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SAPERE AUDE! ACCESS TO KNOWLEDGE AS A HUMAN RIGHT AND A KEY INSTRUMENT OF DEVELOPMENT

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SAPERE AUDE! ACCESS TO KNOWLEDGE AS A HUMAN RIGHT AND A KEY INSTRUMENT OF DEVELOPMENT

Valentina Vadi[*]

This article focuses on access to knowledge as a human right and instrument to development with particular regard to the pharmaceutical field. In the first part of this essay, after attempting to define knowledge, the two processes of knowledge creation and knowledge diffusion will be explored. At first sight, access to knowledge seems to gravitate in orbit round knowledge diffusion. However, because of the osmosis between knowledge creation and knowledge diffusion, access to knowledge in fact plays an essential role in knowledge creation as well. Therefore, the role of access to knowledge in both spheres will be analysed. It will be argued that access to knowledge is a fundamental human right and a key instrument to development.

The policy tools to promote access to knowledge will be scrutinized. In particular, both Intellectual Property (IP) and open access models of knowledge creation and diffusion will be considered.

In the second part of this essay, the impact of IP on knowledge creation and diffusion will be analysed with regard to the pharmaceutical sector. My conclusion will be that IP is just one method of knowledge governance and other conceptual and legal models are needed to promote fairness and equity in accessing knowledge.

I. INTRODUCTION

Sapere Aude! is a Latin phrase meaning "Dare to know!" or "Have the courage to use your own reason".[1] Knowledge is a fundamental human aspiration and a form of individual and collective empowerment. In the first part of this essay, after attempting to define knowledge, the two processes of knowledge creation and knowledge diffusion will be explored. At first sight, access to knowledge seems to gravitate in orbit round knowledge diffusion. However, because of the osmosis between knowledge creation and knowledge diffusion, access to knowledge in fact plays an essential role in knowledge creation[2] as well. Therefore, the role of access to knowledge in both spheres will be analysed. It will be argued that access to knowledge is a fundamental human right and a key instrument to development.

With regard to knowledge governance, the policy tools to promote access to knowledge will be scrutinized. In particular, both Intellectual Property (IP) and open access models of knowledge creation and diffusion will be considered. It will be argued that in order to broaden access to knowledge non-proprietary approaches to knowledge governance should be encouraged. In this context, non proprietary does not imply lack of moral or economic rights. It implies a different management of inventor's moral and economic rights.

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[1] Immanuel Kant famously stated: "Enlightenment is man's emergence from self-imposed immaturity for which he himself was responsible. Immaturity and dependence are the inability to use one's own intellect without the direction of another. One is responsible for this immaturity and dependence, if its cause is not a lack of intelligence, but a lack of determination and courage to think without the direction of another. *Sapere Aude! Dare to Know!* Is therefore the slogan of the Enlightenment". *See* Immanuel Kant, *Answering the Question: What is Enlightenment?* In IMMANUEL KANT, PERPETUAL PEACE AND OTHER ESSAYS (1784), at 41.

[2] Knowledge creation and knowledge diffusion should not been perceived as adversarial or conflicting concepts but as two different phases of a continuum.

In the last part of this essay, the impact of IP on knowledge creation and diffusion will be analysed with regard to the pharmaceutical sector. My conclusion will be that IP is just one method of knowledge governance and other conceptual and legal models are needed to promote fairness and equity in accessing knowledge.

II. ACCESS TO KNOWLEDGE

A. Knowledge Creation

Historically, people have always sought knowledge.

Centuries ago a Florentine poet lapidary wrote: "Consider the seed from which you sprang; You were not made to live like unto brutes, But for the pursuit of virtue and knowledge".[3]

Defining knowledge is a difficult task.[4] Indeed, for its wideness, knowledge has been compared to the oceans. The image of the new oceans of knowledge to be discovered is everywhere in the Baconian philosophy, starting with the celebrating image of the ship passing through the columns of Hercules, on the frontispiece of the *Novum Organum Scientiarium.*[5] In the attempt to find a suitable working definition, it seems necessary to highlight that knowledge contains something more than mere information. As a practitioner once put it "Knowledge is information combined with experience, context, interpretation and reflection".[6] Distinguishing between the two concepts is important because while access to information is generally available, access to knowledge is far more difficult. Knowledge appears much stickier than information as it was "harder to communicate, more subjective, less easy to define".[7] Is this really the case? While externalities can make knowledge viscous, knowledge *per se* is fluid. As Thomas Jefferson wrote in a letter: "That ideas should freely spread from one to another over the globe […] seems to have been […] designed by nature, when she made them, like fire, expansible over all space without lessening their density at any point […]".[8]

Indeed, intellectual creations have some characteristics of *public goods*,[9] possessing a particular set of properties that distinguishes them from ordinary commodities, namely indivisibility, limitless reproduction at low incremental costs, and non-rivalness of use. Knowledge is not exhausted by use: it can be used over and over again without any individual consumer depriving another of the use of that knowledge. Further, wide dissemination of knowledge can promote the creation of ameliorative knowledge. An example can help clarifying this concept. When I play the piano, a given Bach sonata can be performed by me or by other

[3] Dante Alighieri, The Divine Comedy Inferno canto XXVI, at 120.

[4] Peter Burke, A Social History of Knowledge. From Gutemberg to Diderot (2000), 22.

[5] Francis Bacon, Instauratio Magna (1620).

[6] Bill Gates, *The New Road Ahead* Newsweek, 100 (2005[-2006]).

[7] *See* Gates *supra* note 6.

[8] Thomas Jefferson, Letters, quoted by Paul David in *Intellectual Property Institutions and the Panda's Thumb: Patents, Copyrights and Trade Secrets in Economic Theory and History* in M. Wallerstein, M.E. Mogen & R. Shoen (Eds), Global Dimensions of Intellectual Property Rights in Science and Technology (1993) at 26.

[9] *See* e.g. Carlos Primo Braga, Carsten Fink & Claudia Paz Sepulveda, *Intellectual Property Rights and Economic Development*, in (Keith E. Maskus Ed.) The WTO, Intellectual Property Rights and The Knowledge Economy -Critical Perspectives on the Global Trading System and The WTO (2004) at 266; Joseph Stiglitz, *Knowledge as a Public Good* in Inge Kaul et al. (ed) Global Public Goods: International Cooperation in the 21st Century (1999); Paul David *The Political Economy of Public Science* in Helen Lawton Smith (ed), The Regulation of Science and Tecnology (2001) 38.

persons, in different occasions and places, but every performance does not alter its essence. Besides, enjoying the concert may inspire composers to develop new melodies.

However, knowledge is not a public good, as the author or the inventor can legitimately exclude others from access to it.[10] This exclusion can be total or limited. Total exclusion occurs when the creator does not disclose its invention. This may happen for different reasons. For instance, the author does not want competition in the economic exploitation of a given idea. It is the case of the secret formula which makes *Coca Cola* one of the most appreciated soft drink. Although total exclusion generally has an economic rationale, sometimes motivations differ. *Exempli gratia*, if an inventor thinks that his invention is harmful to humanity, she can decide to keep it secret.[11] Needless to say, total exclusion in most cases is a loss for humanity.

Scientific progress based on knowledge creation is a fundamental element of the knowledge economy. How can community fuel inventive activity and disclosure? Intellectual property rights attempt to stimulate knowledge creation, by granting a monetary incentive to the inventor.[12] Governments grant time-limited property rights in inventions and creative works to encourage people to spend time and resources innovating and creating. The theoretical assumption is that humans are self-interested, and research and development (hereinafter R&D) of inventions can be promoted only by ensuring inventors property rights over the given invention. Intellectual property is a form of property.

Still, knowledge is not a static concept, but it develops in a cumulative manner. As Thomas Jefferson once put it, "[…] one new idea leads to another, that to a third, and so on through the course of time, until someone, with whom no one of these ideas was original, combines all together, and produces what is justly called a new invention".[13] Creating knowledge is very much like sewing a patchwork quilt, each piece designed by a different author, all of which are going to have to work with each other to form a coherent whole: "the creator of innovation is also always the borrower of ideas and information from others".[14] Similarly, Hettiger pointed out that "Invention, writing, and thought in general do not operate in a vacuum; intellectual activity is not a creation ex nihilo. Given this vital dependence of a person's thoughts on the ideas of those who came before her, intellectual products are fundamentally social products".[15] In this respect, Isaac Newton famously observed that he had seen further than other men by standing upon the shoulders of giants.[16] Separating out the individual contribution of the inventor from this social component is no easy task. Nozick paradoxically wondered why a person should gain what she mixes her labour with instead of losing her labour. For example, pouring a can of tomato juice into the ocean does not entitle the people to gain the ocean but to lose their tomato juice.[17]

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[10] *See* Keith E. Maskus & Jerome H Reichman *The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods* 7 J. INT'L ECON. L. (2004) 279-320.

[11] One of the most talented scientists who were working with Enrico Fermi on the nuclear fission was Ettore Majorana. It seems that, being aware of the potential applications of the invention, i.e. the atomic bomb, Majorana simply decided to stop doing research and he eventually disappeared. *See* LEONARDO SCIASCIA, *LA SCOMPARSA DI MAJORANA* (1975).

[12] Renée Marlin-Bennett wrote: "What sets the Information Age apart from prior periods in history is the price tag we put on […] intellectual creation". *See* RENÉE MARLIN BENNETT, KNOWLEDGE POWER (2004) at 1.

[13] JEFFERSON, *supra* note 8.

[14] DRAHOS & BRAITHWAITE, INFORMATION FEUDALISM: WHO OWNS THE KNOWLEDGE ECONOMY? (2003) at 2.

[15] Edwin Hettiger, *Justifying Intellectual Property*, 18 PHIL. & PUB. AFF. 31 (1989) at 38.

[16] *See* Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, 5 J. of Economic Perspective 29 (1991).

[17] ROBERT NOZICK, ANARCHY, STATE AND UTOPIA (1974) at 175.

Further, although profit is a powerful incentive to creative activity, incentive-based views of creativity are "an impoverished account of what motivates people to create […] people, to a large extent, are naturally disposed to create".[18] Great inventors of the past did not innovate merely because of monetary incentives. They may have created for the sake of knowledge, celebrating a deity to secure a place in the afterlife or intellectual or spiritual enlightenment. As Albert Einstein once put it, "who knows scientific research merely by its practical effects, cannot have an adequate opinion about the mood of these inventors […] and what made them pursue their objectives notwithstanding countless failures. Cosmic religion lavishes such strength".[19] In particular, by cosmic religion he meant "profound joy before the structure of the world and burning desire for knowledge".[20]

Thus, some authors have been concerned about the *anti-commons* arising from IP on basic research tools and methodologies[21] as protecting IP would lead to knowledge *feudalism*.[22] As in the Middle Ages a traveller usually had to pay as many tolls as many different properties he crossed during his journey, likewise, modern inventors must respect others' intellectual property rights, paying expensive royalties to use a segment of knowledge necessary for them to do research. The creation of barriers to free movement of ideas represent one of the great dangers posed by the protection of intellectual property rights which can seriously interfere with freedom of research and a series of fundamental human rights.

B. Knowledge Diffusion: Access to Knowledge and Its Benefits

Access to knowledge has a multifaceted aspect, because knowledge itself has both an extrinsic value and an intrinsic one. While this paragraph will adopt an *esoteric* approach, approaching the more evident value of knowledge, the next one will apply an *exoteric* one, focusing on access to knowledge as a human right.

When considering the extrinsic value of knowledge, the necessary premise is that "knowledge is power".[23] If it is true that in stories lies deeper meaning than in the truth taught by life, the *Arabian Nights* tell us the importance of creativity and knowledge. Indeed, what saved Shahrazad from being killed was not her beauty, but her knowledge.[24] In the well-known story, when Shahrazad got married to the sultan, she entertained him, not only displaying her feminine arts, but also telling him stories. He was so fascinated by her stories and so desirous to listen the follow-up to indefinitely suspend her execution night after night. This story teaches us the extrinsic value of knowledge, as a form of individual empowerment in human relations.

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[18] DRAHOS & BRAITHWAITE *supra* note 14, at 211.

[19] ALBERT EINSTEIN, *KOSMOLOGISCHE BETRACHTUNGEN ZUR ALLGEMEINEN RELATIVITÄTSTHEORIE* (1988) at 27.

[20] EINSTEIN, *supra* note 19 at 27.

[21] Michael Heller & Rebecca Eisenberg, *Can Patents Deter Innovation? The Anti-commons in Biomedical Research* 280 Science 698 (1998); James Boyle, *The Second Enclosure Movement and the Construction of the Public Domain* 66 LAW & CONTEMP. PROBS (2003) 33; Paul David, *Koyaanisquatsi in Cyberspace: The Economics of an Out-of-Balance Regime of Private Property Rights in Data and Information* in INTERNATIONAL PUBLIC GOODS AND INTELLECTUAL PROPERTY, *supra* note 9; SUSAN K SELL, PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS (2003); Graeme B. Dinwoodie & Rochelle Cooper Dreyfuss *International Intellectual Property Law and the Public Domain of Science* 7(2) Int'l J. Econ. L. 431 (2004); Rebecca Eisenberg *Reexamining Drug Regulation from the Perspective of Innovation Policy* 160 J. INSTITUTIONAL & THEORETICAL ECON. 126 (2004).

[22] DRAHOS & BRAITHWAITE *supra* note 11 at 1.

[23] FRANCIS BACON, RELIGIOUS MEDITATIONS OF HERESIES (1597).

[24] LES MILLE ET UNE NUITS (1986) at 73.

In more modern terms, knowledge creates the possibility for innovation, economic development and human welfare. Knowledge is an important source of wealth as a major asset of corporations.[25] Interesting questions arise concerning the sharing of the benefits created by scientific innovation. According to Danny Quah, professor at the London School of Economics, "the more broadly we disseminate each item of knowledge, the greater the social benefit".[26] Indeed, a growing number of apparently extravagant commentators claim that "Knowing how to capture innovation's benefits requires rethinking old assumptions about creation and ownership".[27] Can this claim be considered truly erratic? Professor Quah puts forward two arguments. The first, supported by empirical evidence, is a factual one. It is obvious that dissemination takes place only with prior invention. But dissemination also drives invention. As already pointed out, knowledge is build up over time by many people. Ideas are triggered by related ones and all ideas have fuzzy boundaries. Because of its essence, knowledge requires networking and tensions in knowledge dissemination surface in knowledge creation. The second argument is grounded in history. History shows that successful societies favour knowledge dissemination. In the 13th century, China had more advanced technology than the West. For instance, Chinese artisans invented the printing press using a moveable type method. But the State tightly controlled that technology and refused to satisfy increasingly broad demand for knowledge. As a result, China's technical lead vanished and has never returned.[28] Therefore, as professor Quah concludes, "Blocking the free flow of knowledge […] diminishes human welfare and puts us on the road of economic extinction".[29]

C. Access to Knowledge as a Human Right

Knowledge has a value *per se*, in the sense that it shapes human personality. Is it possible to conceptualize access to knowledge as a human right? At a philosophical level, the linkage between personality and thought is magically expressed by the Cartesian proposition "I think, therefore I am".[30] Significantly, John Adams wrote "Liberty cannot be preserved without a general knowledge among the people, who have a right, from the frame of their nature, to knowledge, as their great creator, who does nothing in vain, has given them understandings, and desire to know […]".[31]

At the legal level, the linkage between knowledge and human dignity has been acknowledged in the aftermath of WWII. At the international level, article 27 of the Universal Declaration of Human Rights[32] (UDHR) acknowledges the right of everyone to share in scientific advancement and its benefits.[33] Although the Declaration is not binding *per se*, surely it

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[25] *See*, e.g., THOMAS A. STEWART THE WEALTH OF KNOWLEDGE, 2001; THOMAS A. STEWART INTELLECTUAL CAPITAL: THE NEW WEALTH OF ORGANIZATIONS (1997).

[26] Danny Quah, *Knowledge Glut*, Newsweek, *supra* note 6 at 43.

[27] Sam Palmisano, *The Information Puzzle*, Newsweek, supra note 6 at 62.

[28] *See* CURTIS COOK, PATENTS, PROFITS AND POWER –HOW THE INTELLECTUAL PROPERTY RULES THE GLOBAL ECONOMY, 14 (2002).

[29] Quah *supra* note 26.

[30] RENE DESCARTES, DISCOURSE ON THE METHOD AND MEDITATIONS (1637), Chapter IV, Paragraph 1. By these words, the French thinker meant that thought of any kind (and doubt is a mode of thought) requires a thinker. From the fact, therefore, of his doubting all else, he was assured of the necessity of his own existence.

[31] JOHN ADAMS, A DISSERTATION ON THE CANON AND FEUDAL LAW (1765).

[32] G.A. Res. 217A U.N. GAOR, 3rd Sess., Supp. No.13 at 48, U.N. Doc A/810 (1948).

[33] It emerges from the *travaux préparatoires* of the Universal declaration of Human Rights that the phrase "and its benefits" was introduced to make it clear that not everyone could be expected to "participate", but that everyone

is an authoritative source of reference.[34] Moreover, it has gradually assumed the status of customary international law.[35] Thus, access to knowledge can be deemed to be a fundamental human right.

Also the International Covenant on Economic, Social and Cultural Rights[36] (ICESCR) recognises the right of everyone "to enjoy the benefits of scientific progress and its applications",[37] requiring member States to take steps "to achieve the full realization of this right [including] those necessary for the conservation, the development and the diffusion of science and culture".[38] Notably, the ICESCR has the status of a treaty and as such is legally binding on state parties.

At the regional level, article 14 of the 1988 Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights[39] (Protocol of San Salvador) recognizes the right of everyone "to enjoy the benefits of scientific and technological progress"[40] and that "the steps to be taken by the States Parties to this Protocol to ensure the full exercise of this right shall include those necessary for the conservation, development and dissemination of science, culture and art".[41]

Interestingly, an initiative to produce a draft of a treaty on access to knowledge is currently being led by a coalition of civil society actors.[42] This initiative flows out of a WIPO General Assembly decision to examine proposals for a development agenda that were put forward by Argentina and Brazil in 2004.[43] A treaty on access to knowledge was a key part of these proposals. As Helfer points out, "The origins [of the Treaty] are firmly rooted in civil society. In fact, the treaty's genesis resembles the decentralised, open source collaboration models that its text endorses. A diverse group of NGOs, whose members include medical researchers, educators, archivists, disabled people, and librarians from industrialised and developing nations, drafted and circulated numerous suggestions for provisions to be included in the treaty".[44] After extensive negotiations, a decision was adopted by the General Assembly to hold a series of meetings to discuss the issue.[45]

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should have the right to share in the benefits of scientific advancement.: A/C.3, General Assembly Official Records 1948: Draft International Declaration on Human Rights (E/800), item 179, at 627.

[34] Scholars emphasize the importance of nonbinding norms, or soft law as a method to promote international cooperation. *See* Harmut Hillgenberg, *A Fresh Look at Soft Law* 10 EUR. J. INT'L L. 499-515; DINAH SHELTON, COMMITMENT AND COMPLIANCE: THE ROLE OF NON-BINDING NORMS IN THE INTERNATIONAL LEGAL SYSTEM (2003); Kenneth W. Abbott & Duncan Snidal, *Hard and Soft Law in International Governance*, 54 IN'L ORG. 421 (2000).

[35] *See* ANDREW CLAPHAM, HUMAN RIGHTS OBLIGATIONS OF NON-STATE ACTORS (2006) p. 86.

[36] G.A. Res. 2200A, U.N. GAOR, 21st Sess., Supp. No. 16, at 49, U.N Doc. A/6316 (1966).

[37] ICESCR Article 15.1 (b).

[38] ICESCR Article 15, 2.

[39] Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights, 17 November 1988, OAS Treaty Series n. 69.

[40] Protocol of San Salvador Article 14, 2.

[41] Protocol of San Salvador Article 14, 1 (b).

[42] The number of these groups is large and their goals diverse. Some focus on development, others on human rights. Still, their common interest is a more balanced regulation of knowledge. *See*, for instance, Peter Drahos, *Access to Knowledge Time for a Treaty*? 9 Bridges 4 (2005) 15-18.

[43] Proposal by Argentina and Brazil for the Establishment of a Development Agenda for WIPO, WIPO General Assembly Document WO/GA/31/11, Geneva 27 September 2004 available at: http://www.wipo.int.

[44] Laurence R. Helfer, *Toward a Human Rights Framework for Intellectual Property* 40 U. C. DAVIS L. REV. 972 (2006-2007) 1012.

[45] *See* Tove Iren Gerhardsen, *Negotiators Agree to Add Access to Knowledge to WIPO Mandate* INTELLECTUAL PROPERTY WATCH 14 June 2007, at http://www.ip.watch.org.

The goal of the Draft Treaty -as expressed in its Preamble- would be to create opportunities for the creation and diffusion of knowledge on a global level.[46] Also, the Preamble expresses concerns about an arbitrary expansion of intellectual property and the effect this can have for individual participation to the benefits of science. In more specific terms, the proposed Access to Knowledge treaty has two basic objectives. First, it is aimed at restricting some of the more expansive property rights claims in the areas of patent and copyright (*pars destruens*). In particular, "it endorses *maximum standards* of intellectual property protection to counterbalance the minimum standards approach that intellectual property agreements have followed for more than a century".[47] Indeed, the TRIPS Agreement, the most comprehensive international agreement on IP, sets international minimum standards for intellectual property protection.[48] While Members cannot derogate or provide lower ceilings of protection, they still have the right to institute more extensive protection than is required by the Agreement, as long as they apply the general principles of the most-favoured nation clause and national treatment under the Agreement. Thus, any intellectual property agreement negotiated subsequent to TRIPS can only create similar or higher standards-commonly known as *TRIPS-plus*. The problem is that this allowance does not set maximum levels of protection.[49] In their vest of intellectual capital exporters, industrialised countries have increasingly used bilateral and regional investment agreements in a strategic fashion to incorporate *TRIPS-plus* commitments that they would have not been able to obtain in the WTO.[50] In their vest of intellectual capital importers, developing countries would benefit from laxer levels of protection. However, these countries generally accept higher IP standards to obtain favourable concessions in other areas, notably agriculture. Thus, some authors compared the rationale of investment agreements to a form of imperialism, similar to the Roman strategy '*divide et impera*'.[51] As Helfer highlights, "By placing a mandatory ceiling on how high these standards can rise, the proponent of the A2K Treaty are attempting to counteract the upward drift of intellectual property rules".[52]

However, the Treaty has not a mere negative approach, but has a propositive nature as well, in that it is aimed at promoting open source models of innovation and creativity, expanding and enhancing the knowledge commons.[53] This is the most interesting part of the treaty: although

[46] Draft Text of the Access to Knowledge Treaty, 9 May 2005, available at http://www.cptech.org.

[47] Helfer, *supra* note 44.

[48] Article 1 of the TRIPS Agreement reads as follows: "Members may, but shall not be obliged to implement in their law more extensive protection than is required by this Agreement." Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) Annex 1C to the Marrakesh Agreement Establishing the World Trade Organization, 33 ILM 1994, p. 1197 ff. in force since 1 January 1995.

[49] On bilateral IP negotiation, *see* e.g. Valentina Vadi, *Access to Essential Medicines and International Investment Law: The Road Ahead* 8 J. WORLD TRADE & INVESTMENT 4 (2007) 505-532; Laurence R Helfer, *Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking* 29 YALE J. INT'L L. 1 (2004); Mohammed El Said, *The Road From TRIPS-Minus to TRIPS, to TRIPS-Plus: Implications of IPRs for the Arab World* 8 J. WORLD INTEL. PROPERTY (2005) 53-65; Rosa Castro Bernieri, *Intellectual Property Rights in Bilateral Investment Treaties and Access to Medicines: The Case of Latin America* 9 J. WORLD INTEL. PROPERTY 5 (2006) 548-572; Frederick M Abbott, *Toward a New Era of Objective Assessment in the Field of TRIPS and Variable Geometry for the Preservation of Multilateralism* 8 J. INT'L ECON. L. 1, 77-100.

[50] *See* M. RYAN, KNOWLEDGE DIPLOMACY –GLOBAL COMPETITION AND THE POLITICS OF INTELLECTUAL PROPERTY (1998) 92.

[51] *See* Peter Drahos, *Expanding Intellectual Property's Empire: The Role of FTAs*, 2003 at http://www.grain.org /rights/tripsplus.cfm?id=28#.

[52] Helfer, *supra* note 44.

[53] Kal Raustiala, *Density and Conflict in International Intellectual Property Law*, 40 U. C. DAVIS L. REV. 1021 (2006-2007) 1036.

revision is needed, this chaotic *pars construens* has the potential to promote further reflection and intellectual effort.

Bearing the "fingerprints of multiple authors with different (if not divergent interests)"[54] the actual draft consists of a bundle of ideas on how to promote and protect access to knowledge. It is now for the drafting committee to extract from this pool of ideas the most relevant ones. However, a detailed rules-based treaty is not the only option. Another possibility is to draft a framework treaty containing a few general principles essentially declarative in nature, drawing on the existing human rights framework and widely accepted principles.[55] More specific and enforceable obligations could each become the subject of an annex to the treaty.

Barton and Maskus argue that the agreement could be structured around open access for inputs (coordination of scientific projects) and open access to outputs (research results). Moreover, the agreement could include provisions for preferential treatment for developing countries.[56] Interestingly, Musungu doubts that an A2K Treaty can be limited to the WIPO, because this would imply that intellectual property is the main (if not the only) means to frame access to knowledge. Thus, he recommends that such a treaty should be pursued in the frame of UN-wide discussion.[57]

In conclusion, Access to Knowledge Treaty is an ambitious initiative whose major merits rests on the fact of being elaborated by a group of technical experts from different disciplines and background. This various composition enables the synopsis of a wide range of different perspective on the topic. Further, the document at least provides a starting point for further discussion, crystallising a series of different approaches and demands. Crucially, the treaty's proponents strongly support the view that "access to knowledge is a basic human right, and that restrictions on access ought to be the exception, not the other way round."[58] As Helfer further points out, although the draft text does not expressly mention human rights nor cite the ICESCR or the UDHR, many of its provisions echo the human rights discourse,[59] thus enriching discussion on human creativity with all inter-wined human rights and, fundamentally, human dignity.

D. Access to Knowledge as a Key Instrument to Development

Development constitutes one of the most important challenges facing the international community. This challenge has been widely acknowledged in many international fora since the Declaration on the Right to Development.[60] The United Nations has recently established a firm commitment to address the problems affecting developing countries and less developed countries.[61] Similarly, in the context multilateral trade negotiations, the Doha Development Agenda was launched at the WTO 4th Ministerial Conference, in November 2001.

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[54] Helfer, *supra* note 44, 1012.

[55] *See* Edward Kakwa, *Some Comments on Rulemaking at the World Intellectual Property Organization*, 12 DUKE J. COMP. & INT. L. 179 (2002) (discussing the WIPO's attitude to issue soft-law instruments).

[56] John Barton & Keith Maskus, *Economic Perspectives on a Multilateral Agreement on Open Access to Basic Science and Technology*. The speakers presented at *The World Trade Forum*, Berne (June 16-17 2003).

[57] Sisule Musungu, *Rethinking Innovation, Development and Intellectual Property in the UN: WIPO and Beyond* Research Paper (2005) 17, at http://www.quno.org .

[58] William New, *Experts Debate Access to Knowledge* INTELL. PRO. WATCH Feb 15, 2005.

[59] Helfer, *supra* note 44.

[60] G.A. Res. U.N. Doc. A/RES/41/128 (1986).

[61] G.A. Res. U.N. Doc. A/RES/55/2 (2000).

Technological innovation and creative activity are generally recognised as important means to stimulate economic development and welfare: "technology has always been important to economic wellbeing; the current technological context makes it critical to development".[62] Actually, development is seen "as less like the construction business and more like education in the broad and comprehensive sense that covers knowledge, institutions and culture".[63] In other words, development seems about "improving the quality of people's lives, expanding their ability to shape their own futures".[64]

In many areas a significant knowledge gap continues to separate the wealthy nations from the poor.[65] Actually, intellectual property protection is intended as an instrument to promote technological innovation and the transfer of technology.[66] Indeed, in the Preamble of the TRIPS Agreement, the Member States recognize "the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives".[67]

However, commentators caution that the significance of IP in economic activity differs across countries depending on the amount of resources devoted to creating intellectual assets.[68] Particularly, in the relationship between IP protection and development, the critical point is the ratio knowledge owned and the knowledge needed by a country to develop a given economic sector. [69]

Does IP help developing countries to promote research and to gain access to appropriate technologies to promote their development? Where there is lack of domestic research and production capacity, a further issue is whether an IP system can ensure affordable imported products for consumers. Indeed, all developing countries are net importers of IP while industrialised countries, are IP exporters.[70] Therefore, it may be in the South's interest to provide lower patent protection.[71]

Historically, when the developed countries themselves were industrialising and developing, they put no constraints on their right and freedom to design their own regimes to suit their circumstances. All countries at some point used the strategy of *free riding* that is taking the benefit of scientific innovation without meeting its costs. As the producer has to face competition from the free-rider, in economic theory, free-riding is not bad *per se*. It becomes economically inefficient only if it reaches levels that deter producers from investing in R&D.[72]

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[62] U.N.C.T.A.D., WORLD INVESTMENT REPORT FOREIGN DIRECT INVESTMENT AND THE CHALLENGE OF DEVELOPMENT (1999) 195.

[63] WORLD BANK, THE QUALITY OF GROWTH (2000), XXIII.

[64] WORLD BANK, *supra* note 63.

[65] *See*, e.g. Margaret Chon, *Intellectual Property and the Development Divide* 27 CARDOZO L. REV. 2821, 2853 (2006).

[66] Keith E. Maskus & Mohan Penubarti, *How Trade Related Are Intellectual Property Rights?* 39 J. INT'L ECON. (1995), 227-248.

[67] TRIPS Agreement, Preamble.

[68] Braga, Fink & Paz Sepulveda, *supra* note 9 at 254.

[69] *See*, e.g., David M. Gould & William C. Gruben, *The Role of Intellectual Property Rights in Economic Growth* 48 J DEVELOPMENT ECON. (1996), 324.

[70] On the North-South asymmetries, *see* e.g., CARLOS CORREA, INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES (2000), 5-6.

[71] *See* e.g. Judith Chin & Gene Grossman, *Intellectual Property Rights and North-South Trade* NBER Working Paper n. 2769, 1988.

[72] Peter Drahos, *Introduction*, GLOBAL INTELLECTUAL PROPERTY RIGHTS – KNOWLEDGE, ACCESS AND DEVELOPMENT, PETER DRAHOS AND RUTH MAYNE (EDS.) 2002, at 4.

Economic literature has reached controversial results about the relationship between IP and development. The consensus of industrialised countries about IP appears not to be based on the theoretical- empirical literature on patents but "on the political economy considerations surrounding this policy, i.e., on the demand and supply of patent protection".[73]

To sum up, while innovation and access to knowledge are generally considered to be a key factor of development, it is controversial whether the IP protection is the best means to ensure access to knowledge while promoting innovation. Its impact on development must be carefully assessed on a case-by-case basis. IP protection is a policy tool which may *de facto* produce benefits as well as costs depending on a country's specificities. Action is therefore needed to ensure that the costs do not outweigh the benefits of IP protection.

III. KNOWLEDGE GOVERNANCE

A. Intellectual Property or the State of Play

Widespread access to knowledge and its benefits is the real basis for sustainable human development and for further research. If knowledge is crucial to human welfare under many perspectives, so is its governance. How should society regulate its most precious resource? In abstract terms, two different models of knowledge governance are conceivable. The first one is characterised by a proprietary approach, the second describes managing knowledge as commons. Instead of relying on exclusion, this regulatory approach is based on access.

Giving a look at proprietary approaches to knowledge governance, the question is whether intellectual property provides an adequate balance between knowledge creation and knowledge diffusion. Intellectual property rights give their owners the legal enforceable power to produce and commercialise the patented good in an exclusive manner and to prevent others from using an intellectual creation.[74] Under the classic theory, IPRs would have both the private finality of remunerating the inventor and the public aim of promoting research therefore enhancing human welfare.[75]

From a functional angle, IPRs would be meant to the final disclosure of a certain process or product. Patents induce inventors to disclose their inventions when otherwise they would rely on secrecy, and facilitate knowledge about and use of inventions. Indeed, after the expiration of the patent, the knowledge is owned by the public.[76] The temporal limits to the monopoly rights granted to inventor and the condition of adequate commercialisation of the given product show the instrumental character of patents. If patent owner does not fulfil his obligations, the IPRs system provides *ad hoc* remedies. Where rightly intended in the light of their purposes, IPRS are rights instrumental to the realisation of other fundamental human rights.

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[73] Julio J. Nogués, *Social Costs and Benefits of Introducing Patent Protection for Pharmaceutical Drugs in Developing Countries* in *THE WTO, INTELLECTUAL PROPERTY RIGHTS AND THE KNOWLEDGE ECONOMY*, *supra* note 9, 325-354.

[74] From an historical perspective, systematic protection of intellectual property rights can be traced back to Renaissance Italy. The Venetian government allowed glassmakers to export their products, but not their craft. By the XV century, patents were introduced to reward strangers who brought new knowledge to Venice. *See* David, *supra* note 8.

[75] Mazzoleni & Nelson call this the *invention motivation* argument. *See* Roberto Mazzoleni & Richard R. Nelson, *Economic Theories about the Benefits and Costs of Patents* XXXII J. ECON. ISSUES 4 1032 (1998)

[76] Mazzoleni & Nelson call this the *invention dissemination* argument. *See* Mazzoleni & Nelson *supra* note 75.

However, by granting exclusive rights, patents restrain competition and determine high prices thus obstructing access to knowledge. Monopolies or oligopolies may lead to less than optimal dissemination of new knowledge and to abuse of the dominant position in a given market.[77] With regard to this market distortion, some authors argue that besides imposing high costs on consumers, IP would retard innovation too. If individuals only innovate to capture or hold a share of the market, they may not increase their rate of innovation with stronger intellectual property rights when their share of the market is already guaranteed. In any case, authors, artists and innovators face mounting barriers to follow-on innovation.[78]

IP approaches have become stronger than ever since the inception of the TRIPs Agreement[79] under the aegis of the WTO System.[80] While the Agreement sets minimum standards, according to many observers, most of its terms are based on the prevailing standards in developed countries. The major consequence is that developing countries have to strengthen the legal protection of IPRs. The Agreement also makes disputes between members subject to the WTO dispute settlement procedures.

The TRIPS attempts to strike a balance between the long term social objective of providing incentives for future inventions, and the short term objective of allowing people to use existing inventions and creations: "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations".[81] However, the flexibilities *de iure* provided by TRIPS, have been extremely difficult to implement *de facto*, mainly because of political pressures.

B. Open Access Models of Knowledge Creation: A Paradigm Shift?

Many recent studies support the development of an alternative system of knowledge creation.[82] In this context, the concept of *open knowledge* seems to be an attractive formula since knowledge is, by its very essence, stratified and floating. The key element of this paradigm shift is the idea that there is a strategic advantage in sharing ideas[83], because of the improved identification and allocation of human creativity. An outstanding example of the *commons-based peer production* is Wikipedia,[84] the free online encyclopaedia that thousands of people are voluntarily writing and placing under free licenses as gift to the world.

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[77] *See*, e.g, Robert D. Anderson & Hannu Wager, *Human Rights, Development, and the WTO: The Cases of Intellectual Property and Competition Policy* 9 JIEL 3 (2006) 707-747.

[78] *See* Rosemarie Ham Ziedonis, *Don't Fence Me In: Fragmented Markets for Technology and The Patent Acquisition Strategies of Firms* 50 MANAGEMENT SCIENCE 6 (2004) 804-820.

[79] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), *supra* note 48.

[80] For a detailed commentary, *see* e.g. DANIEL GERVAIS THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS (2003).

[81] TRIPS Agreement, Article 7.

[82] *See* CASS SUNSTEIN, HOW MANY MINDS PRODUCE KNOWLEDGE (2006); HENRY CHESBROUGH, WIM VANHAVERBEKE & JOEL WEST, OPEN INNOVATION: RESEARCHING A NEW PARADIGM (2006); HENRY CHESBROUGH, OPEN BUSINESS MODELS: HOW TO THRIVE IN THE NEW INNOVATION LANDSCAPE (2006); YOCHAI BENCKLER, THE WEALTH OF NETWORKS (2006).

[83] Indeed, many growing companies have figured out a way to pool and leverage shared information, like Google. In the digital environment, some providers offer their information and services for free while charging for ancillary services.

[84] Wikipedia is the biggest multilingual open access encyclopaedia on the internet at http://en.wikipedia.org. *See* DON TAPSCOTT & ANTHONY WILLIAMS, WIKINOMICS: HOW MASS COLLABORATION CHANGES EVERYTHING (2006).

The US academic community has become one of the principal defender of the public domain.[85] In particular, academics are duelling to coin the definitive jargon for this phenomenon: some call it *distributed creativity*; others *peer production*, or *commons production* or *open-source business model*. Is this shift a mere organizational tool or a new paradigm in knowledge creation? According to professor Moglen "we are talking not merely about a form of production or a system of industrial relations, but also about the beginning of a social movement with specific political goals […]".[86]

This emerging trend has reached its major dimension in the software field.[87] In the 1960s software manufacturers made its source code available in order to facilitate the diffusion of their operating system on the market. Through the source code, other programmers could understand the way it worked and eventually copy and modify it.[88] However, since the 1980s, companies have begun hiding the source code made object of copyright protection.

Nowadays the Open Source movement rejects the practice of keeping source code secret, holding that source code should be freely accessible and available. The Open Source movement traces its roots in the Free Software Movement.[89] While the two movements are both working toward the goals of making all software free of intellectual property restrictions, the Open Source movement takes a more pragmatic approach, basing its arguments on the economic and technical merits of making source code freely available, rather than the moral and ethical principles that drive the Free Software Foundation. In other words, while Open source is a development methodology; free software is a social or philosophical movement. To explain the rationale of the extraordinary flourishing of the Free Software idea, both the theoretical argument and the practical one will be scrutinized.

The underlying philosophy of the Free Software Movement is that software should free in the sense that should be publicly available or accessible without restraint. More precisely, this philosophy refers to four kinds of freedom for the users of software: the freedom to run a program for any purpose; the freedom to study how the program works, and adapt it to contingent needs; the freedom to redistribute copies; the freedom to improve the program, and release improvements to the public, so that the whole community will benefit. Further, the so-called copy-left rule requires that, when redistributing the program, the use of the central freedoms must be available to users. The goal of this provision is maintaining the central freedoms over time. In essence, free software is an attempt to guarantee certain rights for both

[85] The term public domain generally indicates information resources free from intellectual property rights.

[86] Eben Moglen *Freeing the Mind: Free Software and the Death of Proprietary Culture* key note address at the University of Maine Law School's *Fourth Annual Technology and Law Conference*, Portland, Maine, (June 2, 2003), at http://emoglen.law.columbia.edu/publications/maine-speech.html . For a critical appraisal, *see* Severine Dusollier, *The Master's Tools v the Master's House: Creative Commons v Copyright* 29 COLUMBIA J. L. & ARTS (2006) 271-293.

[87] *See*, e.g, Alessandro Nuvolari, *Open Source Software Development: Some Historical Perspectives*' Eindhoven Centre for Innovation Studies, Faculty of Technology Management, Eindhoven University, The Netherlands, Research paper at http://opensource.mit.edu/papers/nuvolari.pdf .

[88] Source code is the computer language in which the instructions of the program are expressed. Without the source code it is very difficult to understand how a program works and write another program that might work in connection with it.

[89] On the differences between the two movements, see *Why Free Software is Better than Open Source* at http://www.gnu.org/philosophy/free-software-for-freedom.html and *Open Source and Free Software* at http://www.slackbook.org/html/introduction-opensource.html.

users and developers and, as Boettiger and Burk point out, it "is strongly grounded in concepts of communality and sharing […]".[90]

The major pillar of the Open Source movement is the assumption that open source provides a superior production method. Open source would be a better means of producing software than the traditional hierarchical firm model, as its products would display higher quality, shorter development time and lower production costs because it benefits from decentralised production. As a methodology, open source has much in common with the culture of science. Besides, through open source programmers can develop something society really needs.

Free software does not mean gratuitous or non-commercial: "Free software is a matter of liberty, not price".[91] Commercial development of free software has an increasing importance. Actually, open-source software is run by companies,[92] financial institutions and governments. In the last few years, dozens of countries, including Peru,[93] China, India, Brazil and South Korea have begun moving away from proprietary, closed software and toward an open-source model in which programming technology is free and shared. Open source is a revenue generator. Conventional economics, which has little to do with altruism, would not have predicted any of this. But then economics itself is changing; Thomas Schelling, Nobel Laureate in Economics, showed that people tend to co-operate a lot more than traditional, rational economic models say they will.[94] Economic models of selfishness and competition evolve under pressure from the open-source philosophy: connection to the others has an important role in shaping our own world.

IV. ACCESS TO KNOWLEDGE AND ITS BENEFITS ON THE PHARMACEUTICAL FIELD

A. Knowledge Creation in the Pharmaceutical Field

In the context of the human right to health, there are both obligations relating to the *distribution* of the benefits of scientific research (medicines) and obligations relating to their *creation*. Medical research is fundamental for the fight against illnesses. The very essence of the right to health includes obligations on States to promote medical research.[95] As the High Commissioner puts it, "The obligation on States to fulfil the right to health includes the need for States to take positive measures including through fostering research into trade-related areas".[96]

Scientific research is often multidisciplinary and multinational. Importantly, as scientific knowledge builds on past knowledge, it requires information transfer and collaboration. The point is whether patents can be considered a *condicio sine qua non* for medical R&D or whether different methods can be envisaged. Traditionally, pharmaceutical patents have been considered to be necessary to promote medical research. In particular, the monopoly created by the grant of

[90] Sarah Boettiger & Dan L. Burk, *Open Source Patenting* 1 J. INT'L BIOTECH. L. (2004) 221-231.

[91] The Free Software Definition is available at http://www.gnu.org/philosophy/free-sw.html.

[92] IBM, that each year files more than 3,000 patents, is the leading proponent of open-source software. In January 2005, IBM made 500 software patents available to developers working on open-source projects. Then in October, the company offered all its patents royalty –free to anyone designing standards for the health and education industries.

[93] *See*: *Use of Free Software in Government Agencies Law* at http://www.opensource.org

[94] THOMAS SCHELLING, CHOICE AND CONSEQUENCE. PERSPECTIVES OF AN ERRANT ECONOMIST (1984).

[95] *Report of the High Commissioner of the Human Rights Commission*, The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights, U.N. Doc. E/CN.4/Sub.2/2001/13 ¶ 30.

[96] High Commissioner *supra* note 95.

a pharmaceutical patent from the relevant authorities would allow the inventor to recover the costs and help stimulate further research.

However, pharmaceutical patents present a series of flaws. A first problem is given by the fact that pharmaceutical companies do not invest in products oriented primarily to the developing world market. For instance, only 13 of 1223 new drugs marketed between 1975 and 1997 were specifically developed to treat tropical diseases (and only four of these were the result of pharmaceutical industry R&D).[97] The fact is that when there is no market, patents will not help create that market.

Second, as patents are increasingly becoming corporate assets that reflect a company competitiveness on the market, many patents cover *me-too drugs*, drugs that are just different enough to be considered novel for the purposes of patent protection, but in fact have similar effects as prior patented drugs. With me-too drugs, the economic gain for the patent holders is likely to be significant, but real scientific progress is mystified.

Third, the practice of granting broad patents – especially in the area of biomedical research- can lead to the concentration of control over the dissemination of drugs in the hands of certain companies:[98] "Questionable IPRS may give rise to significant competitive concerns, and they may also obstruct innovation. Sham litigation can paralyse technological progress for years [as] dominant companies may use their IPRS in an anticompetitive manner and prevent new products from coming into the market".[99] Beside possible abuses of dominant position,[100] loose standards for the grant of patents may contribute to *ever-greening* phenomenon: a process where patenting minor innovations to patented molecules can effectively extend the life of the patent beyond the original twenty years.

Fourth, patents can be used to block research efforts.[101] The issue is relevant where research into a drug relies on several levels of innovation all of which are subject to IP protection: a proliferation of patents upstream may be stifling life-saving innovations further downstream in the course of research and product development. For instance, in *Madey v. Duke University*,[102] the US Court of Appeals for the Federal Circuit denied an experimental use defence in a patent

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[97] Andy Coglan *Technology the Key to Banishing Poverty* NEW SCIENTIST (2001). *See also* Gregg Martin, Corinna Sorenson and Thomas Faunce *Balancing Intellectual Monopoly Privileges and the Need for Essential Medicines* 3 GLOBALIZATION AND HEALTH (2007).

[98] *See* J. H. Reichman, *Of Green Tulips and Legal Kudzu; Repackaging Rights in Subpatentable Innovation* 53 VAND. L. REV (2000) 1743; J Lerner, *The Importance of Patent Scope: An Empirical Analysis*'25 RAND J. ECON. 2 (1994) 319-333; R Merges & R Nelson, *On The Complex Economics of the Patent Scope* 90 COL. L. REV. 4 (1990) 839-916.

[99] Katarzyna A Czapracka, *Where Antitrust Ends and IP Begins- On the Roots of the Transatlantic Clashes* INT'L J. COMMUNICATIONS L & POLICY (2006) 26; Josef Drexl, *The Critical Role of Competition Law in Preserving Public Goods in Conflict with Intellectual Property Rights* in KEITH MASKUS & JEROME REICHMAN, INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME (2005) 709-723; Eleanor M Fox, *Can Antitrust Protect the Global Commons from Excesses of IPRS?* in KEITH MASKUS & JEROME REICHMAN, INTERNATIONAL PUBLIC GOODS, *supra*, 758-769; Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 JIEL 849 (2002); Shanker Singham, *Competition Policy and the Stimulation of Innovation: TRIPS and the Interface Between Competition and Patent Protection in the Pharmaceutical Industry* BROOK. J. INT'L L 363 (2000); Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust* 16 BERKELEY TECH. L. J. (2001) 813.

[100] For an overview of the functioning of the pharmaceutical industry, *see*, e.g., Iain M. Cockburn, *The Changing Structure of The Pharmaceutical Industry* 23 HEALTH AFFAIRS 1 (2004) 10-22.

[101] *See* Jerome Reichman, *Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation*, 53 VAND. L. REV. 1743 (2000).

[102] *Madey v. Duke University*, US Court of Appeal for the Federal Circuit, 3 October 2002, 307 F 3d 1351.

infringement lawsuit against Duke University, signalling that academic researchers may be liable for use of patented products or processes notwithstanding the non commercial character of their research.[103]

Fifth, concern is given by the fact that even universities, traditionally committed to commons' creation, have been transforming into *entrepreneurial institutions*[104] introducing market considerations into the conduct of science.[105] This shift from public to proprietary science has eroded the space dedicated by academia to basic research (and with it the possibility for serendipity and unexpected innovation), and has imposed constraints on science's tradition of open publication.[106]

What seems to be obvious, after this preliminary overview, is that the scientific community cannot just rely on the market dynamics to address global collective needs.[107] Market considerations can favour applied research in specific processes and products with commercial applicability vis-à-vis more theoretical and independent approaches. Further, certain large scientific projects can only be pursued by scientist working together as an international community and with public funding.[108] The knowledge emerging from such projects is too important to be locked up by IP and it has to remain a public good.

B. Open Source Scientific Knowledge

Can the concept of open source be extended to scientific research? As Arti Rai puts it "the advent of open source software has prompted theoretical speculation about the applicability of open source innovation principles to biomedical research".[109] A positive answer to this question would involve a communalization of scientific knowledge, based on the assumption that science will progress more fruitfully if its findings are in the public domain.[110]

A classic problem with a commons is that, as a shared resource which all may access freely, there are strong incentives for individuals to maximise their use at the expense of others, resulting in Hardin's well known *tragedy of the commons*.[111] In a seminal paper, Hardin argued

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[103] In the absence of patent harmonization, different nations have divergent formulations of the research exemption. Clearly, the formulation of a research exemption will determine a nation's competitive advantage relative to other nations with respect to R&D. *See* Kevin Iles, *A Comparative Analysis of the Impact of Experimental Use Exemptions in Patent Law on Incentives to Innovate* 4 NORTHWESTERN J. TECH. AND INT'L PRO. (2006) 61.

[104] *See* H. Etzkovitz, A Webster, C Gebhart et al., *The Future of the University and the University of the Future: Evolution of Ivory Tower to Entrepreneurial Paradigm* 29 RESEARCH POLICY (2000) 313-330.

[105] The US Bayh Dole Act, entered into force in 1981, allows universities and small businesses to own patents in inventions that they have developed with federal funds. Prior to this Act, the inventions were put straight into the public domain. For an overview and critique of this act, *see*, e.g., Chester G. Moore, *Killing the Bayh-Dole Act's Golden Goose* 8 TUL. J. TECH. & INTELL. PROP. 151 (2006).

[106] *See* Howard K Shachman, *From "Publish or Perish" to "Patent and Prosper"* 281 J. BIOL. CHEM. 11 (2006) 6889-6903.

[107] Richard Smith et al., *Genomics Knowledge and Equity: A Global Public Goods Perspective of the Patent System* 82 BULLETIN OF THE WORLD HEALTH ORGANIZATION 5, 2004, 385-389.

[108] The human genome project is a paradigmatic example. *See* e.g., John Sulston, *Intellectual Property and the Human Genome* in GLOBAL INTELLECTUAL PROPERTY RIGHTS *supra* note 72 at 61-73; James Boyle, *Enclosing the Genome: What the Squabbles over Genetic Patents Could Teach Us* in F. SCOTT KIEFF (ED), PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT (2003).

[109] Arti K Rai, *Open and Collaborative Research: A New Model for Biomedicine* in ROBERT W HAHN (ED) *Intellectual Property Rights in Frontier Industries* (2005) at 131.

[110] On the relationship between public and proprietary science, *see*, e.g., Rebecca Eisenberg, *Public v. Proprietary Science: A Fruitful Tension?* DAEDALUS (2002).

[111] *See* G. Hardin, *The Tragedy of the Commons* 162 SCIENCE (1968) 1246-1258.

that when a resource is open to all it becomes available to no one, as people often overuse resources they own in common because they have no incentives to conserve them. Interestingly, to explain this idea, Hardin made reference to the freedom of the seas, highlighting that "the oceans of the world continue to suffer from the survival of the philosophy of the commons. […] Professing to believe in the inexhaustible resources of the oceans [maritime nations] bring species after species of fish and whales closer to extinction".[112] For its appeal, Hardin's metaphor has been a powerful justification for privatizing biomedical research.

However, it may be questioned whether the issue of exhaustibility can be transposed from the physical world to the world of ideas. Unlike most other kinds of commons, the knowledge oceans are not threatened by over-use, but they are instead improved through free access, through the sharing and consumption of information. The knowledge commons is threatened by enclosure and ownership. Because of the difference between tangible and intangible goods, the proliferation of patents in medical research suggests the so-called *tragedy of the anti-commons*.[113] As Eisenberg puts it, "the tragedy of the anti-commons refers to the […] complex obstacles that arise when a user needs access to multiple patented inputs to create a single useful product".[114] Privatization of biomedical research is resulting in the tragedy of the underutilization of knowledge resources.

To date, open source methods of knowledge creation have made little headway beyond software. However, computational studies and biology are converging as "in both cases, research consists of finding and fixing tiny problems hidden in an ocean of code".[115] An open source approach to drug development would be a decentralised, community-wide effort where scientists would work together for a common cause. The commons-based models of knowledge production would be more efficient than monopoly-based ones, because of cost containment. Volunteers would be offered non-monetary rewards, such as personal satisfaction, the acquisition of new skills, and enhancement of professional reputation. Medical formulae would be available to anyone interested in developing them.[116]

Financial incentives might be envisaged as well through the formula of *domaine public payant*.[117] This mechanism that has already been proposed with regard to traditional medicine,[118] subjects certain transactions to a levy even if the intellectual values at stake are already put in the public domain. Indeed, companies have already examined similar new business models.[119]

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[112] Hardin, *supra* note 111 at 1250.

[113] *See* Heller & Eisenberg, *supra* note 21 at 701.

[114] *See* Heller & Eisenberg, *supra* note 21 at 701.

[115] *See* Stephen M Maurer, Arti Rai & Andrej Sali, *Finding Cures for Tropical Diseases: Is Open Source and Answer?* 1 PLOSMED 3 (2004) 181.

[116] There are precedents for private companies developing drugs off patents. For instance, during the 1950s, March of Dimes developed polio vaccines without any patents at all. It then signed guaranteed purchase contracts with any drug maker willing to develop commercial sale method.

[117] Cristophe Germann, *Collecting Societies* in S. BIBER-KLEMM & T COTTIER (EDS) RIGHTS TO PLANT GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE –BASIC ISSUES AND PERSPECTIVES (2006) 268.

[118] Valentina Vadi, *Intangible Heritage: Traditional Medicine and Knowledge Governance* 2 J. INTEL. PROPERTY L. & PRACTICE 10 (2007) 682-692.

[119] For instance, in the pharmaceutical sector, a few years ago, Eli Lilly launched an online company called Inno-Centives, where rewards are offered for posted research problems. Forty companies, from Dupont to Procter & Gamble, now use the site, where 80,000 solvers from 175 countries regularly come to work.

Thus, borrowing the concepts of open source and general public licences (GPL)[120] from the software patenting and applying them to medical R&D could represent a *crosswalk* to facilitate the meeting of supply and demand of drugs.

C. Towards a Medical Research and Development Treaty?

With regard to pharmaceutical R&D, interesting proposals have been put forward. Among these, it must be mentioned the draft Medical Research and Development Treaty (hereinafter MRDT)[121] under discussion at World Health Organization.[122] The MRDT is meant to "create a new global framework for supporting medical research and development, based upon equitable sharing of the costs of research and development in the areas of need and public interest"[123] while recognizing "human rights and the goal of all sharing in the benefits of scientific advancement".[124] The proposed MRDT provides obligations for minimum levels of investment in medical research and development, and incentives to support medical research and dissemination of scientific knowledge and transfer of technology.[125]

The draft includes provisions that member countries reduce intellectual property protection in certain areas as to permit exceptions to patentability relating to certain open source medical databases, and increase flexibility in issuing compulsory licensing and in broadly interpreting research exception. Another important provision of the draft agreement is the *immunity clause*: Members agree to forgo certain WTO TRIPS dispute resolution cases, or bilateral or regional trade sanctions or unilateral trade policies, in areas where compliance with the terms of the Treaty provides an alternative and superior framework for supporting innovation.[126]

The core country obligation is to support medical R&D. According to the Draft, medical research includes basic research, development of biomedical databases, development of pharmaceutical drugs and the preservation and dissemination of traditional medical knowledge.[127] The mechanisms listed by the draft include classic approaches such as national public sector funding, tax exemptions, philanthropic expenditures or collective purchasing of patented medicines as well as newer methods such as medical innovation prize funds[128] or

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[120] *See* Andrés Guadamuz Gonzalez *Open Science: Open Source Licenses in Scientific Research* 7 NORTH CAROLINA J. L. & TECH. 2 (2006) 321-366.

[121] Medical Research and Development Treaty (MRDT), Discussion draft 4, February 7, 2005, draft available at http://www.cptech.org/workingdrafts/rndtreaty4.pdf. In May 2006, the WHO's Executive Board approved a highly bracketed version of a draft resolution on this topic, which was debated at the WHO's World Health Assembly (EB117.R13). On the 27th May 2006, the WHA adopted a milestone resolution (WHA59.24), establishing an intergovernmental working group open to all interested member states to develop a global plan on medical research and development.

[122] Tove Gerhardsen, *Health Assembly Sets Up Drafting Group on Brazil IP Proposals* INTELLECTUAL PROPERTY WATCH 21 May 2007 at http://www.ip-watch.org.

[123] MRDT, Preamble.

[124] MRDT, Preamble.

[125] MRDT, Article 2.2.

[126] *See* Nicoletta Dentico & Nathan Ford, *The Courage to Change the Rules: A Proposal for an Essential Health R&D Treaty*, 2 PUB. LIB. SCI. MED. 96, 97-98 (2005).

[127] MRDT, Article 4.

[128] At a national level, the US has recently considered the introduction of a Medical Innovation Prize Act. *See* Alan Lyles, *Creating Alternative Incentives for Pharmaceutical Innovation* 28 CLINICAL THERAPEUTICS 1 (2006) 126-128; James Love, *Prizes Rather than Prices* LE MONDE DIPLOMATIQUE May 2006; Keith E Maskus, *Ensuring Access to Essential Medicines: Some Economic Considerations*, 20 WISC. INT' L L. J. (2002) 563, 578 (reviewing and criticizing proposals linked to prize incentives); James Love, *Measures to Enhance Access to Medical Technologies, and New Methods of Stimulating Medical R&D* 40 U.C. DAVIS L. REV. 679 (2006-2007).

various open source collaborative research projects as an alternative to patents and the monopoly drug pricing they engender. Parties are free to decide themselves on specific investments and finance mechanisms.

Country obligations are tailored according to their GDP, under a progressive rate. Member states can meet this obligation by funding research projects within their own border. But they can also fund research in other countries, as similarly to the Kyoto Protocol,[129] the proposal creates a system of credits to reward and stimulate investments in research projects that can be traded across borders. Countries that exceed the benchmark obligations can sell excess credits.[130]

The proposal has to be welcomed as it brings a very contentious issue to the fore. Importantly, it is refocusing the debate away from trade policy considerations towards innovation and access. All these issues must be considered concurrently and creatively. While some authors have strongly opposed it,[131] the whole initiative has to be welcomed as increased state funding of R&D is highly desirable. In abstract terms, it is possible to envisage this MRDT as a *Protocol* to the Draft Treaty on Access to Knowledge. While the Draft Treaty would be a framework convention expressing general principles and goals, the MRDT would have detailed provisions that would be binding upon the signatories.

Although the MRDT's future remains uncertain, many concurrent moves have been furthered at the WHO. The WHO Executive Board has adopted a resolution concerning a new Global Framework on Essential Health Research and Development,[132] calling for the creation of a group of member states to establish a global framework for supporting medical research. Will this open the door to multilateral negotiations leading to formal obligations or a treaty?[133] In a parallel move, the WHO Assembly adopted a resolution requesting the WHO to get more involved in supporting member states using the TRIPS flexibilities and to encourage discussion of new incentive mechanisms for medical R&D.[134] From an institutional perspective, an ongoing intergovernmental process has been permanently established on public health and intellectual property, referred to as IGWG. All these concurring initiatives clearly need to be harmonised, still they are evidence that consensus has been gradually been reached on the necessity of working on the issue.

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[129] The Kyoto Protocol to the UN Framework Convention on Climate Change was adopted in Kyoto, Japan, on 11 December 1997 and entered into force on 16 February 2005, text available at http://unfccc.int. The Protocol assigns member states mandatory targets for reducing their greenhouse gases or emissions trade if they maintain or increase emission of these gases. *See* Andrew Jack, *WHO Members Urged to Sign Kyoto-Style Treaty*, FIN. TIMES, Feb. 24, 2005.

[130] MRDT, Article 12.

[131] *See*, e.g., Richard Tren & Roger Bate, *Government-Controlled Pharmaceutical Research and Development: A Recipe for Disaster* 8 AM. ENTERPRISE INSTITUTE FOR PUBLIC POLICY RESEARCH (2006).

[132] WHO Executive Board, 117th Session, Agenda item 4.10, draft resolution EB117.R13, *[Global Framework on] Essential Health Research and Development* (2006).

[133] For commentary, *see*, e.g., James Love, *WHO to Debate Global R&D Framework* REAL HEALTH NEWS March 2006, 14-16.

[134] For commentary, *see* Tove Gerhardsen, *World Health Assembly Agrees on IP and Innovation; US Abstains* INTELLECTUAL PROPERTY WATCH 23 May 2007; *see also* Tove Gerhardsen, *WHO Draft Negotiating Text on IP Cautiously Received* INTELLECTUAL PROPERTY WATCH 8 August 2007.

D. Access to Essential Medicines

Access to essential medicines is a key component part of the right to health. As such, it is a fundamental human right, expressly recognised in a series of international and regional treaties.[135] The UDHR makes reference to the right to medical care[136] and the right to share in the benefits of scientific advancement.[137] Further, Article 12 of the ICSECR recognizes "the right of everyone to the enjoyment of the highest attainable standards of physical and mental health".[138] As the Economic, Social and Cultural Rights Committee has further set out, States are bound to promote the right to health through ensuring access to affordable treatment.[139]

At the regional level, for instance, Article 10 of the Protocol of San Salvador recognizes the right to health and it states that "in order to ensure the exercise of the right to health, the States Parties agree to recognize health as a public good and, particularly, to adopt […] essential health care […] prevention and treatment of endemic […]diseases, […] satisfaction of the health needs of the highest risk groups and of those whose poverty makes them the most vulnerable".[140]

Thus, as professor Haugen puts it, "Realization of social human rights, such as the right to food or the right to health, is about the accessibility to important goods and resources."[141] In particular, both physical and economic accessibility to medicines is crucial in order to enjoy the right to health.[142] The question is not whether access to medicines is a human right but, rather, how governments intent to give practical effect to this objective. As Helfer puts it "Economic, social and cultural rights are the most expansive and, for many countries, the most controversial. Whereas civil and political rights are negative liberties that require government officials to refrain from particular actions, economic, social and cultural rights obligate governments to provide minimum levels of subsistence and well-being to individuals and to groups. Achieving these goals requires affirmative measures […]".[143] The gradual and progressive nature of economic, social and cultural rights should not be considered as a justification for inaction though. If the state fails to adopt appropriate policies, it might be found internationally responsible under the ICESCR.[144] What is more important, there is a rich jurisprudence, both at a regional and national level which confirms the justiciability of the right to health.[145] Thus,

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[135] On the right to health, *see* e.g., BRIGIT C. A. TOEBES, THE RIGHT TO HEALTH AS A HUMAN RIGHT IN INTERNATIONAL LAW (1999).

[136] UDHR, Article 25.

[137] UDHR, Article 27.

[138] ICSECR, Article 12, 1.

[139] Economic, Social and Cultural Rights Committee, *General Comment n. 14* (E/C.12/2000/4) adopted on 11 May 2000.

[140] The Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights, Article 10, 2, (a), (d) and (f)

[141] *See* Hans Morten Haugen *Patents Rights and Human Rights: Exploring their Relationship* 10 J. WORLD INT'L PRO (2007) 97-124, at 98.

[142] *See* Haugen *supra* note 141, at 112.

[143] See Helfer *supra* note 44, 981.

[144] *See* Haugen *supra* note 141, at 113. *See also* Audrey Chapman, *Conceptualizing the Right to Health: A Violations Approach*, 65 TENN. L. REV. 389, 395 (1998).

[145] For an exhaustive account of regional jurisprudence on the right to health, Alicia Ely Yamin, *Not Just a Tragedy: Access to Medications as a Right under International Law* 21 BOSTON U. L. INT'L L. J., 2003, 101-144. For a comparative analysis of national constitutional case law, *see* Foons Coomans, *Some Introductory Remarks on the Justiciability of Economic and Social Rights in a Comparative Constitutional Context* (2006) in FOONS COOMANS (ED), JUSTICIABILITY OF ECONOMIC AND SOCIAL RIGHTS – EXPERIENCES FROM DOMESTIC SYSTEMS 2006, 1-15. More generally, with regard to economic, social and cultural rights, *see* e.g., Ida Elisabeth Koch *The Justiciability of*

defining the ICESCR as "a programmatic treaty"[146] is an obsolete view of the whole matter which does not take into account international experience on the matter. It can be said that some contents of the right to health have gradually achieved prescriptive force.

Medicines are knowledge-based products, and as such, they share a fundamental characteristic of knowledge goods.[147] While it is expensive to develop a medicine, it is often not expensive to copy one, by means of *reverse engineering*. Thus, for knowledge products, an author argues that "scarcity is a deliberate choice, enforced through social mechanisms such as patents, which create monopolies and predictably drive prices above the costs of making copies".[148] Granting a right to patent is akin to a grant of a monopoly[149] because it allows the patent holder to manipulate the market price of the product. Thus, if patent rights for pharmaceuticals results in higher prices, the issue is whether the existing patent regime, by treating pharmaceuticals at par with other fields of technology, conflicts with the right to health,[150] by *restricting* access to new inventions. The particular nature of intellectual property rights implies that the potential positive effects are only seen after a certain period. As the High Commissioner points out, "while the incentive to innovate has the potential to promote the enjoyment of the right to health, this does not, *ipso facto*, justify the conclusion that IPRs promote respect for the right to health in all cases".[151]

E. Access to Medicines and IP

One of the significant departures under the TRIPS Agreement from previous treaties on intellectual property rights is that the Agreement obliges WTO members to provide patent protection to cover all fields of technology, including pharmaceuticals.[152]

The TRIPS states that "Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect health […] provided that such measures are consistent with the provisions of TRIPS".[153] Hence, the Agreement provides for a number of flexibility elements,[154] such as limited exceptions and compulsory licensing.[155] In particular, by the issuance of compulsory licences, public authorities authorize a third party to make, use or sell

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Indivisible Rights 72 NORDIC J. INT'L L. (2003) 3-39; J. K. Mapulanga-Hulston *Examining the Justiciability of Economic, Social and Cultural Rights* 6 INT'L J. H. R. (2002) 29-48 (claiming that civil and political rights and economic, social and cultural rights are universal, indivisible and interrelated.); Yash Ghai & Jill Cottrell, *The Role of the Courts in the Protection of Economic, Social and Cultural Rights* in YASH GHAI & JILL COTTRELL (EDS), ECONOMIC, SOCIAL & CULTURAL RIGHTS IN PRACTICE (2004) 58-90.

[146] Helfer, *supra* note 44, 987.

[147] *See*, e.g., John H Barton, *The Economics of TRIPS: International Trade in Information-Intensive Products* 33 Geo. Wash. Int'l L. Rev. (2001) 473.

[148] James P. Love, *Drug Development Incentives to Improve Access to Essential Medicines* 84 BULLETIN OF THE WORLD HEALTH ORGANIZATION 5 (2006) 408.

[149] ROBERT HOWSE & MICHAEL TREBILCOCK, THE REGULATION OF INTERNATIONAL TRADE 309 (1999). *See also* John Barton, *TRIPS and the Global Pharmaceutical Market*, 23 HEALTH AFFAIRS (2004) 146-154.

[150] *See* Amit Gupta, *Patent Rights on Pharmaceutical Products and Affordable Drugs: Can TRIPS Provide a Solution?*, 2 BUFF. INTELL. PRO. L. J. 127 (2003-2004) at 129.

[151] High Commissioner, *supra* note 95.

[152] TRIPS Agreement, Article 27(1).

[153] TRIPS Agreement, Article 8.

[154] *See* K Balasubramaniam, *Access to Medicines and Public Policy Safeguards under TRIPS* CHRISTOPHE BELLMANN, GRAHAM DUTFIELD AND RICARDO MELENDEZ ORTIZ (EDS), TRADING KNOWLEDGE – DEVELOPMENT PERSPECTIVES ON TRIPS, TRADE AND SUSTAINABILITY, (2003) 135-142.

[155] TRIPS Agreement, Articles 31 and 40.

a patented medicine without the patent owner's consent in case of health emergency or as a remedy against anti-competitive practices.

Another flexibility instrument is *differential pricing* which requires lowering drug prices in nations with low ability to pay and imposing high prices in wealthy nations, while maintaining patent protection. To encourage differential pricing, parallel imports i.e. the diversion of low price medicines through international trade channels should be barred from low income nations to nations in which the patent holder attempts to maintain high prices.[156] However, the TRIPS Agreement does not settle the pattern of exhaustion explicitly: article 6 merely excludes from the WTO dispute resolution jurisdiction the question of whether patent rights could block parallel trade. Therefore, WTO Members deal with parallel importation in different ways.

Notwithstanding the number of flexibilities *de iure* provided by the TRIPS Agreement, since its inception, problems have arisen as to the actual implementation of its flexibility clauses because of the *de facto* fear of retaliation measures. A major case is represented by *South African Pharmaceutical Manufacturers Association v. the Government of South Africa.*[157] In 1997 the South African government introduced a bill that allowed parallel imports into South Africa of pharmaceuticals. However, 41 pharmaceutical corporations began proceedings in the High Court of Pretoria against the South African government. Their argument was that TRIPs required that patents be enjoyable without discrimination as to the field of technology. Only after massive condemnation by public opinion, in 2001 the pharmaceutical companies withdrew from the litigation. This case has triggered a broad discussion on the relationship between IP and the right to health.

The Doha Ministerial Declaration[158] and the Doha Declaration on the TRIPS Agreement and Public Health[159] both adopted on 14 November 2001 marked a turning point in the subject, integrating the TRIPS Agreement into the international strategy addressing public health emergencies.[160] In Doha, Ministers agreed that "the TRIPS Agreement [...] can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all".[161] Thus, WTO Members have the right to use to the full, the TRIPS flexibilities. In particular, each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licenses are granted. Further, according to the Declaration, each Member has the right to determine what constitutes national emergency or other circumstances of extreme urgency.

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[156] When prices are higher in one nation than in others, there is a tendency for arbitrage to occur through parallel trade.

[157] *South African Pharmaceutical Manufacturers Association v. the Government of South Africa*, Case n. 4183, 1998, High Court of Pretoria, available at http://www.cptech.org .

[158] Doha Ministerial Declaration adopted 14 November 2001 (WT/MIN (01)/DEC/1) available at http://www.wto.org .

[159] Declaration on the TRIPS Agreement and Public Health, IV Ministerial Conference, Doha, WT/MIN(01)/DEC/W/2, 20 November 2001.

[160] See, e.g. Alan O Sykes, *TRIPS, Pharmaceuticals, Developing Countries and the Doha Solution*, 3 CHI. J. INT'L L. (2002) 47; Ruth L. Okediji, *Public Welfare and the Role of the WTO: Reconsidering the TRIPS Agreement* EMORY INT'L L. REV. (2003) 821; Carmen Otero Garcia-Castrillon, *An Approach to the WTO Ministerial Declaration on the TRIPS Agreement and Public Health*, J. INT'L ECON. L. 212 (2000); Tshimanga Kongolo, *TRIPS, the Doha Declaration and Public Health* 6(2) J WORLD INTELL. PRO. (2003) 373-378; Eric Noehrenberg, *TRIPS, the Doha Declaration and Public Health* 6(2) J WORLD INTELL. PRO. (2003) 379-383; Thomas Cottier, *TRIPS, the Doha Declaration and Public Health* 6(2) J WORLD INTELL. PRO. (2003) 385-388; Frederick M. Abbott, *The Doha declaration on the TRIPS Agreement and Public health: Lightinh a Dark Corner at the WTO* J. Int'l Econ. L. (2002).

[161] Declaration on the TRIPS Agreement and Public Health, paragraph 4.

As article 31 (f) of the TRIPS requires that compulsory licensing must be predominantly for the supply of the domestic market, the problem was that Least Developed Countries (hereinafter LDCs) lack the infrastructure and technical capabilities to build a domestic industry. Hence, the TRIPS Council[162] adopted a waiver,[163] permitting countries with insufficient or no manufacturing capacity to issue compulsory licenses for importation.[164] Finally, on 6 December 2005 the TRIPS Council adopted a Protocol of Amendment and opened it for signature.[165] The waiver will be permanently built into the TRIPS Agreement if two thirds of the WTO Members ratify the change. The amendment allows pharmaceutical products made under compulsory licenses to be exported to countries lacking production capacity and establishes a notification scheme.[166]

V. CONCLUSIONS

Access to knowledge is a fundamental human right and a key instrument to development. Focus on IP's effects on knowledge creation and knowledge diffusion shows that this policy instrument can promote innovation in the long term, but it can create negative short term effects for poor people. Therefore the international community as a whole must take all possible steps to reduce inequalities in access to knowledge and, in particular, in access to essential drugs.

The pursuit of prosperity must tamed by economic and social rights. The TRIPS Agreement, like any other treaty, is not a self-contained *regime*, but must be consistent with public international law.[167] The Doha Declaration and the recent Amendment to the TRIPS Agreement suggest that the trading system is already moving in the required direction.

Under the ICESCR, the balance between IP and other human rights should have the primary objective of promoting and protecting human rights as article 5 of the same Covenant states that nothing in the Covenant can justify any act aimed at the destruction of any of the rights recognized therein or their limitation to a greater extent than is provided for in the Covenant. In particular, the High Commissioner has called for "interpretations of the [TRIPs Agreement] that do not lose sight of the public interest in the wide dissemination of knowledge under article 15 [of the ICSECR]".[168]

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[162] At the Doha Ministerial Conference, the WTO Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council) was given a mandate to recommend a solution to the problem faced by countries with insufficient or no manufacturing capacities in the pharmaceutical sector.

[163] Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, 30 August 2003 (document WT/L/540) at http://www.wto.org.

[164] *See*, e.g. Paul Vandoren & Jean Charles Van Eeckhaute, *The WTO Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health Making it* 5(6) J WORLD INTELL. PRO. (2003) 373-378; Jacques H. J. Bourgeois & Thaddeus J Burns, *Implementing Paragraph 6 of the Doha Declaration on TRIPS and Public Health the Waiver Solution*, 5(6) J WORLD INTELL. PRO. (2003) 835-864; Duncan Matthews, *WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?* 7(1) J. INT'L ECON. L. (2004) 73-107.

[165] WTO Council for Trade-Related Aspects of Intellectual Property Rights 'Implementation of Paragraph 11 of the General Council decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (IP/C/41) 6 December 2005, available at http://www.wto.org.

[166] See, e.g., Frederick M Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT'L L. 317 (2005) 324-26.

[167] For a more detailed analysis on this point, *see* Valentina Vadi, *Balancing the Human Right to Health and Intellectual Property Rights after Doha*, XIV ITALIAN YEARBOOK OF INT'L L. (2004) 213-218.

[168] High Commissioner, *supra* note 95, § 62.

The Draft Treaty on Access to Knowledge bears this discussion in mind, when it consider the TRIPS minimum standards as the *maximum*, and defines binding *minimum* standards for access to knowledge. The Draft also requires consideration of the public interest when there is an argument about the TRIPS compliance of an exception. It includes limits on patentable subject matter and other stipulations designed to ensure an appropriate balance between knowledge creation and knowledge diffusion. Open standards and the establishment of a repository of public knowledge (*Knowledge Commons*) are other important points.

Actually, there is the risk of posing too much emphasis on IP solutions, as they were the only means to promote knowledge creation. On the contrary, the above analysis has shown that proprietary approaches to knowledge governance are far from being a panacea. Breaking with many established assumptions on how innovation ought to work, open source software projects may offer innovation models for practitioners in many fields.[169] Open source seems to be a useful tool to promote both knowledge creation and knowledge diffusion. Crucially, open source models can be transplanted in the pharmaceutical area. In the pharmaceutical field, framing access to essential medicines within the access to knowledge framework may be complementary to the traditional conception according to which access to essential medicines is a part of the right to health. The recent MRDT considers intellectual property as a tool to foster medical innovation. However, the Draft offers alternatives within the patent system, with a look at solutions outside the IP cosmology.

Knowledge governance requires the coexistence of two institutional devices: open science and intellectual property. While market-driven research may be successful in certain fields, open science is necessary in others. No solution is better than the other in all respects; each exhibits some flaws as well as virtues. Regaining a better balance between the two sub-systems is particularly needed in the pharmaceutical sector. Importantly, IP and the public domain should not be viewed as binary opposites, but rather as points along a continuum.[170] According to the knowledge governance model proposed, IP and public domain dimensions are complementary. This would avoid the clash between different values -property versus commonality- which seems to characterise the current debate. A holistic approach to knowledge governance tries to make this new-born discipline more dialectically attuned to its social spill-over, by acknowledging the multidimensional nature of knowledge:

> *"Thought has not Hercules' columns […].*
> *Neither Ulysses nor Columbus expected*
> *a thousand and one islands to discover.*
> *Entire Continents are waiting for you.*
> *They sleep into your mind: dare!*
> *The world has to be created*."[171]

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[169] *See* Georg von Krogh & Eric von Hippel, *The Promise of Research on Open Source Software*, 52 MANAGEMENT SCIENCE 7 (2006) 975-983.

[170] *See* James Boyle, *The Second Enclosure Movement and the Construction of the Public Domain* 66 L. & CONTEMPORARY L. PROBLEMS (2003) 68 and Pamela Samuelson, *Enriching Discourse on Public Domains* 55 DUKE L. J. (2006) p 104. Many academic commentators believe that as a general matter IP rules have become overly protective, and that the vitality of the public domain has suffered as a result. *See* JAMES BOYLE, SHAMANS, SOFTWARE, AND SPLEEN: LAW AND THE CONSTRUCTION OF THE INFORMATION SOCIETY 155 (1997); LAWRENCE LESSIG, THE FUTURE OF IDEAS: THE FATE OF THE COMMONS IN A CONNECTED WORLD 14-16 (2001).

[171] Maria Luisa Spallanzani's poem printed in RITA LEVI MONTALCINI, ABBI IL CORAGGIO DI CONOSCERE (2004) p. 9 [translated into English by the writer].