

Intellectual Property, Human Rights and Access to Medicines

A Selected and Annotated Bibliography



Third Edition

Germán Velásquez
Carlos M. Correa
Vitor Ido



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THIRD EDITION

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THE SOUTH CENTRE

In August 1995 the South Centre was established as a permanent inter-governmental organization. It is composed of and accountable to developing country Member States. It conducts policy-oriented research on key policy development issues, and supports developing countries to effectively participate in international negotiating processes that are relevant to the achievement of the Sustainable Development Goals (SDGs). The Centre also provides technical assistance and capacity building in areas covered by its work program. On the understanding that achieving the SDGs, particularly poverty eradication, requires national policies and an international regime that supports and does not undermine development efforts, the Centre promotes the unity of the South while recognizing the diversity of national interests and priorities.

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ABBREVIATIONS AND ACRONYMS

ACTA	Anti-Counterfeiting Trade Agreement
AFRO	World Health Organization Regional Office for Africa
AIDS	Acquired Immunodeficiency Syndrome
DNDi	Drugs for Neglected Diseases initiative
ECHR	European Court of Human Rights
ECJ	European Court of Justice
EMRO	World Health Organization Regional Office for the Eastern Mediterranean
ESCWA	Economic and Social Commission for Western Africa
EU	European Union
FDA	Food and Drug Administration
FTA	Free Trade Agreement
GATS	General Agreement on Trade in Services
GATT	General Agreement on Tariffs and Trade
HAI	Health Action International
HIV	Human Immunodeficiency Virus
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IP	intellectual property
IPP	intellectual property protection
IPRs	intellectual property rights
MSF	Médecins Sans Frontières
NAFTA	North American Free Trade Agreement
NGO	nongovernmental organization
NOC	notice of compliance
OECD	Organisation for Economic Co-operation and Development
OTC	over-the-counter (drug)
PCT	Patent Cooperation Treaty
PPP	public-private partnerships
R&D	research and development

SEARO	World Health Organization Regional Office for South-East Asia
SPLT	Substantive Patent Law Treaty
S&T	science and technology
SUNS	South-North Development Monitor
TRIPS	Trade-Related Aspects of Intellectual Property Rights
TRM	traditional medicine
TWN	Third World Network
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UPOV	International Union for the Protection of New Varieties of Plants
US	United States (of America)
WCC	World Council of Churches
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WPRO	WHO Regional Office for the Western Pacific
WTO	World Trade Organization

PREFACE

The South Centre is an intergovernmental organization of developing countries working as a think tank that provides policy research and advice to the countries of the South in various areas, such as global governance, sustainable development and climate change, trade and development, innovation, intellectual property and public health.

With the creation of the World Trade Organization (WTO) in 1994, the most comprehensive treaty on intellectual property rights to date was established: the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). This Agreement has substantially limited the freedom that countries previously enjoyed to design and implement their own intellectual property systems. Under the Agreement all WTO Members are now bound to grant patent protection for at least 20 years to any invention of a pharmaceutical product or process which fulfils the criteria of novelty, inventiveness and usefulness. Prior to the negotiation of the TRIPS Agreement, more than 50 countries did not provide patent protection for pharmaceuticals, many provided only process and not product patents and the duration was much less than 20 years in many countries.

It is now generally acknowledged that the current regime of patent protection, as “globalized” by the TRIPS Agreement, has a significant effect on the pharmaceutical sector. It has also been observed that the standards specified in the TRIPS Agreement are not necessarily appropriate for countries struggling to meet health and development needs. Accordingly, the UK Commission on Intellectual Property Rights (CIPR) in its 2002 report cautioned countries “to ensure that their intellectual property protection regimes do not run counter to their public health policies and that they are consistent with and supportive of such policies”. As recognized by the consensus of the Member States of the World

Health Organization in the resolution WHA61.21 on “the global strategy on public health, innovation and intellectual property”, there is a need to promote new thinking on innovation and access to medicines, in view of the findings that the present system had failed to produce medicines for the majority of the world population, which lives in developing countries. The world has never had at its disposal such a massive arsenal of treatments to combat the diseases that afflict humanity. At the same time, many people die because they lack essential medicines.

In many developing countries, there is still a need to facilitate informed approaches to address health implications of trade and intellectual property-related issues at the national, sub-regional and regional levels. Given that there is still insufficient awareness and assessment of the provisions in international, regional and bilateral trade agreements that can be used to safeguard access to medicines, the South Centre’s strategic priorities in technical cooperation have been to support developing countries in their efforts to improve access to health and medicines through policy guidance, direct country support and technical assistance on the use of flexibilities and safeguards.

The South Centre seeks to provide the appropriate technical assistance and country support to developing countries, within a comprehensive and coherent national IP strategy, to promote an implementation of the TRIPS Agreement that is consistent with the protection of public health and promotion of access to medicines. To this end the South Centre has prepared a third edition of this selected and annotated bibliography to assist developing countries in implementing IP policies and regulations consistent with development goals and public health principles. The growing volume of literature being produced around the issue of IP, innovation, human rights and access to medicines in the last five years can help countries find the opportunities and room to manoeuvre to protect their citizens from the unhealthy environment created by the new international trade rules.

This bibliography does not provide an exhaustive list, but rather highlights some of the most pertinent works from Southern views

and perspectives. These selected references are a valuable instrument for those interested to promote universal access to medical innovation.

Germán Velásquez

1. INTELLECTUAL PROPERTY AND INNOVATION IN PHARMACEUTICALS

Banerji, J., and Pecoul, B. **Pragmatic and principled: DNDi's approach to IP management.** In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A. Krattiger, R.T. Mahoney, L. Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, USA 2007.

The mission of the Drugs for Neglected Diseases initiative (DNDi) is to develop safe, effective, and affordable new drugs for patients suffering from neglected diseases and to ensure equitable access to these drugs. DNDi believes that intellectual property (IP) rights should not pose a barrier to access to these medicines. Hence, a balanced approach to IP management is critical for effective implementation of the DNDi mission. The organization has written an IP policy that both encapsulates and articulates DNDi approach to IP based on core principles and beliefs. The policy reflects the DNDi philosophy, vision, and mission, ensuring that its products are accessible and affordable to patients who need them most. DNDi recognizes the reality of IP and seeks to implement its humanitarian mission using best, pragmatic practices for IP management. Indeed, DNDi has already demonstrated that this is feasible, having successfully negotiated with both private and public sector institutions in order to actualize its principled mission.

Barton, J. *New Trends in Technology Transfer. Implications for National and International Policy.* Geneva: ICTSD, 2007.

Available from:

<https://www.ictsd.org/sites/default/files/downloads/2012/03/new-trends-in-technology-transfer.pdf>.

This paper describes how technology is today transferred to developing countries and the barriers that affect that transfer. It then identifies policy approaches that might overcome those barriers. It covers (1) the flow of human resources, as through international education, (2) the flow of public-sector technology

support, as through licensing, and through research and licensing by international organizations, and (3) the flow of private technology, as through the sale of consumer products (e.g. medicines) that may incorporate embodied technologies through licensing and through foreign direct investment. The paper concentrates on policy approaches directly associated with technology transfer, thus avoiding issues of the overall investment, legal or political climate in specific developing countries.

Barton, J. **Reforming the patent system.** *Science*, 2000, 287(5460): 1933–1934.

The number of intellectual property lawyers in the United States is growing faster than the amount of research. This suggests that legal costs are growing as well – and these costs are substantial; lawyer's costs alone approach \$10,000 to obtain a patent and \$1.5 million (per side) to litigate a patent. To respond to this problem, this article proposes three reforms: to raise the standards for patentability, to decrease use of patents to bar research, and to ease legal attack on invalid patents. These proposals are based on following facts. Firstly, there is no economic value in conferring a patent monopoly except for an invention that will have a significant impact. Secondly, broad basic patents on fundamental research processes deter and complicate follow-on research. Thirdly, many patents are currently issued erroneously.

Barton, J., and Emanuel, E. **The patents-based pharmaceutical development process: rationale, problems, and potential reforms.** *Journal of the American Medical Association JAMA*. 2005 Oct 26;294(16):2075–2082.

The authors examine the substantial criticism that the pharmaceutical industry is facing from many directions, including financial barriers to access to drugs in both developed and developing countries, high profits, spending on advertising and marketing, and other issues. Underlying these criticisms are fundamental questions about the value of the current patent-based drug development system. Six major problems with the patent system are: (1) recovery of research costs by patent monopoly

reduces access to drugs; (2) market demand rather than health needs determines research priorities; (3) resources between research and marketing are misallocated; (4) the market for drugs has inherent market failures; (5) overall investment in drug research and development is too low, compared with profits; and (6) the existing system discriminates against US patients. Potential solutions fall into 3 categories: change in drug pricing either through price controls or tiered pricing; change in drug industry structure through a "buy-out" pricing system or with the public sector acting as exclusive research funder; and change in development incentives through a disease burden incentive system, orphan drug approaches, or requiring new drugs to demonstrate improvement over existing products prior to US Food and Drug Administration approval. The authors recommend 4 complementary reforms: (1) having no requirement to test new drug products against existing products prior to approval but requiring rigorous comparative post approval testing; (2) international tiered pricing and systematic safeguards to prevent flow-back; (3) increased government-funded research and buy-out for select conditions; and (4) targeted experiments using other approaches for health conditions in which there has been little progress and innovation over the last few decades.

Batson, A., and Ainsworth, M. **Private investment in AIDS vaccine development: obstacles and solutions.** *Bulletin of the World Health Organization*, 2001, 79(8): 721–727.

Available from:

[http://www.who.int/bulletin/archives/79\(8\)721.pdf](http://www.who.int/bulletin/archives/79(8)721.pdf).

The development of vaccines for the prevention of AIDS, malaria, tuberculosis, and other diseases requires both public and private investment. Private investment, however, has been far lower than might have been hoped, given the massive human toll of these diseases, particularly in the poorest countries. With a view to understanding this situation and exploring potential solutions, the World Bank AIDS Vaccine Task Force commissioned a study on the perspectives of investment in research and development work on an AIDS vaccine. It was found that different obstacles to the development of an AIDS vaccine arose during the product

development cycle. During the earlier phases, before obtaining proof of product, the principal barriers were scientific. The lack of consensus on which approach was likely to be effective increased uncertainty and the risks associated with investing in expensive clinical trials. The later phases, which involved adapting, testing, and scaling up production for different populations, were most influenced by market considerations. In order to raise the levels of private research and development in an AIDS vaccine there will probably have to be a combination of push strategies, which reduce the cost and scientific risk of investment, and pull strategies, which guarantee a market.

Boldrin, M., and Levine, D. K. **The case against patents.** *Journal of Economic Perspectives*, 2013, No. 27: 3–22.

This straightforward economic article argues that there is no empirical evidence that patents increase innovation and productivity. Using various historical examples and concrete case studies, as well as debating the economic theoretical arguments usually used to justify the existence of patents, authors consider that, on the contrary, there is strong evidence that patents have negative consequences. The authors conduct their own empirical analysis to conclude that the relationship among patents, innovation and productivity drastically diverges from what it is supposed to be, according to the conventional assumption that increased IP leads to increased innovation. The paper also proposes a number of policies that could replace patents and foster more innovation.

Boyle, J. **The second enclosure movement and the construction of the public domain,** *Law and Contemporary Problems*, 2003, 66: 33–74.

In this article, Professor Boyle offers a historical sketch of various types of scepticism about intellectual property, from the antimonopolist criticisms of the Framers of the U.S. Constitution, through the emergence of affirmative arguments for the public domain, to the use of the language of the commons to defend the possibility of distributed methods of non-proprietary production. Professor Boyle states that the commons of facts and ideas is being

enclosed through the protection of intellectual property rights. He compares this actual phenomenon – the contemporary expansion of intellectual property rights – with the English enclosure movement, the process of fencing off common land and turning it into private property that started in the fifteenth century and went on until the nineteenth century. The article states that things that were formerly thought of as either common property or uncommodifiable are being covered with new or newly extended property rights. According to the author, the effects may be devastating: it may be that intellectual property rights slow down innovation, by putting multiple roadblocks, multiple unnecessary licenses, in the way of subsequent innovation.

Commission on Intellectual Property Rights, Innovation, and Public Health. ***Public Health, Innovation and Intellectual Property Rights***. Geneva: WHO, 2006.

Available from:

<http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf>.

This is a fundamental report to understand the current state and international initiatives regarding pharmaceutical research and development and access to medicines. The Commission's report deals with the intersections between intellectual property rights, innovation and public health. It summarizes existing evidence on the prevalence of diseases of public health importance and reviews the volume and distribution of existing research, development and innovation efforts. It also considers the importance and effectiveness of intellectual property regimes and other incentive and funding mechanisms in stimulating research and the creation of new medicines and other products. The Commission's report also summarizes and analyses proposals for improvements to the current incentive and funding regimes designed to stimulate the creation of new medicines and other products, and facilitate access to them. The report also contains concrete proposals for action by national and international stakeholders.

Correa, C. M. **Intellectual Property and Access to Science.** Research Paper 69. South Centre, July 2016.
Available from: <https://www.southcentre.int/research-paper-69-july-2016/>.

The paper argues that the boundaries between scientific and technological knowledge are nebulous in some technical fields, such as the biological sciences and their applications. This has led to the appropriation under patents of knowledge (such as on specific genes) of a scientific nature, which may not only have negative effects for the further development of science and new technological contributions but also encroach on the fundamental right of access to science. In this sense, the patenting policies adopted by some universities and other research institutions may aggravate this problem. The author sustains that court decisions in the USA and Australia and some national laws (e.g. Brazil) have limited the possibility of that appropriation, which is still feasible, however, in many jurisdictions. Other measures – such as a well formulated research exception, the limitation of the scope of patent claims and legislation mandating open access to the results of research conducted with public funding – may mitigate the effects of the exclusivity granted by patent rights, but more fundamental policy changes may be necessary to preserve scientific outcomes in the public domain for free use and follow-on research.

Correa, C. M. **Ownership of knowledge – the role of patents in pharmaceutical R&D.** *Bulletin of the World Health Organization*. 2004, 82(10): 784–786.

Available from:
<http://www.who.int/bulletin/volumes/82/10/784.pdf>.

Professor Correa discusses the role of patents in the research and development of pharmaceutical products. Acknowledging that under certain conditions patents may provide the incentives to develop new drugs, the author states that, by their very nature, patents also limit the diffusion of knowledge. In addition, different techniques have been developed to, through the invocation of weak and possibly invalid patent rights, exploit lax patentability standards and the shortcomings in the patent examination process.

The article suggests that strategic patenting should be prevented and the quality of patents should be controlled. To achieve this goal, a stronger control of the patentability requirements should be set up.

Correa, C. M. ***Trends in Drug Patenting. Case Studies.*** Buenos Aires: Corregidor, 2001. Available from: <http://apps.who.int/medicinedocs/en/d/Js4915e/1.html>.

This study focuses on the shortcomings that cast doubt on the use of patents as a tool to protect and promote innovation. Professor Correa states that “the patent system (especially as it operates in the United States of America) is in crisis and that there is a danger of it stifling the very innovation it is supposed to foster”. Professor Correa highlights the low standards being applied to notions such as non-obviousness and usefulness in the examination and granting of patents, particularly in the field of drugs. It examines nine specific cases and illustrates types of patenting that potentially divert patents from their real purpose of encouraging and providing reward to genuinely inventive efforts, while negatively affecting early access to cheaper alternative products for the public. As regards the issue of R&D of new drugs and its relation to patents, the author concludes that “a substantial part of the R&D budget that pharmaceutical firms claim is devoted to the development of new products is, in reality, allocated to developing a vast array of patents around existing products, with the clear intent of expanding and/or extending over time the exercise of exclusive rights.”

Drahos, P. ***The regulation of public goods.*** *Oxford Journals, Journal of International Economic Law*, 2004. Volume 7, Issue 2, pp. 321–339.

This paper examines the complex ways in which public goods are regulated. The provision and distribution of public goods is deeply affected by the degree of excludability of those goods and the regulatory context of that excludability. Using a decentred conception of regulation, the paper shows through various examples how state and non-state actors regulate each other's capacities to provide, access, and distribute public goods. The paper

includes a discussion of the regulation of knowledge by the rules of intellectual property.

Drexel, J., and Lee, N., eds. ***Pharmaceutical Innovation, Competition and Patent Law – A Trilateral Perspective***. Cheltenham UK and Northampton USA: Edward Elgar Publishing, 2013.

A comprehensive book addressing the interface between competition law and intellectual property, with a focus on the pharmaceutical sector and how to balance protection with access. The various articles share views from the United States, Europe and Japan, with a number of specific topics in a comparative perspective: (i) patent protection for pharmaceutical methods, (ii) data exclusivity and patent term extension and, particularly for the European context, (iii) balancing incentives and competition. Under the last topic, the notion of abusive practices of protection, anticompetitive marketing and patent filings as violations of competition law are discussed. As more and more developing countries adopt thorough competition law policies, these concerns will likely become more important and deserve input from the South.

Francisco A., and Matlin S., eds. ***Monitoring Financial Flows for Health Research 2006. The Changing Landscape of Health Research for Development***, Geneva: Global Forum for Health Research, 2007.

The 2006 Global Forum for Health Research report surveys the changing scene of global financing for health research and provides estimates of the resources available and the patterns of ill-health for 2003, as well as projections of these patterns in 2030. It examines the vital roles that the public sector across all countries must play in supporting health research, creating an enabling environment and strengthening research capacities to meet the present and future challenges. This study is in line with the Global Forum for Health Research mission to regularly track the world's resources for health research and analyse the information gathered in relation to the health challenges faced by developing countries.

Gehl Sampath, P. **Breaking the fence: can patent rights deter biomedical innovation. In Technology followers?** *Journal of Technology Assessment and Strategic Management*. Vol. 19, Issue 5, September 2007, pp. 677–696.

This paper develops a framework of analysis for the impact of patent rights on biomedical innovation in “technology follower” developing countries. Based on the framework developed in the paper, empirical data collected in an industry-level survey of the Indian pharmaceutical industry between November 2004 and January 2005 is used to analyse the impact of patent rights as recognized under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) on biomedical innovation in technology followers. The paper concludes that the same/similar sets of patent policies and institutions can have different impacts on knowledge flows, diffusion of innovation and habits and practices of actors in different systems of innovation. These inter-linkages need to be assessed in country-specific contexts. It advocates that technology follower countries should look at reducing the problem of restricted access through appropriate design of patent regimes. Analysis of these inter-linkages should take into account the nuanced relationship between patent policies on creating widespread technological interdependence in the biomedical sector. Additionally, solutions such as extended disclosure requirements in patent laws and increased pre-grant procedures that have been successful in inducing technological spill-overs between firms in other sectors should be considered.

Gehl Sampath, P. **Intellectual property and innovation in least developed countries. Background Study for the Least Developed Countries Report.** UNCTAD, 2007. Available from: http://www.unctad.org/sections/ldc_dir/docs/ldcr2007_Shree_en.pdf.

This study aimed at generating empirical evidence on whether IPRs can directly stimulate R&D and innovation in least developed countries, or at least promote firm-based innovative capabilities through diffusion of knowledge, technology transfer, foreign direct investments (FDI) and licensing, among others (hereafter referred

to as indirect effects). The study compared the performance of the firms in the local pharmaceutical sector (which is a thriving example in a LDC context), with similar firms in its agro-processing and readymade garments sectors. Firm-level evidence indicated that in a least developed country context, IPRs do not have a major role to play both directly (as a stimuli for R&D) and more indirectly (to promote FDI, technology transfer, technology licensing, etc.). Firm-level performance showed clearly that reverse engineering and copying were the main modes of new product development in the same way for the pharmaceutical sector, as they were for two other domestic processing sectors in the economy. Coherent national policies that focus strategically on enabling innovation played a key role in enabling local firms to access knowledge.

Gehl Sampath, P. ***Promoting Local Pharmaceutical Capacity in Developing Countries: A Discussion on Inventive Step and Compulsory Licensing***. A study for the IDRC, 2010/2011.

Patents over minor variations of existing products have been proliferating in recent times, with profound implications for pharmaceutical production (and related innovation) and access to medicines in developing countries. Such patents, by systematically promoting the patenting of incremental innovations that simply extend patent life on products and processes, unnecessarily extend the life of the drug in question, affecting the production options of generic companies in developing countries. This paper seeks to move the discussion forward by analyzing some key issues that confront policy makers and academics alike in this area. First, are there any potential benefits of applying a lax inventive step in the pharmaceutical sector for the local industry, and if so, would such benefits offset the costs associated with the proliferation of patents over minor technical changes? Second, the grant of patents on minor variants of already existing drugs may unnecessarily extend patent monopolies on drugs of importance to public health. The same drugs may then be the subject of compulsory licenses/government use by developing countries, in order to promote the right to access medicinal products of relevance to public health. Can the grant of compulsory licenses for importation be minimized *ex-ante* by simply defining a higher level of inventive step in the

pharmaceutical sector? Further, since drugs subject to compulsory licenses/government use are imported, does a stringent inventive step also imply greater potential for local firms to engage in generic production and greater health security in the long run? These issues are analysed at length from both an economic and legal perspective.

Gehl Sampath, P. ***Reconfiguring Global Health Innovation***. Routledge Publishing, 2010.

This book contains a comprehensive study on health innovation in developing countries. Using findings of multi-year research and data collection, the book analyses the emerging industrial structures in health innovation as more and more developing countries are foraying into what is a highly difficult and technologically intensive terrain, with the aim of finding means to achieve public health for their people. Comprehensive and wide ranging, the following issues are covered in the book: the role of states to provide health-oriented industrial policies, the inter-play between global “pull” institutions (like the WTO multilateral regime and the TRIPS Agreement) and national “push” institutions (local frameworks for technology, innovation and intellectual property), and finally the linkages between local health innovation, health systems efficiency and access to medicines.

Global Alliance for TB Drug Development. ***The Economics of TB Drug Development***, Global Alliance for TB Drug Development, 2001. Available from:
http://www.tballiance.org/downloads/publications/TBA_Economics_Report.pdf.

This report summarizes the work and projects of the Global Alliance for TB Drug Development, a partnership gathering private companies, international agencies, NGOs and others with the common goal of developing a new, more effective anti-TB drug. Firstly, it examines TB epidemiology. The second part is devoted to the potential market of anti-TB drugs, quantified between 412.5 million and 470.5 million dollars per year and expected to increase to 670 million dollars in 2010. Thirdly, it focuses on the possible costs of a new anti-TB drug and considers that between 76 million

and 115 million dollars will be required in order to achieve Phase III clinical trials and approval. The fourth part looks into the potential return on investment. From the financial point of view, the internal rate of return of a new anti-TB drug would be between 15 and 32 per cent, depending on a number of factors. The final part of the report focuses on the options available for conducting and funding a new anti-TB drug. The report explores new partnerships between public and private actors in order to share and balance risks and investment related to the development of any new drug.

Gold, E.R., Kaplan, W., Orbinski, J., Harland-Logan, S., and N-Marandi, S. **Are patents impeding medical care and innovation?** PLoS Med. 2010, 7(1) © 2010. *Public Library of Science*. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2795161/>.

This article examines the current debate on whether and how patents are impeding health care and innovation. Pharmaceutical and medical device manufacturers argue that the current patent system is crucial for stimulating research and development (R&D), leading to new products that improve medical care. The financial return on their investments that is afforded by patent protection, they claim, is an incentive toward innovation and reinvestment into further R&D. But this view has been challenged in recent years. Many commentators argue that patents are stifling biomedical research, for example by preventing researchers from accessing patented materials or methods they need for their studies. Patents have also been blamed for impeding medical care by raising prices of essential medicines, such as antiretroviral drugs, in poor countries.

Heller, M. A., Eisenberg, R. **Can patents deter innovation? The anticommons in biomedical research.** *Science*, 1998, 280: 698–701. Available from: <http://www.sciencemag.org/content/280/5364/698.full>.

The authors argue that the recent proliferation of intellectual property rights in biomedical research suggests an “anticommons” tragedy, in which people underuse scarce resources because too many IP owners block each other through a proliferation of

fragmented and overlapping intellectual property rights. According to the authors, policy-makers should seek to ensure coherent boundaries of upstream patents and to minimize restrictive licensing practices that interfere with downstream product development. Otherwise, more intellectual property rights may lead paradoxically to fewer useful products for improving human health.

Ito, B., Yamagata, T. **Who develops innovations in medicine for the poor? Trends in patent applications related to medicines for HIV/AIDS, tuberculosis, malaria, and neglected diseases.** *Developing Economies*, 2007, 45 (2): 141–171.

This paper analyzes patent data of medicines and vaccines for diseases that are prevalent in low-income countries. The data was retrieved from a database of the Japan Patent Office. Who invents medicines for the poor of the world? This is the main question that the paper addresses. Results indicate that not only public institutions but also private firms have played an important role in developing innovations for fighting both global diseases such as HIV/AIDS and tuberculosis, and so-called neglected diseases including malaria, which seem to spread almost exclusively in low-income countries. Moreover, the basic mechanism of innovation is similar between the development of medicines for HIV/AIDS and those for neglected diseases. Finally, among firms, innovations for fighting infectious disease are quite diverse. R&D stock and economies of scope are used to explain frequent patent applications by a high-performing pharmaceutical firm.

Jack, W., Lanjouw, J. O. **Financing pharmaceutical innovation: how much should poor countries contribute?** *The World Bank Economic Review*, 2005, 19(1): 45–67.

According to the authors, the debate over the suitability of pharmaceutical prices tends to be polarized between those who focus on the incentive effects and those who concentrate on other social objectives. This article provides a framework for determining a policy that respects both objectives. To this end, most of the legal aspects of the debate are abstracted and well-established techniques of applied public finance are employed to integrate both

efficiency and distributional concerns. A variety of policy options can be used to support research and address distributional concerns. The broad composition of these policies is taken as given, and the focus is on how best pharmaceutical prices can be structured. Specifically the concern is how the burden of generating any given profit from sales should be shared across countries. The basic principles of optimal pricing presented are consistent with broadly defined social objectives.

Kesselheim, A. S. **Intellectual property policy in the pharmaceutical sciences: the effect of inappropriate patents and market exclusivity extensions on the health care system.** *AAPS Journal* (2007) 9: E306. <https://doi.org/10.1208/aapsj0903033>.

The authors argue that though patents are effective tools for promoting innovation and protecting intellectual property in the pharmaceutical sciences, there has been growing concern about 2 important ways that patents in this field can have a negative effect on patient care and the practice of medicine. First, inventors can seek and receive patents on pharmaceutical products or research tools that stretch the statutory requirements for patenting. Second, patent holders in the pharmaceutical market can use legal loopholes or aspects of the patent registration system to extend exclusivity for inventions beyond what was anticipated by the Patent Act or subsequent legislation. The monopoly control bestowed by such inappropriate patents or manipulation of the patent system can limit options available to patients, increase the cost of health care delivery, and make cooperative research more difficult. In response, several different government and market-based efforts have emerged to promote more equitable patent policy in health care that encourages dissemination of ideas while still supporting the development of innovative products.

Kettler, H., and Marjanovic, S. **Engaging biotechnology companies in the development of innovative solutions for diseases of poverty.** *Nature Reviews*, 2004(3), 171–174.

Kettler and Marjanovic present an overview of the role of biotechnology in the development of medicines for neglected diseases and point out ways to facilitate higher levels of involvement in the future. They discuss present obstacles and disincentives and state that, if more biotechnology companies are to be encouraged to pursue technical solutions for global health priorities, incentives and provisions that cater specifically to their needs and capabilities must be established. An interesting proposal formulated is the creation of a broker for global health, a strategy based on the premise that many biotech companies have technologies that are relevant to global health but lack information on how to get involved in neglected-diseases projects, as well as on the funds, foundations and initiatives working in R&D issues.

Kettler, H., and Modi, R. **Building local research and development capacity for the prevention and cure of neglected diseases: The case of India**, *Bulletin of the World Health Organization*, 2001, 79(8): 742–747. Available from:
[http://www.who.int/bulletin/archives/79\(8\)742.pdf](http://www.who.int/bulletin/archives/79(8)742.pdf).

This paper examines the proposal to build R&D capabilities for dealing with neglected infectious and tropical diseases in countries where they are endemic, as a potentially cost- and time-effective way to fill the gap between the supply of and need for new medicines. With reference to the situation in India, the competence and incentives required by companies are considered so that their strategy can be shifted from reverse engineering of existing products to investment in R&D for new products. This requires complex reforms, of which intellectual property is only one. The authors consider whether Indian companies that are capable of conducting R&D are likely to target neglected diseases. Patterns of patenting and of R&D suggest that Indian companies are likely to target global diseases because of the prospect of much greater returns. Further studies are required on how Indian companies would respond to push and pull incentives originally designed to persuade multinational corporations to carry out more R&D on neglected diseases.

Kettler, H., and Towse, A. ***Public-private Partnerships for Research and Development: Medicines and Vaccines for Diseases of Poverty***. London: Office of Health Economics, 2002.

This report examines the potential of public-private partnerships (PPP) to encourage the development of therapeutics for those infectious diseases responsible for most deaths in developing countries. The authors looked at four case studies: the Medicines for Malaria Venture, the International AIDS Vaccine Initiative, the Malaria Vaccine Initiative and The Global Alliance for TB Drug Development. The report examines firstly the challenges to which PPP are bound to respond, notably the lack of R&D investment. Secondly, the authors look closely at the major trends which are transforming the traditional model of pharmaceutical R&D, stressing the necessary collaboration between parties and the increasing presence of biotechnology and specialist genomic technology companies. Thirdly, the authors analyse the PPP models set as case examples, concluding that substantial progress has been made in all areas except one, namely the ability to create a viable financial model that addresses the R&D funding gap. While the authors consider PPP as a valuable part of a total solution, they state that further international support is needed as PPP cannot achieve their goals in isolation.

Light, D. W., and Warburton, R. ***Demythologizing the high costs of pharmaceutical research***. *BioSocieties* (2011) 6, 34–50. doi:10.1057/biosoc.2010.40; published online 7 February 2011.

It is widely claimed that research to discover and develop new pharmaceuticals entails high costs and high risks. High research and development (R&D) costs influence many decisions and policy discussions about how to reduce global health disparities, how much companies can afford to discount prices for lower- and middle-income countries, and how to design innovative incentives to advance research on diseases of the poor. High estimated costs also affect strategies for getting new medicines to the world's poor, such as the advanced market commitment, which built high estimates into its inflated size and prices. This article takes apart the most detailed and authoritative study of R&D costs in order to show

how high estimates have been constructed by industry-supported economists, and to show how much lower actual costs may be. Besides serving as an object lesson in the construction of “facts”, this analysis provides reason to believe that R&D costs need not be such an insuperable obstacle to the development of better medicines. The deeper problem is that current incentives reward companies to develop mainly new medicines of little advantage and compete for market share at high prices, rather than to develop clinically superior medicines with public funding so that prices could be much lower and risks to companies lower as well.

Love, J. **Measures to enhance access to medical technologies, and new methods of stimulating medical R&D.** *UC Davis Law Review*, 2007, 40: 679–715.

This article presents four methods of managing a traditional patent system to more effectively administer limitations and exceptions, and enhance patent quality and transparency. On the other hand, the article introduces three new ideas which are relevant to more fundamental changes in the methods used to support medical research and development. Concerning the methods of managing the patent system more effectively, it states that national governments need to enact appropriate grounds for non-voluntary authorizations to use patents, to adopt guidelines for remuneration for non-voluntary authorizations, to increase the use of patent pools and other approaches to the collective management of intellectual property and to manage the identification of relevant patents and the elimination of inappropriate patent grants. As far as the new proposal is concerned, the article introduces the medical innovation prize, the system of competitive intermediaries to invest in R&D projects on behalf of employers and the global framework for essential health R&D.

Maskus, K. *Encouraging International Technology Transfer*. Geneva: UNCTAD-ICTSD, 2004.

Available from <http://ictsd.net/downloads/2008/07/b.pdf>.

Encouraging International Technology Transfer reviews comprehensively the basic theory and evidence regarding how

intellectual property protection affects incentives for international technology transfer. Professor Maskus provides an analysis of market-mediated international technology transfer (ITT) through trade, foreign direct investment, licensing, and personnel movements, along with informal means through imitation, reverse engineering, and spillovers. The report points out that there are inherent shortcomings in markets for technology that justify public intervention. Empirical evidence suggests that enforceable patents can increase inward flows of ITT in middle-income and large developing countries but probably have little impact in the least-developed countries.

Maskus, K. ***Reforming the US Patent Policy***, CSR No. 19. Washington D.C.: Council on Foreign Relations, 2006.

Professor Maskus argues that capacity for innovation is imperilled by an increasingly overprotective patent system. The misguided principle that stronger patent protection engenders more innovation has resulted in the opposite result, the impediment of the development and use of new technologies. The present scenario is characterized by high litigation costs, overly broad patents, patents unclear about the breadth of protection, and the use of patents as strategic anti-competitive tool that allows firms to use patents to actively exclude potential competitors. The report recommends changing domestic patent policy in order to return to basic patenting principles and restore the system to one that encourages innovation. It also proposes to abandon the high-level harmonization agenda, especially in free trade agreements (FTAs).

Maskus, K., and Reichman, J., eds. ***International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime***. Cambridge: Cambridge University Press, 2005.

This book consists of thirty-five chapters written by several authors coming from different fields of expertise, mainly economics, law and political science. *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime* is the outcome of a conference with this same title held in April 2003 at Duke University. The aim of that conference was to assess the public

processes and inputs likely to become indispensable in a transnational system of innovation that, while still dependent on territorial law, must aim to promote technical progress, economic growth and welfare for all participants. The contributions to this book are organized under four major rubrics: "International Provision of Public Goods under a Globalized Intellectual Property Regime", "Innovation and Technology Transfer in a Protectionist Environment", "Sectorial Issues: Essential Medicines and Traditional Knowledge", and, lastly, "Reform and Regulation Issues". This book provides an introduction to the consequences on the provision of public goods derived from the globalized protection of intellectual property. It offers a view on the broad spectrum of subjects, laws and institutions involved in the innovation process, both at the national and international levels, and collects proposals to foster the provision of public goods.

Merz J. F. **Disease gene patents: overcoming unethical constraints on clinical laboratory medicine**, *Clinical Chemistry*, 1999, 45:324–330.

Available from <http://www.clinchem.org/content/45/3/324.full>.

The rapidly growing numbers of disease gene patents –patents that claim all methods for diagnosis of a particular genetic condition– threaten the ability of physicians to provide medical care to their patients. This article discusses some of the ramifications of creating a monopoly over a medical service, assesses the implications of disease gene patents for clinical laboratories, and proposes some strategies for responding to this new phenomenon. The analysis concludes with a recommendation that the patent law be amended to require compulsory licensing of medical process patents. According to the author, "it is time to evaluate the need for such a provision for medical process patents in light of the serious harms to the practice of medicine, and arguably, to the public health, that may result from a refusal to license".

Miller, S. P. **Where's the Innovation? An Analysis of the Quantity and Qualities of Anticipated and Obvious Patents** (10 February 2012).

This empirical study analyses 980 patents litigated in the United States that were subject to anticipation or obviousness decisions from 2000–2012 in various business sectors, including pharmaceuticals. The author's findings show that 27 per cent of all patents would be found at least partially invalid if subject to an anticipation or obviousness decision. This counters the general assumption that patent protection results in more innovation and is in line with the idea that the US Patent Office has granted many patents with no or little innovation value.

Moon, S., Bermudez, J., and 't Hoen, E. **Innovation and access to medicines for neglected populations: Could a treaty address a broken pharmaceutical R&D system?** *PLoS Med*, vol. 9, No. 5 (May 2012): p. e1001218.

Available from: <https://doi.org/10.1371/journal.pmed.1001218>.

The current R&D model of new medicines is inadequate, the authors argue. In particular, there is a lack of funding for “neglected populations”. Furthermore, the uniformization of patent rules in a world of massive wealth disparities is unable to equitably distribute the costs of R&D, apart from blocking access to medicines to the majority of populations. In this sense, new approaches to access and innovations are needed, and in this context a strong component could be the proposal for an international binding treaty at WHO to address the issue in a systematic way ensuring innovation and equitable access to medicines. The paper considers four particular areas where the global R&D model needs stronger norms: affordability, sustainable financing, efficiency in innovation and equitable health-centred governance. The authors also recognize other initiatives, such as DNDi, which, although fragmented, may play an important role. The authors adopt the approach that medical R&D is to be seen as a global public good to which both fair contributions from all and fair benefit-sharing for all should ensue. This article aims to further the recommendations by CEWG and

remains relevant for current debates on R&D, as the core of the system remains largely unchanged.

MSF/DNDi. ***Fatal Imbalance. The Crisis in Research and Development for Drugs for Neglected Diseases***, Geneva: Médecins sans Frontières, 2001.

Available from: <https://www.msfaccess.org/fatal-imbalance-crisis-research-and-development-drugs-neglected-diseases>.

In 1999, MSF convened an international body of health experts to study the current state of drug R&D for diseases that affect people in the developing world. This independent body, the Drugs for Neglected Diseases (DND) Working Group, has since undertaken an analysis and made some recommendations for moving forward. When treatment options do not exist or are inadequate, a disease can be considered “neglected”, or even “most neglected” in some cases. The neglect is a result of market and public policy failure. Strategies must be developed to specifically address neglected and most neglected diseases. Recent initiatives and policies seeking to redress the R&D imbalance are outlined. Recommendations for moving forward are presented, among them: that a well-defined and needs-driven research agenda be established at the global level; that governments fulfil their responsibility to become directly and proactively involved in searching for solutions; that funding be increased for research into neglected and most neglected diseases; and that a new not-for-profit enterprise be explored as one way to address the shortage of R&D for the most neglected diseases.

OECD. ***Vers une économie fondée sur le savoir***, Paris, OECD, 2001.

This report of the OECD focuses on the knowledge-based economy and its implications for different fields and domains. It acknowledges the growing importance of R&D, closely linked to the innovation capacity, in contributing to economic progress. The report notes the existing disparities in terms of R&D investments between OECD members and industrial sectors, with specific mention of private pharmaceutical companies. Particular attention is devoted to R&D in the health domain and the linkage between R&D and biotechnological patents. The report illustrates the rise in

public spending on health R&D in recent years, in contrast with the decline in funds devoted to defence research. It concludes by stressing the growing partnership between private companies and universities in the field of scientific research, a partnership and collaboration which is increasingly transnational, just like the property of most inventions.

Opderbeck, D. W. **Patents, essential medicines, and the innovation game. Working Paper Series, Seton Hall University – School of Law, 2001.**

Available from SSRN: doi:10.2139/ssrn.458620.

Current international patent rules strike an uneasy balance between conflicting views about patents. The precarious nature of this balancing act is illustrated by the recent heated debate about the conditions under which compulsory licenses will be available for certain essential medicines under the Trade Related Aspects of Intellectual Property (TRIPS) agreement. That debate produced a compromise that will do little to fix the essential medicines problem.

This paper argues that the recent debate was misplaced because it ignored differing elasticities of demand between developed and developing country markets. Demand elasticity is a primary driver of the utility of patent rules. If demand is inelastic, strong patent protection allows the patent owner to charge a price premium and the social cost of the patent monopoly is minimized. If demand is elastic, however, the justification for strong patent protection evaporates. In a demand elastic market, the patent owner cannot sustain supercompetitive pricing, and the social cost of such pricing is high.

This paper argues that the level of patent protection in developing countries is irrelevant when there is inelastic demand and a relatively large market in developed countries. The author supports this argument with a game theory analysis of the essential medicines debate. The author's analysis shows that, at least with respect to essential medicines for which there is strong demand in developed countries, the level of patent protection in developing

countries makes no difference. The author concludes that the international patent system governing such products should allow greater flexibility for generic imitator competition in developing country markets.

Outterson, K. **Should access to medicines and TRIPS flexibilities be limited to specific diseases?** *American Journal of Law and Medicine*, vol. 34, 2008, 279. Available from:
http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1090270.

The author argues that from the perspective of public health, limiting access programs and TRIPS flexibilities to particular diseases would be quite dangerous and unnecessary. Dangerous because the diseases of the world's rich and poor countries are converging, including non-communicable diseases such as heart disease, stroke, diabetes, cancer and depression. Radically cheaper medicines for these conditions could significantly improve health in LMICs. Limitation is also unnecessary because proven tools can be deployed to preserve high-income markets while LMICs pursue equitable flexibilities.

To date, the important global legal texts retain broad application to all relevant diseases, but the some parties continue to propose disease-specific limitations, most recently in the World Health Organization's Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (the "WHO IGWG"). The WHO IGWG task is to distil the WHO CIPIH Report into a global strategy and plan of action. This article hopes to influence the final text of the IGWG Global Strategy, finding that disease-specific limitations on access programs and TRIPS flexibilities are inappropriate in markets for medicines, but disease-specific programs are important in markets for neglected disease innovation.

Pécoul, B. et al. **Access to essential drugs in poor countries – a lost battle?** *JAMA*, January 27, 1999 – vol. 281, No. 4.
Available from:
<https://jamanetwork.com/journals/jama/article-abstract/188412>.

Several important factors related to access to essential drugs in poor countries are described by Dr. Pécoul and colleagues. While drugs offer a simple, cost-effective solution to many health problems, effective treatment for many diseases is lacking in poor countries. For the majority of the world's poor and most vulnerable citizens, there is no practitioner in their community trained in the prescription of essential drugs. There are indigenous practitioners in essentially all of these countries who are experienced clinicians but not formally trained in the allopathic system of medicine. They need to be trained in the use of essential drugs if these medications are to be truly accessible to the world's poor. The development of field-based drug research is needed to determine optimum use and re-motivate R&D for new drugs for the developing world. Potential consequences for the availability of old and new drugs are expected from recent WTO agreements.

Remiche, B., ed. *Revue Internationale de Droit Economique*. Special edition: pharmaceutical patents, innovation and public health, 2001.

This special issue of the International Revue of Economic Law (RIDE) reproduces the main contributions to the symposium organized by the International Association of Economic Law (AIDE) in Toulouse at the end of January 1999 on the theme "Pharmaceutical patents, innovations and public health". Contributors include Carlos Correa, Claude Crampes, Vincenzo Di Cataldo, Jérôme Dumoulin, Jean-Christophe Galloux, Alain Gouyette, Georges Houin, Christian Huveneers, Jacques Larrieu, Marília Bernades Marques, Franz Muennich, Adrian Otten, Sylvaine Poillot Peruzzetto, Norbert Reich, Bernard Remiche, Frederick Scherer and Germán Velásquez.

Rodríguez V. **Material transfer agreements: open science vs. proprietary claims.** *Nature Biotechnology*, 2005, 23(4): 489–491.

This article deals with the very precise problem posed by material transfer agreements, which may constrain the free flow of knowledge by limiting the available mechanisms of research collaboration. The author underscores that while pharmaceutical

and biotechnological product development has been based on patents, biomedical research in academia comes from the very different tradition of open science. Research materials were often freely exchanged without formal agreements, a tendency that changed in 1970s when life science research brought academia and industry closer together. Industry defends its commercial and property interests by acquiring and protecting exclusivity in the market through patents and trade secrets, which contrasts with academics and governments' aim to preserve the flow of ideas. Material transfer agreements are a field of potential conflict between these two diverging approaches.

Scherer F. M. **The pharmaceutical industry and world intellectual property standards.** *Vanderbilt Law Review*. November 2000, 53(6): 2245–2254.

This article focuses on the link between the enforcement of IPR and the possibilities for private pharmaceutical companies to invent and produce new drugs. One of the declared goals of the IPR framework is to protect companies that have heavily invested in the development of new products. Granting these companies with exclusivity rights for a fixed period of time would allow them to recover previous investment and at the same time provide a stimulus to keep on innovating. Developed countries are not only home to all major international pharmaceutical companies, but also represent the biggest market for pharmaceutical products. This market, considered to be secure, has been driving the R&D efforts of pharmaceutical companies, leaving behind the needs of a majority of the population who, living in developing countries, do not represent an interesting market. (Abstract from *IPR, Innovation, Human Rights and Access to Drugs. An Annotated Bibliography*, WHO/EDM/PAR/2003.9).

Shashikant S. ***The Substantive Patent Law Treaty: The Dangers of Global Patent Policy Harmonization.*** TWN, 2009.

Available from: <https://www.twn.my/title2/IPR/ipr11.htm>.

Negotiations at the World Intellectual Property Organization (WIPO) to draw up a Substantive Patent Law Treaty (SPLT) have

long been bogged down by differences among WIPO member states over the scope and orientation of the agreement. As part of efforts to break the negotiating deadlock, WIPO convened an open forum in Geneva on 1-3 March 2006 to discuss the major issues which lie at the heart of the debate surrounding the SPLT.

While the forum did not lead to a resolution of the impasse, the discussions that took place there shed light on the import and potential impacts of a treaty which would harmonize patent norms the world over.

In this compilation of articles on the WIPO forum, originally written for the South-North Development Monitor (SUNS), Sangeeta Shashikant reports that many of the participating experts cautioned against global harmonization of patent laws based on the loose patentability criteria and strict protection standards of the developed countries. If effected under an SPLT, such a move, it is feared, would “export a dysfunctional system to the rest of the world”. These and other issues raised in the forum should be borne in mind in dealing with any attempts to revive the SPLT negotiations or to harmonize national patent regimes through other means.

Simon, J. H. M., et al. **Managing severe acute respiratory syndrome (SARS) intellectual property rights: the possible role of patent pooling.** *Bulletin of the World Health Organization*, 2005, 83(9): 707–710. Available from: <http://www.who.int/bulletin/volumes/83/9/707.pdf>.

This article addresses the problem that multiple patents over a genomic sequence may pose to the development of drugs. The article, which takes the case of the severe acute respiratory syndrome (SARS) as an example, states that the fragmentation of intellectual property rights may adversely affect the development of pharmaceutical products. In response, it is proposed to pose these patent rights into a patent pool to be licensed on a non-exclusive basis.

Smith, R. D., Correa, C., and Oh, C. **Trade, TRIPS, and pharmaceuticals.** *The Lancet*, vol. 373, Issue 9664, pp. 684–691, 21 February 2009 doi:10.1016/S0140-6736(08)61779-1. Published Online: 22 January 2009.

This paper focuses on options that are available to the health community for negotiation to their advantage under TRIPS, and within the presence of TRIPS-plus. (Original text.)

The World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) set global minimum standards for the protection of intellectual property, substantially increasing and expanding intellectual-property rights, and generated clear gains for the pharmaceutical industry and the developed world. The question of whether TRIPS generates gains for developing countries, in the form of increased exports, is addressed in this paper through consideration of the importance of pharmaceuticals in health-care trade, outlining the essential requirements, implications, and issues related to TRIPS, and TRIPS-plus, in which increased restrictions are imposed as part of bilateral free-trade agreements. TRIPS has not generated substantial gains for developing countries, but has further increased pharmaceutical trade in developed countries. The unequal trade between developed and developing countries (i.e., exporting and importing high-value patented drugs, respectively) raises the issue of access to medicines, which is exacerbated by TRIPS-plus provisions, although many countries have not even enacted provision for TRIPS flexibilities.

Stiglitz, J. E. and Jayadev, A. **Medicine for tomorrow: Some alternative proposals to promote socially beneficial research and development in pharmaceuticals.** *Journal of Generic Medicines* (2010) 7, 217-226. doi:10.1057/jgm.2010.21.

The authors state that the current models of pharmaceutical drug discovery display significant inefficiencies. One inefficiency is the widespread prevalence of me-too drugs. Second, some patents can act as barriers to knowledge, by slowing down the pace of new discoveries. Third, there are higher costs for the public, who end up paying double costs – subsidizing or funding research and

development (R&D) that leads to new discoveries on the one hand, and, on the other, paying the social costs of restricted access to knowledge when the discoveries are privatized. Fourth, when the market returns are the sole guide to R&D of new drugs, diseases that are prevalent in markets with weaker buying power are neglected. Thus, policymakers need to identify a new, more cost-effective and innovative productive system for R&D. Policymakers are faced with very complex choices in designing their regulations. They want to promote access to medicines, to lower costs and to encourage research. Politically, they have to balance pressure from the industry with increasingly forceful demands from health advocacy groups. The article looks at four different sorts of policies that may be used to address some of the inadequacies in the current system, especially with regard to the management of R&D: promoting prizes over patents; directing innovation toward socially beneficial outputs by adopting some form of value-based pricing; publicly funding clinical trials to reduce conflicts of interest while reducing costs; and actively managing frontier technologies to maximize positive social spill overs.

Stolley P.D., Laporte J-R. **The public health, the university and pharmacoepidemiology.** In *Pharmacoepidemiology*, Third Edition, Strom, B.L., ed. Chichester: John Wiley & Sons Ltd., 75-89, 2000.

Pharmacoepidemiology is the study of the effects of drugs on populations and of the factors influencing drug use. Its prime goals are the gathering of information leading to the protection of the health of populations, and improving the efficacy and safety of medicines. The authors state that in each country the ultimate effectiveness of drugs depends on a number of factors. These include the priorities of the pharmaceutical industry, local drug regulation and drug policies, drug supply, the priorities of the health care system, training and continuous education of health professionals, etc. These factors have a great influence on the patterns of prescribing, dispensing and use. The document argues that four processes have contributed to shaping globalization in the field of pharmaceuticals: the TRIPS Agreement, health sector reform and liberalization, moves to closer harmonization (in particular the

International Conference on Harmonization) and pharmaceutical company mergers. (Abstract from *IPR, Innovation, Human Rights and Access to Drugs. An Annotated Bibliography*. WHO/EDM/PAR/2003.9).

The Royal Society Working Group on Intellectual Property. ***Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science***. London: The Royal Society, 2003.

Available from:

<http://royalsociety.org/policy/publications/2003/keeping-science-open/>.

This report of the United Kingdom independent scientific academy looks on how intellectual property policies impact on the evolution of scientific work, paying particular attention to three areas: patents, copyright and database copyright. While accepting the potential benefits of IPR for science by, for instance, stimulating innovation, the report also warns about the possible tensions created due to their monopolistic nature. The climate of secrecy that patents might encourage can, according to the report, limit the free flow of ideas and information which are critical for productive research. At the same time, research may be constrained by patents being excessively broad, which could have a very negative impact, particularly in the early stages of development of a given discipline. With regard to the TRIPS Agreement, intended to harmonize intellectual property laws at the international level, the report wonders whether there is not sufficient flexibility or whether the flexibility accorded is sufficiently utilized. It notes that, for developing countries, the disadvantages of TRIPS implementation outweigh the possible benefits. The report concludes that the original balance established by intellectual property law, where the right-holder obtains exclusive rights in exchange for rights to the society, should be improved in order to guarantee just sufficient incentive to encourage R&D by potential right-holders while retaining a high level of benefit for society. The report considers that new intellectual property legislation that unreasonably restricts freedom of access and use of information goes against this desirable balance.

Thurrow L. Needed: a new system of intellectual property rights.
Harvard Business Review, September-October 1997, 95–103.

According to the author: “Fundamental shifts in technology and in the economic landscape are rapidly making the current system of IPR unworkable”, Suthersanen, U., Dutfield, G., Boey Chow, K., (Eds.), *Innovation Without Patents: Harnessing the Creative Spirit in a Diverse World*, Cheltenham: Edward Elgar Publishing, 2007.

This volume brings together economic thinking on innovation and legal thinking on patents. Focusing on innovation and development, this book, easy to read and full of interesting detail, provides both valuable insight into the theoretical framework of innovation as supported by intellectual property protection and contains valuable case studies of national systems of innovation in the Pacific Rim States. It introduces the debate on how far legal protection should extend to inventions considering its level of inventiveness.

The book questions the benefits of patenting for developing countries through empirical studies and analysis, and it considers the impact of intellectual property protection on the ability of developing countries manufacturers to learn to innovate. It deals with specific national and regional situations, such as those concerning Singapore, Japan, South Korea, the People’s Republic of China, the ASEAN States and Latin America ineffective. Designed more than 100 years ago to meet the simpler needs of an industrial era, it is an undifferentiated, one-size-fits-all system.

Four main reasons explain the problems with the old system: the centrality of IPR, the decline of public knowledge, the emergence of new technologies and the globalization of the economy. Thus, a new system of IPR should strike the right balance between the production and the distribution of new ideas, but should also be really enforceable, quick and efficient. A revised system should reflect diverse interests, such as public versus private knowledge, developed versus developing countries and different types of industry, knowledge and inventors. (Abstract from *IPR, Innovation*,

Human Rights and Access to Drugs. An Annotated Bibliography. WHO/EDM/PAR/2003.9).

Trouiller P. et al. **Drug development for neglected diseases: a deficient market and a public-health policy failure.** *The Lancet*, 2002, 359(9324): 2188–2194. Available from: http://www.dndi.org/images/stories/pdf_scientific_pub/2002/trouiller_p_lancet.pdf.

There is a lack of effective, safe and affordable pharmaceuticals to control infectious diseases that cause high mortality and morbidity in the developing world. The authors analysed outcomes of pharmaceutical R&D over the past 25 years, and reviewed current public and private initiatives aimed at correcting the imbalance in R&D that leaves diseases that occur predominantly in the developing world largely unaddressed. They compiled data by searches of Medline and databases of the US FDA and the European Agency for the Evaluation of Medicinal Products, and reviewed current public and private initiatives through an analysis of recently published studies. The authors found that, of 1,393 new chemical entities marketed between 1975 and 1999, only 16 were for tropical diseases and tuberculosis. There is a 13-fold greater chance of a drug being brought to market for central nervous system disorders or cancer than for a neglected disease.

The pharmaceutical industry argues that R&D is too costly and risky to invest in low-return neglected diseases, and public and private initiatives have tried to overcome this market limitation through incentive packages and PPP. The lack of drug R&D for "non-profitable" infectious diseases will require new strategies. No sustainable solution will result for diseases that predominantly affect poor people in the South without the establishment of an international pharmaceutical policy for all neglected diseases. Private sector research obligations should be explored, and a public sector not-for-profit R&D capacity promoted.

Van Overwalle, G. **Turning Patent Swords into Shares.** *Science*, vol. 330, No. 6011 (17 December 2010): pp. 1630–1631; DOI: 10.1126/science.1189592.

This article examines the decision earlier this year in US District Court to deny patent protection for isolated human genes and associated diagnostic methods, which shocked the biotech community. The case related to genetic tests for familial breast and ovarian cancer developed by the company Myriad Genetics. The product claims (used to describe the compound in question) were directed to isolated DNA containing human *BRCA1* and *BRCA2* gene sequences. The method claims (used to describe the activity exercised upon the compound) covered the process of identifying certain mutations in the *BRCA* genes. The court held that the claimed isolated DNA “is not markedly different from native DNA as it exists in nature” and constitutes unpatentable subject matter. The court also ruled that the claimed method is “directed only to the abstract mental process of comparing or analysing gene sequences”, fails the so-called “machine or transformation test” and is unpatentable as well.

Velásquez, G. **Public-Private Partnerships in Global Health: Putting Business before Health?** Research Paper 49, South Centre, January 2014. Available from: <https://www.southcentre.int/research-paper-49-january-2014/>.

Public and private sector interaction in health has always existed at the national level; in the United Nations (UN) system, public-private partnerships (PPPs) began at the end of the 1990s with the reform of the UN system launched by Kofi Annan. In response to Resolution 55/215, “Towards global partnerships”, the United Nations General Assembly asked the Secretary General “to seek the views of all Members States on ways and means to enhance cooperation between the United Nations and all relevant partners, in particular the private sector, on how to enhance cooperation with the United Nations”. The introduction of the report of the Secretary General states that “[o]ver the past decade...there has been an increase in the number of non-state actors interacting with the United Nations...such as through consultative status with governing bodies,

procurement contracts, and philanthropic-based fund raising activities”, later reiterates that “[t]he number, diversity and influence of non-state actors has grown dramatically over the past 10 years” and concludes that “[s]pecial efforts are needed to ensure that cooperation with business community and other non-state actors adequately reflects the Organization’s membership and pays particular attention to the needs and priorities of developing countries”.

Velásquez, G. **The Right to Health and Medicines: The Case of Recent Negotiations on the Global Strategy on Public Health, Innovation and Intellectual Property** Research Paper 35, South Centre, January 2011. Available from: <https://www.southcentre.int/research-paper-35-january-2011/>.

The purpose of this paper is to describe, above all, a negotiating process which many have qualified as historical. More than an analysis on the subject of public health and intellectual property, this is an analysis of a negotiating process. The negotiations of the inter-country group known as the “IGWG”, undertaken by the Member countries of the WHO, were the result of a deadlock in the World Health Assembly held in 2006 where the Member States of the WHO were unable to reach an agreement on what to do with the 60 recommendations in the report on “Public Health, Innovation and Intellectual Property” submitted to the Assembly in the same year. The intention of the Global Strategy and Plan of Action (GSPOA) which was produced by the IGWG was to substantially revamp the pharmaceuticals’ research and development system in view of the findings that this system, whose purpose is to produce medicines for diseases which affect the greater part of the world population which lives in developing countries, had failed.

These negotiations leave several questions unanswered: 1) Will the IGWG be able to address the problem of access to medicines in all its complexity? 2) Is the problem which the IGWG has identified restricted to developing countries, as suggested in different parts of the strategy, or is it a global problem which even the developed countries will have to face sooner or later? 3) And finally, what can

be the expected outcome of this exercise? Will these negotiations change the nature of the WHO?

Velásquez, G., and Seuba, X. **Rethinking Global Health: A Binding Convention for R&D for Pharmaceutical Products**. Research Paper 42, South Centre, December 2011. Available from: <https://www.southcentre.int/research-paper-42-december-2011/>.

This research paper contributes to the debate and reform process of the WHO, enabling it to respond to the health and health-policy challenges of the twenty-first century. More specifically, this paper addresses the issue of the pharmaceutical innovation system within the perspective of access to medicines, exploring possible structural changes in the current system. To do so, it addresses the question of how the constitutional powers of the WHO, which are often ignored by the organization itself, can contribute positively to a paradigm shift in biomedical research stimulation.

Webber D., Kremer M. **Perspectives on stimulating industrial research and development for neglected infectious diseases**. *Bulletin of the World Health Organization*. 2001, 79(8): 735–741. Available from: [http://www.who.int/bulletin/archives/79\(8\)735.pdf](http://www.who.int/bulletin/archives/79(8)735.pdf).

This paper summarizes thinking on stimulating industrial R&D for neglected diseases and argues that it is critical to enlarge the value of the market for medicines and vaccines through, for example, global purchase funds. The most important economic barriers to R&D are small commercial markets and severely limited individual purchasing power, even though the number of patients may be very large. Various mechanisms have been proposed to address this economic imbalance. Economic devices which reduce the cost of R&D – push factors – are useful, but this review suggests that high costs do not explain the shortfall in R&D. Economic devices which address the lack of viable markets have been termed pull factors and are designed to create or secure a market. The authors identify as a useful pull mechanism the commitment to purchase a product that meets specified criteria. Pull programmes effectively mimic the market and lead companies to favour lines of attack that they

believe will lead to marketable products. Overall, a combination of push and pull mechanisms is an attractive approach. This could combine increased funding for public laboratories, PPP in R&D, purchases of under-utilised existing products, and a pre-commitment to purchase new drugs and vaccines when developed.

Wheeler, C., Berkley, S. **Initial lessons from public-private partnerships in drug and vaccine development.** *Bulletin of the World Health Organization*, 2001, 79(8): 728–34. Available from: [http://www.who.int/bulletin/archives/79\(8\)728.pdf](http://www.who.int/bulletin/archives/79(8)728.pdf).

In recent years, venture capital approaches have delivered impressive results in identifying and funding promising health discoveries and bringing them to market. This success has inspired public sector experiments with “social venture capital” approaches to address the dearth of affordable treatment and prevention for diseases of the developing world. Employing the same focus on well-defined and measurable objectives, and the same type of connections to pool and deploy resources as their for-profit counterparts, social venture capitalists seek to use the tools and incentives of capitalism to solve one of its biggest failures: the lack of drugs and vaccines for diseases endemic to low-income populations. As part of a larger trend of partnerships emerging in health product donation and distribution, public–private partnerships for pharmaceutical development have led R&D efforts to generate more accessible and efficacious products for diseases such as malaria, tuberculosis, and AIDS. In this article, three R&D-focused partnerships are explored: the International AIDS Vaccine Initiative; the Medicines for Malaria Venture; and the newly-formed Global Alliance for TB Drug Development. The article highlights key elements essential to the success of these ventures.

2. INTELLECTUAL PROPERTY REGULATION

2.1 General

Abbott F. A. **First report (final) to the Committee on International Trade Law of the International Law Association on the subject of parallel importation.** *Journal of International Economic Law*, 1998, 607–636.

The first report on parallel imports approaches the exhaustion/parallel imports question in broad economic terms, asking whether there may be an economic and social welfare benefit to permitting IPRs holders to block parallel imports that outweighs the potential harm to liberal trade. The Report addresses each major form of IPR (patent, trademark and copyright) separately. It concludes with respect to each form that the evidence of benefits that might flow from allowing parallel imports to be blocked is insufficient to justify the potential inhibition of trade. The Report observes that most objectives which IPRs holders seek to achieve by the allocation of geographic markets can be attained through less trade restrictive means, namely through the vertical allocation of distribution territories by contract. The interests of the developing countries are a focus of the Report. Some economists have suggested that allowing rules on parallel information to enforce price discrimination in favour of developing countries may increase global economic welfare. The Report concludes that developing and developed countries are better served by open markets and the operation of comparative advantage. The Report recommends that the WTO adopt a rule precluding governments from blocking parallel imports save in certain exceptional cases, and it also suggests that further study of this issue would be desirable.

Abbott, F. M., Correa, C. M., and Drahos, P. **Emerging Markets and the World Patent Order.** Cheltenham UK and Northampton USA: Edward Elgar Publishing, 2013.

The book presents how the implementation of patent law in emerging markets, particularly BRICS (but also ASEAN and the

Middle East) affects the international patent system as a whole. The book is divided into an Introduction that highlights these changes, a contextual Part II that addresses the geopolitics and the economics of the system, as well as the role of patent offices, technology transfer, and what will change due to climate change, a Part III focused on the BRICS countries, with chapters dedicated to each of them, a Part IV on ASEAN, a Part V on the Middle East and a Part VI on the OECD response, with chapters on Europe, Japan and the USA. This comprehensive overview argues compellingly that developing countries are “adapting patent law to their own unique environments” more through the adaptive management of existing standards than through innovation of new standards and models. The field of most of this activity is the public-health sector. Emerging countries are also making use of preferential procurement policies and other industrial policy mechanisms – which are, the authors note, also fully used by OECD countries. Overall, this book illustrates a new global landscape of patent law – one perhaps also already in the midst of deep change for the last few years, for which the role of emerging economies is at least partly responsible for setting the future agenda and the global order.

Bergel, S. D., and Negro, S. C. **Propiedad Intelectual: Presente y Futuro – Homenaje al Profesor Carlos María Correa.** Buenos Aires: Editorial BdeF, 2019.

This compilation of articles on intellectual property provides an account of both general and specific topics in the field. It includes, among others: a discussion on intellectual property in free trade agreements and their protection as investment (Perez Miranda), an analysis of the “uniform” rules in intellectual property chapters in free trade agreements (Negro), reflections on the pharmaceutical industry and public health (Velásquez) and an analysis of the enforcement of intellectual property rights (Seuba). Other topics include technology transfer in Latin America before and after TRIPS (Roffe), States' regulatory power to achieve public-health goals in light of the protection of trademarks (Barrios Kübler) and the term of patent protection (Maito). The book also contains topics in the areas of biodiversity, geographical indications, trade secrets,

copyrights, plant variety protections and intellectual property in the international environment.

Bigdeli, M., Jacobs, B., Tomson, G., et al. **Access to medicines from a health system perspective.** *Health Policy Plan*, vol. 28, No. 7 (2013): pp. 692–704. doi:10.1093/heapol/czs108.

This widely cited article attempts to connect various variables related to access to medicines in a holistic manner, adopting the perspective of a health system. Intellectual property barriers are among the topics of consideration within the larger landscape of access to medicines, while the authors recognize that all elements are interconnected, occurring at multiple levels of the health system. The paper provides a framework through which the topic of access to medicines may be addressed.

Bulletin of the World Health Organization. Special Theme: **Intellectual Property Rights and Public Health**, 2006, 84(5), 337–424.

Available from:

<http://www.who.int/bulletin/volumes/84/5/itmb.pdf>.

In May 2006 the *Bulletin of the World Health Organization* was exclusively devoted to the relationship between public health and intellectual property rights. The central theme of this issue of the WHO Bulletin: what can governments, the private sector and research institutes do to meet the need for medicines, vaccines and diagnostics in developing countries in the absence of a lucrative market for these products. It brings together views from academicians, industry representatives and public health activists. Among the themes addressed are the development of drugs in absence of lucrative markets, the relation between access to medicines and human rights, the work of the WHO Commission on Public Health, Innovation and Intellectual Property and an interesting proposal to establish benchmarks to assess progress in tackling the challenges of intellectual property and access to medicines in developing countries.

Cimoli, M., Dosi, G., Maskus, K. E., Okediji, R. L., and Reichman, J. H., eds. ***Intellectual Property Rights – Legal and economic challenges for development***. Oxford: Oxford University Press, 2014.

The book reflects upon the role of intellectual property with respect to development, which can in multiple ways be negative and detrimental to innovation and development. Divided into five parts, the book starts with a theoretical and historical exploration of the relationship among IPRs, innovation and development. Part II deals with knowledge appropriation and development, including ethical incentives for innovation and the experience of the Bayh–Dole Act in the United States. Part III, the largest section, comprises experiences in the fields of public health, agriculture and green technology. In particular, the chapter on “IPRs, Public Health, and the Pharmaceutical Industry: Issues in the Post-2005 TRIPS Agenda” provides a comprehensive background and empirical data for Brazil, Thailand and India, comparing their use of TRIPS flexibilities and its constraints. Part IV deals with challenges for governance and policymaking, with articles on the multilateral agreements, preferential trade agreements and industrial policy. The Part V is a multi-authored conclusion that seeks to address the main issues regarding IP and development; despite the divergences among the editors, they reaffirm how a balanced and renewed IP system is needed, particularly for the needs of developing countries.

Commission on Intellectual Property Rights (CIPR). ***Integrating Intellectual Property Rights and Development Policy***, London: Commission on Intellectual Property Rights, 2002. Available from: http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf.

This land marking report of the *ad hoc* Commission on Intellectual Property Rights created by the UK Department of International Development addresses a number of issues related to IPR and their impact on development in a variety of fields: health, agriculture, traditional knowledge, new technologies and patent reform. The Commission considered whether the rules and institutions of intellectual property protection (IPP) can contribute to

development and reduction of poverty in developing countries. According to the report, the impact of IPP in developed countries also affects developing countries as, for example, most of the research on diseases that affect developing countries is conducted in developed ones. While accepting that the IPP system does provide incentives for research and innovation, the Commission noted that incentives have different impacts depending on the economic and social circumstances of the country where they are being applied. It considers IPR as a public policy instrument which should be translated into a means for the promotion of human economic and social rights. In this context, the report considered that a further extension of IPR should take into consideration the weaker position of developing countries and the need to explore how these countries could adapt their domestic IPP systems to their own conditions. The Commission concluded that IPP is not the only factor that affects poor people's access to health care but it can play a very negative role. Among the policies that both developed and developing countries can adopt to promote cheaper prices for medicines without adversely affecting the incentives for research on relevant diseases, the Report recommends the compulsory licensing mechanism while observing that, to date, the IPP system has done little to stimulate research on neglected diseases. (Abstract from *IPR, Innovation, Human Rights and Access to Drugs. An Annotated Bibliography*. WHO/EDM/PAR/2003.9).

Correa, C. M. ***Designing Intellectual Property Policies in Developing Countries***. TWN, Penang, 2010. Available from: https://www.twn.my/title2/books/Designing_Intellectual_Property_Policies_in_Developing_Countries.htm.

Few areas have seen greater erosion of developing countries' policy options than in the field of intellectual property (IP). Over the years, the scope for these countries to formulate their own national intellectual property policies has narrowed considerably as a result of binding international rules which impose high standards for IP protection. Nevertheless, there remains room for governments to draw up IP policies tailored to their countries' needs and level of development. The ultimate aim of these policies, stresses this book, should not be to protect the private proprietary rights of inventors

and creators per se but to design an IP regime that is instrumental to attaining the development objectives of the country.

Towards this end, developing countries must make full use of the policy-making flexibilities provided for in international IP law. This book sets out recommendations on how this can be done, in relation to the key development objectives of promoting industrial and agricultural advancement, safeguarding public health and the environment, and enhancing access to knowledge and creative works. It also looks at how developing countries can better defend their interests in global IP fora and, beyond that, steer the international standard-setting process in a more development-friendly direction.

Correa, C. M., ***How Developing Countries Can Manage Intellectual Property Rights to Maximize Access to Knowledge*** (edited with Li, Xuan), South Centre, Geneva, 2009. Available from: <https://www.southcentre.int/book-by-the-south-centre-2009/>.

This book addresses the debate on access to knowledge as a tool for development in three parts. Part I describes some of challenges for access to knowledge. Part II provides an account of recent developments in multilateral forums. Finally, Part III seeks to advance the strategic considerations that should be useful to developing countries in addressing the challenges with regard to access to knowledge.

Correa, C. M. ***Innovation and the Global Expansion of Intellectual Property Rights: Unfulfilled Promises***. Research Paper 70, August 2016. Available from: <https://www.southcentre.int/research-paper-70-august-2016/>.

The paper advances the argument that the incorporation of intellectual property into trade agreements has not brought about the promised benefits. The premises that have underpinned the global strengthening and expansion of intellectual property through such agreements – namely that the same standards of protection are suitable for countries with different levels of development and that they will boost innovation – do not match the reality. The effects of

high standards of protection – like those mandated under the TRIPS Agreement and further extended under FTAs – have been critically examined in the developed countries themselves: “[i]ntellectual property is...a social contrivance purportedly designed to increase welfare, by supposedly enhancing innovation (though...it may actually have exactly the opposite effect)”. If intellectual property does not work in developed countries as generally described by their proponents, the situation can only be worse in developing countries with weak infrastructure for science and technology, scarcity of risk capital and unsophisticated production profiles. According to the author, these countries are currently paying the price of a system which serves primarily as a platform to extract rents (in the form of royalty payments and high prices) and which does little to promote local innovation and economic development. The scenario for innovation in the pharmaceutical sector clearly illustrates that the conception underpinning the TRIPS Agreement was flawed from a global perspective. The rate of innovation has not increased – rather, it has declined, and while developing countries struggle with the high prices of medicines, the R&D necessary to address their particular health needs continues to be marginalized.

Correa, C. M. **Ownership of knowledge-the role of patents in pharmaceutical R&D**. *Bulletin of the World Health Organization*, vol. 82, No. 10, October, Geneva, 2004. Available from: <http://www.who.int/bulletin/volumes/82/10/en/784arabic.pdf>.

Both the public and the private sectors contribute to research and development (R&D) in pharmaceuticals. The public sector originates many of the discoveries of new drugs. The private sector, which focuses on development, is heavily reliant on patents. This article considers that though patents are presumed to reward genuine inventions, lax rules on patentability and shortcomings in procedures permit protection to be obtained on a myriad of minor developments. These patents, though weak and possibly invalid in many cases, are used to restrain competition and delay the entry of generic competition. Developing countries should design and implement their patent laws so as to prevent strategic patenting and promote competition and access to medicines.

Correa, C. M. ***Protection and Promotion of Traditional Medicine. Implications for Public Health in Developing Countries***, Geneva: South Centre, 2002. Available from: <https://www.southcentre.int/book-by-the-south-centre-2002-2/>.

This study highlights the value of traditional medicine (TRM) in developing countries while describing how it might be affected by the implementation of international intellectual property rights standards. The author first identifies some characteristics of TRM relevant to IPP issues. He then considers the rationale behind the need for protection of TRM under IPR (either existing or to be created). Thirdly, he discusses the extent to which existing modes of IPR (notably patents, trade secrets, trademarks and geographical indications) may be applied to TRM. Particular emphasis is given to the discussion of patents, with the other forms of IPR being analysed more briefly. Fourthly, the study presents those policy options available for the protection and promotion of TRM in the broader context of health policy. Finally, the author raises the issue of IPR protection of TRM within the framework of public health policy, considering that “policies on TRM should aim at balancing considerations of equity and public health”, protecting and rewarding knowledge without reducing access to TRM.

Correa, C. & Seuba, X., eds. **Intellectual Property and Development: Understanding the Interfaces: Liber Amicorum Pedro Roffe.**: Springer, Switzerland, 2019.

The book analyses both longstanding and emerging topics at the interface of intellectual property and development. It focuses on three main themes: (i) international trade and the transfer of technology, (ii) development and public policy and (iii) traditional knowledge and genetic resources. A wide range of experts are co-authors of the publication, with relevant insights into issues of innovation in developing countries, including in the field of pharmaceuticals. The book includes reflections on the role of patent authorities in the twenty-first century, the challenges surrounding WIPO technical-assistance activities, and the current role of technology transfer. One article in particular examines the issue of patent infringement in medical second-use cases. This is a

contemporary and comprehensive book with diverse perspectives on critical topics of relevance to understanding the broader picture of access to medicines in relation to intellectual property.

Drahos, P. **“Trust me”: patent offices in developing countries.** *American Journal of Law & Medicine* 34, 2008, 151–174.

The paper outlines the connections that have developed amongst the Trilateral Patent Offices and then one of those offices (the European Patent Office) and developing country patent offices. It argues that a relationship of technocratic trust exists between the EPO and developing country patent offices. The consequences of this for pharmaceutical patenting are considered. Two regulatory ideas for improving the quality of pharmaceutical patenting are put forward.

Foreman, M. ***Patents, Pills and Public Health. Can TRIPS Deliver?*** London: Panos Institute, December 2002.

Poverty and lack of access to healthcare are closely linked. Today, a third of the world's population has no means of obtaining essential medicines; a figure that rises to a half in the poorest countries of Africa and Asia. Ironically, it is in these countries that individuals have to spend the largest proportion of their incomes on health care. Many experts argue that the introduction of patent rules in developing countries will drive up the cost of medicines, and point out that patents prevent other companies from marketing cheaper “generic” versions of a drug. Supporters of patents reply that they are needed to protect drug company profits that pay for much-needed R&D of new drugs, and that inadequate public health systems, rather than the cost of medicines, are the biggest barrier to health care for the poor. This report examines the pros and cons of the TRIPS Agreement for the developing world. It outlines different ways of ensuring access to essential drugs for all, including the poorest. It also stresses the importance of ensuring a public debate in every country in order to put the issues of patenting, pills and public health under the spotlight. (Abstract from *IPR, Innovation, Human Rights and Access to Drugs. An annotated Bibliography*, WHO/EDM/PAR/2003.9).

Gostin, Lawrence O., J.D., Monahan, John T., J.D., Kaldor, Jenny, LL.B., DeBartolo, Mary, J.D., Friedman, Eric A., J.D., Gottschalk, Katie, LL.M., Kim, Susan C., J.D., Alwan, Prof. Ala, M.D., Binagwaho, Prof. Agnes, Ph.D., Burci, Gian Luca, J.D., Cabal, Luisa, LL.M., DeLand, Katherine, J.D., Evans, Timothy Grant, M.D., Goosby, Prof. Eric, M.D., Hossain, Sara, M.A., Koh, Prof. Howard, Ph.D., Ooms, Prof. Gorik, Ph.D., Periago, Mirta Roses, M.D., Uprimny, Prof. Rodrigo, Ph.D., and Yamin, Alicia Ely, J.D. **The legal determinants of health: Harnessing the power of law for global health and sustainable development.** *The Lancet Commissions* | vol. 393, No. 10183 (4 May 2019), pp. 1857–1910.

This comprehensive joint article by 20 authors articulates the multiple dimensions of the role played by the law with regard to global health, focusing on four different “legal determinants” to health. The overall approach of the article is that the law plays a critical role that may have either positive or negative outcomes, so the authors advocate for adequate actions and the thoughtful consideration of interests to be undertaken in the field of global health. Various global health issues are touched upon, but in particular, the articles recognize the constraints posed by intellectual property and the case of Hepatitis C, when different approaches at the national level led to drastically different health outcomes in terms of access. Other topics include health litigation in national courts, the role of international norms and the current governance of global health. The article further explores governance challenges and recommends a number of policies.

Hein, W., and Moon, S. ***Informal Norms in Global Governance: Human Rights, Intellectual Property Rules and Access to Medicines.*** London: Routledge, 2013.

The book argues that “universal access to essential medicines” was established largely as an informal, but effectively implemented, norm in global politics. Tracing the history of the access-to-medicines movement, its relation to intellectual property and human rights, the emergence of the (informal) “access norm” during the HIV/AIDS crisis and its expansion to a broader scope, the authors provide thoughtful insights and analysis of the global

governance system. They analyse the role and effect of non-state actors, particularly civil society, in shaping and sustaining the global movement of access to medicines, while directly engaging with international organizations and governments. They also pose theoretical and practical questions concerning the stability of a system based on informal norms, how to reframe it in order to incorporate innovation issues and its broader implications for how the governance of global themes is undertaken overall. In this comprehensive and influential book, the authors provide a strong case for the idea of an informal-access norm, but even more importantly, draw attention to the complexity and importance of a participatory global governance model to ensuring access to medicines for all.

Kesselheim, A. S., Avorn, J. **Biomedical patents and the public's health. Is there a role for eminent domain?** *Journal of the American Medical Association*, 2006, 295(4): 434–437.

The authors reflect on the fact that pharmaceutical industries have been criticized for restricting access to products in the face of public health crisis, namely AIDS, and distorting the patent system in pursuit of higher revenues. While recognizing that patents are useful legal constructs designed to reward innovation they suggest that, under certain circumstances the way manufacturers manage their patents can also negatively impact on public health. One example has been pharmaceutical manufacturers' aggressive management of patent rights for AIDS drugs, making them unaffordable in developing countries. The article maintains the necessity of certain limitations to intellectual property rights to protect the public welfare.

Khor, M. ***Patents, Compulsory License and Access to Medicines: Some Recent Experiences***, Penang: The Third World Network, 2007.

Available from: <https://www.twn.my/title2/IPR/pdf/ipr10.pdf>.

The author states that “Access to medicines, which is part of the human right to health services, has emerged as a major public health issue...” The TRIPS Agreement contains flexibilities for

Members of WTO to formulate the drug patent policies of their choice. In order to exercise their right to use these flexibilities, developing countries can take advantage of the policy options available to them and introduce the appropriate laws and concrete measures. In the longer term, the author suggests the revision of the TRIPS Agreement. The paper gives examples of countries which recently used such policy options and comments on the implications of bilateral FTAs on the implementation of the TRIPS flexibilities that are related to public health.

Lobo F., Velásquez G., eds. ***Medicines and the New Economic Environment***, Madrid: Civitas and World Health Organization, 1998.

This book incorporates all the papers presented in the Seminar on Social Studies on Health and Medicines held at the Universidad Carlos III, Madrid from 29 to 31 March 1995. From these papers there is one of a particular importance, *The Uruguay Round and Drugs*, by Professor Carlos Correa, this paper is the first article discussing TRIPS flexibilities and access to medicines. Experts in health economics, medicines and from the pharmaceutical industry gave presentations and discussed the effects on health services of the new economic environment and of the changing situation in the international economy and the pharmaceutical markets. The book covers the role of the state and the reform of health care systems, together with the implications for medicines, drug regulation and changes in the structure of the pharmaceutical industry.

Mani, S., and Nelson, R. **TRIPS Compliance, National Patent Regimes and Innovation**. Cheltenham UK and Northampton USA: Edward Elgar Publishing, 2013.

The book addresses the implementation of the TRIPS Agreement within four developing countries: Brazil, China, India and Thailand. It analyses both micro and macro implications of TRIPS compliance for innovation in domestic settings generally, with a particular focus on agrochemicals, automotives and pharmaceuticals. The book adopts a broad approach focused on development and evolutionary economics, providing input into how countries necessarily have

different strategies and IP policies to best suit their developmental goals, all in accordance with the TRIPS Agreement.

Maskus, K. E. **Lessons from studying the international economics of intellectual property rights.** *Vanderbilt Law Review*, 2000, 53(6): 2219–2239.

This article provides an overview of international economists' discussions on intellectual property rights protection effects, and states that many of the results remain subject to statistical and analytical uncertainty, while wide areas remain unexplored. The data evaluated suggests that the short-run impacts of TRIPS are essentially redistributive between countries, and most of the gains accrue to the United States of America and other technology developers. On the longer term, however, there are mechanisms that could enhance technical change and growth in the technology importing countries if adequate policy reforms are undertaken.

Matthews, D., and Munoz Tellez, V. **Parallel trade: a user's guide.** In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. 2007.

Available from: <http://www.iphandbook.org/handbook/ch15/p04/>.

This chapter provides guidance about parallel trade to developing country policy-makers and other stakeholders in intellectual property. What is parallel trade? And how can it be utilized to promote access to medicines and support poor farmers in developing countries? Engaging in parallel trade is an option provided by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) under the World Trade Organization. Furthermore, the 2001 Doha Declaration on TRIPS and Public Health confirmed that developing countries could use parallel imports to support public health. As a result, developing countries can ensure access to lower-priced patented and/or branded products, such as medicines and basic agricultural inputs, by incorporating legislation to allow for parallel imports. When implementing measures to facilitate parallel trade, developing

countries can establish and maintain an effective system by adequately regulating the quality, safety, and health of parallel imports. At the same time, developing countries need to prevent low-priced patented products available in their countries from entering high-priced developed country markets.

Mayne R., and Drahos, P. ***Global Intellectual Property Rights***. Oxford: Oxfam, 2002.

This book analyses the impact of the TRIPS Agreement and suggests ways in which the intellectual property system can be changed to serve development goals. It synthesizes the views of academic experts and NGOs at the cutting edge of current campaigning and debate. IPR, such as patents, can reduce access to knowledge in genetics, health, agriculture, education and information technology, particularly for people in developing countries. *Global Intellectual Property Rights* shows how the new global rules of intellectual property have been the product of the strategic behaviour of multinationals, rather than democratic dialogue. The final section of the book suggests strategies to develop more flexible standards for poor countries and to keep knowledge in the public domain.

Munoz Tellez, V. **Dispute settlement under the TRIPS Agreement: the United States–Brazil (2000) and United States–Argentina (2002) Patent Disputes**. In *Research Handbook on the Interpretation and Enforcement of Intellectual Property under WTO Rules*, Volume II. Ed. Carlos M. Correa, Edward Elgar Publishing Ltd, UK. 2010.

This Chapter analyses two pharmaceutical patent disputes initiated by the United States against Brazil and Argentina that could potentially have redefined how the TRIPS standards are to be interpreted in national law.

Musungu, S. F. **Benchmarking progress in tackling the challenges of intellectual property, and access to medicines in developing countries**. *Bulletin of the World Health Organization*, 2006, 84(5): 366–370. Available from: <http://www.who.int/bulletin/volumes/84/5/366.pdf>.

The article underscores the need of objective parameters to measure whether a particular series of actions, events, decisions or processes contribute to progress in intellectual property related challenges, namely access to drugs and pharmaceutical innovation. The article proposes six possible benchmarks with regard to the development of medicines and ensuring access to medicines in developing countries: (1) The extent to which innovation and R&D priorities are based on health needs, (2) the extent to which sustainable investments in R&D are made in areas that are of the greatest priority, (3) the extent to which access is ensured to quality medicines at affordable prices, (4) the extent of consistency with human rights obligations, particularly the obligations relating to the right to health, (5) the extent of a long-term view on the nature, costs, and distribution of medical knowledge, and (6) the extent of fair sharing of innovation costs between and within countries.

Musungu, S. F. **Rethinking Innovation, Development and Intellectual Property in the UN: WIPO and Beyond**, Ottawa: Quaker International Affairs Programme, 2005. Available from: <https://quino.org/resource/2005/1/rethinking-innovation-development-and-intellectual-property-un-wipo-and-beyond>.

The author states that intellectual property is not like health, education, food or agriculture, but a form of business regulation. As such it is a subordinate activity which should be modified, reviewed and restructured according to how it helps or hinders meeting human needs. According to the author, R&D and intellectual property policy is too important in today's knowledge society to be left to the bureaucracies of intellectual property organisations such as WIPO or intellectual property offices at the country level. It is stated that bodies dealing with health, food, education and the like should have the internal competence and ability to assess intellectual property rules and their impact and then play a major role in promoting the kind of business regulation that will help meet their fundamental development aims. Departing from this basis, the paper discusses how the mandates and competencies of key UN institutions relevant to innovation, development, and intellectual property can be brought to bear in addressing the challenges of the 21st century knowledge society.

Outterson, K. **Pharmaceutical arbitrage: balancing access and innovation in international prescription drug markets.** *The Yale Journal of Health Policy, Law and Ethics*, 2005, 1:193–291.

This Article explores key functions of pharmaceutical arbitrage, including its impact on access to drugs and pharmaceutical innovation. It affirms that several forms of pharmaceutical arbitrage are beneficial, delivering lower prices to consumers without harming innovation. More broadly speaking, it states that optimal economic incentives for innovation can be maintained while providing low income populations with greatly expanded access to patented medicines. On the other hand, it determines that the threat of pharmaceutical arbitrage is overstated and rarely observed empirically, and it describes the legal and commercial frameworks which generally obstruct arbitrage, and argues that the most dangerous threat to innovation comes from counterfeit drugs, rather than from arbitrage.

Panos Institute. *Beyond Our Means?* London: Panos Institute, 2000.

This report from the Panos Institute explores the problems of access to treatment for people living with HIV/AIDS. It puts the main focus on the issue of the high cost of treatment. The price of a drug is determined by a series of factors, including the cost of R&D, manufacture, company overheads, distributor's costs and commission, taxes and fluctuating exchange rates. Uniform patent protection under the TRIPS Agreement is seen as one of several means the pharmaceutical companies use to protect their markets and their profit. The report discusses the possibility of using compulsory licensing for AIDS-related medicines, and other ways to bring down the price of pharmaceutical products. Compulsory licensing, preferential pricing and parallel importation in themselves are not the complete solution to the problem of providing full access to treatment for AIDS. Questions of production capacity, national monopolies and manufacturing standards, and the threats of counterfeiting and the black market still need to be resolved. However, compulsory licensing, in particular, would seem to represent, on the one hand, no threat and, on the other, a potential source of income considerably greater than that which the

pharmaceutical companies currently receive from most of Africa and Asia.

Rathod, S. K. **Ever-greening: a status check in selected countries.** *Journal of Generic Medicines* (2010) 7, 227–242. doi:10.1057/jgm.2010.14.

This article examines the evergreening or extension of drug life through various product life cycle management tactics, as an issue that significantly affects the generic pharmaceutical sector. Evergreening results in delayed market access for generic companies as well as higher drug prices in market for a longer duration. Both of these results are detrimental to patients. This article looks at evergreening practices seen in various countries across the development index. It covers diverse countries on the development spectrum, ranging from countries like Canada and Australia to countries like India, Philippines and Thailand. It highlights the response that Governments and generic companies are taking to regulate and to counter ever-greening practices. The types of evergreening practices noted are follow-on or secondary patents, aggressive litigation practices, and finally patent mechanisms being linked with regulatory approval (linkage) introduced via Free Trade Agreements.

Reichman J. H. **From free riders to fair followers: global competition under the TRIPS Agreement.** *Journal of International Law and Politics*, 1997, 29(1-2): 12–93.

The article identifies the sources of tension between developed and developing countries, and evaluates the impact of the TRIPS Agreement on developing countries' capacity to acquire the knowledge and skills they need to compete on the market of technological goods. It argues that developing countries have much to gain by accepting the challenge implicit in the Agreement to become fair followers in the worldwide quest for technical innovation. The author outlines a pro-competitive strategy for implementing the TRIPS Agreement in developing countries in five points: tilt their intellectual property laws in favour of local competitors; distance themselves from protectionist measures

adopted by developed countries; institute incentive structures to stimulate innovation at the local level; resist any further elevation of international intellectual property standards beyond the TRIPS Agreement; and resort to the global information infrastructure to acquire scientific and technical knowledge.

Roemer-Mahler, A. **Business conflict and global politics: The pharmaceutical industry and the global protection of intellectual property rights.** *Review of International Political Economy*, vol. 20, No. 1 (2013): pp. 121–152. ISSN 0969-2290.

Competition within pharmaceutical companies at the global politics level is an important element for understanding the history and trends of intellectual property rights protection. Apart from highlighting the political interests of and policy role performed by private companies in international norms, the author argues that governance mitigates competition for some companies, while limiting market opportunities for others. At the same time, companies understand political activities as an integral part of their business strategies. In this sense, the rise of generic companies around the world may be understood as the main reason for the push towards a global IP regime in the 1970s and 1980s. In the 1990s, the access-to-medicines movement enabled an economically viable alternative because of the existence of generic companies, which competed with traditional ones. Under this approach, the pushback against the Doha Declaration and civil society campaign was an attempt to avoid compulsory licensing around the world as a legitimate tool, more than the risks of losing developing countries' markets. Finally, the shift towards enforcement measures, data exclusivity and counterfeit markets is due to a shift in traditional R&D pharmaceutical companies, which now wish to expand their market share in "pharmemerging markets". In this regard, this article provides an important analytical tool to understand also the contours of how companies shape international policy in intellectual property, and how there are conflicting interests within the business communities.

Roffe, P., Tansey, G., and Vivas-Eugui, D., eds. ***Negotiating Health: Intellectual Property and Access to Medicines***. London: Earthscan, 2006.

Negotiating Health offers a selection of think-pieces, analyses and proposals from scholars, international organisations, civil society and the private sector. The contributions in the first part of the book analyse the implications of patents for public health and access policies. The second part deals with the protection of pharmaceutical and agrochemical test data and its potential for delaying the entry of generic products into the market. It also examines a range of proactive options that could be taken to promote broader access to medicines. The book was prepared by the Programme on Intellectual Property Rights and Sustainable Development of the International Centre for Trade and Sustainable Development, drawing from activities in the context of its joint project with the Secretariat of the United Nations Conference on Trade and Sustainable Development.

Smith S. R. **Introduction to intellectual property, trade and access to medicines**. In ***Our Health Our Right***, APN+, 9–22.

This chapter gives a basic explanation of what the WTO requires in terms of intellectual property in relation to medicines. It then briefly explains some of the flexibilities and safeguards possible under the WTO Agreement on Trade-Related aspects of Intellectual Property Rights (TRIPS). The chapter notes the way in which countries can end up with stronger IP laws than TRIPS requires (“TRIPS-plus”) and gives a simple explanation of some of the main TRIPS-plus provisions that can make medicines more expensive.

t’Hoen, E. **Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines**. Amsterdam, Health Action International, 2016.

This comprehensive and straightforward book presents an overview of how to currently address intellectual property rules to ensure broader access to medicines. Going back briefly to the TRIPS Agreement and the Doha Declaration on TRIPS and Public Health in

2001, the author presents cases and evidence on the practical implementation of the Declaration since, including instances of government use, and the creation of the medicines patent pool. The author also presents the consequences of TRIPS-Plus provisions negotiated through trade agreements and mentions new frontier areas, such as cancer, hepatitis C and biological medicines. Finally, she presents arguments in favour of a reformed global R&D system model that ensures both innovation and access to medicines, which require drastic changes in how R&D is currently done, including proposals such as one to delink the costs of production from prices. She concludes with a call for a public health approach to IP that can go beyond the successful experience of HIV.

United Nations Secretary-General. **Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines – Promoting Innovation and Access to Health Technologies.** September 2016. Available from: <http://www.unsgaccessmeds.org/final-report/>.

Under the auspices of the UN Secretary-General, in order to propose solutions to incoherencies among international human rights, trade, IP and public-health objectives, the High-Level Panel on Access to Medicines submitted in September 2016 its final report. The report sets forth a number of concrete recommendations that widely and explicitly recognize the difficult interactions between trade and health norms, in particular those of intellectual property, and proposes a way forward. The Panel addresses the importance of the use of TRIPS flexibilities, including how countries may tailor their national laws on intellectual property, competition law, government procurement, drug regulatory laws and regulations to fulfil their public-health obligations. The Panel also describes with concern the pressure on the use of TRIPS flexibilities, despite the legitimate framework of the Doha Declaration and various human-rights instruments. Voluntary licenses, national policy coherence and the issue of IP generated from publicly funded research are also mentioned. The Panel calls for the full use of TRIPS Flexibilities. The report also addresses new incentives for the R&D of health technologies, including the proposal to delink the costs of R&D from the end product price, as well as proposing financing strategies. It

criticizes the lack of transparency in the negotiations surrounding trade and investment negotiations, as well as with regard to the costs of R&D, production, marketing, distribution and the final prices of health technologies. The report of the High-Level Panel may be seen as a milestone and a crucial document towards the effective implementation of TRIPS flexibilities, ensuring policy coherence and favouring real measures of access to health technologies.

Velásquez, G. **Access to Medicines and Intellectual Property: The Contribution of the World Health Organization.** South Centre Research Paper 47, May 2013. Available from: <https://www.southcentre.int/research-paper-47-may-2013/>.

The paper provides a historical account of access to medicines and intellectual property within the World Health Organization, which first began in 1996, right after the creation of the World Trade Organization. The author presents the main occurrences pursuant to that, including the World Health Assemblies resolutions, the WHO “Red Book”, the creation of the expression “TRIPS flexibilities”, the Commission on Intellectual Property Rights, Innovation and Public Health, the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property and the CEWG and describes numerous initiatives during implementation. The paper notes, however, that many of those activities have been halted since 2010, concluding with the need for a stronger stance by WHO on ensuring access to medicines and adopting a public-health approach to intellectual property, including a binding international treaty on the matter.

Velásquez, G. **Hold-up sur le médicament.** *Le Monde Diplomatique*, July 2003, 26–27. Available from: <http://www.monde-diplomatique.fr/2003/07/VELASQUEZ/10226>.

The author states that “The cost of pharmaceutical drugs is already a desperate problem for developing countries, but during the next two decades the rest of the world is likely to be affected. People in industrialized countries have become used over the past half-century to automatic and free access to the drugs they need. But

that right could disappear. This article sets out the perception of essential drugs and medicines as public goods, to which no exclusive rights or patents shall be applied as they primarily belong to those who are most in need. The author looks at the current situation of the AIDS pandemic, and also at other illnesses that are much less publicised but are also taking a heavy toll in terms of human lives in developing countries. Bearing this in mind, the author expresses the need for a new approach to those drugs that can make a difference for millions of people, not only as regards distribution but also invention and production. He suggests that this approach needs to be consistent with the global nature of the situation and the multiplicity of involved factors. He considers it critically urgent to change many patterns of apathy and the lack of coordination that contributed to the current extent of the AIDS pandemic.

Velásquez, G. **Intellectual Property, Public Health and Access to Medicines in International Organizations**. South Centre Research Paper 78, July 2017.

Available from: <https://www.southcentre.int/research-paper-78-july-2017/>.

This South Centre research paper by Dr. Germán Velásquez describes and analyses the mandate, programmes, strategies and activities that different international organizations, such as WHO, WTO, WIPO, UNCTAD, UNDP, UNAIDS, the UN Human Rights Council and the UN Secretary-General's High Level Panel on access to medicines (UNHLP) have undertaken on the subject of access to medicines, intellectual property, international trade rules and human rights. The paper also analyses two cases of existing inter-agency cooperation: the WHO-WTO-WIPO tripartite partnership and the WHO-UNDP-UNCTAD collaboration on developing guidelines for examining pharmaceutical patents from a public-health perspective.

VVAA, *Wisconsin International Law Journal*, **Proceeding of the 2002 Conference Access to Medicines in the Developing World: International Facilitation or Hindrance**, 2002, 20(3).

This issue of the *Wisconsin International Law Journal* collects the articles presented by various reputed authors to an international conference devoted to the topic of access to drugs. It presents diverse points of view and analyses from authors with a wide range of backgrounds, including law, economics and political science. It covers issues, such as the transfer of technology, the internationalization of the patents system and the access to medicines campaign.

World Health Organization Regional Office for South-East Asia. ***Intellectual Property and Access to Medicines: Papers and Perspectives***. World Health Organization, SEA-TRH, 2010.

Available from:

<http://apps.who.int/medicinedocs/documents/s17521en/s17521en.pdf>.

This volume contains a selection of papers used in the course “Towards an Intellectual Property Regime that Protects Public Health”. They explore the principal issues in intellectual property related to public health. This publication is intended to facilitate the conducting of further courses on the implications of intellectual property rights on access to medicines. However, it can be used as a reference for readers who, having already acquired an understanding of the basic concepts in this field, would like to gain a deeper understanding of the issues. The authors of the 17 papers contained in the publications are: Avafia, T.; Berger, J.; Correa, C.; Gopalakrishnan, N.S.; Gopakumar, K.M.; Gover, A.; Hartzenberg, T.; Krishnaswamy, S.; Khor, M.; Park, C.; Smith, S.R.; So, A.; Timmermans, K.; Velásquez, G.

2.2 The TRIPS Agreement

Abbott F. M. **The Doha Declaration on the TRIPS Agreement and Public Health: lighting a dark corner at the WTO.** *Journal of International Economic Law*, 2002, 5: 469–505.

The author states that: “The adoption by Ministers on 14 November 2001, in Doha, of the Ministerial Declaration on the TRIPS Agreement and Public Health marked a turning point in political and legal relations at the WTO. Developing country Members sent a clear signal that they would take steps to protect and advance their essential interests”. In this article, the author enumerates and describes the actors, regulations, and historic moments related to the controversy arisen from the subject of access to medicines and its relation to IPR. In addition to providing recommendations, this article offers a general overview of the components that are set into use in order to elaborate an interpretation of the TRIPS Agreement. Included in this paper are several sections such as: (1) the context of the Doha Declaration, (2) the pre-Doha setting, (3) the legal effects of the Doha Declaration, and finally (4) the post Doha Agenda.

Abbott F. M., Van Puymbroeck R. V. ***Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision***, World Bank Working Papers Series No. 61, 2005.

The Doha Declaration on the TRIPS Agreement and Public Health recognized that developing countries with insufficient or no manufacturing capacity in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing. The WTO Decision of August 30, 2003 set up a system intended to overcome these difficulties. This World Bank report guides the implementation of that system. The first part gives the reader an understanding of the issues involved and the second part provides model documents for use by governments. Four model instruments of notification are included: three for notification of the WTO as required by the Decision and one for notification of the patent or right holder pursuant to Article 31 of the TRIPS Agreement. Because

most countries will have to amend their legislation to implement the system, model amendment provisions are provided both for exporting countries and for importing countries.

Abbott, F. M., Correa, C. M. ***World Trade Organization Accession Agreements: Intellectual Property Issues***, Geneva: Quaker United Nations Office, 2007.

This paper addresses intellectual property issues that arise in the context of the WTO accession process with a view to assisting prospective WTO Members in their accession negotiations. It deals with a not widely known problem, concerning the condition imposed to certain developing countries that ask for accession to the WTO. The report states that accession negotiations have been used by certain Members as a mechanism for securing commitment to obligations in the field of intellectual property rights that are more extensive than those established by the TRIPS Agreement.

Avafia, T., Mullapudi Narasimhan, S. ***The TRIPS Agreement and Access to ARVs***. UNDP Discussion Paper, 2006. Available from: <https://www.undp.org/content/dam/aplaws/publication/en/publications/hiv-aids/the-trips-agreement-and-access-to-arvs/5.pdf>.

This paper highlights two possible areas of intervention for developing countries: a reassessment of policy space created within the TRIPS Agreement negotiations at the WTO in 2005 and exploring options outside TRIPS to increase access to treatment. As part of the reassessment of TRIPS, the paper proposes three measures. The first pertains to the utilization of TRIPS flexibilities and proposes that developing countries should be enabled to take full advantage of the flexibilities contained in the TRIPS Agreement as well as the Doha Declaration on TRIPS and Public Health of 2001, the WTO General Council Agreement of 30 August 2003 and the December 2005 decision to amend Article 31. Second, the implementation of TRIPS (as well as any amendments that take place) should keep in mind the requirements and goals of developing countries. Third, there is a need to build capacity to re-evaluate certain aspects of TRIPS to make it more development-friendly and to improve technology transfer which is yet to be taken

advantage of on a large scale. Developing countries may also explore options outside TRIPS which can be utilized in a legal environment that makes full use of TRIPS flexibilities. Such measures may include establishing an aggressive generics policy by not awarding frivolous patents and limiting provisions that create barriers for generic companies to enter and operate in markets. Lastly, existing technical cooperation networks need to be strengthened and more needs to be done to understand the impact of patent monopolies on innovation and access to drugs most needed by developing and underdeveloped countries.

Bartelt, S. **Compulsory licences pursuant to TRIPS Article 31 in the light of the Doha Declaration on the TRIPS Agreement and Public Health.** *The Journal of World Intellectual Property*, 2003, 6(2): 283–310.

With the adoption of The Doha Declaration on the TRIPS Agreement and Public Health, WTO Members stressed the need for the TRIPS Agreement to be part of the wider national and international action to address health problems afflicting many developing countries. The Doha Declaration also recognized that compulsory licenses could become useless for those countries that have no production facilities, since Article 31 of the TRIPS Agreement requires that goods manufactured under a compulsory licence shall be “predominantly for the supply of the domestic market of the Member authorizing such use”. In order to find a solution to this problem, a variety of proposals have been made. The crucial point about implementing a solution is how far a compulsory licence for export could be subject to possible abuses, such as the re-exportation of the medicines. (Abstract from *IPR, Innovation, Human Rights and Access to Drugs. An Annotated Bibliography*, WHO/EDM/PAR/2003.9).

Bourgeois, J., Burns, T. J. **Implementing paragraph 6 of the Doha Declaration on TRIPS and Public Health: the waiver solution.** *The Journal of World Intellectual Property*, 2002, 5(6): 835–864.

The magnitude of the HIV/AIDS pandemic in developing countries was not foreseen at the time of the conclusion of the TRIPS

Agreement, and was one of the paramount concerns at the origin of the Doha Declaration on the TRIPS Agreement and Public Health. In paragraph 6 of that Declaration, WTO Members recognized that countries with insufficient or no manufacturing capacities could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. Accordingly, they instructed the WTO Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002. In this article, the authors consider the options before the Council for TRIPS and conclude that a waiver under Article IX of the Marrakesh Agreement establishing the WTO is the most workable, transparent, sustainable and legally secure solution to the problem. (Abstract from *IPR, Innovation, Human Rights and Access to Drugs. An Annotated Bibliography*, WHO/EDM/PAR/2003.9).

Chaves, G. C., Oliveira, M. A. **A Proposal for measuring the degree of public health-sensitivity of patent legislation in the context of the WTO TRIPS Agreement.** *Bulletin of the World Health Organization*, 2007, 85(1): 49–56. Available from: <http://www.who.int/bulletin/volumes/85/1/06-033274.pdf>.

This article aims to propose a framework for measuring the degree of public health-sensitivity of patent legislation reformed after the WTO TRIPS Agreement entered into force. The methodology for establishing and testing the proposed framework involved three main steps: (1) a literature review on TRIPS flexibilities related to the protection of public health and provisions considered "TRIPS-plus"; (2) content validation through consensus techniques (an adaptation of Delphi method); and (3) an analysis of patent legislation from 19 Latin American and Caribbean countries.

Cornides, J. **European Union adopts regulation on compulsory licensing of pharmaceutical products for export.** *The Journal of World Intellectual Property*, 2007, 10(1):70–77.

On 17 May 2006, the European Union adopted new legislation implementing the WTO General Council Decision of 30 August 2003 – Council Regulation 816/2006. This regulation aims to reflect faithfully the compromise negotiated at the WTO without creating

an unnecessary burden for importing countries. Not all expectations articulated by the non-governmental organization community could be met. Yet, criticism against the regulation seems premature: the value of compulsory licensing rules does not depend on the number of compulsory licences granted, but on the pressure such provisions exert on patentees to make their product available at a reasonable price.

Correa, C. M. **Can the TRIPS Agreement foster technology transfer to developing countries?** In *International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime*, Keith E. Maskus and Jerome H. Reichman (eds.). Cambridge: Cambridge Press, 2005.

Since the 1970s, developing countries have expressed in various international fora their preoccupation about access to foreign technologies as a means of enhancing their technological capabilities and of narrowing the deep North-South gap in development levels. In response, developed countries argued during the Uruguay Round negotiations that strengthening and expanding the protection of intellectual property rights (IPRs) was a key condition to promote increased flows of technology transfer to developing countries. This paper analyzes the impact of IPRs on technology transfer, the implications of IPRs regimens on the flows of foreign direct investment.

Correa, C. M. ***Implications of the Doha Declaration on the TRIPS Agreement and Public Health***. Geneva: WHO, Health Economics and Drugs, EDM Series No. 12, 2002. Available from: <http://apps.who.int/medicinedocs/pdf/s2301e/s2301e.pdf>.

This study analyses the antecedents and consequences of the Doha Declaration on the TRIPS Agreement and Public Health. The author highlights how the Declaration acknowledges the seriousness of the public health problems faced by developing countries, such as AIDS, tuberculosis and malaria, while equally noting developing countries' concerns about possible implications of the TRIPS Agreement for public health in general. The report notes that the specific wording of "protection of public health" will be critical for future cases

presented to the WTO panels and Appellate Body. The author highlights the Declaration's instruction to the governing body of the WTO to address the issue of use of compulsory licensing in countries with little or no manufacturing capacity or insufficient market demand. According to the report, some critical factors for a sustainable IPP framework are a stable international legal framework, transparency and predictability of the applicable rules in exporting and importing countries and the facilitation of a multiplicity of potential suppliers of the required medicines. The study considers that the apparent concession for an extension of the transitional period, as established by Article 66.1 of the TRIPS Agreement, is deceptive, as most developing countries already grant patents for pharmaceuticals. The report concludes by underlining how the Declaration acknowledges that differentiation in patent rules might be necessary to protect public health. The author considers the Declaration a strong political statement which may be used by developing countries to adopt measures to ensure and improve access to health care, while recalling that, as a Ministerial Declaration, it will have legal effects on both administrators of the TRIPS Agreement and WTO bodies. (Abstract from *IPR, Innovation, Human Rights and Access to Drugs. An Annotated Bibliography*, WHO/EDM/PAR/2003.9).

Correa, C. M. ***Integrating Public Health Concerns into Patent Legislation in Developing Countries***. Geneva: South Centre, 2000. Available from: <https://www.southcentre.int/book-by-the-south-centre-2000/>.

This document was prepared to assist developing countries in adapting their laws to the standards set by TRIPS in relation to pharmaceuticals; as such legislative reform can have a major impact on people's access to drugs and on public health policies. It includes chapters on patentable subject matter, scope of claims, patentability requirements, disclosure of the invention, exceptions to exclusive rights, examination and observation procedures, claim interpretation, and compulsory licensing. A model of legal options is presented in each chapter to provide elements for national legislation based on the existing Agreement provisions. According to the author, priority should be given to: (1) the patentable subject

matter and the treatment of the specific cases concerning pharmaceuticals, (2) the crafting of exceptions to patents rights, especially for experimentation and early working, and (3) the development of a sound compulsory licensing system. (Abstract from *IPR, Innovation, Human Rights and Access to Drugs. An Annotated Bibliography*, WHO/EDM/PAR/2003.9).

Correa, C. M. ***Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options.*** London -New York: Zed Books, 2000.

This book is the result of research undertaken by the author to explore the implications of the TRIPS Agreement, focusing on developing countries. It explores the possible room for manoeuvre these countries have at national level. Some aspects relating to the incorporation of the Agreement's provisions into national laws are also covered. The book looks at interpretation and implementation problems that have arisen. It presents some of these problems in the implementation process faced by developing countries, particularly in Latin America and the Caribbean. Finally, issues relating to the possible revision of the TRIPS Agreement and the revision of its implementation are described and discussed. An annex includes a report (updated and revised by an Expert Group on the TRIPS Agreement and Developing Countries), on the options for implementing the TRIPS Agreement in developing countries. (Abstract from *IPR, Innovation, Human Rights and Access to Drugs. An Annotated Bibliography*, WHO/EDM/PAR/2003.9).

Correa, C. M. **Managing the provision of knowledge: the design of intellectual property laws.** In ***Providing Global Public Goods – Managing Globalization***, edited by I. Kaul, P. Conceicao, K. Le Goulven and R. Mendoza, New York: Oxford University Press, 2003.

This article considers the efficiency effects of IPRs, with a focus on patent rights. Specifically, it examines the dilemma facing policy-makers in fostering innovation: how to reconcile the restrictions that intellectual property rights impose on the use of innovations – to encourage their creation by knowledge providers– with society's interest in maximum use of innovative products. First it discusses

two types of efficiency –static and dynamic– and the different considerations for achieving them. It then examines how IPRs can influence the balance between the two types of efficiency. Next, it considers the options available under the TRIPS Agreement to increase either or both. Finally, it discusses the possibility of compulsory licensing as a means of increasing static efficiency.

Correa, C. M. **Patenting human DNA: what flexibilities does the TRIPS Agreement allow?** *The Journal of World Intellectual Property*, vol. 10, No. 6, 2007, pp. 419–437.

The TRIPS Agreement does not define what an invention is, it does not determine either how the novelty and other patentability requirements are to be applied. Hence, national laws may exclude genes– even if claimed as isolated– altogether from patent protection. If gene patents were issued, they may nonetheless apply limitations to the scope of claims, such as circumscribing protection to the uses specifically claimed by the applicant. An exception based on moral considerations is also viable, particularly in the case of human genes. In view of this flexibility, this article analyzes the policies that the countries may adopt on this subject that best suit their cultural and moral values and their technological or industrial policies.

Correa, C. M. **Pharmaceutical inventions: when is the granting of a patent justified?** *International Journal of Intellectual Property Management*, vol. 1, No. 1, 2006.

The paper elaborates on the leeway left by the TRIPS Agreement to determine how patentability requirements are applied, particularly for pharmaceuticals. In addition to claims on the active ingredients as such, numerous patents are applied in relation to pharmaceutical formulations, compositions, combinations, dosage forms, salts, polymorphs, optical isomers, metabolites, etc. Often claims encompass large families of compounds while “selection patents” cover a sub-group of previously disclosed compounds. The paper also briefly considers the case of second pharmaceutical indications. It contains some recommendations to handle these issues, taking public health interests into account.

Correa, C. M. ***Protection of Data Submitted for the Registration of Pharmaceuticals. Implementing the Standards of the TRIPS Agreement.*** Geneva: South Centre/WHO, 2002. Available from: <https://www.southcentre.int/book-by-the-south-centre-2002/>.

The protection of submitted data for the registration of pharmaceuticals is one of the most disputed patent-related issues. As a condition for registering pharmaceuticals, national authorities normally require registrants to submit data relating to drug quality, safety and efficacy. Article 39.3 of the TRIPS Agreement requires Members to establish protection for submitted test data. But this requirement is in fact narrowly drawn, and countries maintain substantial flexibility in its implementation. Article 39.3 does not require that protection be given to already public data. Protection is required only for new chemical entities. Members have considerable discretion in defining “new” and may exclude applications for second indications, formulations and dosage forms. The pharmaceutical industry and some countries have argued for much broader coverage of Article 39.3, and for a requirement that countries confer exclusive rights on originators of marketing approval data. However, these positions are not well grounded in either the text or negotiating history of TRIPS. The author highlights the long-term implications of the so-called “TRIPS-plus” protection schemes for developing countries, illustrating the different choices that policy-makers have in order to protect the interests of the originators of data without undermining competitiveness. (Abstract from *IPR, Innovation, Human Rights and Access to Drugs. An Annotated Bibliography*, WHO/EDM/PAR/2003.9).

Correa, C. M. ***Trade Related Aspects of Intellectual Property Rights.*** (Volume VI of Commentaries on the GATT/WTO Agreements) Oxford University Press, 2007.

The TRIPS Agreement stipulates the same rules for developed and developing countries. Given the profound asymmetries existing amongst WTO Member States in their levels of development, this agreement became one of the most controversial pieces of the multilateral trade system. This book provides elements for the interpretation and application of the TRIPS Agreement, having in

view the implications of different provisions in various sectors of the economy. The analysis is based on the rules of interpretation codified in the Vienna Convention on the Law of the Treaties. A basic notion underlying this book is that the TRIPS Agreement does not set forth a uniform law on intellectual property; rather it stipulates a set of minimum standards that may be differently implemented in member countries.

Correa, C. M., Velásquez, G. ***Comment préserver l'accès aux médicaments: Innovation pharmaceutique et santé publique***, Ed. L'Harmattan, Paris 2010. Available in French.

This book addresses one of the most difficult debates of contemporary society. On one hand, we seek to legitimately support innovation in the pharmaceutical industry in order to better tackle the serious problems caused by human diseases, which sometimes endanger entire populations. On the other hand, we do not want that the privileges granted to some in order to encourage them to innovate, reduce access to medicines if these privileges are misused. Is it possible to reach a balance between the promotion of innovation and the protection of intellectual property and access to medicines for all?

Lokuge, B., Drahos, P. and Neville, W. **Pandemics, antiviral stockpiles and biosecurity in Australia: what about the generic option?** *The Medical Journal of Australia*, 2006; 184 (1): 16–20.

The authors argue that compulsory licensing provisions, permitted under domestic patent law, would allow Australian generic manufacturers to start producing antivirals locally or import them from generic producers at affordable prices. Australia also has an opportunity and a responsibility to promote compulsory licensing and generic antiviral production in the Asian region, to ensure their neighbours can establish pandemic stockpiles in a timely and affordable manner.

In view of the possibility of a human pandemic of avian influenza, a first-line strategy for many countries is stockpiling of antiviral neuraminidase inhibitors (oseltamivir [Tamiflu] and

zanamivir [Relenza]), which can reduce mortality, morbidity and influenza transmission. However, global supply of the antivirals is controlled by the European-based patent owners, Roche and GlaxoSmithKline. This prevents competition in the manufacturing and distribution of antivirals and has reduced global supply capacity and affordability.

The Australian Government has acknowledged that, in the event of a pandemic, its own stockpile of antivirals will be limited and reserved for those on a confidential rationing list. Pharmacies are running out of stocks, limiting opportunities for individuals to secure supplies privately.

Drahos, P., Lokuge, B., Faunce T., Goddard, M. and Henry, D. **Pharmaceuticals, intellectual property and free trade: the case of the US-Australia free trade agreement.** *Prometheus*, 2004, 22(3): 243–257. Available from: <https://law.anu.edu.au/sites/all/files/users/u9705219/236-artprometheusfta.pdf>.

The authors argue that Australia did poorly in several key areas of the free trade agreement with the US. It failed to insulate the Pharmaceutical Benefits Scheme (PBS) from significant change, and conceded to increased intellectual property standards. The PBS, as a system of effective bargaining with multinational pharmaceutical firms, has been deeply compromised and higher drug prices can be expected over time. The intellectual property chapter strengthens the position of patent owners and undermines the evolution of a competitive generics industry. These developments are part of a broader and internationally coordinated strategy being pursued by pharmaceutical multinationals to globalize and strengthen patent rights and monopolize profits.

European Generic Medicine Association. **EGA Position Paper: TRIPS Article 39.3 does not Require Data Exclusivity Provisions. A Critical Issue for Access to Medicines.** Brussels: EGA, 2000.

The paper states that: “Article 39.3 obliges WTO Members States to protect clinical data made for registration purposes against ‘acts of

unfair competition'. Certain pharmaceutical companies are now claiming that article 39.3 requires the introduction of 'data exclusivity' provisions as operated in the EU or USA. However, 'exclusivity' and protection from acts of unfair competition are not the same and should not be confused".

This paper contends that the clause "protect such data against unfair commercial use" provided in Article 39.3 of the TRIPS Agreement is not the same as "data exclusivity" which is operated in the EU or USA. It emphasizes the difference between the "repression of unfair competition" and other forms of IPP. Furthermore, it maintains that the interpretation that Article 39.3 requires data exclusivity is beyond the agreed terms of the TRIPS Agreement. According to the author, Article 39.3 cannot be interpreted in a way to prevent a regulatory authority from using/relying on the data registered for a particular product in order to assess and register other "similar" products, as in the case of generic pharmaceuticals. The paper also includes the definition and examples of unfair competition as provided by WIPO, together with other supporting evidence.

Fellmeth, A. X. **Secrecy, monopoly, and access to pharmaceuticals in international trade law: protection of marketing approval data under the TRIPS Agreement.** *Harvard International Law Journal*, 2004, 45(2): 443–503.

This article analyzes the contested TRIPS data protection regime and proposes an interpretation aimed at achieving a balance between maximizing drug developers' incentives and fostering competition in drug markets. The article addresses the question of whether the TRIPS Agreement requires WTO Members to adopt a data exclusivity standard or whether alternative standards would comply with the TRIPS Agreement. It also analyzes the policy considerations that led to the adoption of TRIPS Article 39.3 and discusses three potential solutions to the current situation. The first is the model consistently advocated by the United States and pushed upon its trading partners – the five-year data exclusivity. The second model is based on U.S. legislation that provides for a kind of compulsory licensing through a combination of negotiation and

arbitration. The third model is a simple cost-sharing model that spreads the risk and the cost of obtaining marketing approval over all drug manufacturers equally. Finally, the author proposes a model based on re-adjustable royalties under a license.

Love, J. ***Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies***. World Health Organization. Health Economics and Drugs, TCM Series No. 18, 2005.

State practice regarding the determination of “reasonable” royalties or “adequate” remuneration is extensive and highly varied. There is no single accepted approach. Not only do countries have very different practices from each other – practices also differ considerably within countries, depending upon the industry sector or the purpose of the authorization.

In recent years, a number of countries have issued compulsory licences on HIV/AIDS drugs. Malaysia set a royalty rate of 4 per cent for such licences; Mozambique established a 2 per cent royalty, Zambia set a 2.5 per cent royalty; and Indonesia arrived at a 0.5 per cent royalty. A number of royalty systems have been adopted or proposed in recent years, and establish useful frameworks for consideration. Royalty guidelines proposed by the Japanese Patent office (1998) and UNDP (2001) set royalties from 0-6 per cent of the price charged by the generic competitor. The 2005 Canadian royalty guidelines for the export of medicines to countries that lack manufacturing capacity set royalties at 0-4 per cent of the generic price, depending upon the level of development of the importing country.

Matthews, D. **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?** *Oxford Journal of International Economic Law*, 2004, 7(1):73–107.

The need for a legal solution to the compulsory licence problem was outlined in the Doha Declaration on the TRIPS Agreement and Public Health of 14 November 2001. The agreement subsequently reached by WTO Members on 30 August 2003 in response to

paragraph 6 of the Doha Declaration is seen as key to improving access to essential medicines in developing countries. This article re-examines the negotiations that led to the 30 August agreement and assesses its likely impact. It then argues that compulsory licensing is one of a range of policy approaches that will ultimately assist in improving access to essential medicines in developing countries. The article suggests that a long-term achievement of the Doha-based negotiations is likely to be in refocusing attention on the potential of other measures that can operate alongside compulsory licensing provisions. It concludes that the debate about the Doha Declaration and compulsory licensing is part of a much wider problem and the solution requires a mix of policy initiatives.

Milstien, J., and Kaddar M. **Managing the effect of TRIPS on availability of priority vaccines.** *Bulletin of the World Health Organization* (2006). Volume: 84, Issue: 5, World Health Organization, pp. 360–365.

Available from: www.who.int/bulletin/volumes/84/5/360.pdf.

The stated purpose of intellectual property protection is to stimulate innovation. The TRIPS Agreement requires all Members of the World Trade Organization (WTO) to enact national laws conferring minimum standards of intellectual property protection by certain deadlines. Critics of the Agreement fear that such action is inconsistent with ensuring access to medicines in the developing world. A meeting convened by WHO on intellectual property rights and vaccines in developing countries, on which this paper is based, found no evidence that TRIPS has stimulated innovation in vaccine development (where markets are weak) or that protection of intellectual property rights has had a negative effect on access to vaccines. However, access to future vaccines in the developing world could be threatened by compliance with TRIPS. The management of such threats requires adherence of all countries to the Doha Declaration on TRIPS, and the protections guaranteed by the Agreement itself, vigilance on TRIPS-plus elements of free trade agreements, developing frameworks for licensing and technology transfer, and promoting innovative vaccine development in developing countries. The role of international organizations in defining best practices, dissemination of information, and

monitoring TRIPS impact will be crucial to ensuring optimal access to priority new vaccines for the developing world. The paper discusses the potential role of the WHO and other international partners in ensuring innovation in and access to vaccines in developing countries. It recommends that organisations can help ensure equitable access by: developing guidelines and best practice standards; developing and disseminating case studies on different intellectual property approaches; and monitoring the impact of TRIPS on innovation and access. The authors conclude that in order to ensure access to vaccines, it is necessary to manage the effects of the TRIPS Agreement at regulatory and strategic levels. At the regulatory level countries can use the protections guaranteed by the TRIPS Agreement to maintain access to new priority vaccines. At the strategic level, licensing and technology transfer agreements can help ensure access. (Adapted from authors.)

Milstien, J., Kaddar, M., and Kieny, M. P. **The impact of globalization on vaccine development and availability.** *Health Affairs* 25, No. 4 (2006): 1061-1069. Available from: <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.25.4.1061>.

Globalization is likely to affect many aspects of public health, one of which is vaccine-preventable communicable diseases. Investing in “weapons of mass protection” has payoffs throughout the world, in both developing and wealthy countries. Important forces include increased funding initiatives supporting immunization at the global level; regulatory harmonization; widespread intellectual property rights provisions through the World Trade Organization agreements; the emergence of developing country manufacturers as major players in vaccine supply; and the appearance of new communicable disease threats, including those potentially linked to bioterrorism. All of these forces can affect, either positively and negatively, the development and availability of vaccines. Harnessing these will be a challenge for policymakers and immunization stakeholders.

Oh, C. **Compulsory licences: recent experiences in developing countries.** *International Journal of Intellectual Property Management*, 2006, 1(1-2): 22-36.

Since the adoption of the Doha Declaration, few countries have actually made use of the so-called TRIPS flexibilities. The Cecilia Oh paper examines the use of the TRIPS flexibilities, in particular, compulsory licensing, by developing countries in the post-Doha environment. The paper discusses the legal clarity afforded by the Doha Declaration with regard to the concept of compulsory licensing and its use in the public health context. Secondly, it reviews the available information regarding cases of compulsory licensing in developing countries, to assess the effect of such licences, and for the purpose of drawing useful lessons from these cases. Finally, the paper highlights some of the factors preventing or hindering effective use of compulsory licensing in developing countries and puts forward some suggestions for structuring an effective compulsory licensing system for public health purposes.

Oh, C. The new 'deal' on TRIPS and drugs: what does it mean for access to medicines? The Third World Network Briefing Paper No. 17, 2003.

This paper deals with the significance and implications of the 30 August 2003 WTO Decision, which set up a system for the export of affordable medicines to countries which lack the capacity to produce them. The author examines the main provisions of this Decision and finds that it may still pose obstacles to the supply of cheap drugs to nations in need. The paper also deals with the problems related to compulsory licenses in Paragraph 6 of the Doha Declaration, the steps to follow in order to grant a compulsory license to import, the pertinent procedures to gain a compulsory license to export, procedural deterrents present in the Decision, and potential problems that might arise from the Chair's Statement on the Decision. The author concludes that "International public opinion will have to be the judge of whether the declarations and decisions in the WTO have had a real impact on improving people's access to affordable medicines. If it is judged that these have not been effective, it may be that pressures will then begin for more far-reaching changes."

Reichman, J. H. **Universal minimum standards of intellectual property protection under the TRIPS component of the WTO Agreement.** *The International Lawyer*, 1995, 29(2): 345–388.

According to the author, “the absorption of classical intellectual property law into international economic law will gradually establish universal minimum standards governing the relations between innovators and second comers in an integrated world market”. This article provides a detailed and comprehensive picture of all the important substantive provisions contained in the TRIPS Agreement, including patents, trademarks and the ongoing trade-based initiatives, such as the compensation expected by developing countries and the uncertainties of the dispute settlement process. A section specifically discusses the issue of compulsory licences and the new dimension of the public interest exception under the TRIPS Agreement. (Abstract from *IPR, Innovation, Human Rights and Access to Drugs. An Annotated Bibliography*, WHO/EDM/PAR/2003.9).

Roffe, P., Tansey G. and Vivas-Eugui, D., eds. ***Negotiating Health: Intellectual Property and Access to Medicines.*** London: Earthscan Publishers, 2006.

In developing countries, access to affordable medicines for the treatment of diseases such as AIDS and malaria remains a matter of life or death. Previously, access to essential medicines was made possible by the supply of much cheaper generics, manufactured largely by India, from 2005 however, the availability of these drugs is threatened as new WTO rules take effect. Informed analysis is provided by internationally renowned contributors who look at the post-2005 world and discuss how action may be taken to ensure access to medicines is not sacrificed to corporate attempts to protect business interests.

Santa Cruz, M. and Roffe, P. **A review of recent developments at the multilateral level with respect to intellectual property and the pharmaceutical industry.** *Journal of Generic Medicines* 6, 323–331, 2009.

The adoption in 1994 of the World Trade Organization's Agreement on Trade Related aspects of Intellectual Property Rights (TRIPS) meant the incorporation of intellectual property as an important component of the international trading system. It meant also an end to the exclusive treatment of intellectual property issues in the World Intellectual Property Organization (WIPO). TRIPS meant also, the end of the accepted practice of excluding pharmaceutical products and or processes from patent protection, a practice that was particularly important for developing countries. The note reviews recent developments at the multilateral level after the adoption of TRIPS, namely the adoption of the Declaration on the TRIPS Agreement and Public Health in 2001 and the subsequent decision to amend the TRIPS for the effective use of the compulsory licensing system; the adoption of the Development Agenda by the WIPO General Assembly in 2007 and related recent developments in WIPO; and finally the adoption of the Global strategy and plan of action on public health, innovation and intellectual property by the 61st World Health Assembly in 2008. One common feature of these developments is the attempt to bring some balance to the international intellectual property system that has been characterised by an upward tendency to strengthen private rights and their enforcement to the detriment of public interest considerations.

Sell S. ***Private Power, Public Law. The Globalization of Intellectual Property Rights.*** Cambridge: Cambridge University Press, 2003.

This book shows how power in international politics is increasingly exercised by private interests rather than governments. To illustrate this point, the author uses the example of the TRIPS Agreement, adopted by the WTO in 1994, which dictated to states how they should regulate the protection of intellectual property. According to the author, final approval of the TRIPS Agreement resulted from lobbying by twelve powerful CEOs of multinational corporations who wished to mould international law to protect their markets. This book examines the politics leading up to the TRIPS Agreement, the first seven years of its implementation, and the political backlash against TRIPS in the face of the HIV/AIDS

crisis. Focusing on global capitalism ideas, and economic coercion, this work explains the politics behind TRIPS and the controversies created in its wake. It is an in depth study of the influence of private interests in government decision-making, and in the shaping of the global economy.

Sridhar D. **Improving access to essential medicines: how health concerns can be prioritised in the global governance system.** *Public Health Ethics*. 2008;1(2):83–88. doi:10.1093/phe/phn012.

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This paper discusses the politics of access to essential medicines and identifies “space” in the current system where health concerns can be strengthened relative to trade. This issue is addressed from a global governance perspective focusing on the main actors who can have the greatest impact. These include developing country coalitions and citizens in developed countries through participation in civil society organisations. These actors have combined forces to tackle this issue successfully, resulting in the 2001 Doha Declaration on TRIPS and Public Health. The collaboration has been so powerful due to the assistance of the media as well as the decision to compromise with pharmaceutical companies and their host countries. To improve access to essential medicines, six C's are needed: coalitions, civil society, citizenship, compromise, communication and collaboration.

’t Hoen, E. ***The Global Politics of Pharmaceutical Monopoly Power.*** The Netherlands: AMB Publishers, 2009.

The author explains why the new global rules for pharmaceutical patenting are affecting access to medicines in the developing world. The book gives an account of the current debates on intellectual property, access to medicines and medical innovation, and provides historical context that explains how the current system emerged.

More importantly perhaps, it also analyses the latest mechanisms and policy changes that may help change the broken system of medical innovation and access to medicines today. In particular, the book highlights recent alternative mechanisms to encourage medical R&D in a way that also ensures access to the developed product – by separating the cost of research and development from the price of diagnostics, medicines, and vaccines.

This book is available under a Creative Commons License for free download or online reading.

Third World Network, ***Options for Implementing the TRIPS Agreement in Developing Countries. Report of an Expert Group on the TRIPS Agreement and Developing Countries.*** Penang: Third World Network, 1998.

The expert group was convened by the Third World Network with the objective of bringing together a team of individuals with in-depth knowledge of IPR in order to provide guidelines and proposals to policy-makers and the public in developing countries on the options available to them during the process of implementing the TRIPS Agreement. The TRIPS Agreement had been actively promoted by industrialized countries with the aim of obtaining worldwide protection for the innovations and technologies generated by their corporations. The implementation of the Agreement could have some serious adverse consequences for developing countries, including placing greater obstacles in the way of their technological development. This report points out the options available in various aspects of the TRIPS Agreement, and proposes recommendations on options which would be more appropriate to and consistent with the interests of developing countries. The report focuses on the provisions related to patents, undisclosed information, computer programmes and restrictive practices in contractual licences.

Third World Network. **TRIPS, Drugs and Public Health: Issues and Proposals**. Intellectual Property Rights Series No. 2, Penang: TWN, 2001. Available from: <https://www.twn.my/title/ipr2.htm>.

Millions of people die each year of preventable or treatable diseases in developing countries. Most patients in poor countries do not have access to the required drugs due to their high prices. These prices are set by producers who enjoy a monopolistic position over the manufacture and distribution of life-saving drugs. Control is granted by the IPR framework, developed under the TRIPS Agreement. This report discusses the policy options permitted by certain safeguards, in particular compulsory licensing and parallel importation, in order to secure access to medicines. It makes proposals for clarifying these provisions to affirm the right of developing countries to invoke them with full flexibility. The report recommends that TRIPS rules be amended in order to ensure that the TRIPS Agreement does not represent an obstacle for those developing countries that take measures to protect public health and save human lives.

Thuo Gathii, J. **How necessity may preclude state responsibility for compulsory licensing under the TRIPS agreement**. *North Carolina Journal of International Law and Commercial Regulation*, 2006; 31: 943–970.

This article argues that a rule based on rules of State responsibility under international law might provide an equally persuasive basis for improving access to affordable and essential medicines. Ordinarily, the problem of accessibility and affordability of essential medication for HIV/AIDS, malaria, and tuberculosis is viewed as humanitarian in nature and as a permissible exception to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Here, however, the article proposes the use of targeted licensing of essential medicines to facilitate access for citizens of those countries with major health pandemics without bearing State responsibility for departing from the TRIPS Agreement. This argument is based on necessity as a customary international legal principle to relieve State responsibility at a time of grave and imminent peril. While this is not the first argument for nations breaking from international law, it is, nevertheless, a necessary

consideration in the access to medicine debate in order to remedy such problems.

Timmermans, K. **Monopolizing Clinical Trial Data: Implications and Trends** *PLoS Med* 4(2):e02. Doi:10.1371/journal.pmed.0040002. 2007.

The Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement, Box 1) has to a large extent harmonized standards for intellectual property rights, including patents. For many countries, the TRIPS standards were higher than their previous standards. For example, TRIPS obliges countries to allow patenting of pharmaceuticals and imposes a minimum duration of 20 years for patents. Before TRIPS entered into force, a number of (developing) countries either did not grant patents for medicines, or had a shorter patent term. Since generic medicines can only be marketed in the absence of a patent or after its expiry, the implementation of TRIPS in those countries means it will take longer before generic versions of new medicines can enter the market. The TRIPS Agreement has therefore been criticized for its anticipated detrimental effect on access to medicines, especially in developing countries.

UNCTAD-ICTSD. **Resource Book on TRIPS and Development: An Authoritative and Practical Guide to the TRIPS Agreement**. New York: Cambridge University Press, 2005.

This book is an extremely valuable guide to the TRIPS Agreement, its background and technical aspects. It is conceived as a guide that will provide background and technical information on the main issues under discussion in TRIPS. It should be a practical tool for negotiators and policymakers in order to facilitate their informed participation in negotiations and decision-making processes. It provides the framework and options to implement the TRIPS Agreement in the broad context of growth and development. The Resource Book deals with each provision of the TRIPS Agreement, aiming at a thorough understanding of Members' rights and obligations. It clarifies the TRIPS implications for developing and least-developed countries, especially highlighting the areas in which

the TRIPS Agreement leaves some leeway to WTO Members to pursue their own policy objectives, according to their respective levels of development. In doing so, the Resource Book does not produce tailor-made prescriptions but gives guidance on the implications of specific issues and on the options available.

United Nations Development Programme (UNDP). ***Good Practice Guide: Improving Access to Treatment by Utilizing Public Health Flexibilities in the WTO TRIPS Agreement***. UNDP, 2010.

Available from:

<http://apps.who.int/medicinedocs/en/m/abstract/Js17762en/>.

This guide has been prepared by the UNDP HIV/AIDS Group at the Bureau for Development Policy. In line with the objectives of the UNAIDS Strategy 2011 – 2015 “Getting to Zero”, the Good Practice Guide explains the impact of and connection between intellectual property rights and access to treatment. The Guide analyses many of the public health flexibilities in the TRIPS Agreement and provides examples where and how have they been used by national governments. This Guide can be used by legislators, policy makers and government officials in discussions on adopting or reforming relevant legislation, in the process of formulating national IPR and public health policies, as well as in negotiating WTO accession agreements, or bilateral trade agreements that contain reference to IPR obligations. As a tool, this Good Practice Guide provides the basics.

United Nations Development Programme (UNDP). ***Human Development Report 2001. Making New Technologies Work for Human Development***. New York: UNDP, 2001.

Available from: <http://hdr.undp.org/en/content/human-development-report-2001>.

The 2001 edition of the Human Development Report of the UNDP devoted considerable attention to the issue of TRIPS and patents in connection with the Millennium Development Goals. As signatories to the TRIPS Agreement, developing countries are now implementing national systems of IPR following an agreed set of minimum standards, such as 20 years of patent protection. In this

new global regime, two problems are creating new hurdles for progress in human development. First, consensus is emerging that IPR can go too far, hampering rather than encouraging innovation and unfairly redistributing the ownership of knowledge. Second, there are signs that the cards are stacked against fair implementation of TRIPS. Views vary tremendously on the expected impact of the TRIPS Agreement on developing countries. Under TRIPS, countries can use compulsory licensing and can choose whether or not to permit patented goods to be imported from other countries where they are sold by the same company but at cheaper prices. Yet, under pressure and without adequate advice, many developing countries have not included these possibilities in their legislation, or are challenged when they try to put them to use.

Velásquez, G., and Boulet, P. **Essential drugs in the new international economic environment.** *Bulletin of the World Health Organization*, 1999, 77(3): 288–292. Available from: [http://www.who.int/bulletin/archives/77\(3\)288.pdf](http://www.who.int/bulletin/archives/77(3)288.pdf).

The new international economic and social context is likely to have an important effect on the equitable access of populations to health and to drugs, especially in developing countries. The new rules in the area of intellectual property could increase these countries' dependence still further. In implementing the TRIPS provisions at the national level, developing countries should be aware that there are some options for ensuring access to essential drugs for the poorest populations, as some provisions of the TRIPS Agreement may be used to protect public health goals. Therefore, say the authors, each country's strategy in regard to globalization in the field of the production and distribution of drugs will have to be incorporated into its national pharmaceutical policy, a component of national health policy.

Velásquez, G., and Boulet, P. ***Globalization and Access to Drugs: Perspectives on the WTO/TRIPS Agreement.*** Geneva, WHO, Health Economics and Drugs, EDM Series No. 7 (Revised). 1999. Available from: <http://apps.who.int/medicinedocs/en/d/Jwhozip35e/3.html>.

This is a pioneer study on the impact of globalization and the WTO/TRIPS Agreement on access to medicines. The authors identified and analyzed the flexibilities, unknown by the health authorities and health policy makers, contained in the TRIPS agreement to protect public health and access to medicines. This monograph, nicknamed the “Red Book” (because of its red cover) advocated new interpretations from the public health perspective, fully consistent with the TRIPS Agreement. The publication was well received and widely accepted by developing countries, academic and well known international independent experts. However, its publication provoked a heated response from US Government, and the Pharmaceutical Research and Manufacturers of America – PhRMA, in their opinion the publication was “a deeply flawed document that misleads the public and creates a false impression of how TRIPS Agreement will affect pharmaceuticals”. To address this criticism WHO Director General requested three independent legal experts (from USA, Latin America and Europe) to express their views on the document. The experts concluded that: “The WHO document is technically correct... and argues for a full compliance with TRIPS Agreement in a manner that is also consistent with public health requirements”. They added that the publication “is a clear, well-structured and informative document on the TRIPS Agreement, extremely useful for health authorities and other readers in developing countries. The main message of the publication is that the public health concerns should be a priority consideration when interpreting and implementing the TRIPS Agreement.

Velásquez, G., and Correa, C. M. ***Accès aux médicaments: entre le droit à la santé et les nouvelles règles de commerce international***. Ed. L'Harmattan, Paris 2009. Available in French.

In recent years in the WTO Doha negotiations, health and trade have been competing; talks have aimed to determine which of the two issues was prevailing and what health exceptions should be conceded. It is now recognized that the right to health is one thing and trade expansion a different thing. Access to health and medicines are citizen rights enshrined in many international treaties and recognized by the vast majority of States.

This book comprises two parts. The first part shows how to read the TRIPS Agreement from a public health perspective. It also aims to identify how much policy space is given to States in the regulation of intellectual property protection. The second part analyses the impact of the Declaration on TRIPS and Public Health on access to medicines. Will these agreements affect their production and availability? Will they boost research and development (R&D) for medicines designed to address priority issues in public health? Will these agreements lead to an increase in drug prices? Will there be an impact on least protected populations' access to health and medicines in developing countries?

Verma, S. K. **Exhaustion of intellectual property rights and free trade – Article 6 of the TRIPS Agreement.** *International Review of Industrial Property and Copyright Law*, 1998, 29(5): 534–567.

This study examines the issue of IPR exhaustion in the GATT/TRIPS context, and tries to analyse whether territorial exhaustion fits into the GATT stated objective of free trade, its legality under the GATT/WTO provisions, and its effects on developing countries. The author argues for world-wide rather than territorial exhaustion, for the sake of free trade and international competition. In this context, the study first briefly discusses the concept of IPR exhaustion and current practice thereon, as exhibited in the legal systems of the EU, Japan and the USA. It follows an analysis of the legal and economic commitments to international exhaustion within the GATT/WTO framework. Finally, the issue is examined from developing countries point of view.

Weissman, R. **Public health-friendly options for protecting pharmaceutical registration data.** *International Journal Intellectual Property Management*, 1(1-2), 2006: 113–130.

To gain marketing approval, generic firms typically rely on the clinical safety and efficacy testing data that brand-name pharmaceutical companies previously submitted (registration data). Big Pharma and the US Government are pushing developing countries to provide brand-name companies with a minimum of five years exclusive rights to registration data. But restrictions on use of

registration data delay the introduction of price-lowering generic competition. This paper considers public-health friendly alternatives, emphasising a cost-sharing approach, in which generic firms have an absolute right to use registration data, but must pay a proportionate share of the cost of generating the data.

World Health Organization. **Network for monitoring the impact of globalization and TRIPS on access to medicines. Meeting Report, Thailand, February 2001.** Geneva: WHO, Health Economics and Drugs, EDM Series No. 11, 2002.

Available from: <http://apps.who.int/medicinedocs/en/d/Js2284e/>.

At a meeting held in Bangkok in February 2001, WHO initiated the process to monitor and analyse the impact of trade agreements on access to drugs in partnership with four WHO collaborating centres in Brazil, Spain, Thailand and the United Kingdom. The meeting established that a network, through the individual and collective work of the Collaborating Centres, would undertake research that shed light on four questions: patents and prices, patents and generics, TRIPS and drug development and TRIPS and technology transfer. The participants developed a harmonized model of selected indicators to be adapted according to the characteristics of different regions. These indicators are intended to offer important information, though of course not definitive answers, regarding the four questions. This report seeks to explore one element of this stark reality: the lack of R&D into drugs to treat the diseases of the poor. Recent initiatives and policies seeking to redress the R&D imbalance are also outlined. Public-private partnerships (PPP) have been successful in mobilizing public and private sector expertise around certain diseases. Recommendations for moving forward are presented, including the need for a well-defined and needs-driven research agenda. (Abstract from *IPR, Innovation, Human Rights and Access to Drugs. An Annotated Bibliography*. WHO/EDM/PAR/2003.9).

Yusuf A. A., and Correa C. M. ***Intellectual Property and International Trade: TRIPS Agreement***, Second Edition, Alphen aan den Rijn – London: Kluwer Law International, 2007.

Comprising 14 chapters contributed by a panel of experts representing diverse parties, *Intellectual Property and International Trade* is the second edition of a treatise published in 1998. This volume, which incorporates the analysis of key provisions resulting from dispute settlement procedures, offers a framework for understanding the background, principles, and provisions of the TRIPS Agreement. It incorporates the analysis of a broad range of topics, such as substantive standards established under the TRIPS Agreement; enforcement measures; legislative latitude allowed to Member States; protection of copyrights and related rights; protection of trademarks, geographical indications and industrial designs; patent protection and conditions and limitations of compulsory licences; protection of integrated circuit design; protection of confidential (undisclosed) information; interface between competition law and intellectual property protection; implications of the Agreement on the realization of human rights; and its relation with the protection of public health. In general, the authors emphasize the implications of the Agreement for different groups of countries, especially for developing countries, and pay particular attention to the degree of autonomy left for Member States in the implementation of the various provisions of the Agreement.

2.3 TRIPS Flexibilities

Bhaven, S., and Shadlen, K. **Secondary pharmaceutical patenting: A global perspective.** *Research Policy*, vol. 46, No. 3 (April 2017), pp. 693–707.

This evidence-based article conducts an assessment of existing measures to curb secondary patents that may extend periods of exclusivity and limit access to medicines. Comparing samples from international patent applications in the USA, Japan and the European Patent Office (EPO) and corresponding filings in India, Brazil and Argentina, three countries that adopt restrictions on secondary patents (section 3(d) of the Patent Law, Prior Consent by the health regulatory agency and guidelines on patentability criteria

that restrict second medical uses, respectively), the authors conclude that there is actually a limited effect, with Argentina the most successful case. The reasons for the findings are that the specific provision to limit secondary patents is usually not the principal determinant of grant rates, i.e. there is no major difference between the grants of primary and secondary patents, and that other provisions, such as the general inventive step and novelty tests, may have proven more relevant. The authors then propose that other procedural aspects of patent systems are important for outcomes in the countries. This is an important study that highlights that the role of avoiding secondary patents without real innovation cannot rest on the shoulders of one specific exclusive norm or approach, but must rather be part of a larger ecosystem. Furthermore, they recognize that Section 3(d) and Prior Consent may indirectly affect the whole examination process, subjecting them to more scrutiny and signalling a higher threshold. It is important to note, however, that the conclusions of the authors do not dismiss the importance and relevance of such provisions, nor do they question its legitimacy in light of international law. It provides, however, input on how to design comprehensive patent policies that may be more efficient in curbing wrongfully granted patents.

Correa, C. M. **The Bolar Exception: Legislative Models and Drafting Options.** South Centre Research Paper 66, March 2016. Available from: <https://www.southcentre.int/research-paper-66-march-2016/>.

The basic principle of patent law is that once the term of a patent has expired, the protected subject matter becomes a part of the public domain. Hence, it can be freely used, including for commercial purposes, without interference by the former patent owner. This allows competitors to enter the market immediately after such expiry, eventually leading to lower prices for consumers and welfare gains. Pharmaceutical products, however, cannot be marketed without prior authorization from the relevant regulatory agency. Such authorization is conditional upon the submission and approval of an application that normally must be accompanied by certain pieces of information. Regulatory requirements differ among countries, and, despite some efforts towards harmonization, there is

considerable diversity with respect to what evidence is required, the applicable procedures and how long it can take to obtain the approval. The interface between the regulations for the marketing approval of medicines and patent law explains the need for what has been termed as the “early working” or “Bolar exception”. If a producer of a generic or similar version is bound to wait until the last day of the term of patent(s) covering a pharmaceutical product, the owner of expired patent(s) will enjoy a *de facto* additional period of monopoly power, as long as a generic version of the product obtains market permission from the regulatory authority. During this period there can be no competition and, hence, the owner of the expired patent may continue to charge a monopolistic price. Since governments and consumers would benefit from lower prices as the result of generic competition, the article argues that the Bolar exception may play an important role in reducing the burden on health budgets and increase access to more affordable pharmaceuticals.

Correa, C. M. ***A Guide to Pharmaceutical Patents***. Geneva: South Centre, 2012.

Despite the decline in the number new chemical entities discovered for pharmaceutical use, there is a significant proliferation of patents on products and processes that cover minor, often trivial, innovations. Some patents protect – through a single broadly defined claim – millions of untested compounds. Others create monopolies for new uses of known products. One factor explaining such a proliferation is the latitude with which some patent offices and national courts apply the patentability requirements. Thus, legal fictions weaken the novelty standards; technical developments that are obvious to a person skilled in the chemical or pharmaceutical fields are deemed “inventive”. The implications of this trend for public health are significant, since in many cases such patents are aggressively sued to delay or block generic competition that brings down the prices of medicines.

This book examines in detail the purpose and characteristics of the patentability standards and analyses typical claims in pharmaceutical patents. It recommends ways to implement such

standards in a manner that avoids the grant of patent right on developments which are genuine innovations or which are not properly described.

Correa, C. M. ***Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective***, Working Paper, Geneva: ICTSD – WHO – UNCTAD, 2007.

Available from: <http://ictsd.org/i/publications/11393/>.

In response to growing concerns about the proliferation of patents that protect minor or obvious variants of existing drugs or processes, this document provides a set of public health-sensitive guidelines for the assessment of some of the common types of pharmaceutical patent claims. Patents quality is basic so as not to prevent generic competition, which is fundamental to increase access to affordable medicines. The document discusses the scope allowed to WTO Member countries to determine the standards under which the novelty and inventive step of claimed inventions are assessed. It also provides examples of different categories of patent claims for pharmaceutical products, indicates the practice of some patent offices, and includes recommendations for each category of claims. The guidelines proposed do not suggest the application of a new requirement of patentability, but rather to take into account specific considerations relating to innovation in pharmaceuticals.

Correa, C. M. **Implementing Pro-Competitive Criteria for the Examination of Pharmaceutical Patents**. South Centre Research Paper 64, February 2016. Available from: <https://www.southcentre.int/research-paper-64-february-2016/>.

This paper discusses the criteria for implementing the patentability requirements with regard to patent applications covering products and processes, as well as the use of pharmaceutical products. The adoption of rigorous criteria with this purpose is important for four main reasons. First, although pharmaceuticals share common features with other inventions, there are unique elements in patent claims relating to pharmaceuticals, determined by their intended use. Second, a set of examination criteria will help speed up patent

procedures, increase uniformity in the treatment of applications and offer applicants greater certainty about the possible outcome of the procedures. Third, there is a proliferation of patent applications in the field of pharmaceuticals for polymorphs, salts, formulations and so on, which are often made to prevent generic competition rather than to protect genuine inventions. So-called “evergreening” patents do not contribute to the technological pool, and they limit the market entry of generic products. Fourth, given the impact of patents on the availability, accessibility and affordability of treatments and technologies, the manner in which pharmaceutical patent applications are examined can have critical implications for public health. Patent offices and examiners play vital roles in ensuring an appropriate balance between protecting inventions and incentivizing innovation on the one hand and promoting accessibility and affordability of treatments and health technologies on the other. This balancing process is also important for achieving broader development priorities, from national efforts to promote research and development (R&D), technology transfer and pharmaceutical production, to achieving universal health coverage. Several countries (e.g. Argentina, Ecuador, India and the Philippines) have adopted legislation or policies for examining patent applications relating to pharmaceutical products and processes in a manner that accounts for public-health considerations. Analysis of pharmaceutical patent claims has shown that the proper application of patentability standards can prevent the grant of “poor quality” or trivial patents, which, by preventing the timely entry of generic competition, may harm public health. Importantly, the application of the discussed criteria would not mean modifying the standards of patentability established by patent law or adding additional standards. Instead, they aim to ensure the correct application of those standards in view of the specific nature of the claimed subject matter and the public-health relevance of the decisions.

Correa, C. M., ed. ***Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing***. Geneva: South Centre, 2013.

This book examines patent trends and the use of compulsory licenses relating to pharmaceuticals in five developing countries:

Argentina, Brazil, Colombia, India and South Africa. It finds a number of common features and problems and shows how the application of rigorous standards of patentability may contribute to the protection of public health by promoting local production and competition. Apart from the case studies, the book offers a general chapter on the proliferation of patents (associated with reflexions on the adequate inventive step and compulsory licenses) and a chapter on how to promote local pharmaceutical capacity in developing countries and how strengthening patent standards are an alternative route to compulsory licenses.

Correa, C. M. ***Public Health Perspective on Intellectual Property and Access to Medicines – A Compilation of Studies Prepared for WHO***. Geneva: South Centre, 2016.

The book compiles various studies prepared for the WHO on the intersection of IP and access to medicines. Chapter I, “The Uruguay Round and Drugs”, is a pioneering study from 1997 of how the TRIPS Agreement affects access to medicines. Chapter II, “Trends in Drug Patenting”, from 2001, analyses various cases of patenting in medicines, including salts, prodrugs, formulations and isomers. Chapter III, “Protection of Data Submitted for the Registration of Pharmaceuticals. Implementing the Standards of the TRIPS Agreement” (2002), deals with Art. 39.3 of the TRIPS regarding the exact commitment by countries on the issue of data protection: rejecting the idea that data exclusivity protection is required, the article allows policy space for countries to be compliant through other measures, such as a trade secret regulation. Chapter IV, “Implications of the Doha Declaration on the TRIPS Agreement” (2002), discusses the content and main forms of implementation of the Declaration, particularly with regard to Art. 39.3, as well as areas not covered by the instrument. Chapter V, “Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health” (2004), discusses practical steps to be taken to use the mechanisms established by Paragraph 6 of the decision. Chapter VI, “Guidelines for the Examination of Pharmaceutical Patents” (2005), contains guidelines that received input by dozens of representatives from various institutions to achieve examination procedures in

accordance with public-health objectives. Chapter VII, “Guidelines for the Application and Granting of Compulsory Licensing and Authorization of Government Use of Pharmaceutical Patents” (2009), provides guidelines on how to implement such TRIPS flexibilities. Notably, these articles are all available as stand-alone pieces (some of which are referred to separately in this bibliography). Nonetheless, this compilation provides an important historical account and a number of policy recommendations that remain useful to date.

Correa, C. M. **Tackling the Proliferation of Patents: How to Avoid Undue Limitations to Competition and the Public Domain.** South Centre Research Paper 52, August 2014. Available from: <https://www.southcentre.int/research-paper-52-august-2014/>.

The steady increase in patent applications and grants taking place in developed and some developing countries (notably in China) is sometimes hailed as evidence of the strength of global innovation and of the role of the patent system in encouraging it. Such an increase, however, does not correspond with a genuine augmentation in innovation. It points, instead, to a major deviation of the patent system away from its intended objective: to reward those who contribute to technological progress by creating new and inventive products and processes. Firms are increasingly using patents for strategic purposes. In this context, the paper points out measures to reduce the proliferation of patents, including raising the standards of patentability, involving other public authorities in examination or litigation and increasing registration and maintenance fees.

Gurgula, O. **The “Obvious to Try” Method of Addressing Strategic Patenting: How Developing Countries Can Utilise Patent Law to Facilitate Access to Medicines.** South Centre Policy Brief 59, April 2019. Available from: <https://www.southcentre.int/policy-brief-59-april-2019/>.

The current patentability standards for pharmaceutical inventions, as well as the strategic patenting used by pharmaceutical companies, have substantially affected access to affordable

medicines. This has been especially detrimental to developing countries, which are under significant pressure to remain compliant with their international and bilateral obligations while also providing their people with essential drugs. Developing countries may choose from a range of various mechanisms to facilitate such access. This policy brief suggests that one such mechanism is strengthening the obviousness requirement by applying the “obvious to try with a reasonable expectation of success” test to pharmaceutical follow-on inventions. It is argued that the application of this test may be an effective tool in addressing the negative effect of strategic patenting. It may help prevent the extension of patent protection and market exclusivity of existing drugs by pharmaceutical companies and, as a result, may open such medicines up to generic competition.

Kupecz, A., et al. **Safe harbors in Europe: An update on the research and Bolar exemptions to patent infringement.** *Nature Biotechnology*, vol. 33 (2015), pp. 710–715.

The article compares various different European Union countries’ national legislation on research and Bolar exemptions, two recognized TRIPS flexibilities. As the first refers to an exemption of scientific research from patent-infringement claims, the second refers more specifically to clinical trials for the development and approval of a generic or biosimilar drug. These provisions are therefore critical for the rapid entry into the market of generics and represent major economic interests for countries with pharmaceutical industrial capacity. The article presents the main differences (research **on** or research **with** a patent, the use of research tools and exemptions for academia) and argues that many issues have yet to be resolved. More importantly, they serve as examples of how developing countries adopt different approaches in enacting such flexibilities.

Khor, M. ***Compulsory License and “Government Use” to Promote Access to Medicines: Some Examples.*** Penang: Third World Network, 2014.

The book contains a useful compilation of national experiences with the use of compulsory licenses and government use, two recognized TRIPS flexibilities, in order to promote broader access to medicines. The book described the cases of Malaysia, Indonesia, Thailand, Zimbabwe, Ghana and Brazil, but also United States and Italy, two developed countries (which typically are considered not to make use of such provisions, but which in fact do so widely in various ways). The book also contains an appendix with some other recent cases on compulsory licenses, including Ecuador, India and Zambia. The publication also debates some national public-health measures that are TRIPS-consistent, such as importing a drug and local manufacture, as well as negative implications of bilateral FTAs on TRIPS flexibilities.

United Nations Development Programme. **Guidelines for the Examination of Patent Applications Relating to Pharmaceuticals: Examining Pharmaceutical Patents from a Public Health Perspective.** New York, 2016. Available from: <https://www.undp.org/content/undp/en/home/librarypage/hiv-aids/guidelines-for-the-examination-of-patent-applications-relating-t.html>.

This follow-up to the 2007 “Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective” takes into account the developments since the publication of the previous document. It includes new examples of patent applications and/or grants and analysis of and references to initiatives in different countries that have adopted policies and/or laws that seek to factor in public-health considerations in the examination of patent applications. It reinforces the arguments deployed in the 2007 Guidelines and aims to further them in new settings.

United Nations Development Programme. **Using Competition Law to Promote Access to Health Technologies – A Guidebook for Low-and Middle-Income Countries.** New York, May 2014.

This resource guide provides an account of the emerging notion of using competition law to promote access to health technologies, dealing in particular with the abusive anticompetitive practices that

patent-holders may incur. The book contains comparative analyses through cases studies, the policy space to legislate in competition law under international law, an account of the anticompetitive behaviours and the remedies available for redress, the definition of “market” and how to advance frameworks in the low- and middle-income country context.

Velásquez, Germán. **Guidelines on Patentability and Access to Medicines**. South Centre Research Paper 61, March 2015.

Available from: <https://www.southcentre.int/research-paper-61-march-2015/>.

Until recently, the link between the examination of patents carried out by national patent offices and the right of citizens to access medicines was not at all clear; they were two functions or responsibilities of the State that apparently had no relationship. Examining the growing literature on intellectual property and access to medicines, it seems that the analysis of one actor has been left out: the patent offices. The reason is clear: patent offices are administrative institutions. Patentability requirements are not defined by patent offices, but frequently by the courts, tribunals, legislation or treaty negotiators. There is now greater understanding that the examination of patents and the role played by patent examiners are key elements that could facilitate or obstruct access to medicines. Given the effect of pharmaceutical patents on access to medicines, the article argues that patent offices should draw up public policies and strategies that respond to national health and medicine policies.

2.4 TRIPS Plus and Free Trade Agreements

Abbott, F. M. *Intellectual Property Provisions of Bilateral and Regional Trade Agreements in Light of U.S. Federal Law*. Geneva: UNCTAD-ICTSD, 2006.

Available from: <http://ictsd.org/i/publications/11732/>.

This paper examines recent bilateral and regional FTA containing intellectual property provisions from the perspective of United States law and policies. Professor Abbot points out that recent US bilateral and regional FTA include substantial commitments in the field of intellectual property rights which exceed those required by the TRIPS Agreement. This study suggests that it is not only the public in developing countries that encounters risk from these FTAs, but also the U.S. public. The United States is increasingly bound by a set of highly restrictive intellectual property and regulatory commitments that may not over time be seen to be consistent with the American public interest. According to this paper, the USTR assures the United States Congress that the agreements do not tie the hands of the domestic legislator, yet it is almost inevitable that when Congress considers changing domestic law, arguments will be made by industry groups that to do so may violate America's international obligations and damage the national interest. Congress may choose to ignore U.S. international obligations, but it would be surprising if Congress were not reluctant to do so.

Abbott, F. M. **Toward a new era of objective assessment in the field of TRIPS and variable geometry for the preservation of multilateralism.** *Journal of International Economic Law*, 2005 8(1):77-100.

This article gives some suggestions regarding ways in which the atmosphere surrounding TRIPS negotiations and implementation might be improved. Principal among them is the objective impact assessment of new IPRs treaties, particularly those containing TRIPS-plus provisions. Professor Abbot states that new agreements concerning IP rights should be subject to objective impact assessment, taking into account that IP rules have significantly different public welfare implications depending on their field of application and the level of development of the implementing country.

Abbott, F. M. **The WTO medicines decision: world pharmaceutical trade and the protection of public health.** *American Journal of International Law*, 2005, 99(2): 317-358.

This article firstly analyzes developing country negotiating strategy regarding the August 30, 2003 Decision in light of the result achieved, and draws lessons from that experience. The article also considers that Decision in the context of U.S. trade policy toward the use of bilateral and regional arrangements to correct what the United States perceives as specific deficiencies in WTO rules, with particular reference to the TRIPS Agreement. The article considers this trend from the standpoint of developing countries, which have substantially increased their negotiating effectiveness in Geneva but have yet to come to grips with the U.S. forum-shifting strategy. The success of this strategy to date suggests that economic and political power remains a key factor in determining the outcome of trade negotiations and that the United States may be more effective in exerting its power in bilateral or limited multilateral settings than at the global multilateral level. Finally, it also considers ways that developing countries might address U.S. efforts to restrict flexibilities regarding TRIPS and public health in bilateral and regional settings.

Avafia, T. The potential impact of the proposed US-SACU FTA on public health in Southern Africa. A Tralac working paper, 2004.

This Working Paper examines the potential impact of the proposed Free Trade Agreement (FTA) between Southern African Customs Union (SACU; comprised of South Africa, Botswana, Lesotho, Namibia and Swaziland) and the United States from the perspective of public health. Avafia expresses concerns about the possible impact of the FTA on public health in the SACU region. He draws particular attention to the impact that the proposed FTA is likely to have on the ability of SACU countries to access the most affordable essential medicines required to address urgent public health concerns. Avafia goes on to say that it would be imprudent to enter into a bilateral agreement that contains less favourable provisions on essential medicines than those found in the multilateral arena such as the Doha Declaration on TRIPS and Public Health and the WTO General Council Decision of 30 August 2003.

Bradford V., and Lee K. **TRIPS, the Doha Declaration and Paragraph 6 Decision: what are the remaining steps for protecting access to medicines?** *Globalization and Health*, 2007, 3:3.

Available from:

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1892549/>.

This article states that, despite the important clarifications of the TRIPS Agreement provided by the Doha Declaration and the Decision on the Interpretation of Paragraph 6, the actual implementation of TRIPS safeguards to improve access to medicines remains uncertain. It also stresses the concerns posed by that so-called TRIPS-plus provisions contained within many regional and bilateral trade agreements, which may be further undermining the capacity of the poor to access affordable medicines. This paper reviews policy debates among governments, nongovernmental organisations and international organisations from 1995, and notably since 2003, surrounding access to medicines and trade agreements. The provisions for protecting public health provided by the Doha Declaration and Paragraph 6 Decision are reviewed in terms of challenges for implementation, along with measures to protect intellectual property rights under selected regional and bilateral trade agreements.

Correa, C. M. **Expanding patent rights in pharmaceuticals: the linkage between patents and drug registration.** In *The Development Agenda: Global Intellectual Property and Developing Countries*, Neil Netanel (ed.). Oxford University Press, 2008.

In some developed countries, the patent owners' exclusive rights have been stretched by allowing them to block the marketing approval of competing pharmaceutical generic products. This creates a "linkage" between patent protection and drug approval, two separate areas of regulation with distinct objectives. This form of "linkage" has been systematically introduced in the free trade agreements signed by the USA with a number of countries, often under conditions that are more stringent than those applicable in the USA itself. This chapter examines the judicially-based "linkage" implemented in the USA and Canada, and the administrative

regimes generated by the referred to agreements. The implications for public health in developing countries may be significant, particularly as patents on variants of existing pharmaceuticals may be unduly used to exclude competition of low priced generic medicines.

Correa, C. M. **Implications of bilateral free trade agreements on access to medicines.** *Bulletin of the World Health Organization*, Volume 84, Number 5, May, Geneva, 2006. Available from: <http://www.who.int/bulletin/volumes/84/5/399.pdf>.

The WTO TRIPS Agreement mandated the introduction of protection of intellectual property rights, notably patents, for pharmaceutical products. While the implications for the access to medicines contained in the terms of this Agreement raised significant concerns, a recent new wave of free trade agreements, negotiated outside the WTO, requires even higher levels of intellectual property protection for medicines than those mandated by that Agreement. The measures involved include the extension of the patent term beyond 20 years; prohibition of use of test data on drug efficacy and safety for certain periods for the approval of generic products; the linkage between drug registration and patent protection; in some cases, limitations to the grounds for granting compulsory licenses. This article reviews some of these measures that further limit the competition of generic products and discusses their possible implication for access to medicines.

Correa, C. M. **Intellectual Property in the Trans-Pacific Partnership: Increasing the Barriers for the Access to Affordable Medicines.** South Centre Research Paper 62R, July 2017. Available from: <https://www.southcentre.int/research-paper-62r-july-2017/>.

Most free trade agreements (FTAs) signed by the United States, the European Union and the members of the European Free Trade Association (EFTA) in the last 15 years contain chapters on intellectual property rights with provisions applicable to pharmaceuticals. Such provisions considerably expand the rights recognized of pharmaceutical companies under the TRIPS

Agreement established in the context of WTO. The text on intellectual property of the Trans-Pacific Partnership (TPP) goes further than those FTAs. It reflects the ambition of such companies to obtain even higher levels of protection. This paper discusses some characteristics of the TPP negotiations and their main outcomes and how the adopted TRIPS-Plus provisions may impede access to medicines, notably in developing countries that may become parties to that agreement.

Correa, C. M. **Modelling Patent Law through Investment Agreements.** In *Investment Treaties – Views and Experiences from Developing Countries*. Geneva: South Centre, 2015.

The article concerns how bilateral investment treaties, and the compensation claims that rise thereof on the basis of intellectual property as investment, may ultimately harm public-health policies that are legitimate tools, and furthermore, how many of these treaties have promises to developing countries that remain unfulfilled. Drawing on the experience of NAFTA's investment chapter, which, alongside many BITs includes intellectual property as a form of investment, the article describes the legal and political discussion surrounding the case of *Canada v. Eli Lilly*. In this case, an investment complaint was set following the invalidation of two of the company's patents in Canada, even though patent invalidation is recognized in the TRIPS Agreement. It then comments on the legal doctrines used and the possible consequences of such decisions.

Correa, C. M. **Test Data Protection: Rights Conferred Under the TRIPS Agreement and Some Effects of TRIPS-Plus Standards.** Cheltenham, UK and Northampton USA: Edward Elgar, 2011, pp. 568–590.

The TRIPS Agreement was the first international set of binding rules with provisions regarding the protection of “undisclosed information”, states the author. Focusing on the protection of test data (i.e. the results of clinical trials made to demonstrate the efficacy and safety of pharmaceutical and agrochemical products) and the content of Article 39(3), the author delineates the exact level of protection required under the TRIPS Agreement, which falls

short of the ample protection originally envisioned by the United States during the negotiations of the agreement. It further clarifies that the use of data by a government “for the purpose of approving the generic version of a drug product for marketing is not an unfair commercial use and that the provision does not mandate either exclusive rights or compensation” (p. 570). The article also addresses the effects of TRIPS-Plus standards, particularly for developing countries, as data exclusivity creates numerous barriers.

Drahos, P. **Four lessons for developing countries from the trade negotiations over access to medicines.** *Liverpool Law Review*, 28 (1) (2007), 11–39.

Available from: <https://doi.org/10.1007/s10991-007-9014-5>.

After the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) came into operation in 1995, developing countries have found themselves in a process of continual negotiation over intellectual property rights and access to medicines. These negotiations have taken place in the WTO and in the context of free trade agreements. The paper suggests that the only real win for developing countries has been the Doha Declaration on the TRIPS Agreement and Public Health in 2001. What have been the lessons for developing countries in a decade of negotiations over access to medicines? Drawing on themes of rule complexity and regulatory ritualism the paper discusses four key lessons for developing countries. It concludes by arguing that developing countries will do better if they adopt a networked governance approach to negotiation rather than continuing to rely on traditional coalition formation.

Linares, R. ***La salud pública en riesgo. Los medicamentos en el TLC.*** Lima: Consorcio de Investigación Económica y Social – Acción Internacional para la Salud, 2005.

La salud pública en riesgo deals with the precise case of the FTA between Peru and the United States of America, and its implications on access to medicines. It states that the intellectual property provisions included in the said treaty pose a real risk to the Peruvian public health due to the restriction that they impose on

public policy options. Recalling human rights obligations and the Doha Declaration, it compels the Peruvian Government not to treat health just as another commodity. The report backs previous statements from the Peruvian Health Ministry and from the United Nations Special Rapporteur on the Right to Health recalling the priority of public health protection.

Lopert, R., and Gleeson, D. **The high price of “free” trade: U.S. trade agreements and access to medicines.** *J Law Med Ethics*, vol. 41, No. 1 (Spring 2013): pp. 199–223. Doi: 10.1111/jlme.12014.

Focusing on the United States’ position in free trade agreements, the paper delineates efforts to expand not only TRIPS-Plus provisions with regard to intellectual property protection for medicines but also to influence health coverage programmes themselves. This was the case, for instance, with the US–South Korea free trade agreement (KORUS), which established provisions regarding the operation of coverage and reimbursement programs for medicines and medical devices. The United States had proposed even stronger provisions in the negotiations of the then-Trans-Pacific Partnership Agreement (TPPA). Understanding the politics and trends of United States’ behaviour in free trade agreement negotiations is a relevant tool for policymakers in adequately understanding and recognizing the possible risks of such agreements to their national health systems.

Max Planck Institute for Innovation and Competition. **Principles for Intellectual Property Provisions in Bilateral and Regional Agreements.** Munich, 2015.

The document compiles principles set forth by the revered Max Planck Institute for Innovation and Competition with the support of experts from around the world, with an ultimate aim of achieving a better and more balanced regulation of international IP. It also expresses “core concerns” regarding the use of IP provisions as bargaining chip in negotiations, as well as the increasing comprehensiveness of international IP norms and the lack of transparency and inclusiveness of such negotiating processes. This is an important academic initiative that recognizes trends in global

IP and the importance of a clearer procedural and substantive view of these negotiations in achieving a more balanced system. Among the principles mentioned are the recognition of the interest principles of Articles 7 and 8 of the TRIPS Agreement, the importance of exceptions and limitations and the principle of not employing unilateral certification or processes. Although brief, this principles document provides a synthesized and valuable overview of some of the main concerns of the increasingly enhanced IP protection through bilateral and regional agreements.

Médécins sans Frontières (MSF). **Blank Cheque for Abuse: ACTA and its Impact on Access to Medicines.** Technical Brief, Geneva, 16 February 2012.

This technical brief by MSF Access Campaigns analyses in detail the reasons that the enforcement provisions contained in the proposed Anti-Counterfeiting Trade Agreement (ACTA) treaty would have detrimental effects on access to medicines: for instance, strong measures in trademark disputes that would impede access to genuine generic medicines, possible penalties for third parties that might intervene in judicial litigations, even if working on the public interest and the permission to detain in-transit medicines. These considerations remain useful for negotiations taking place at other fora currently.

Musungu, S. F. and Dutfield, G. ***Multilateral agreements and a TRIPS-plus world: The World Intellectual Property Organisation (WIPO)***. Geneva-Ottawa: QUNO-QIAP, 2003.

This paper focuses on the development of TRIPS-plus standards at the World Intellectual Property Organisation. Three broad concerns have prompted the focus on WIPO. First, despite the major role that WIPO has played in globalising intellectual property rules, the overwhelming majority of literature on intellectual property and development issues has been devoted to the TRIPS Agreement. Secondly, there is a perception that the mandate of WIPO is limited to the promotion of intellectual property and does not embrace development objectives. The final concern arises over WIPO activities aimed at harmonising patent law standards and at

providing technical assistance to developing countries. The paper concludes that for WIPO activities to fully take into account the development perspective and to ensure that new multilateral treaties do not result in TRIPS-plus standards, there is a need to properly construe the mandate of WIPO in the context of its agreement with the UN, increase the participation and influence of developing countries, civil society and other development organisations in WIPO processes, ensure that the International Bureau serves the interests of all WIPO members, and separate the norm setting functions of the International Bureau from its technical assistance activities.

Musungu, S. F. and Oh, C. ***The Use of Flexibilities in TRIPS by Developing Countries: Can they Promote Access to Medicines?*** Geneva: South Centre – WHO, 2006.

This study is the third in a series published by the South Centre in collaboration with the World Health Organization. The publication examines the extent to which the flexibilities contained in the TRIPS Agreement have been incorporated into the legislation of developing countries and its actual use for public health purposes. It also reviews the trade policies of major industrialized countries *vis-à-vis* developing countries, and examines the public health effects of certain provisions contained in recent FTAs. The authors conclude that there remain important gaps both in terms of incorporation and usage of medicines; that United States, Canada, EU, Japan and Switzerland, trade policies fail to adequately take into account the public health priorities of developing country trading partners; and that a number of provisions in recently concluded FTA between developed and developing countries may undermine the effective use of TRIPS flexibilities.

Roffe, P. ***Bilateral Agreements and a TRIPS-plus World: The Chile-USA Free Trade Agreement***. Quaker International Affairs Programme, Ottawa, TRIPS Issues Papers 4, 2004. Available from: <https://quno.org/resource/2004/10/bilateral-agreements-and-trips-plus-world-chile-usa-free-trade-agreement>.

This paper focuses on the FTA between Chile and the United States of America with the aim to contribute to a better understanding of TRIPS-plus issues, the specific contents of the FTA and the lessons that could be drawn from the negotiations. It explains how, for pharmaceutical products, the FTA expands protection by different means, including: the reinforcement of the provisions on marketing and sanitary approvals; the adjustment of the term of the patent to compensate for unreasonable delays in its granting; the prohibition of the use of undisclosed information about the safety and efficacy of pharmaceutical products for 5 years from the date of its marketing or sanitary approval; the extension of the patent term to compensate for unreasonable curtailment of the patent term as a result of marketing approval; and the granting of marketing approval to third parties requires the consent or acquiescence of the patent owner.

Roffe, P., and Seuba, X. ***The ACTA and the Plurilateral Enforcement Agenda: Genesis and Aftermath***. Cambridge, UK: Cambridge University Press, 2014.

The Anti-Counterfeiting Trade Agreement (ACTA) was a major proposal to establish a strict binding framework for countering counterfeit products, with numerous provisions on the enforcement of intellectual property rights. ACTA was never approved (it was, for instance, rejected by the European Parliament) due to, among other reasons, the massive possible impact on access to medicines. These measures would largely restrict the circulation of legitimate products, such as generic medicines. This large compilation addresses the history, details and consequences of ACTA. Even if it never became an international agreement, many of these norms laid the groundwork for pursuant free trade agreement negotiations. The understanding of the consequences of enforcement measures, including ACTA, continues to be critical to the debate on access to medicines.

Roffe, P. and Spennemann, C. **The impact of free trade agreements on public health policies and TRIPS flexibilities.** *International Journal of Intellectual Property Management*. Volume 1 - Issue 1/2, 2006. Available from: <http://ictsd.org/downloads/2008/08/roffe-spennemann.pdf>.

After providing a brief historical overview of the ways international agreements deal with public health-related intellectual property rights (IPRs), it analyses the TRIPS-plus trend in Free Trade Agreements (FTAs) and its impact on access to medicines policies. It focuses on FTAs concluded by the USA and the Member states of the European Free Trade Association (EFTA) with a number of developing countries and their provisions on patents and test data protection. New obligations in this field go well beyond the TRIPS minimum standards and may seriously affect access to affordable generic pharmaceutical products in developing countries.

Roffe, P., Spennemann, C., and von Braun, J. **Intellectual property rights in free trade agreements: moving beyond TRIPS minimum standards.** In *Research Handbook on the Protection of Intellectual Property under WTO Rules* (ed. Carlos M. Correa). Edward Elgar Publishing, 2010.

Regional and bilateral free trade agreements (FTAs) and their rapport with the WTO TRIPS Agreement are the main focus of this work. In exploring these matters the authors examine, first, how the TRIPS Agreement marks the starting point of a major shift with respect to the pre-existing intellectual property landscape by both breaking with the traditional evolution of the international system and by opening the way to new and expansive developments in the international protection and enforcement of IPRs. It analyzes the main features of FTAs negotiated after the conclusion of the TRIPS Agreement and their implications for developing countries. Particular attention is paid throughout the paper to a number of public interest-related policy matters, where the FTAs increase and expand the minimum standards of protection and enforcement established under TRIPS, with particular attention to issues such as public health, the protection of life forms and of traditional knowledge, access to knowledge in general and to the new

obligations on enforcement and dispute settlement. The final section draws some overall conclusions around these recent developments and their implications.

Roffe, P., Vivas, D., and Veal, G. ***Maintaining Policy Space for Development. A Case Study on IP Technical Assistance in FTAs.*** Geneva: ICTSD, 2007.

The paper begins with a broad consideration of the FTA phenomenon and what it represents in terms of challenges in the area of technical assistance to developing countries. The paper focuses on some of the technical assistance concerns raised by FTAs, including the challenges to developing countries with regard to implementation and human institutional capacity building. The authors pay particular attention to FTAs between the US and a number of developing countries, especially those in Latin America. The attention is justified on the basis that technical assistance may be a vehicle for promoting TRIPS-plus implementation. It centres its analysis on the issues arising from the implementation of the FTA once negotiation phase ends, and it provides a set of preliminary recommendations for providers of technical assistance.

Roffe, P., von Braun, J., and Vivas-Eugui, D. **A new generation of regional and bilateral trade agreements: lessons from the US-CAFTA-DR agreement.** In *Trade and Health: Seeking Common Ground*, (eds. Chantal Blouin et al). McGill-Queen's University Press, 2008.

The paper illustrates how pharmaceutical protection has evolved through time and the importance of the TRIPS Agreement in this respect. It analyzes the recent phenomenon of bilateral trade agreements and why countries negotiate these agreements in the first place. It further refers to some of the structural concerns inherent in free trade agreements between large and small countries. The paper argues that policy options exist to protect public health in developing countries in the context of recent FTAs. It also describes the individual TRIPS-plus provisions as they relate to public health and underline their legal and political effects. Finally, the paper provides suggestions on how policy coherence in

trade and public health could be better achieved with respect to the challenges posed by the new generation of FTAs.

Santa Cruz, M. ***Intellectual Property Provisions in European Union Trade Agreements. Implications for Developing Countries.*** Geneva: International Centre for Trade and Sustainable Development, 2007.

This report addresses the scope, content and potential impact of proposed intellectual property provisions in Economic Partnership Agreements (EPAs) with the European Union. The study states that EPAs have generated deep concern among various stakeholders due to their potential impact of TRIPS-plus provisions on the use of flexibilities and exceptions designed to safeguard public interests and development objectives. According to the author, EPAs raise many negotiating and implementation challenges regarding policy coherence and the maintenance of flexibilities in such agreements, as well as in improving predictability in the IP field. Until now, the IP chapters in the existing agreements were quite homogeneous, with relatively small variations between them. With very few exceptions, the provisions of the EU agreements did not incorporate substantive provisions. Instead, they were essentially built on commitments to adhere to the TRIPS Agreement and to multilateral agreements negotiated in the framework of the World Intellectual Property Organisation. This structure contrasts with the more aggressive approach adopted by other developed countries in negotiating chapters that include substantial provisions on types of protection not included in TRIPS. The author reports how the EU has moved from the former model to negotiating far more elaborate chapters on intellectual property.

Seuba, X. ***Free Trade of Pharmaceutical Products: The Limits of Intellectual Property Enforcement at the Border.*** ICTSD: Geneva, 2010. Available from: <http://ictsd.org/i/publications/74589/>.

Free Trade of Pharmaceutical Products: The Limits of Intellectual Property Enforcement at the Border examines the nature and scope of existing EC custom border regulations in light of international law and particularly WTO law. The paper emphasizes that, although

TRIPS Article 1 allows WTO Members to “implement in their law more extensive protection”, this faculty is made conditional on not contravening other TRIPS provisions. The author argues that Regulation 1383/2003 grants patentees rights not contemplated in TRIPS Article 28, in particular, the right to seize patented goods in transit, which also can be excluded invoking other TRIPS articles, such as articles 41, 51 and 52. The author further argues that Regulation 1383/2003 might impose unnecessary restrictions and delays that impede the freedom of transit enshrined in GATT Article V, and emphasizes that the Doha Declaration, and its mandate to interpret the TRIPS Agreements in a manner supportive of WTO Members’ right to protect public health, could be decisive in a WTO panel’s ruling on the TRIPS compliance of Regulation 1383/2003 and its implementing measures.

Shaikh, O. *Access to Medicine Versus Test Data Exclusivity. Safeguarding Flexibilities under International Law*. Switzerland, Springer, 2016.

This comprehensive book examines test data exclusivity protection for pharmaceuticals with a comparative perspective. It focuses on the interpretation of Art. 39(3) of the TRIPS Agreement, provisions in free trade agreements and domestic laws. The book proposes an Index of Data Exclusivity and Access (IDEAS) to assess the strength of exclusivity and access to medicine. The author also provides policy recommendations to design legal systems more suitable for promoting access to medicines in light of data exclusivity.

Vivas-Eugui, D. *Regional and Bilateral Agreements and a TRIPS-plus World: The Free Trade Area of the Americas (FTAA)*. Geneva: QUNO-QIAP, ICTSD, 2003. Available from: <https://quno.org/resource/2003/8/regional-bilateral-agreements-and-trips-plus-world-free-trade-area-americas-ftaa>.

This paper provides an overview, based on IPRs negotiations in the Americas, of some of the implications of regional and bilateral TRIPS-plus agreements for the current minimum standards under TRIPS. It states that an IPRs chapter in the FTAA would only make sense if adequate commercial and sustainability assessments are

undertaken; transparency and consultation processes are enhanced; policy spaces to undertake measures necessary to protect public health in the IPRs system are kept and enhanced; the Convention on Biological Diversity (CBD) and the new FAO treaty principles together with adequate legal mechanisms for assuring legal access are incorporated; protection of traditional knowledge and folklore is provided for and fully developed; effective ways for facilitating technology transfer are included; flexibilities to address public interest concerns in national patent laws and copyright laws are kept; flexibilities to choose and use the most convenient system to protect plant varieties whether through patents or a *sui generis* system, are kept; regulation against abuse of rights is allowed and developed; and special and differential treatment is incorporated and enhanced. The author recommends that developing countries refrain from negotiating on IPRs at the regional and bilateral level but to keep these negotiations in the multilateral level where more balanced results can be obtained.

Vivas-Eugui D., and von Braun J. **Beyond FTA negotiations: implementing the new generation of intellectual property obligations.** In *Intellectual Property and Information Wealth: Issues and Practices in the Digital Age*. Yu P (ed.). Praeger Publishers, 2007. Available from: <http://www.peteryu.com/praeager.htm>.

This article discusses the particular challenges many developing countries face in implementing new obligations in the field of intellectual property (IP) as a result of the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), completing accession processes for new members of the WTO, increasing ratification of WIPO treaties, as well as the negotiation and subsequent ratification of a new generation of bilateral and regional free trade agreements (FTAs) with comprehensive IP chapters. The varying degree the above negotiation frameworks incorporate new forms of IP, raise existing levels of protection, and reduce opportunities for using flexibilities and exceptions in the implementation of intellectual property policies. Rather than discussing the nature of these obligations, the objective of this paper is to identify a set of options that policymakers could take into account in pro-development

implementation of new IP obligations arising from these negotiations.

Waxman H. A. ***Trade Agreements and Access to Medications under The Bush Administration***. Washington DC: United States House of Representatives. Committee on Government Reform – Minority Staff, 2005.

According to this report, since the adoption of the Doha Declaration the Bush Administration has signed and the United States Congress has ratified numerous bilateral and regional free trade agreements with severe implications for access to medicines due to their intellectual property provisions. The report examines whether the North-American Administration is complying with the Doha Declaration in its pursuit of these trade agreements. The report finds that contrary to the Doha Declaration, U.S. Trade negotiators have repeatedly used the trade agreements to restrict the ability of developing nations to acquire medicines at affordable prices. In effect, the President's trade representatives have elevated the protection of pharmaceutical patents above the pressing health needs of developing countries. Specifically, the report finds that the agreements delay approval of generic drugs, require patent extensions, link drug approval to patent status, restrict compulsory licensing, prohibit parallel importation and expand patent protections.

Yu, Peter K. **The Investment-Related aspects of intellectual property rights**. *American University Law Review*, vol. 66, No. 3, Article 4 Washington, (2017). Available from: <https://digitalcommons.wcl.american.edu/aulr/vol66/iss3/4>.

The treatment of intellectual property as an investment, and its application under the scope of investment treaties, is an increasing trend. In this article, the author critically examines “the investment-related aspects of intellectual property rights with a focus on the use of investor-state dispute settlement (ISDS) to address international disputes involving intellectual property investments”. He assesses the ISDS systems and the proposal then under discussion under the TPP and makes critical proposals on the issue.

2.5 IP, Pandemics and Global Burden Diseases

Correa, C. M., and Velásquez, G.. **Access to Medicines: Experiences with Compulsory Licenses and Government Use – The case of Hepatitis C.** South Centre Research Paper 85, April 2019.

Available from: <https://www.southcentre.int/research-paper-85-april-2019/>.

This South Centre research paper discusses first, the limitations of the current R&D model and its implications for access to medicines. Second, it considers the tension between intellectual property rights applied to medicines and States' observance of the fundamental right to health. Third, it examines the case of access to medicines for the treatment of Hepatitis C, illustrating the barriers to access created by intellectual property and the high prices normally associated with its exercise. Fourth, it presents the background, main aspects and obstacles to the achievement of the objectives of the Doha Declaration on the TRIPS Agreement and Public Health (2001). To conclude, this paper examines the experiences of compulsory licensing and government use of patents in Latin America (particularly in Ecuador, Peru and Colombia).

Lokuge, B., Drahos, P., and Neville, W. **Pandemics, antiviral stockpiles and biosecurity in Australia: what about the generic option?** *Medical Journal of Australia*, 184(1) (2006) 16–20.

Available from:

http://www.mja.com.au/public/issues/184_01_020106/lok10852_fm.html.

In view of the possibility of a human pandemic of avian influenza, a first-line strategy for many countries is stockpiling of antiviral neuraminidase inhibitors (oseltamivir [Tamiflu] and zanamivir [Relenza]), which can reduce mortality, morbidity and influenza transmission.

However, global supply of the antivirals is controlled by the European-based patent owners, Roche and GlaxoSmithKline. This prevents competition in the manufacturing and distribution of

antivirals and has reduced global supply capacity and affordability. The Australian Government has acknowledged that, in the event of a pandemic, its own stockpile of antivirals will be limited and reserved for those on a confidential rationing list. Pharmacies are running out of stocks, limiting opportunities for individuals to secure supplies privately.

Compulsory licensing provisions, permitted under domestic patent law, would allow Australian generic manufacturers to start producing antivirals locally or import them from generic producers at affordable prices.

Australia also has an opportunity and a responsibility to promote compulsory licensing and generic antiviral production in the Asian region, to ensure their neighbours can establish pandemic stockpiles in a timely and affordable manner. eMJA rapid online publication 26 October 2005.

Shashikant, S., ed. ***Pandemic Preparedness Creating a Fair and Equitable Influenza Virus and Benefit Sharing System***. TWN, 2010.

The World Health Organisation is mandated to achieve the highest possible level of health for all peoples. However, in 2007 world attention was focused on WHO when it emerged that WHO “Global Influenza Surveillance Network” (GISN) was unfair to the interests and needs of developing countries. This scheme, focused on ensuring that countries shared influenza viruses, failed to deliver fair and equitable benefit sharing, a crucial element to ensure access to vaccines, antivirals and other technologies at affordable prices to developing countries that were most affected during a severe influenza outbreak of pandemic potential. It also emerged that developed country governments and their entities were winners in the scheme as they profited from the virus sharing system, including by having timely access to vaccines and making intellectual property rights claims over the shared biological materials and products developed using such materials.

Meanwhile, developing countries could face astronomical bills for the purchase of vaccines and other medical supplies, as well as difficulties in accessing such supplies, due to their limited availability. Latest technologies as well as know-how used in vaccine development and production (largely based in developed countries) were also protected by IPRs, creating more obstacles for developing countries that might seek to build their own production capacity.

All these issues came to a head at the 60th World Health Assembly in 2007, leading to the adoption of Resolution WHA60.28 titled “Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits”. Negotiations to create a fair and equitable influenza virus and benefit sharing framework in the context of pandemic influenza preparedness are on-going in WHO.

This book provides an in-depth understanding of the background to, and rationale for, the current WHO negotiations on influenza virus and benefit sharing as well as a front-line view of the negotiations.

Velásquez, G. **Access to Hepatitis C Treatment: A Global Problem.** South Centre Research Paper 77, May 2017. Available from: <https://www.southcentre.int/research-paper-77-may-2017/>.

This document addresses the global problem of the hepatitis C virus within the broader context and against the background of the debate over access to medicines, also presenting the issue of access to new direct-acting antiviral (DAA) treatments for hepatitis C. The author then proposes the use of TRIPS flexibilities as a means of overcoming barriers to access and shares examples of countries which have launched new affordable and accessible HCV treatments. The conclusions draw on these experiences and the policy space allowed by the TRIPS Agreements for countries to overcome the global hepatitis C treatment problem.

World Health Organization. **Global Report on Access to Hepatitis C Treatment – Focus on Overcoming Barriers.** Geneva, October 2016.

This WHO report is the first of its kind on the topic of access to hepatitis C medicines. It shares experiences from different countries that overcame barriers, including those generated by intellectual property rights. It also provides further information on the production of new drugs and generic versions, including their registration, patent status and licensing opportunities. The report explicitly mentions patent oppositions, voluntary license agreements and compulsory licenses, as well as discussions on price transparency, negotiation and control. The important role of civil society and political will are mentioned among with different strategies for enhancing access and the need for generic competition and local production.

World Health Organization. **Pricing of Cancer Medicines and Its Impacts.** Geneva, 2018.

Pursuant to the World Health Assembly Resolution 70.12, this technical report addresses pricing approaches and their effects on the availability and affordability of medicines for the prevention and treatment of cancer. The comprehensive report debates various pricing approaches, including national, industry and payer approaches. Importantly, it debates the effects on price, availability, affordability, R&D and price transparency and the unintended consequences of such approaches, as well as the lack of any approaches at all. The report constitutes part of an increasingly important debate on the transparency of costs with regard to medicines, including their final price and their R&D costs, a topic that led to the approval of a first-ever (albeit limited) Resolution on the matter during the 72nd World Health Assembly in May 2019.

2.6 IP and Counterfeit Medicines

Gopakumar, K.M., and Shashikant S. ***Unpacking the Issue of Counterfeit Medicines***. TWN, 2010. Available from: <https://www.twn.my/title2/books/Unpacking.the.Issue.of.Counterfeit.Medicines.htm>.

Numerous anti-counterfeiting initiatives driven by an intellectual property enforcement agenda have emerged in international organisations. The World Health Organisation (WHO) has also accelerated action against “counterfeit medicines”, through the International Medical Product Anti-Counterfeit Taskforce (IMPACT). The WHO approach has resulted in concerns that legitimate generic medicines may get caught up in the web of definitions and enforcement of “counterfeit products”, with adverse consequences for access to medicine as well as legitimate trade.

This book discusses the background to the issue of “counterfeit medicines” in WHO as well as the problems of using the term “counterfeit” (in connection with intellectual property rights violations) to refer to products with compromised quality, safety and efficacy issues against a background of anti-counterfeiting initiatives in the context of IP enforcement aggressively being pushed by businesses and governments of the Organisation for Economic Cooperation and Development (OECD). The book also discusses the origins of IMPACT and analyses issues and concerns about the Taskforce pertaining to legitimacy, transparency, accountability, links to IP enforcement, and the creation of barriers to trade in, and access to, affordable generic medicines.

Shashikant, S., ed. ***The IMPACT Counterfeit Taskforce, Intellectual Property Rights Enforcement and Seizure of Medicines***. TWN, 2010. Available from: <https://www.twn.my/title2/IPR/ipr13.htm>.

There has in recent years been a major push to set restrictively high standards of intellectual property (IP) protection and enforcement internationally. Driven by large corporations and governments of

industrial countries, this push extends even to the critical medicines and medical products sector.

In this sector, the introduction of stricter IP enforcement measures is sought, among others, through pursuing the agenda of combating “counterfeits”. This book looks at recent moves at the World Health Organisation (WHO) to seek endorsement of an initiative called the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) and its proposed definition of counterfeits. This approach has drawn criticism from many developing-country WHO members for seeking to address health issues relating to the quality and safety of medical products through an IP framework.

Concerns over the focus on counterfeits have been heightened by a spate of seizures by European customs authorities of generic medicines in transit to developing countries on grounds of IP infringement. These seizures have further fuelled fears that linking health and IP issues would impede production of and trade in affordable, good-quality generic drugs – and poor countries’ access to them.

This book is a compilation of articles – most of which appeared in the South-North Development Monitor (SUNS), a daily bulletin on development issues published by the Third World Network – which examine the concerns expressed by developing countries and civil society over the anti-counterfeit drive and medicine seizures, and report on the lively recent debates on these subjects at WHO and WTO.

2.7 Generic Medicines of Biological Origin

Gaviria, A., Vaca González, C. P., Gómez Muñoz, C., and Morales, Á. A. **El debate de la regulación de medicamentos biotecnológicos: Colombia en el contexto internacional.** *Rev Panamericana de Salud Publica*, Washington, vol. 40, No. 1 (2016).

This paper describes the debate on the regulation of biotechnological drugs in Colombia within the international context following its 2014 norm on the evaluation of biologicals during its regulatory approval for commercialization. The Colombian approach explicitly takes a “fast-track” approach that, although controversial at the time of adoption, strongly facilitates access to medicines of biological origin and that is in line with global regulatory tendencies. To do so, it critically explains the notion of “equivalence” used for regulatory purposes in biologicals, and presents a comparison between countries to conclude that the Colombian “fast-track” approach simultaneously ensures the need to guarantee the quality of biological products and reduces costs, which leads to more competition, lower prices and less public expenditure. This is an important precedent for other countries within this debate.

Velásquez, G. **The International Debate on Generic Medicines of Biological Origin**. South Centre Research Paper 82, November 2017. Available from: <https://www.southcentre.int/research-paper-82-november-2017/>.

The debate on generic medicines is not new. What makes it different today is that attacks levelled against biological products are couched in ever more “technical” and abstruse language that confuses even the World Health Organization (WHO), argues the paper. Innovative biological drugs, which have been introduced on the market in the past 20 to 30 years, make up, in terms of numbers, no more than two per cent of the WHO Model List of Essential Medicines but, in terms of cost, account for 15 to 20 per cent of national drug expenditure. The high price of biological drugs stems mainly from two new factors: a change in the pharmaceutical industry’s approach to price-setting and the introduction of additional barriers to the entry of generics into the market. In any debate on the impossibility of producing “identical” drugs, it should be made clear that what is at stake is not identical products but therapeutic equivalents. What matters to the patient, after all, is whether the drug can prevent, cure or mitigate the effects of the illness.

3. HUMAN RIGHTS AND ACCESS TO MEDICINES

Aginam, O. **Between life and profit: global governance and the trilogy of human rights, public health and pharmaceutical patents.** *North Carolina Journal of International Law and Commercial Regulation*, 2006, 31: 901–920.

Focusing on one of the key governance frameworks of economic globalization –the normative architecture of the WTO and the TRIPS agreement– Professor Aginam explores the marginalization of public health and human rights at WTO. The paper is divided into five parts. Part I gives an overview of the tension between human rights, public health and pharmaceutical patents in the contemporary global interdependence. Part II explores HIV/AIDS as a global emergency. Part III explores the interface between the WTO, TRIPS, and access to essential medicines, particularly how can TRIPS flexibilities be employed to save millions of lives. Part IV traces the public health fingerprints in the global trade regime. Focusing on international trade jurisprudence, this section argues that public health imperatives as well as other public goods are marginalized by the dogma of free trade. Part V presents the conclusion and an agenda for the future based on policy coherence and balancing the imperatives of human rights, public health, and trade liberalization within the mandates of WHO and WTO.

Chapman, A. R. **The human rights implications of intellectual property protection.** *Journal of International Economic Law*, 2002, 5(4), 861.

This article outlines the provisions of a human rights perspective on the requirements for intellectual property and then discusses its potential conflicts with current developments in intellectual property law. A variety of human rights organizations and agencies have begun to realize that the manner in which creative works, cultural heritage, and scientific knowledge are turned into property has implications for human rights. These concerns have led to a series of initiatives by United Nations human rights institutions, the

most significant of which is the November 2001 statement on “Human Rights and Intellectual Property Issues” adopted by the Committee on Economic, Social and Cultural Rights. Its central theme is that intellectual property protection and international trade regulation must respect and abide by international human rights law.

Cullet, P. **Human rights and intellectual property protection in the TRIPS era.** *Human Rights Quarterly*, 2007 (29): 403–430.

Available from: <http://www.ielrc.org/content/a0702.pdf>.

This article examines the different aspects of the relationship between intellectual property rights, human rights, and science and technology-related provisions in human rights treaties. Human rights and intellectual property protection are two distinct fields that have largely evolved separately. Their relationship needs to be re-examined for a number of reasons. First, the impacts of intellectual property rights on the realization of human rights such as the right to health have become much more visible following the adoption of the TRIPS Agreement. Second, the increasing importance of intellectual property rights has led to the need for clarifying the scope of human rights provisions protecting individual contributions to knowledge. Third, a number of new challenges need to be addressed concerning contributions to knowledge, which cannot effectively be protected under existing intellectual property rights regimes. The article analyzes existing knowledge protection-related provisions in human rights treaties. It also examines some of the impacts of existing intellectual property rights regimes on the realization of human rights. Further, it analyzes the recently adopted General Comment 17 on Article 15(1)(c) of the International Covenant on Economic, Social and Cultural Rights (ICESCR) and proposes an alternative broader reading of this provision focusing on traditional knowledge.

Cullet, P. **Patents and medicines: the relationship between TRIPS and the human right to health.** *International Affairs*, 2003, 79(1): 139–160.

Available from: <http://www.ielrc.org/content/a0301.pdf>.

The author states that the legal arguments concerning the relationships between human rights and intellectual property rights, and the practical debates concerning access to drugs in developing countries, both point toward the existence of potential conflicts between the introduction of patents on drugs in developing countries and the realization of the rights to health. TRIPS Agreement compliance requires substantial changes in existing patent laws in some countries. These changes must be analysed in the context of the spread of epidemics, and in relation to other international obligations that states have, for instance, regarding the human right to health. IPR treaties have a significant impact on the realization of some human rights, such as the right to health. This article examines the extent to which the TRIPS Agreement encompasses flexibility for developing countries to be able to foster greater access to medicines. The article also examines these issues from the point of view of human rights and considers how the relationship between human rights and intellectual property can be addressed in international law.

Evans, T. **A human right to health?** *Third World Quarterly*, 2002, 23(2): 197–215.

The right to health is one of a range of socio-economic rights for which states accept an obligation under international law. However, the politics of rights has meant that socio-economic rights are rarely given the same status as liberal freedoms associated with civil and political rights. This article discusses the liberal rationale for rejecting socio-economic claims as rights and examines the basic rights challenge to liberal arguments. Given the dominance of liberalism, the article concludes with an examination of the potential for promoting a right to health within the context of globalization.

Gathii, J. T. **Rights, patents, markets and the global AIDS pandemic.** *Florida Journal of International Law*, Spring 2002, 263–346.

This article contributes to the current initiatives to provide access to and increase the affordability of drugs and health services

available to low-end consumers facing life threatening illnesses, such as AIDS. According to the author, it is possible to combine a market-based approach with a human rights one. Moreover, the use of market-based arguments contributes to expanding the traditional registry of legal and social causes. To illustrate the necessary combination between market-based and other approaches, the article develops three different strategies to achieve the stated goals of access and affordability. The first strategy consists of using social and economic rights clauses in constitutional charters. The second strategy is derived from a market-based argument and the author attempts to establish the TRIPS consistent possibilities that are available for combining pharmaceutical producers and consumers. The third proposed strategy is also related to a market-based argument and is related to the US FDA framework of control which, according to the author, constitutes an important obstacle for the entry of new drugs into the market, particularly generic versions of branded drugs or applications which have been approved in other countries. The author perceives competition in the pharmaceutical industry as one of the best ways to ensure access and affordability of drugs for low-income consumers and an effective pricing mechanism and concludes that any increase in IPP would have a negative impact on competition. The author finally considers the potential for market-based arguments to advance legal and social cases while demonstrating the feasibility of assimilating diverse approaches.

Harrington, J., Stuttaford, M., eds. ***Global Health and Human Rights: Legal and Philosophical Perspectives***. Routledge Research in Human Rights Law. London: Routledge, 2010.

The right to health, having been previously neglected is now being deployed more and more often in litigation, activism and policy-making across the world. International bodies such as the WHO, UNAIDS, World Bank and WTO are increasingly using or being evaluated with reference to health rights, and international NGOs frequently use the language of rights in campaigning and in more concrete litigation. This book brings together an impressive array of internationally renowned scholars in the areas of law, philosophy and health policy to critically interrogate the development of rights-

based approaches to health. The volume integrates discussion of the right to health at a theoretical level in law and ethics, with the difficult substantive issues where the right is relevant, and with emerging systems of global health governance. The contributions to this volume will add to our theoretical and practical understanding of rights-based approaches to health.

Hestermeyer, H. P. ***Human Rights and the WTO: The Case of Patents and Access to Medicines***. Oxford: Oxford University Press, 2007.

Human Rights and the WTO. The Case of Patents and Access to Medicines discusses both the patent law and the international human rights law involved in great depth, distinguishing between obligations under different human rights instruments. It explains the concept of conflict between legal regimes and why patent law and human rights law are in conflict. The current state of international law on the conflict between legal regimes and the origin of such conflicts is analyzed, covering such issues as hierarchy in international law and introducing the concept of “factual hierarchy”. The book then turns to the role of human rights law in the WTO system, concluding that such law currently is limited to aiding the interpreting of the WTO agreements. It shows how a further integration of human rights law could be achieved and describes the progress made towards accommodating human rights concerns within the TRIPS Agreement, culminating in the first ever decision to amend a core WTO Agreement in December 2005.

Heywood, M. **Drug access, patents and global health: “chaffed and waxed sufficient”**. *Third World Quarterly*, 2002, 23(2): 217–231.

In July 2000, the UN Committee on Economic, Social and Cultural Rights issued a General Comment on the Right to the Highest Attainable Standard of Health, and stated that “Since the adoption of the International Covenant on Civil and Political Rights and the International Covenant on Economic, Social and Cultural Rights in 1966 the world health situation has changed dramatically and the notion of health has undergone substantial changes and widened in

scope. More determinants are being taken into consideration, such as resource distribution and gender differences. A wider definition of health also takes into account such socially related concerns as violence and armed conflict. Moreover, formerly unknown diseases, such as HIV and AIDS, and others that have become more widespread, such as cancer, as well as the rapid growth of the world population, have created new obstacles for the realization of the right to health". The need to understand why and how "the notion of health has undergone substantial changes and widened in scope", the forces that are contributing to this redefinition, and the implications for governments, multinational pharmaceutical companies and ordinary people is the subject of this article. In particular, global health is assessed according to the extent of global access to life improving-medicines, and the surmountable barriers that prevent this.

Joseph, S. **Pharmaceutical corporations and access to drugs: the "fourth wave" of corporate human rights scrutiny.** *Human Rights Quarterly*, 2003, 25: 425–452.

Access to essential medicines is a human right which is currently compromised by high prices facilitated by the global protection afforded to pharmaceutical patents by the TRIPS Agreement. However, pharmaceutical patents are arguably justified as they promote R&D in the industry. The arguments for and against patents are examined in this article, along with the salient human rights duties of pharmaceutical companies and governments, as well as recent victories in the battle for access to essential drugs in the developing world. Alternative strategies for facilitating access to essential medicines, without compromising R&D, are put forward.

Lazzarini, Z. **Making access to pharmaceuticals a reality: legal options under TRIPS and the case of Brazil.** *Yale Human Rights and Development Law Journal*, 2003, 6: 103–138.

This article presents the Brazilian experience to illustrate possible strategies for other developing countries, which can be used to strike a balance between respect for public health and human rights and protection of intellectual property rights. The article presents

the problem of access to pharmaceuticals in the context of intellectual property rules and human rights norms, and lays the groundwork for possible ways to resolve the tension between intellectual property rights and human rights. It states that many middle-income countries could provide wider access to medicines by fully utilizing certain safeguards and exceptions. For the poorest nations, however, there are no easy solutions.

Loff, B., and Heywood, M. **Patents on drugs: manufacturing scarcity or advancing health?** *Journal of Law, Medicine and Health*, 2002, 30(621–631).

This article focuses on the framework provided by the right to health and its relation with intellectual property rights. The authors examine the consequences of international trade law and intellectual property law for the treatment of ill health. The authors state that despite the acknowledgment of other factors as influencing access to medicines, the effect of price in limiting access to life-saving medicines is significant, and that the patent status of a medicine is the major determinant of that medicine's price.

Mzikenge Chirwa, D. **The right to health in international law: its implications for the obligations of state and non-state actors in ensuring access to essential medicine.** *South African Journal of Human Rights*, 2003, 19: 541–566.

This article argues that access to medication, treatment and care is an essential element of effective responses to pandemics and other diseases. In particular, it is argued that international law imposes a minimum core (and non-derogable) obligation on states to provide essential medicine. In recognition of the increasing role that private actors are playing in ensuring access to essential medicine, their human rights obligations relating to access to essential medicine are also explored.

OHCHR/UNAIDS. **International Guidelines on HIV/AIDS and Human Right**. Geneva: United Nations, 2006. Available from: http://data.unaids.org/Publications/IRC-pub07/jc1252-internguidelines_en.pdf.

This is a joint effort by the Joint United Nations Programme on HIV/AIDS and the Office of the United Nations High Commissioner for Human Rights to address and provide assistance to states, NGOs and individuals on human rights issues affecting HIV-positive people, such as discrimination, education or access to drugs. This version of the international Guidelines on HIV/AIDS and Human Rights consolidates the Guidelines first published in 1998 and revised Guideline 6 first published in 2002. Through 12 clearly formulated guidelines it offers guidance on how to respond to the human rights implications of the AIDS pandemic. Of special significance is Guideline 6 (Regulation of Goods, services and information) which refers to legal and economic obstacles to access to drugs and the necessity to overcome them. This guideline was the object of a specific debate during the Third Consultation on HIV/AIDS and Human Rights (Geneva, July 2002) where it was reformulated into access to prevention, treatment, care and support as a step forward in linking human rights and access to drugs.

Pogge, T. W. **Human rights and global health: a research program**. *Metaphilosophy*, 2005, 36(1/2): 182–209.

This paper proposes a global health-system reform that would make medical knowledge freely available as a global public good. The author states that rules should be redesigned so that the development of any new drug is rewarded in proportion to its impact on the global disease burden (not through monopoly rents). This reform would bring drug prices down worldwide close to their marginal cost of production and would powerfully stimulate pharmaceutical research into currently neglected diseases concentrated among the poor. Its feasibility shows that the existing medical-patent regime (trade-related aspects of intellectual property rights – TRIPS) as supplemented by bilateral agreements) is severely unjust – and its imposition a human-rights violation on

account of the avoidable mortality and morbidity it foreseeably produces.

Santoro, M. **Human rights and human needs: diverse moral principles justifying third world access to affordable HIV/AIDS drugs.** *North Carolina Journal of International Law and Commercial Regulation*, 2006, 31(4): 923–941.

After describing the moral discourse and economic considerations that led to the integration of IP provisions into the WTO, this article examines the moral discourse leading up to the Doha Declaration. The objective of this article is two-fold: first, to demonstrate the role of moral discourse in shaping legal transformation; second, to demonstrate the variety of moral arguments, in addition to those founded on human rights principles, which lead to the conclusion that citizens of poor countries should have access to affordable HIV/AIDS drugs and that pharmaceutical patents should be subjected to compulsory licensing and parallel importing to accomplish this aim.

Seuba, X. **Mainstreaming the TRIPS and human rights interactions.** In: C. Correa (ed.), *Research Handbook on the Protection on Intellectual Property under WTO Rules*. Cheltenham: Edward Elgar, 2010, pp. 192–215.

The relationship between the TRIPS Agreement and international human rights law must be studied in two broad frameworks, namely, that concerning the more general relation between intellectual property law and human rights law, and the other related to the interaction between public international law and WTO law. It is the combination of both that gives adequate answers to specific cases. This chapter devotes special attention to the effects on the TRIPS and human rights relationships of the WTO legal system anchorage in public international law. It sustains that thanks to the room for manoeuvre existing in TRIPS, permits solving many of the potential problems arising from the TRIPS from a human rights angle. As far as actual conflicts are concerned, it argues that although responses can be found in rules on conflict of treaties, the gravity of problems arising out of TRIPS-plus and extra provisions

indicates that much more than solutions based on legal technique is needed.

Seuba, X. ***La protección de la salud ante la regulación internacional de los productos farmacéuticos***, Madrid: Marcial Pons, 2010.

For the study of the international pharmaceutical regulation the notion of “pharmaceutical chain” is a useful connecting thread, which refers to the sum of phases in the life of a medicine, from its R&D to its use. The analysis of the international norms concerning each of the phases of the pharmaceutical chain helps to assess whether health protection has been the pursued goal when enacting legislation that has to do with a health product such as medicines. Each one of the phases of the pharmaceutical chain presents particular problems, some of them closely related to its normative treatment. This book studies norms pertaining to the fields of drug innovation, development, quality assurance and access from a human rights perspective. The book identifies specific human rights violations in each one of the phases that go from medicines’ research to pharmaceuticals use. The need to promote an international treaty on pharmaceutical R&D, the international legal void regarding the protection in many respects of participants in clinical essays, the appropriation of norm-setting functions in the quality assurance area by actors with vested interests, the possibility and the means to adopt a “healthy interpretation” of the TRIPS agreement and the existence of a conflict of treaties between human rights obligations and TRIPS-plus provisions are some of the topics addressed by *La protección de la salud ante la regulación internacional de los productos farmacéuticos*.

Shah S. **Illuminating the possible in the developing world: guaranteeing the human right to health in India**. *Vanderbilt Journal of Transnational Law*, March 1999(2): 435–485.

Deprivations such as malnourishment and under-nourishment are a major human rights offence and result in the systematic disempowerment of individuals as citizens. According to the author, the recognition of the social right to health contributes to a greater

sense of citizenship on the part of individuals. The second part of the article is devoted to the potential of social human rights and the positive impacts that they could have on the situation in the developing world. The author stresses the notion of state obligation, particularly with regard to guaranteeing human dignity. This obligation is explored in the third part of the article, with particular attention to the challenges posed by the implementation of social rights. The fourth part is entirely devoted to the notion of a human right to health and other social rights, taking into consideration not only the conceptual and practical problems posed but also the critical role of the right to health in the empowerment of individuals. The author identifies those conditions necessary for good health as also being essential for promoting human dignity. The final part of the article focuses on the experience in social rights (and the right to health) in India, noting the positive potential impact on economic institutions, social priorities and power imbalances. (Abstract from IPR, Innovation, Human Rights and Access to Drugs. An Annotated Bibliography, WHO/EDM/PAR/2003.9).

United Nations Development Programme. **HIV and the Law: Risks, Rights & Health – 2018 Supplement**. New York. Available from: <https://hivlawcommission.org/>.

This report by the Global Commission on HIV and the Law presents the global state of the fight against HIV, updating the previous 2012 report. The Commission finds that, while HIV treatment increased, AIDS is not over. Furthermore, other epidemics loom, including viral hepatitis and tuberculosis. New scientific achievements have changed the landscape of HIV treatment, including the introduction of PrEP and self-testing diagnostics. Still, civil space has shrunk, donor funding has dropped and borders have tightened, creating or complicating existing matters of concern. Other problems persist, including criminalization, anti-sex work laws and the war on drugs. The report notes that women and girls are being left further behind than ever before. In this context, the Commission presents numerous recommendations, including (i) ending all types of discrimination against people living with and vulnerable to HIV, TB or viral hepatitis, (ii) increasing funding for R&D of new health

technologies (through governments and other funders) and (iii) ensuring affordable access to most effective health technologies, as well as many other human rights-related activities.

Wojahn, P. L. **A conflict of rights: intellectual property under TRIPS, the right to health and AIDS drugs.** *UCLA Journal of International Law and Foreign Affairs*, Fall-Winter 2001-2002, 463-497.

According to this article, modelled on the intellectual property laws of the United States of America, the TRIPS Agreement established global standards for stringent protection of patents for new pharmaceutical developments. Stringent IPRs, however, are in direct conflict with the international right to health, established by the International Covenant on Economic, Social and Cultural Rights, which specifically states that the right to health requires states-parties to take the necessary steps for the “prevention, treatment and control of epidemic, endemic, occupational and other diseases” and “the creation of conditions which would assure to all medical service and medical attention in the event of sickness”. Strict protection of IPR raises the price of pharmaceuticals, blocking access to these drugs for many people in developing countries who need them to survive. Certain provisions of the TRIPS Agreement, however, allow countries to permit private manufacturers to produce generics, subject to certain conditions, through compulsory licensing. In addition, countries can use parallel importation to provide cheaper access to life-saving drugs. Although there are many uncertainties in TRIPS relating to when and under what conditions compulsory licensing and parallel importation are permitted, the whole framework can be interpreted to allow these strategies in order to provide greater access to drugs.

World Health Organization. **25 Questions & Answers on Health and Human Rights.** Geneva: WHO, 2002.

This was the first issue of a WHO series specifically focused on a rights-based approach to health topics. This publication seeks to clarify some key concepts and notions critical for a better understanding of the right to health and its implications for policy

makers, health workers and patients alike. What are human rights and how health care can be effectively framed within them is one of the questions that find an answer in this publication, which is intended to be used as an education tool and an advocacy resource. It offers brief, concise explanations about each concept providing a non-specialized reader with a comprehensive view of what is implied by a rights-based approach to health. (Abstract from *IPR, Innovation, Human Rights and Access to Drugs. An Annotated Bibliography*. WHO/EDM/PAR/2003.9).

Yamin, A. **Promoting and protecting the right to health in Latin America: selected experiences from the field.** *Health and Human Rights*, 2000, 5(1): 117–148.

Through a description of the four major challenges faced by Latin American human rights groups and the strategies that they have adopted to overcome these challenges, this article seeks to incorporate the human rights perspective into the discussion of how to make health a universally recognized human right. The ill-defined normative content of the right to health, the lack of precedents and procedures for enforceability and the lack of consciousness of health as a right have presented major obstacles to the implementation of this right in the Region. It is proposed that Latin American human rights groups move beyond traditional legal methods and expertise to work in an interdisciplinary fashion with health professionals and grass root health groups.

4. COUNTRY STUDIES BY REGION

4.1 Africa

Avafia, T., Berger, J. and Hartzenberg, T. **The Ability of Select Sub-Saharan African Countries to Utilise TRIPS Flexibilities and Competition Law to Ensure a Sustainable Supply of Essential Medicines: A Study of Producing and Importing Countries.** Tralac Working Paper No 12. Stellenbosch: US Printers. Available from:
<http://apps.who.int/medicinedocs/en/m/abstract/Js18249en/>.

This paper examines the degree to which countries in Eastern and Southern Africa have utilised the flexibilities contained in the 30 August 2003 WTO Decision to increase access to treatment in their countries. The paper further examines the use of competition law and policy as a tool for reducing prices and consequently increasing access to essential medicines and points out the advantages to developing countries of using competition law and policy: first, the TRIPS Agreement accords member countries considerable flexibility in implementing competition law and policy most appropriate for its purposes; second, countries have leeway to define what constitutes anti-competitive behaviour; third, competition law and policy is well suited to implementation by an independent competition authority vested with strong investigative powers; and finally, competition law and policy has been successfully employed by South African activists and stakeholders to reduce the prices of essential medicines. Despite these successes in using competition law to reduce drug prices in South Africa, the prospects of other countries in the SADC region for being able to utilize competition law and policy to attain similar objectives are not high due to a lack of institutional capacity (in some cases) and a lack of expertise. With deepening regional integration in southern Africa, the role of competition law and policy increases. While trade remedies still play an important role in free-trade areas, deeper integration requires that competition policy check for anti-competitive practices. National competition policy can go some way to providing

oversight in cases of anti-competitive conduct but the longer term solution lies in a regional competition policy.

Bond, P. **Globalization, pharmaceutical pricing, and South African health policy.** *International Journal of Health Services*, 1999, 29(4): 765–792.

The author examines the case of South Africa after legislation aimed at lowering drug prices was passed by Parliament. This article considers post-apartheid public health policy, US Government pressure to change the law, and pharmaceutical industry interests and links to the US Government, and evaluates various kinds of resistance to US corporate and government behaviour.

The Medicines and Related Substances Control Amendment Act (“Medicines Act”) of 1997 provides room for generic substitution by pharmacists. Scheduling of medicines, licensing of dispensers, establishment of a pricing committee and prohibition of pharmaceutical bonusing and rebates for bulk buyers are included in the Act. More controversially, it also allowed parallel imports and compulsory drug licensing. The article describes the strong response by the pharmaceutical industry and some governments towards the Medicines Act, which was the subject of legal proceedings.

Chaudhuri S., Park, C., and Gopakumar K. M. ***Five Years into the Product Patent Regime: India’s Response.*** UNDP, 2010.

Available from: <http://content.undp.org/go/cms-service/download/publication/?version=live&id=3089934>.

The report is intended to be a contribution towards understanding the continued role of India as a supplier of affordable medicines five years after having complied with the TRIPS Agreement. The report compiles three main studies commissioned by UNDP. The studies demonstrate that developments in India have impacts well beyond its borders, given the reliance thus far of much of the global market, especially in developing countries and LDCs, on the supply of low-cost, quality Indian generic pharmaceutical products. The studies analyze the role of both the Indian pharmaceutical industry and the

Indian legal system in building a post-TRIPS scenario that continues to be conducive to sourcing affordable medicines.

David, B. **In the High Court of South Africa, Case No. 4138/98: the global politics of access to low-cost AIDS drugs in poor countries.** *Kennedy Institute of Ethics Journal*, Volume 12, Number 2, June 2002, pp. 159–174; DOI: 10.1353/ken.2002.0008.

This article examines how in 1998, thirty-nine pharmaceutical manufacturers sued the Government of South Africa to prevent the implementation of a law designed to facilitate access to AIDS drugs at low cost. The companies accused South Africa –the country with the largest population of individuals living with HIV/AIDS in the world– of circumventing patent protections guaranteed by intellectual property rules that were included in the latest round of world trade agreements. The pharmaceutical companies dropped their lawsuit in the spring of 2001 after an avalanche of negative publicity. Yet, despite the Government's victory, AIDS drugs remain very expensive in South Africa, and the Government still refuses to provide antiretroviral therapy to adults. These events have shone a spotlight, not only on the possibilities for coordinated political activism in the era of instant global communications, but also on the tangled social, economic, and political dimensions of AIDS treatment in poor countries.

East African Community (EAC). **EAC Regional Intellectual Property Policy on the Utilisation of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation.** February 2013.

Available from: <https://www.cehurd.org/wp-content/uploads/downloads/2013/05/EAC-TRIPS-Policy.pdf>.

This regional EAC policy is a guide to Member States to adapt their legislation to take full advantage of TRIPS flexibilities, including topics such as strict patentability criteria and compulsory licensing. The Secretariat recognizes the need for a public health perspective in IP laws so that countries are not hurt by unbalanced protection that impedes access to medicines. It contains interesting

recommendations drawing on a comparative perspective and can be seen as a good example of the regional governance of IP.

Haakonsson, S. J., and Richey, L. A. **TRIPS and public health: the Doha Declaration and Africa.** *Development Policy Review*, 2007, 25 (1): 71–90.

This article deals with the Doha Declaration on Public Health and the TRIPS Agreement (2001), and the use of compulsory licenses to import generic medicines. By analysing HIV/AIDS treatment in Uganda, this article discusses the variety of TRIPS-related channels for ensuring drugs for domestic treatment, and argues that emphasising the restrictive nature of TRIPS provisions fails to grasp the scale of the obstacles involved. Lack of domestic resources leaves African countries dependent on donor financing, which in turn constrains their ability to exploit international trade provisions.

Kongolo, T. ***African Contributions in Shaping the Worldwide Intellectual Property System.*** London: Routledge, 2013.

The book argues that Africa plays an increasingly important role in global intellectual property law and details contributions by African countries at the WTO, WIPO and WHO. It addresses the topics of IP and public health; IP and traditional knowledge, traditional cultural expressions and genetic resources; IP and biodiversity; and exceptions and limitations to copyright. The book also provides case studies of African countries: Botswana, Burundi, Egypt, Ghana, Kenya, Mauritius, Morocco, South Africa and Tunisia, as well as regional initiatives of ARIPO, OAPI and the African Union, including the establishment of the Pan-African Intellectual Property Organization (PAIPO). In dialogue with the scholarship that analyses the more prominent role of Global South countries in shaping the global IP system, this book provides thoughtful insights on the participation and role of Africa.

Ncube, C. B. **The Development of Intellectual Property Policies in Africa: Some Key Considerations and a Research Agenda.** *Intel Prop Rights*, vol. 1, No. 1 (2013): p. 101. doi:10.4172/2375-4516.1000101.

The article presents the challenges to and issues for the development of intellectual property in Africa after the 2007 approval of the WIPO Development Agenda. Calling for the careful consideration of the socio-economic reality of countries, tied with the need for a balanced system, the author advocates an evidence-based policy formulation and highlights the need to ensure that the technical assistance provided by WIPO gives due weight to the particularities of African countries, including their national financial resources and expertise. This is an important reflection on the role of WIPO technical assistance and a warning against its potential incongruence to policies as those of access to medicines.

Ngwena, C. **The recognition of access to health care as a human right in South Africa: Is it enough?** *Health and Human Rights*, 2000, 5(1): 29–32.

This article discusses the scope and limitations of the right of access to health care in South Africa. The right of access to health care services is among the economic and social rights guaranteed by the Constitution of South Africa. However, given the jurisprudential novelty of such a right and its dependence on economic resources, its realization is likely to be difficult to secure. Even if, when this article was published, the country's courts had not yet developed clear principles for the interpretation of the right of access to health care, the obstacles identified by the author (country's pervasive poverty, gross income disparities and extremely high burden of disease) were acknowledged as such by South Africa's constitutional court in the Nevirapine case.

Tankoano, A. **Nouveau droit des brevets des états membres de l'Organisation Africaine de la Propriété Intellectuelle, développement industriel et accès aux médicaments.** *Revue Belge de Droit International*, 2005 (1-2): 669–699.

This article explains that the TRIPS Agreement changed the obligations of the Organisation Africaine de la Propriété Intellectuelle (OAPI) Member States, which, in turn, decided to revise the 1977 Bangui Treaty. This article details the modifications introduced in 1999 through an annex to the foundational treaty. It is important to notice that this new annex establishes a uniform law directly applicable in the sixteen OAPI Member States. The new standards are in line with the TRIPS Agreement objective of raising intellectual property standards, which make the article's author question their advisability. In fact, the author affirms that the new OAPI standards go against industrial development and access to drugs policies.

Shashikant, S. **The African Regional Intellectual Property Organization (ARIPO) Protocol on Patents: Implications for Access to Medicines.** South Centre Research Paper 56, November 2014. Available from: <https://www.southcentre.int/research-paper-56-november-2014/>.

This paper was commissioned to better understand the workings of the African Regional Intellectual Property Organization (commonly known as “ARIPO”) with regard to its Protocol on Patents and Industrial Designs and to examine the effect of implementation of the Protocol (Section on Patents) on the promotion of access to affordable medicines. Presently the Protocol has 18 Contracting Parties, the majority of which are least developed countries (LDCs). Pursuant to the Protocol, the ARIPO Office receives and processes patent applications and administers patent grants on behalf of its Contracting Parties. In its examination, the paper focuses especially on the extent to which the Protocol supports the objectives and recommendations of the East African Community Regional Intellectual Policy on the Utilization of Public Health Related WTO–TRIPS Flexibilities. It also aims to identify the practical

recommendations and mechanisms (including an alert mechanism) to minimize their adverse effects on access to affordable medicines.

Syam, N. **Transition Period for TRIPS Implementation for LDCs: Implications for Local Production of Medicines in the East African Community.** South Centre Research Paper 59, December 2014. Available from: <https://www.southcentre.int/research-paper-59-december-2014/>.

Article 66.1 of the WTO TRIPS Agreement grants the least developed countries (LDCs) a transition period during which they are not required to provide intellectual property rights protection according to the minimum requirements of the TRIPS Agreement. This transition period has been granted to LDCs to ensure that they are not prevented by the existence of IP rights from taking suitable measures to develop a sound and viable technological base in different industrial sectors. The TRIPS Council has extended this transition period three times, including a specific extension for pharmaceutical products, and it is possible to seek further extensions of this period. This paper analyses the implications of the transition period available for the local production of pharmaceuticals in LDCs that are Partner States of the East African Community (EAC): Burundi, Rwanda, Uganda and the United Republic of Tanzania. The paper analyses the critical challenges to the local production of pharmaceutical products in these countries and how the transition period can be used fully to address these challenges. Though the EAC Partner States rely predominantly on imported generic medicines, there is a need for local production of medicines, as their reliance on imports may be unsustainable. The LDCs from the EAC Partner States, however, have only recently begun using the TRIPS transition period, and Tanzania has still not introduced the transition period under its national law. Moreover, most LDCs from the region are contracting parties to the Harare Protocol, under which ARIPO grants pharmaceutical patents that are excluded under their respective national laws and would be void *ab initio*. Still, the granting of such patents to come into effect in these countries could create confusion. In this context, the paper recommends that all LDC Partner States of the EAC make use of the general transition period until 2021, that Tanzania start using the

transition period and that LDCs seek an extension of the transition period for pharmaceutical products, which expired in 2016. Moreover, national laws should declare any patent granted by ARIPO on pharmaceutical products void *ab initio* and a similar amendment could be moved in the Harare Protocol.

Syam, N., and Muñoz Tellez, V. **Innovation and Global Intellectual Property Regulatory Regimes – The Tension between Protection and Access in Africa**. South Centre Research Paper 67, June 2016. Available from: <https://www.southcentre.int/research-paper-67-june-2016/>.

This paper discusses the participation of African countries in global intellectual property (IP) regimes centred on the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) and the implications of expanding the scope of IP regimes through bilateral trade and investment agreements. It provides recommendations for an appropriate intellectual property regime to complement Africa's regional integration programmes.

von Braun J, Munyi P. **New Enforcement mechanisms challenge the legality of generics in the name of public health: the emergence of anti-counterfeiting legislation in East Africa**. *African Journal of International and Comparative Law*, 2010, 18.2: 238–253, Edinburgh University Press. Available from: <http://www.eupublishing.com/doi/abs/10.3366/ajicl.2010.0007>.

This paper addresses the inclusion of traditionally exempted forms of intellectual property rights (IPRs), such as patents and plant breeders' rights into anti-counterfeiting legislation in East Africa. In June 2008, the Merchandizing Marks Regulations were promulgated with a view to make provision for dealing with counterfeiting problems in Tanzania. Kenya copied this trend in December 2008, with the enactment of a national legislation on anti-counterfeiting. Uganda and others in the region are following suit. The enacted legislations exhibit a character of "substantive expansion" of the concept of counterfeiting. Similarly, the bill before the Uganda parliament and another that is due to be tabled before the East Africa Parliament to legislate against counterfeits exhibit similar

character. These legislative instruments raise questions over the legality of products put legitimately on the market by third parties without the authority of patent holders. Sadly, these include generic medicines and other products manufactured through legitimate exploitation of patents by third parties.

This paper focuses on the legislative initiatives taken by Kenya and Uganda and seeks to explore whether some of the provisions proposed or otherwise in these countries run counter to the principles and terms of the TRIPS Agreement as both countries are members of the World Trade Organization (WTO) and the challenges they may pose for public health in the region.

World Health Organization Regional Office for Africa (WHO AFRO). ***Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Implementation of TRIPS Safeguards in Relation to Pharmaceuticals in the WHO African Region.*** Summary Report of a Workshop, Zimbabwe. August 2001, Brazzaville, WHO: Regional Office for Africa, 2002.

The main goal of this workshop, organized by the WHO Regional Office for Africa, was to develop strategies for the implementation of the TRIPS Agreement, taking into consideration safeguards related to health and pharmaceuticals. Special attention was paid during to the interaction between TRIPS and national legal frameworks on pharmaceuticals, while some proposals were put forward in connection with principles of model legislation on the implementation of TRIPS safeguards and the type of support that would be required to undertake necessary reforms. The participants represented ministries of health, justice, finance and trade. They concluded the two days of discussions by issuing a set of recommendations, such as the need for increased regional collaboration on all TRIPS-related issues and the necessity for concerned countries to formulate national legislation to implement TRIPS safeguards. (Abstract from *IPR, Innovation, Human Rights and Access to Drugs. An Annotated Bibliography*. WHO/EDM/PAR/2003.9).

Vawda, Yousuf A. **Compulsory Licensing Jurisprudence in South Africa: Do We Have our Priorities Right?** South Centre Research Paper 90, December 2018. Available from: <https://www.southcentre.int/research-paper-90-december-2018/>.

Compulsory licences are generally available on a variety of grounds, most notably on patents where the patentee is found to have abused its rights. This research paper attempts to review South African case law on applications for compulsory licences since the inception of the current legislation, analyse the interpretations placed on the relevant sections and draw conclusions about judicial reasoning, impediments to the grant of such licences and, in general, the courts' approach to patent disputes.

Vawda, Yousuf A., and Shoji, Bonginkosi. **Eighteen Years After Doha: An Analysis of the Use of Public Health TRIPS Flexibilities in Africa.** South Centre Research Paper 103, February 2020. Available from: <https://www.southcentre.int/research-paper-103-february-2020/>.

This research paper provides an overview of the extent to which selected African countries have adopted legal and policy frameworks with regard to TRIPS flexibilities, examines the actual use of these flexibilities in enabling access to medicines in those countries and recommends some actions for optimising the use of the flexibilities in pursuing public-health imperatives. As a result of greater awareness of the necessity for legal reform to support implementation of the TRIPS flexibilities, the past decade has seen an increase in the number of African States that have reworked their IP regimes.

Yusuf, A. A. **Intellectual property protection in the countries of Africa.** *International Journal of Technology Management*, May 2009, 10(2/3): 269–292.

This paper examines the state of IPR and their protection and exploitation in African countries. Listed are the coverage of intellectual property laws, the subject matter of protection and the scope of rights conferred. It is shown that African legislation is

generally comparable to that in developed countries with regard to terms of protection, compulsory licensing, subject matter and government and public interest use. A comparison is made between developed countries and African members of GATT in regard to fields excluded from protection. The results of surveys of some individual African countries reveal the extent of registration of patents and technology transfer to these countries. Finally, the possible impact of new legislation, especially in the context of the TRIPS negotiations of the Uruguay Round, is considered.

4.2 Asia and Oceania

Basheer, S. **India's tryst with TRIPS: The Patents (Amendment) Act 2005.** *Indian Journal of Law and Technology*, Vol. 1, 2005.

Available from:

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=764066.

This paper highlights some of the main changes brought about by the 2005 Act and reflects on some of their broader implications. The controversial Patents (Amendment) Act 2005 was purportedly India's final step towards achieving complete TRIPS compliance. The introduction of pharmaceutical patents and the consequent threat to an internationally renowned generic industry that has, thus far, ensured the supply of affordable drugs catapulted this legislative effort to international significance, of an extent never before witnessed in the annals of intellectual property law-making in India.

The 2005 Act attempts to balance out competing interests of a variety of stakeholders, including domestic generic medicine producers, the domestic research and development community, foreign multinational pharmaceutical companies, civil society groups concerned with access to medicines and last (but certainly not least), intellectual property lawyers. Although this delicate balancing deserves some applause, an unfortunate fall-out has been the hasty introduction of provisions that go against the grain of time

tested patent law principles and are likely to provide excellent fodder for litigation.

Biswajit, D., and Gopakumar, K. M. **Post-2005 TRIPS Scenario in Patent Protection in the Pharmaceutical Sector: The Case of the Generic Pharmaceutical Industry in India.** Geneva: ICTSD, 2006.

Available from:

https://unctad.org/en/PublicationsLibrary/ictsd-idrc2006d2_en.pdf.

This paper explores the ways to meet the challenges posed by the TRIPS Agreement, which changed the conditions that saw the Indian pharmaceutical industry take roots. It is widely held that the future prospects of the industry hinge on the ability of the policy makers to exploit the flexibilities contained in the TRIPS Agreement. The paper examines the features of the TRIPS Agreement that India has put in place through three amendments introduced between 1999 and 2005. It also looks at the changes that have been afoot in the Indian pharmaceutical industry while the patents regime was undergoing changes. And it specifically deals with the issue of access to HIV/AIDS drugs and the role of the Indian pharmaceutical industry.

Ford, N., et al. **The role of civil society in protecting public health over commercial interests: lessons from Thailand.** *The Lancet*, 2004, 363: 560-563.

This article summarizes the efforts of civil society in Thailand to achieve a fair balance between trade and public health. It explains how, in October 2002, two Thai people with HIV won an important legal case to increase access to medicines. In its judgment in the didanosine patent case against Bristol-Myers Squibb, the Thai Central Intellectual Property and International Trade Court ruled that, because pharmaceutical patents can lead to high prices and limit access to medicines, patients are injured by them and can challenge their legality. This ruling had great international implications for health and human rights.

Gehl Sampath, P. **India's product patent protection regime: less or more of "pills for the poor"?** *The Journal of World Intellectual Property*, 2006, 9 (6):694-726.

The author explains that the year 2005 marked the end of the transition period granted by the TRIPS Agreement for many developing countries to comply with its provisions on pharmaceutical product patents. This included those countries with competent pharmaceutical sectors that previously competed in supplying generic versions of patented drugs to least-developed countries. In a post-2005 scenario, the critical issue is whether countries without adequate manufacturing capabilities can make use of compulsory licensing expeditiously to induce price competition and secure lower prices. This article uses empirical evidence collected during a firm-level survey of the Indian pharmaceutical sector to generate evidence on emerging strategies of firms. It shows that the vigour of compulsory licensing as a price-leveraging instrument post-2005 is incumbent mainly on its economic feasibility. It shows that Indian firms view the market potential of the mechanism much more severely than before, and may be less inclined to engage in such production if their commercial expectations are grossly unmet. The analysis assesses implications of emerging strategies of firms in the Indian pharmaceutical sector for access to medicines both domestically and internationally, and highlights the challenges involved.

Gopakumar, K. M. **What should we learn from the Novartis judgment?** *Third World Resurgence*, No. 273 (May 2013).

Available from:

<https://www.twm.my/title2/resurgence/2013/273/cover03.htm>.

After the landmark decision by the Indian Supreme Court on the *Novartis* case, particularly in relation to its take on the validity and applicability of Section 3(d) of the Indian Patent Law, this article presents the positive effects of the decision on access to medicines, as it contains a rigorous patentability criterion. The author thoroughly presents the case in question, the patent application of imatinib mesylate and the subsequent litigation up to the Supreme Court ruling. Finally, he analyses the implication of the decision on the patenting of known substances, which was clearly limited and whose criteria were also refined. He concludes by recognizing the importance of the ruling but affirms that an *ex ante* exclusion of

patenting that did not require a case-by-case analysis would be even more suitable for developing countries.

Government of Australia. **Pharmaceutical Patents Review 2013.**

Available from:

https://www.ipaustralia.gov.au/sites/default/files/2013-05-27_ppr_final_report.pdf.

This report by the Australian Government is an important precedent to a national assessment conducted by an industrialized country recognizing the need for a carefully designed and balanced intellectual property policy. The report mentions multiple negative effects concerning prices and obstacles to innovation due to the creation of legal risks and constraints to competition. It also raises the question of Australia's stance in international forums vis-à-vis the general welfare generated to the country. The report requests amendments to patent law to avoid unduly restricting competition, opposes data exclusivity, requests stricter patentability criteria in patent applications and concludes that the current patent system has worked against the best interests of the country. The report also conducts an important empirical and statistical assessment of all such topics and may be considered a relevant tool for other countries in performing their own equivalent analyses.

Grace, C. **The Effect of Changing Intellectual Property on Pharmaceutical Industry Prospects in India and China: Considerations for Access to Medicines.** London: Health Systems Resource Centre for the Department for International Development, 2004.

Available from: <http://www.who.int/hiv/amds/Grace2China.pdf>.

This study looks at the effects of enhanced IP protection in the People's Republic of China and the introduction of product patent law in India. It states that the introduction of product patents means that Indian firms have reduced revenue options for the sale of drugs domestically, since generic copies of newer medicines have become illegal. To compensate for this revenue loss, Indian firms have increased their emphasis on exporting to the more profitable regulated markets. There is also an increased focus on product

innovation, with the most successful firms investing an increasing amount in R&D. Multinational pharmaceutical companies have been interested in working with Indian firms for some time, attracted by the lower cost structure, advanced chemistry and process engineering skills, and large market size. The study states that the prospects are positive for the future of the Indian industry.

Gupta, R. **TRIPS compliance: dealing with the consequences of drug patents in India.** *Houston Journal of International Law*, 2004, 26(3): 599–639. Available from:
http://www.thefreelibrary.com/_/print/PrintArticle.aspx?id=121949013.

This article deals with the changes to drug patent laws that India was required to make by 2005 to comply with the TRIPS Agreement. Since the end of the TRIPS transitional period, Indian generic companies are no longer able to market a drug by developing a new manufacturing method, and there is a strong belief that the new laws will benefit multinational pharmaceutical companies at the expense of Indian industry and jobs. The author states that this raises legitimate criticisms and generates quite problematic situations. Nevertheless, the paper states that there are many factors and policy choices to mitigate the drawbacks of granting pharmaceutical product patents. The article points out the importance of experimentation and context-specificity with regard to the strengthening of intellectual property rights in the developing world, and with a word of caution about an over-reliance on patents.

Kuanpoth, J. **Patents and access to antiretroviral medicines in Vietnam after World Trade Organization Accession.** *The Journal of World Intellectual Property*, 2007, 10(3-4): 201–224.

The author explains that antiretroviral (ARV) drugs, where they are accessible, have been shown to prolong the lives and increase the health and well-being of people living with HIV/AIDS. In general terms, whether a country is able to provide affordable ARVs to people in need is determined by the pricing structure of the drugs, which is in turn based on the patent environment that regulates

them. Increasing access in many developing countries, including Vietnam, requires a thorough understanding of the patent environment and of the legal options that will allow the production and/or importation of affordable treatments. This article provides an analysis of current patent law in Vietnam with regard to the production and importation of pharmaceuticals. It then reviews the current situation of supply of ARVs with regard to pharmaceutical patents and Vietnam's obligations and practices against international agreements. The study concludes by suggesting options for utilizing current law to improve access to ARVs and makes recommendations for the implementation of Vietnamese patent law.

Moir, H. V. J., Tenni, B., Gleeson, D., and Lopert, R. **Assessing the Impact of Alternative Patent Systems on the Cost of Health Care: The TPPA and HIV Treatment in Vietnam** Paper presented at the Asia-Pacific Innovation Conference, University of Technology, Sydney, 27 November 2014. Available from: SSRN <https://ssrn.com/abstract=2536254>.

In this empirical analysis, the authors compare the current Vietnamese patent regime with regard to its effect on access to antiretroviral medicines for HIV/AIDS to two possible scenarios: one with the full use of TRIPS flexibilities and the other using the model proposed by the United States during the negotiations of the Trans-Pacific Partnership Agreement (TPP). Their finding is that, using the current budget in Vietnam, “82 per cent of the HIV population eligible for treatment would receive ARVs under a full TRIPS flexibility scenario, while only 30 per cent of Vietnam's eligible HIV patients would have access to ARVs under the US 2014 TPPA proposals – more than halving the proportion treated compared to the current 68 per cent receiving treatment”. They further note that other countries would likely experience similar negative consequences.

Raju, K. D. **The debacle of Novartis patent case in India: strict interpretation of patentability criteria under Article 27 of the TRIPS Agreement.** Working Paper Series, Rajiv Gandhi School of Intellectual Property Law, IIT Kharagpur November 2007.

Available from:

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1030963.

This article analyses a larger question of international importance: the jurisdiction of a national court to test the validity of a provision in an international agreement in the light of the Novartis case. In the second part, freedom of the WTO Member States to implement the TRIPS obligations under Article 27 through national legislations and its repercussions on the protection of intellectual property are analysed. At the end of the discussion the controversial discussion of patents versus patients in developing countries were closely examined. The concluding remarks can be used as a guideline for the developing countries in the protection of intellectual property especially in the pharmaceutical sector.

Sampat B. N., and Shadlen K. C. **Indian pharmaceutical patent prosecution: The changing role of Section 3(d).** *PLoS ONE*, vol. 13, No. 4 (April 2013): p. e0194714.

Available from: <https://doi.org/10.1371/journal.pone.0194714>.

This empirical research evaluates the use of Section 3(d) of the Indian Patent Law, considered to be a provision aimed at strong control over the grant of secondary pharmaceutical patents as well as a source of serious criticism from pharmaceutical companies and developed countries, especially the United States. Unlike previous findings, which criticized the provision for being underused, this recent analysis points towards a changing role over time. Section 3(d) has increasingly been used – in conjunction with other legal arguments – in cases of primary patent applications, signalling a potential policy at the Indian Patent Office of introducing a higher threshold for pharmaceutical applications. This is line with both official statements and judicial rulings, including by the Supreme Court, recognizing the legitimacy of such a provision. The authors further explore arguments that may also explain the empirical enhanced importance of Section 3(d), which includes the often

unclear distinction between a new compound and a new form of a known compound, the raised scrutiny generated by the early invocation of the section in the patent application process and the possibility that Section 3(d) makes the entire examination process more rigorous (including through its symbolic effect). This article is then relevant for a thorough and contemporary account of Section 3(d) despite its critics and is entangled with the importance of India as a lead producer of pharmaceuticals to the developing world.

Shanker, D. **India, the pharmaceutical industry and the validity of TRIPS.** *The Journal of World Intellectual Property*, May 2002, 5(3): 315–371.

This article deals with the attempts by developing countries to bring their patent regimes into line with the provisions of the TRIPS Agreement, e.g., in India, through the Second Amendment in 1999 of the Indian Patent Act, and how this development is viewed by pharmaceutical industries abroad (in particular Pharma), governments and supporting institutions. This analysis suggests that it is nearly impossible for developing countries to do so, as the interpretations of these provisions by the pharmaceutical industries, their supporting institutions and indulgent governments are continuously changing. The issue of compulsory licensing and the effect of the WTO Panel Report in the Canada patent protection case on compulsory licensing have been analysed in detail due to their important consequences for patenting practices in developing countries.

The article also analyses other developments, such as the removal of business methods from non-patentable items from the US Patent Act because of certain interpretations of that Act by the Court of Appeal which failed to acknowledge a number of US Supreme Court judgements; the article also refers to the partial modification of Section 48(3) of the UK Patent Act which removed local working conditions as a result of the WTO Act, 1999, and the introduction of computer programmes as patentable subject-matter, as well as many other indiscreet interpretations which were never part of the original TRIPS Agreement. (Abstract from *IPR*,

Innovation, Human Rights and Access to Drugs. An Annotated Bibliography. WHO/EDM/PAR/2003.9).

Supakankunti, S., et al. **Study of the implications of the WTO TRIPS Agreement for the pharmaceutical industry in Thailand.** *Bulletin of the World Health Organization*, 2001, 79(5): 461–470.
Available from:
[http://www.who.int/bulletin/archives/79\(5\)461.pdf](http://www.who.int/bulletin/archives/79(5)461.pdf).

The 1994 WTO TRIPS Agreement established minimum universal standards in all areas of intellectual property. It is intended to implement these standards globally through a WTO enforcement mechanism. The present article proposes a strategy for alleviating the potentially negative impact of TRIPS in Thailand in relation to the following: purchasers; prescribers and dispensers; producers; products; price control; patent-to-third-party; parallel imports; power of the customer; patentable new drugs; personnel; and prevention policies. The following TRIPS provisions are pertinent to the pharmaceutical industry in Thailand: the limited term of product and process patents; the conditions of protection; and the broad scope for compulsory licensing and enforcement procedures in the national patent system.

Thailand, Ministry of Public Health and the National Health Security Office. ***Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand. Document to Support Strengthening of Social Wisdom on the Issue of Drug Patent.*** Bangkok, 2007.
Available from:
<https://apps.who.int/medicinedocs/en/m/abstract/Js18718en/>.

This paper explains the views of the Thai Ministry of Public Health on their decisions on the Government Use of Patents as a form of social movement that aims at improving access to essential medicines and the health of the people. The decisions of the Thai Ministry of Public Health to announce the Government Use of Patents on three patented drugs, i.e., Efavirenz (Stocrin® of Merck Sharp and Dohme), Lopinavir+Ritonavir (Kaletra® of Abbott Laboratory) and Clopidogrel (Plavix® of Sanofi- Aventis), based on proposals from the

National Health Security Office, have raised several questions among the public and also the concerned partners as well as pharmaceutical industries, both in the country and internationally. The paper explains that some questions and concerns are due to lack of information; others are intentional with the aim of creating misunderstanding and objections to the announcements. Thus there is a need to clarify all the questions with the right information and evidence. The staff of the Ministry of Public Health had compiled all the questions and summarized them into 10 burning issues that need to be addressed. Relevant answers and evidence have been collected to address each issue.

This white paper, *The Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand* states that the paper does not only aim at answering all the questions raised, but more importantly aims to serve as a tool to inform and educate the Thai and global society as a whole, on the issue of pharmaceutical patents and public health.

Velásquez, G., Correa, C. M., and Weissman, R. ***Cost-containment Mechanisms for Essential Medicines, Including Antiretrovirals, in China***. Geneva: WHO, Health Economics and Drugs, EDM Series No. 13, 2003.

This paper explains the range of cost-containment options for antiretrovirals and other essential medicines in the People's Republic of China by assessing the experiences of other countries in this domain and mapping out those options that are compatible with the TRIPS Agreement. Notions such as voluntary and compulsory licensing or government price controls are extensively developed. Experiences of other countries, such as Brazil and Indonesia, are used as possible useful examples for the Chinese authorities in their attempts to contain the cost of essential medicines at the national level. Special attention is paid to the right of countries to be protected in voluntary agreements for reduction of prices of medicines as well as practical aspects of the implementation of compulsory licensing. The paper concludes by stressing the importance of public health considerations in the design of policies for cost-containment, while detailing some of the

problems that may appear in the negotiation process for voluntary licences or voluntary price reductions.

Watal, J. **Pharmaceutical patents, prices and welfare losses: policy options for India under the WTO TRIPS Agreement.** *World Economy*, 2000, 23(5): 733–752.

The implications of the TRIPS Agreement for drug prices is a major debate in the international arena. The Indian Patent Act analyzed by the author, that excluded the patentability of pharmaceutical products, was widely credited to be one of the factors that has brought Indian pharmaceutical prices down to one of the lowest levels in the world. This study simulates the maximum likely increase in pharmaceutical prices and the reduction of welfare in India from the introduction of product patents. It further analyses the extent to which policy measures such as price controls and compulsory licences can help to attenuate the adverse effects of patent monopoly. Price controls and compulsory licences are believed to be effective in reducing prices and welfare losses, and they are justifiable and acceptable under current international law. (Abstract from *IPR, Innovation, Human Rights and Access to Drugs. An Annotated Bibliography*. WHO/EDM/PAR/2003.9).

Wilson, D. et al. **Global trade and access to medicines: AIDS treatments in Thailand.** *The Lancet*, 1999, 354 (9193): 1893–1895. Available from: <http://hdl.handle.net/10144/17657>.

This article from Médecins sans Frontières (MSF) describes the problem of access to HIV/AIDS treatment in Thailand. It alleges that pressure from the USA is one important factor that has limited access to affordable treatment for Thai patients. The article concludes by emphasizing the importance for developing and least developed countries of understanding fully the implications of trade agreements. The article states that WHO has the mandate to monitor the public-health consequences of international trade agreements as several less-developed countries have been under pressure from western governments to make changes in trade laws that would restrict their ability to produce or import drugs.

Zhan, Y., Zhu, X. **Intellectual property right abuses in the patent licensing of technology standards from developed countries to developing countries: a study of some typical cases from China.** *The Journal of World Intellectual Property*, 2007, 10 (3-4): 187-200.

The authors argue that while Western countries continually criticize developing countries, especially China, for a lack of effective protection of intellectual property rights (IPRs), the IPR abuses of developed countries in developing countries are also worth paying attention to. This article takes several representative cases that have occurred in recent years in China and discusses the IPR abuses in the licensing of technology standards from developed countries to developing countries. Under *de facto* standards, the IPR abuses of western enterprises are mainly conducted through blocking competitors by taking advantage of the status of controlling the standards. Under *de jure* standards, the most urgent antitrust concerns for developing countries are being charged an excessively high patent royalty and being refused independent licensing in practice by the western patent pools under the standards. In addition, this article also shows China's responses, such as improving its legal system to restrict IPR abuses and commonweal intellectual property litigation filed by IPR scholars. A brief analysis on categories of commonweal relative to IPR abuses is also presented.

4.3 Europe

Correa, C. M. **Patent Examination and Legal Fictions: How Rights are Created on Feet of Clay.** South Centre Research Paper 58, December 2014. Available from: <https://www.southcentre.int/research-paper-58-december-2014/>.

Patents are often presented as an absolute property, comparable to land property. This simplification overlooks the conference of patent rights without a solid determination of the factual conditions required for such rights to arise. The examination process for patent applications faces substantial limitations, even in the case of large

patent offices, to determine whether a claimed invention actually meets the patentability standards, however defined. Such an examination neither offers a guarantee regarding the validity of the titles granted nor, in many cases, ensures a clear delimitation of the boundaries of the protected invention. Despite this, an examination system is a better option than a mere registration system, as the latter creates legal monopolies without even a minimal analysis of what is claimed. Patents are granted on the basis of a number of legal fictions that reveal the precariousness of the basis for the grant of such rights. Importantly, however, no country is obliged under the TRIPS Agreement or any other international instrument to apply such fictions or accept certain types of claim formulations, nor can they be prevented from changing their previous policies by introducing more rigorous standards under which certain claims would be disallowed.

Scherer, F. M., and Weisburst, S. **Economic effects of strengthening pharmaceutical patent protection in Italy.** *International Review of Industrial Property and Copyright Law*, 1995, 26(6): 1009–1024.

This article investigates how Italian producers adapted to the intellectual property regime changes of 1978. In particular, it undertakes a detailed statistical analysis of changes in drug R&D expenditures and patenting. The Italian experience of introducing pharmaceutical patent protection is particularly interesting because it presages legal changes that are likely to happen in some developing countries in the WTO TRIPS era.

Seuba, X. **La invocación del Acuerdo sobre los ADPIC ante los tribunales españoles y sus consecuencias sobre las patentes farmacéuticas.** *Revista General de Derecho Europeo*, nº 14, Octubre 2007. Available in Spanish.

The so-called “innovative pharmaceutical industry” has posed an interesting question regarding the effects in Spain of the TRIPS Agreement. Although pharmaceutical product patents were not valid in Spain until 1992 due to a reservation to the European Patent Convention, the protection of the “existing subject matter”

afterwards recognized in the 1994 TRIPS Agreement has questioned the regime of process patents prior to the application of the Agreement, with or without product claims, and the validity of product patents claimed when said application warranted to be considered null and void. The discussion deals with, firstly, the meaning of article 70 of the TRIPS Agreement, secondly, the effects of the said treaty in the Spanish legal system, and thirdly, the competence of the European Community in the intellectual property field.

Vernaz N., Haller G., Girardin F., Huttner B., Combescure C., et al. **Patented drug extension strategies on healthcare spending: A cost-evaluation analysis.** *PLOS Medicine*, vol. 10, No. 6 (2013). Available from: <https://doi.org/10.1371/journal.pmed.1001460>.

This empirical article estimates the costs of evergreening strategies to the health-care system as a whole, as they generate higher health-care costs. It analyses data from hospitals and from community pharmacy invoice offices from the Canton of Geneva, estimating an extra cost of €503,600 (mainly attributable to two drugs, esomeprazole and escitalopram) between 2000 and 2008. In conclusion, the study shows that, even in a high-income setting, evergreening strategies contribute to an increase in overall health-care costs. Policies encouraging the prescription of generic medicines could have substantial savings on health-care expenditures.

4.4 Americas

Amin, T., and Kesselheim, A. **Secondary patenting of branded pharmaceuticals: A case study of how patents on two HIV drugs could be extended for decades.** *Health Affairs*, vol. 31, No. 10 (2012).

Contributing to the debate on secondary patents and how they can extend market exclusivity and delay generic entry, this article focuses on a deep analysis of two key antiretroviral drugs for HIV:

ritonavir (Norvir) and lopinavir/ritonavir (Kaletra). The authors identify 108 patents in the United States, which could delay generic entry until at least 2028, being “twelve years after the expiration of the patents on the drugs’ base compounds and thirty-nine years after the first patents on ritonavir were filed”. Through an analysis of each patent, they find that some of the secondary patents have limited or questionable inventiveness. This case-study assessment in the context of the USA represents important evidence-based material that highlights the potential implications of broad patentability. The authors argue for more transparency, stricter patentability criteria and more opportunities to challenge patents so as to counter undue market exclusivity extensions.

Cohen, J. C., and Lybecker, K. M. **AIDS policy and pharmaceutical patents: Brazil's strategy to safeguard public health.** *The World Economy*, 2005, 28(2): 211–230. Available from: <https://doi.org/10.1111/j.1467-9701.2005.00668.x>.

The authors analyse the relationship between Brazil’s obligations as a member of the WTO and its drug pricing strategy for HIV/AIDS drugs. This paper examines why the Brazilian strategy was effective in compelling the research-based pharmaceutical industry to lower pharmaceutical prices and considers the wider implications for other developing countries. The paper describes the WTO TRIPS Agreement, presents the Brazilian public health system and pharmaceutical sector, describes the Brazilian AIDS Policy and examines a game-theoretic analysis of the Brazilian strategy. The paper also spells out Brazil’s response to the TRIPS Agreement and introduces the implications for other developing countries.

Correa, C. M. **Reforming the intellectual property rights system in Latin America.** *World Economy*, 2000, 23(6): 851–872.

During the 1990s, significant changes took place in Latin America in order to comply with the TRIPS Agreement. This paper reviews the changes in IPR laws in Latin American countries by examining the introduction of substantive amendments, the main problems faced and some implications of the changes. For example, in relation to foreign direct investment, the paper shows that, in some countries

where product protection for pharmaceuticals is accepted, a large number of foreign-owned plants for formulating pharmaceuticals have been closed down. This is contrary to the situation in Argentina where patents for pharmaceutical products are not granted, and a significant flow of foreign direct investment has been reported as mainly targeting the acquisition of local firms.

Correa, C. M., and Velásquez, G. **Access to Medicines: Experiences with Compulsory Licenses and Government Use – The Case of Hepatitis C**. South Centre Research Paper 85, April 2019.

Available from: <https://www.southcentre.int/research-paper-85-april-2019/>.

This South Centre research paper discusses, first, the limitations of the current research and development (R&D) model and its implications for access to medicines. Second, it considers the tension between intellectual property rights applied to medicines and States' observance of the fundamental right to health. Third, it examines the case of access to medicines for the treatment of hepatitis C, illustrating the barriers to access created by intellectual property and the high prices normally associated with its exercise. Fourth, it presents the background, main aspects of and obstacles to the achievement of the objectives of the Doha Declaration on the TRIPS Agreement and Public Health (2001). To conclude, this paper examines the experiences of compulsory licensing and the government use of patents in Latin America (particularly in Ecuador, Peru and Colombia).

Cortés Gamba, M. E., Rossi Buenaventura F., and Vásquez Serrano, M. D. **Impacto de 10 años de Protección de Datos en Medicamentos en Colombia**. Buscando Remedio Series No. 2 (2012).

Colombia introduced protection for medical data in 2002 under pressure from the United States and in line with its commitments under free trade agreements. This report analyses its negative consequences on access to medicines and competition, the unsuccessful outcome in terms of investments and the economic effects of up to \$400 million on Colombia. In this context the authors

propose a number of policies, including the reform of the free trade agreement with the United States and the use of compulsory licenses.

Costa Chaves, G., Oliveira, M. A., Velásquez, G., and Zepeda Bermudez, J. A. **Has the implementation of the TRIPS Agreement in Latin America and the Caribbean produced intellectual property legislation that favours public health?** *Bulletin of the World Health Organization*, 2004, 82 (11). Available from: <http://www.who.int/bulletin/volumes/82/11/en/815.pdf>.

This study reflects on legislation in 11 Latin American and Caribbean countries, with the aim to determine whether implementation of the TRIPS Agreement in Latin American and Caribbean countries has resulted in patent legislation that is sensitive to public health needs. The variables considered in the analysis were the term of patents issued, patentable subject matter, transition periods, reversal of the burden of proof of patent infringement, exhaustion of rights, compulsory licensing and the early working exception. The authors conclude that the countries in this study did not incorporate all of the mechanisms allowed for by the Agreement and are not adequately using the provisions that enable WTO Member States to obtain better health for the public, particularly in regard to gaining access to medicines. This situation may deteriorate in future if other agreements establish more restrictive rules for intellectual property rights.

Dreyfuss, R., and Rodríguez-Gavarito, C. ***Balancing Wealth and Health: The Battle over Intellectual Property and Access to Medicines in Latin America***. Oxford: Oxford University Press, 2014.

This book presents issues of IP and access to medicines in eleven Latin American countries, as well as some broader global topics. Approaches include human rights, international relations and transnational activism. The book provides analytical tools and data that allow a comparison of countries' approaches as well as the consequences of such decisions for the balance between IP protection and the right to health. It further offers insight into the local implementation of the TRIPS Agreement, the role of

international organizations like the WIPO, the useful role of human rights law and the role of civil society.

Federal Trade Commission. **Generic Drug Entry Prior to Patent Expiration: An FTC Study.** July 2002. Available from: https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf.

This study by the US Federal Trade Commission, which enforces antitrust laws and conducts antitrust investigations in the country, argues for changes in US policy and legislation with an aim of enhancing competition and preventing undue delay in the market entry of generic companies. This is a relevant document in the American context that highlights both the policies undertaken to promote competition and generics and the ties of patent policies with both competition law and judicial enforcement to correct inadequate protection – features that do not always exist in other countries to correct disparities.

Galvao, J. **Access to antiretroviral drugs in Brazil.** *The Lancet*, 2002, 360(9348): 1862–1865. Available from: <http://image.thelancet.com/extras/01art9038web.pdf>.

Since 1996, the Brazilian Ministry of Health guarantees free and universal access to antiretroviral treatment for people living with HIV/AIDS. Implementation of this policy has had political, financial and logistical challenges. The author has investigated the history and context of antiretroviral policy in Brazil, the logistics of drug distribution and the Government's strategies for the acquisition of drugs. Many antiretrovirals used in Brazil are produced domestically; the remainder, including some of the most expensive drugs, are purchased from abroad. Although the Brazilian policy of antiretroviral distribution has had notable success, it remains threatened by the high cost of the acquisition of drugs, which has led to disputes with international pharmaceutical companies over prices and patents. Much can be learnt from the Brazilian model of guaranteeing access to antiretroviral treatment for people living with HIV/AIDS.

Gonzalez, E. **Juridical action for the protection of collective rights and its legal impact: a case study.** *Journal of Law, Medicine and Ethics*, 2002, 30(4): 644–654.

This article refers to the main legal cases recently heard by the Venezuela Constitutional Court, the rulings of which have had important consequences for granting access to drugs for important sectors of Venezuela's population.

The development in 1996 of a new generation of antiretroviral drugs was a major pharmaceutical breakthrough in the struggle against HIV/AIDS. Due mainly to their high costs, access to these new drugs was almost impossible for most HIV-positive people, especially in developing countries. Many of the organizations struggling for the rights of HIV-positive people have since developed human rights advocacy and legal strategies to try to achieve universal access to treatment. This paper draws upon the experience gained in Latin America, focusing on the legal strategies that have been explored in Venezuela and the legal consequences for domestic law.

Guimarães, Eduardo Ribas de Biase. **A Regulação das Patentes Farmacêuticas no Brasil: Entre saúde pública, política e direito.** Ph.D. dissertation, State University of Rio de Janeiro (UERJ), Institute of Social Medicine, 2013.

The thesis historically, sociologically and legally analyses the regulation of pharmaceutical patents in Brazil, with a focus on the mechanisms for protecting public health. Among the topics addressed are the prior consent of the National Health Surveillance Agency (ANVISA) model, as well as patent opposition. It provides an overview of the actions of the Brazilian Government from 1996 to 2012, the proposals to change the Brazilian Industrial Property Law and the controversies linked to some types of patent claims, such as polymorphs, selection patents and second medical use. The author proposes that the regulation of pharmaceuticals is not merely a set of formal norms, but rather assemblages among actors, different types of knowledge and intervention tools.

Hunt, M. I. ***Prescription drugs and intellectual property protection: finding the right balance between access and innovation.*** Washington D.C.: National Institute for Health Care Management Research and Educational Foundation, 2000.
Available from: <http://www.nihcm.org/pdf/prescription.pdf>.

This report examines the most important law pieces on intellectual property protection (IPP) for pharmaceuticals approved in the United States of America from the 1983 Orphan Drug Act to the 2000 Pipeline Drug Proposals, with mention of the Uruguay Round Agreements Act and the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman). It also takes into account the effects of this enhanced protection on technological innovation and the market for prescription drugs. The report asserts the critical impact of current patent laws on the price of prescription drugs and general public health costs. It pays close attention to some of the reported benefits of IPP, such as the support for technological innovation, showing in contrast the major role played by IPP, not only in protecting pharmaceutical industry profits but also in delaying the entry of affordable generic drugs onto the market and shielding brand-name drugs from price competition. The report concludes by asking for greater vigilance on the part of public authorities on the use by private companies of public funds devoted to R&D. (Abstract from *IPR, Innovation, Human Rights and Access to Drugs. An Annotated Bibliography*. WHO/EDM/PAR/2003.9).

I-MAK. **Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Prices.** New Delhi, 2018.

The report analyses the twelve best-selling drugs in the United States in relation to their patent protection. It shows that there are hundreds of patent applications that effectively extend the monopoly of patents far beyond the 20 years of protection provided for under US patent law. It further highlights that prices have increased by 68 per cent since 2012 and that there are 38 years of attempted patent protection, blocking generic competition. More than half of these drugs, which have all been on the US market for at least fifteen years, have had more than 100 attempted patents so

far. For instance, the cancer drug Herceptin had patents filed for it as early as 1985 and has current patent applications that could extend exclusivity until 2033 – a possible 48-year monopoly span. This empirical assessment is important in highlighting both the practices used to extend patent monopolies and their relation to profits generated by drugs without real new innovation.

Jones, G. H., Carrier, M. A., Silver, R. T., and Kantarrjian, H. **Strategies that delay or prevent the timely availability of affordable generic drugs in the United States.** *Blood*, No. 127 (2016): pp. 1398–1402.

The article describes the numerous strategies that prevent or delay the entry into the market of generic drugs in the United States, including: reverse payment or pay-for-delay patent settlements, authorized generics, product hopping, lobbying against cross-border drug importation and buying out the competition. According to the authors, “the complexity presented by the intersection of the patent laws, the antitrust laws, the Hatch-Waxman Act, and state drug product selection laws” creates a door for exploitation. They further argue that generic companies are sometimes involved in similar high-price practices. In conclusion, the authors propose some measures that could counter the problem, including challenging weak patents, allowing the transport of drugs for personal use and allowing Medicare to negotiate drug prices. It is important to note that these practices are not exclusive to the United States, and the fact these are identified within such context are also important evidence for other policymakers globally about which policies they should adopt to curb restricting practices.

OXFAM. **Drug Companies vs. Brazil: The Threat to Public Health.** Oxford: Oxfam International, 2001. Available from: <http://policy-practice.oxfam.org.uk/publications/drug-companies-vs-brazil-the-threat-to-public-health-114469>.

In the midst of the controversy generated by certain actions against the Brazilian intellectual property and public health policies by the end of the nineties, this Oxfam report stated that major drug companies were trying to ensure that Brazil bought expensive

patented drugs manufactured by the major companies rather than making generic versions in Brazil or buying them from countries such as India. The paper summarized the facts, the policies at stake and different pressures that Brazil received and the legal background of that situation. (Abstract from *IPR, Innovation, Human Rights and Access to Drugs. An Annotated Bibliography*. WHO/EDM/PAR/2003.9).

Torremans P. **Compulsory licensing of pharmaceutical products in Canada.** *International Review of Industrial Property and Copyright Law*, 1996, 27(3): 316–331.

Canada had always stood out for its special policy in relation to pharmaceutical patents until important changes took place at international level with the negotiation of the NAFTA and the TRIPS Agreement. Compulsory licences were at the centre of all these debates and they have attracted attention in Europe. This article investigates what pattern is to be found in all these developments and what are the advantages and disadvantages of the various regimes. It seeks to demonstrate that the new system, while perfectly acceptable in principle, can be improved on a series of points, and that experience under European law can be of assistance. (Abstract from *IPR, Innovation, Human Rights and Access to Drugs. An Annotated Bibliography*. WHO/EDM/PAR/2003.9).

von Braun, J. ***The Domestic Politics of Negotiating International Trade: Intellectual Property Rights in US-Colombia and US-Peru Free Trade Agreements***. London: Routledge, 2012.
Available from: <https://doi.org/10.4324/9780203156360>.

This monograph discusses the role that domestic politics play in formulating the basis upon which negotiators engage in international trade negotiations. It pays particular emphasis on the extent to which systemic factors have undermined the role of health authorities in influencing intellectual property negotiations when these are tied into broad trade agreements. Using the US-Peru and US-Colombia Free Trade Agreements as a case study, the book discusses how health authorities in both countries from the onset had little chance in upholding public health objectives throughout

the negotiations in spite of having received commitment to do so from the highest political level. At the same time the monograph traces the domestic origin of the near inflexible IP negotiation mandate in the US at the time of the negotiations, and how this mandate is adapted after the sweeping victory of Democrats in the 2006 Congressional elections. Mirroring the three domestic scenarios the book demonstrates the importance in understanding domestic policy structures when trying to understand international negotiation dynamics.

4.5 Middle East

Basma, A. *The Illusive Trade-off: Intellectual Property Rights, Innovation Systems and Egypt's Pharmaceutical Industry*. Toronto: Toronto University Press, 2006.

The Egyptian pharmaceutical industry serves as a case study for understanding the impact of the global intellectual property regime in this fascinating new addition to the University of Toronto Press Studies in Comparative Political Economy and Public Policy series. *The Illusive Trade-off* examines the Egyptian pharmaceutical industry within a broader context of intellectual property policy making and the multilateral agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Basma Abdelgafar offers a fascinating discussion of Egypt's role in the trade negotiations that led to the establishment of the World Trade Organization, and makes the case that predominant perspectives on intellectual property rights are based on the false assumption that the innovation process is discrete and segmented.

Abdelgafar contends that, in fact, innovation relies upon diffusion, and that inappropriately strong property rights interfere with this process. She uses the case of Egypt's pharmaceutical industry to argue that we must consider relevant aspects of individual countries' systems of innovation as well as public health, if we are to adequately understand the implication of stronger patent protection for the pharmaceutical industries of developing

nations. The Illusive Trade-off is an original and important study crossing the disciplines of political science, law, public policy, and public health.

El Said, M. ***The Development of Intellectual Property Protection in the Arab World***, Lewiston: The Edwin Mellen Press, 2008.

Available from:

<http://www.mellenpress.com/mellenpress.cfm?bookid=7465&pc=9>.

This monograph studies the historical foundations of intellectual property protection in the Arab world with special focus on the case of Jordan. It provides a historical overview of intellectual property protection and its development in the region, with special focus on the alarming speed at which such intellectual property protection regimes were reformed. It argues that the Arab region in general and Jordan in particular, has moved from a TRIPS-minus protection regime to a TRIPS-plus one as a result of WTO accession and the signing of bilateral free trade and association agreements with little negotiation leverage and preparation. The monograph alerts to the negative impact such a process may have on these countries national development plans, public health regimes and access to medicines.

El Said, M. ***Public Health Related TRIPS-plus Provisions in Bilateral Trade Agreements: A Policy Guide for Negotiations and Implementers in the Eastern Mediterranean Region***. Cairo: World Health Organization (WHO) Regional Office for the Eastern Mediterranean and the International Centre for Trade and Sustainable Development (ICTSD), 2010. Available from:

<https://apps.who.int/medicinedocs/en/m/abstract/Js21391en/>.

The policy guide is the first comprehensive guide of its type dedicated to the Arab World and EMRO region. The policy guide provides a historical background of the global trading regime and the participation of the region in that regime. The guide also focuses on bilateral free trade agreements and association agreements (AAs) concluded between the developed countries and other developing states with special attention to the health-related intellectual property provisions concluded under these agreements.

More importantly, the guide provides policy options and recommends strategies to improve the negotiation position and enable developing countries to preserve their public health regimes, improve access to medicines, and implement national intellectual property regimes with a pro development orientation.

El Said, M. **TRIPS-plus implications for access to medicines in developing countries: lessons from Jordan-US FTA.** *Journal of World Intellectual Property*, vol. 10, Issue 6, pp. 438–475, (2007). Co-authored with Hamed El Said. Available from: <http://onlinelibrary.wiley.com/doi/10.1111/j.1747-1796.2007.00330.x/abstract>.

This article analyzes in detail the TRIPS-plus provisions of the Jordan–US FTA. It scrutinizes in detail the main TRIPS-plus provisions included under the FTA such as data exclusivity and marketing authorization. The article challenges the claim that FTAs bring general and specific benefits to developing countries, and provides fresh evidence which strongly suggests that benefits from the Jordan–US FTA have been largely exaggerated while the costs underestimated.

World Health Organization – Regional Office for the Eastern Mediterranean (WHO EMRO). ***Report on the Consultative Meeting on TRIPS and Public Health.*** Cairo: WHO Regional Office for the Eastern Mediterranean, 2005.

This is a report of the meeting held in late 2003 in Amman on the TRIPS and public health situation in the countries of the WHO Eastern Mediterranean Region. The aim of this meeting was to review the situation internationally, discuss the situation in the Region and underline areas where attention needs to be focused. From this analysis, WHO EMRO should determine how best to advise countries in the Region who are in accession or have not yet applied for WTO membership.

5. ELECTRONIC INFORMATION

5.1 Civil Society

Médecins sans Frontières Campaign on access to essential medicines

<https://www.msfacecess.org/>.

The Drugs for Neglected Diseases Initiative

<http://www.dndi.org>.

The International Environmental Law Research Centre

<http://www.ielrc.org/home.php>.

IPRsonline.org

<http://www.iprsonline.org/>.

<https://www.eldis.org/organisation/A7704>.

Intellectual Property Watch

<https://www.ip-watch.org/>.

Knowledge Ecology International

<http://www.keionline.org/>.

Oxfam

<http://www.oxfam.org.uk>.

The Quaker United Nations Office in Geneva

<http://www.quno.org/>.

The Collaborating Centre of WHO for the Investigation and Training in Medicine-epidemiology, Barcelona

www.sietes.org.

South Centre

<http://www.southcentre.int/>.

The Treatment Action Campaign, South Africa
<https://tac.org.za>.

The Third World Network
<https://www.twn.my/index.htm>.

5.2 International Organizations Dealing with Intellectual Property

Food and Agriculture Organization of the United Nations (FAO)
<http://www.fao.org>.

International Union for the Protection of New Varieties of Plants (UPOV)
<http://www.upov.int/>.

United Nations Conference on Trade and Development (UNCTAD)
<https://unctad.org/en/Pages/Home.aspx>.

United Nations Development Programme (UNDP)
<http://www.undp.org/>.

United Nations Educational, Scientific and Cultural Organization (UNESCO)
<https://en.unesco.org/>.

United Nations High Commissioner on Human Rights (UNHCHR)
<http://www.ohchr.org>.

United Nations Industrial Development Organization (UNIDO)
<http://www.unido.org>.

World Health Organization (WHO)
<https://www.who.int/>.

World Intellectual Property Organization (WIPO)
<http://www.wipo.int>.

World Trade Organization (WTO)
<http://www.wto.org/>.

5.3 Interesting Discussion Groups

<http://www.essentialdrugs.org>.

<http://www.hivnet.ch>.

<http://lists.essential.org/mailman/listinfo/ip-health>.

Ip-health@lists.keionline.org.

5.4 WHO Resolutions of the World Health Assembly referring to Intellectual Property

1996 WHA49.14: Revised drug strategy

1999 WHA52.19: Revised drug strategy

2000 WHA53.14: HIV/AIDS: confronting the epidemic

2001 WHA54.10: Scaling up the response to HIV/AIDS

2001 WHA54.11: WHO medicines strategy

2002 WHA55.14: Ensuring accessibility of essential medicines

2003 WHA56.27: Intellectual property rights, innovation and public health

2003 WHA56.30: Global health sector strategy for HIV/AIDS

2004 WHA57.14: Scaling up treatment and care within a coordinated and comprehensive response to HIV/AIDS

2006 WHA59.24: Public health, innovation, essential health research and intellectual property rights: towards a global strategy and plan of action

2006 WHA59.26: International trade and health

2007 WHA60.30: Public health, innovation and intellectual property

2008 WHA61.21: Global strategy and plan of action on public health, innovation and intellectual property

2009 WHA62.16: Global strategy and plan of action on public health, innovation and intellectual property

2011 WHA64.5: Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits

2011 WHA64.14: Global health sector strategy on HIV/AIDS, 2011-2015

2012 WHA65.22: Follow up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination

2013 WHA66.23: Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination

2014 WHA67.21: Access to biotherapeutic products, including similar biotherapeutic products, and ensuring their quality, safety and efficacy

2014 WHA67.22: Access to essential medicines

2014 WHA67.15: Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination

2015 WHA68.18: Global strategy and plan of action on public health, innovation and intellectual property

2016 WHA69.23: Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination

2017 WHA70.12 : Cancer prevention and control in the context of an integrated approach

2017 WHA71.9 : Global strategy and plan of action on public health, innovation and intellectual property: overall programme review

2018 WHA71.8 : Addressing the global shortage of, and access to, medicines and vaccines

2018 WHA71.13: Global strategy and plan of action on public health, innovation and intellectual property: overall programme review

2019 WHA72.8: Improving the transparency of markets for medicines, vaccines, and other health products

Intellectual Property, Human Rights and Access to Medicines

The South Centre seeks to provide appropriate technical assistance and country support to developing countries, within comprehensive and coherent national IP strategies to promote implementation of the TRIPS Agreement that is consistent with the protection of public health and the promotion of access to medicines. This selected and annotated bibliography has been prepared to assist developing countries to implement IP policies and regulations consistent with development goals and public health principles. The growing volume of literature on the issue of IP, R&D, human rights and access to medicines can help developing countries to find the opportunities and room for manoeuvre to protect their citizens from the unhealthy environment created by international trade rules.

This bibliography is not an exhaustive list but it highlights some of the most pertinent works from the South views and perspectives. The selected references are a valuable instrument for those interested in promoting universal access to medical innovation.

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