threat for citizens and consumers - particularly in developing countries - and supplies an extensive list of provisions regarding limitations and exceptions to copyright and related rights (including general limitations and exceptions to copyrights, first sale doctrine, DRM and measures regarding circumvention of TPM, non-original or creative works, orphan works and compulsory licensing of copyrighted works in developing countries, among others).

The proposed Treaty also sets limits and preventions for patentability and includes a special section devoted to promote measures to expand the access to knowledge. The measures included in this section seek to enhance freedoms to access knowledge commons - particularly those based on public funded research.

The promotion of open standards, the control of anticompetitive practices, the transfer of technology to developing countries and a clause of obligation to finance free and open knowledge goods are also included in the draft text for the Treaty.

Medical R&D Treaty

¹² www.wipo.int/documents/en/document/govbody/wo_gb_ga/pdf/wo_ga_31_11.pdf

¹³ www.cptech.org/ip/wipo/genevadeclaration.html

¹⁴ Shashikant, Sangeeta (2005), *Intellectual property and the WIPO “Development Agenda”*, <http://wsispapers.choike.org/>

¹⁵ Draft text of the new treaty proposed is available at www.cptech.org/a2k/

Beginning in 2002, a number of economists, scientists and public health experts began work on an alternative trade framework for medical research and development (R&D). This led to a proposal for a new treaty framework that would ultimately replace existing or planned trade agreements that focus on patents or drug prices.¹⁶

The new paradigm includes minimum national obligations for supporting medical R&D, with flexibility regarding the business models, IP rules or other mechanisms - such as open source approaches - a country would choose to support R&D. There are also priority setting mechanisms, including a system of tradable credits for investments in particular projects that promote social or public interest objectives.

Since 2002, the proposal for a medical R&D Treaty¹⁷ has been discussed at meetings, workshops and consultations and several governments have been asked to evaluate the proposed treaty. On 24 February 2005, a letter was presented to the World Health Assembly Executive Board and the World Health Organization (WHO) Commission on Intellectual Property Rights, Innovation and Health (CIPIH). The letter, signed by 162 scientists, public health experts, law professors, economists, government officials, members of parliaments and civil society organizations, states that the current global framework for supporting medical R&D suffers from profound flaws and imposes important costs - including problems of rationing and access to medicine, costly, misleading and excessive marketing of products, barriers to follow-on research, skewing of investment toward products that offer little or no therapeutic advance over existing treatments, and scant investment in treatments for the poor, basic research or public goods.

The signatories of the letter “call upon the WHO CIPIH to engage in debates over the appropriate global framework to support medical R&D, and to evaluate the Draft R&D Treaty proposal. This initiative seeks to refashion global policy to better fulfill the objective of providing ‘access to medicine for all’.”

The letter also expresses that “the treaty proposal recognizes the importance of ensuring sustainable sources of finance for innovation, including R&D for neglected diseases and other public health priorities, and it provides opportunities to experiment with new and promising mechanisms to finance R&D [...] In order to create the best possible systems, policy makers should consider the fullest range of options, including this innovative, flexible and choice preserving idea.”

¹⁶ Love, James and Tim Hubbard, “Make drugs affordable: Replace TRIPs-plus by R&D-plus”, *Bridges* No.6, June 2004. www.cptech.org/ip/health/rndtf/bridges042004.pdf

¹⁷ A draft version of the proposed Medical Research and Development Treaty is available at CP Tech website, www.cptech.org/ip/health/rndtf/