

DRUGS IN A BRAVE NEW WORLD OF TRIPS+ SCHEMES: THE CASE FOR LEGAL CEILINGS ON EXTRA PATENT PROTECTION*

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Resumen: El comercio de medicamentos genéricos es una condición previa para que los pacientes y autoridades públicas en los países en desarrollo adquieran medicinas asequibles en los mercados farmacéuticos. Sin embargo, la incansable promoción de estándares de protección de patentes por los países exportadores de tecnología está minando la posibilidad la producción y distribución sostenible de genéricos a escala global. En gran medida, los países desarrollados actúan como apoderados de las estrategias de captación de rentas de las empresas farmacéuticas. Las coaliciones de interés público sólo pueden vencer esta desigual batalla (en múltiples frentes paralelos) promoviendo una nueva Declaración sobre el ADPIC como techo legal para la protección de patentes farmacéuticas en el mundo en desarrollo, complementando así la histórica Declaración de Doha de 2001 sobre el ADPIC y la salud pública. Alternativamente, varias instituciones globales con competencias concurrentes en este área están disponibles para promover una solución legal similar.

Palabras clave: comercio global, patentes farmacéuticas, techos legales, flexibilidades, acceso a medicamentos, genéricos.

Abstract: Trade in generics is a prerequisite for patients as well as public health authorities in the developing world in order to purchase affordable medicines in pharmaceutical markets. However, the relentless promotion of stringent global patent protection standards by technology exporting countries is undermining the ability of sustainable generic production and distribution on a global scale. To a great extent, developed countries are acting as proxies of the socially wasteful rent-seeking strategies of pharmaceutical companies. Public interest coalitions can only win the ongoing battle (on multiple parallel fronts) by promoting a new Declaration on TRIPs rules as a legal ceiling for pharmaceutical patent protection in the developing world, to complement the historic 2001 WTO Doha Declaration on TRIPs and public health. Alternatively, several global institutions with concurring competences in this area are already available to promote a similar legal solution.

Key words: world trade, pharmaceutical patents, flexibilities, legal ceilings, access to medicines, generics.

Sumario: I. Proxy states. II. Trips+ schemes. III. Private regulatory captures. IV. Public interest coalitions.

I. Proxy states

1. Many developing countries have scant pharmaceutical manufacturing capacity or none at all and are thus supplied with generics by global pharmaceutical markets. For this reason, patents within

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middle-income developing countries with pharmaceutical manufacturing capacity are of the most critical concern. In essence, sustainable generic production in the latter is a prerequisite for exporting those medicines to the former.

2. In recent decades, an efficient generic drug industry has burgeoned in developing countries such as South Africa, Thailand, India, and Brazil has also become a key source of global generic production and distribution. Manufacturers such as Cipla (India) or Cristalia (Brazil), for example, have long-standing experience in producing quality drugs for export to developing countries where there is no patent, or where the patent has expired or, less frequently, the patent is under compulsory license (CL), or government use. As a result, a wide variety of cheap generic medicines are competing today in global generics markets.

3. However, patents are becoming more widespread as a result of the WTO agreement on intellectual property related to trade (TRIPs), as well as other TRIPs+ initiatives and this has restricted generic competition for newer patented drugs¹. Brazil, for example, passed Decree n° 1355 reintroducing patents, after a 30-year vacuum, as early as 30 December 1994, and India amended its Patent Act in March 2005 on similar lines².

4. Patent protection of new drugs in these countries adversely affects access to second and third treatments in developing countries. The cost structure for drugs in developing countries is bound to be severely affected if the generic manufacturers in these countries operate increasingly strong patent regimes and smaller scale operations. For this reason, it is critical to ensure that generic industries successfully compete in the global pharmaceutical markets and thus, upscale their operations.

5. However, the pharmaceutical industry is not particularly supportive of the export-oriented production of generics in the developing world. Lobbies such as IIA (International Intellectual Property Alliance) or US PhRMA (Pharmaceutical Research and Manufacturers of America) are in fact targeting the sources of generic production and distribution.

6. As a result, needless to say, developing countries with export-oriented generic production are under pressure from aggressive TRIPs+ domestic lobbying and litigation. These strategies deployed by the industry are complemented by technology exporting countries acting as proxies to negotiate (bilateral and regional) TRIPs+ treaties³.

7. In short, some developing countries are bargaining away the existing health-related TRIPs flexibilities in exchange for more expedient market access, in order to obtain (or not to lose) concessions elsewhere (foreign aid withdrawal, refusal to transfer technology, etc), or to avoid becoming a target for unilateral action by technology-importing countries⁴. In addition, no country is interested in suffering the inconvenience of being subject to a campaign depicting it as a piracy-lenient country.

8. As a result, TRIPs flexibilities remain untested in many developing countries. Public policies in developing countries are subject to carrots and sticks from technology-exporting countries⁵. Thus,

¹ B. WANING, M. KYLE, E. DIEDRICHSEN, L. SOUCY and J. HOCHSTADT, *et al.*, "Intervening in global markets to improve access to HIV/AIDS treatment: an analysis of international policies and the dynamics of global antiretroviral medicines markets", 6 *Globalization and Health* (2010): 13.

² Before this, interestingly, both a WTO *panel* and Appellate Body decision had ruled against India for not taking the required steps to prepare its compliance with TRIPs agreements in 2005 (transitional obligations). See WT/DS79/R *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products* (August 24, 1998) and WT/DS50/AB/R *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products* (December 19, 1997), respectively.

³ See V. BRADFORD and K. LEE, "TRIPs, the Doha declaration and paragraph 6 decision: what are the remaining steps for protecting access to medicines?" *Globalization and Health* (2007) 3:3.

⁴ See, in particular, P. DRAHOS and J. BRAITHWAITE, *Information Feudalism*: 187-197 (chapter 12).

⁵ E. HOEN, "Public Health and International Law. TRIPs, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha", 27 *Chicago Journal of International Law* (2002): 32-33.

ministries other than health ministers tend to be reluctant to support critical health policies such as pharmaceutical compulsory licensing (CL). It is noteworthy, for example, that the first CL granted by India to a generic producer was issued as late as 2012. The decision authorizes Natco until 2020 to manufacture a patented anti-cancer drug from Bayer for the domestic market.

9. The USTR (United States Trade Representative) and the EU DG Trade are critical players in this brave game of ratcheting up IP standards, in which diplomatic signals are systematically sent each time an initiative to issue a compulsory license is underway in a developing country⁶.

10. The USTR's Special 301 epitomizes the race for stringent global patent standards, sharply contrasting with the leniency shown towards IP generally in the United States during the period of its trade power formation. As Picciotto recalls, the United States is appointing itself as the main global policeman of IPRs but paradoxically it refused copyright protection for foreign works until 1891, and did not even join the Berne Convention until 1987, just when it finally placed IP on the regulatory agenda of the Uruguay Round. Certainly, "the late converts may be the most fervent apostles"⁷.

11. In fact, the functioning of Special 301 targets accelerated TRIPs implementation singling out the rules and policies of other countries that the United States deems objectionable, irrespective of whether or not they are TRIPs compatible. Thus, the mechanism often pushes countries to go beyond their TRIPs obligations. In the words of Charlene Barshefsky, former USTR, the instrument is much more than an in-depth review of public policies of other countries: it provides "a direct route to press countries to improve their IPR practices"⁸.

12. Unfortunately, the EU has followed suit of the Special 301 strategy by replicating some of its critical elements in its own IP enforcement strategy, adopted in 2005. The EU strategy on IP enforcement outside Europe, currently under revision, functions with a similar rationale: conducting broad surveys on IPR enforcement, which are used to update the list of "priority countries" and acting accordingly⁹.

II. TRIPs+ schemes

13. An extra tool for promoting stronger global IP protection is the negotiation of clone treaties based on TRIPs+ schemes. These instruments inhibit the implementation of health-related TRIPs flexibilities in developing countries, and are thus basically producing international re-regulation through the back door.

14. Recent US FTAs, for example, prevent or undermine the ability to implement TRIPs flexibilities by requiring the adoption of measures such as patent term extensions, data exclusivity, linkage of patents with registration, restrictions on compulsory licensing, restrictions on or elimination of parallel imports and border enforcement requirements, among others¹⁰. The EU also follows the US lead on these practices by promoting its own bilateral TRIPs+ treaties. A recent example is the controversial EU-India FTA originally planned for signature by the end of 2012 but still under negotiation.

⁶ See generally F. ABBOTT "The Doha Declaration on the TRIPs Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements". *Occasional Paper N. 14*, Quaker United Nations Office, 2004.

⁷ See S. PICCIOTTO "Defending the public interest in TRIPs and the WTO", *Global Intellectual property rights: knowledge, access and development*, Palgrave, 2002, p.226.

⁸ See "USTR Announces Results of Special 301 Annual Review", Press Release 97-37, April 30 1997.

⁹ See *Strategy for the enforcement of intellectual property rights in third countries*, Official Journal of the European Union, C129, Volume 48, 26 May 2005, p. 3.

¹⁰ See generally K.M. GOPAKUMAR, and S.R. SMITH, "IPR provisions in FTAs: Implications for access to medicines", *Intellectual property and access to medicines: papers and perspectives*, World Health Organization 2010 and also *Access to Generic medicines and 'TRIPs plus' provisions*, European Generics Association, Position Paper (November 2007).

15. The higher standards of protection in TRIPs+ schemes delay or restrict, by their very nature, trade in generics and thus generic competition¹¹. In essence, through these bilateral and regional treaties, developing countries “are being made to agree” to a ratcheting up of IP standards¹². By strengthening, broadening and lengthening monopolies on medicines generally, their provisions are bound to create a chilling effect on generic market entry and thus they erode the consolidation of a global market for generics.

16. It is important to underline that these treaties are not health+, or human rights+, but IP+ schemes. The contents of some of the new obligations are illustrative in this regard: (a) extending patent terms beyond the 20 years required by TRIPs agreement, (b) requiring new export and burdensome procedures for generics, (c) restricting conditions for compulsory licenses to be issued, (d) delaying approval and registration of generics by providing original manufacturers with exclusive rights on pharmaceutical test data, (e) requiring regulatory authorities to pursue a policing role on patent enforcement, among others¹³.

17. Inevitably, the restricted rationality of these TRIPs+ treaties undermines the flexibilities provided by TRIPs rules and the Doha Declaration on TRIPs agreement and Public Health, adopted in November 2001¹⁴. In theory, WTO law and policies have formally recognized some major legal TRIPs flexibilities with regard to access to medicines. In practice, however, pharmaceutical lobbying is taking those rights away by using proxy states to promote stringent global standards in other fora.

18. A significant example of the present state of affairs is the new IP enforcement trends treating generics as counterfeit. These TRIPs+ enforcement trends have already allowed the seizure of generic medicines transiting through European ports to Africa and Latin America on the basis of the EU Customs Regulation 1383/2003. Cases include several million doses of generics detained in transit at Rotterdam in December 2008 (Losartan, an anti-hypertension drug), Frankfurt in May 2009 (Amoxicillin) and in Paris in October 2009 (Clopidogrel, a blood thinner). As a result, Brazil and India filed a WTO complaint against the EU in May 2010, recently settled¹⁵, on the legal grounds of GATT article V (freedom of transit) and the 2001 Doha Declaration¹⁶.

19. In addition, TRIPs+ treaties such as the Anti-Counterfeiting Trade Agreement (ACTA) also contain measures confusing generics with counterfeit medicines¹⁷. Despite its name, this (“trade-related”) IP enforcement treaty targets border and internal enforcement of IP infringements regarding private monopoly rights. ACTA provisions formally exclude patents from border measures and, in fact, contain safeguards on access to health as well as referring to the 2001 Declaration. However, ACTA also include civil trademark infringement with strong penalties, to name just one qualified

¹¹ See C. CORREA, “Implications of bilateral free trade agreements on access to medicines”, 84 *Bulletin of the World Health Organization* (2006): 402

¹² See P. DRAHOS “Developing Countries and International Intellectual Property Standard-setting”, UK Commission on Intellectual Property Rights, *Study Paper 8*, 2002, p. 21.

¹³ See S. K. SELL, “TRIPs-Plus Free Trade Agreements and Access to Medicines” 28 *Liverpool Law Review* (2007): 56–57 and F. ABBOTT, “A new dominant Trade Species emerges: is bilateralism a threat?”, 10 *Journal of International Economic Law* (2007): 571–583.

¹⁴ The United Nations Development Report of 1999 already referred openly to the “relentless march of intellectual property rights” and underline that this process “needs to be stopped and questioned”. See *Human Development Report 1999*, UNDP, Oxford University Press, 1999, p.73.

¹⁵ See B. MERCURIO, ‘Seizing’ pharmaceuticals in transit: analysing the WTO dispute that wasn’t’, 61 *International and Comparative Law Quarterly* (2012):389-426 and B.K. BAKER, “Settlement of India/EU WTO Dispute re Seizures of In-Transit Medicines: Why the Proposed EU Border Regulation Isn’t Good Enough”, *Northeastern University School of Law Research Paper No. 81-2012* (January 1, 2012).

¹⁶ See WTO/DS408, *European Union and a Member State-Seizure of Generic Drugs in Transit* - Requests for consultations, India (11 May 2010) and see WTO/DS409, *European Union and a Member State-Seizure of Generic Drugs in Transit* - Requests for consultations, Brazil (12 May 2010).

¹⁷ See K. OUTTERSON, and S. SMITH “Counterfeit Drugs: The Good, the Bad and the Ugly”, 15 *Albany Law Journal of Science & Technology* (2006): 525.

regulatory feature. As a result, customs officials could initiate a seizure and even destruction of an allegedly infringing product in order to protect the interests of the rights holder of a commercial trademark.

20. Generally, these IP enforcement trends are in themselves strong disincentives for those companies eager to trade in generics at global scale, and thus for the consolidation and development of a global market for generics to the benefit of patients in developing countries.

21. The drive towards stronger IP enforcement is thus of particular concern. Something wrong is going on in global IP politics when IP advocates such as the former President of the International Anti-Counterfeiting Coalition, Timothy Trainer, with no hesitation whatsoever, makes this formal statement: “ACTA is an initiative that allows governments to voluntarily commit themselves to whatever TRIPS+ standards are agreed”¹⁸. The statement certainly suggests that for some actors global IP protection is nowadays a sort of Wild West in terms of international legislation.

22. Interestingly, the European Parliament has recently rejected ACTA under its Lisbon Treaty power to reject international agreements: for the first time after the entry into force of the Lisbon Treaty, EU MPs have exercised here their power to reject an international agreement (478 votes against, 39 in favor, and 165 abstentions)...¹⁹.

23. The current state of affairs has to be seriously considered from an international legal standpoint. Pro-health TRIPs flexibilities cannot reasonably be interpreted as a floor but rather as a ceiling of pharmaceutical patent protection. In this sense, it is reasonable to argue that TRIPs+ regimes with regard to pharmaceutical patent protection are not WTO compatible. Not only does the TRIPs agreement contain major flexibilities with regard to public health but WTO Members have agreed to adopt the 2001 Doha Declaration on TRIPs agreement and public health.

24. In any basic notion of global equity or justice, it is not legally reasonable to put forward the argument that what WTO Members have agreed on multilaterally with regard to public health can be undone in other fora. Pro-health flexibilities operate as legal *benefits* granted to all WTO Members. These flexibilities contained in WTO primary rules (TRIPs agreement) have in fact been confirmed in WTO secondary rules through WTO decision-making (2001 Doha Declaration).

25. As Correa recalls, implementation of the 2001 Doha Declaration should not be regarded as a matter of political choice if article 26 of the Vienna Convention on the Law of the Treaties is taken into due consideration: the Declaration creates international obligations which should be complied with in good faith by all WTO Members²⁰. In this sense, good faith is a key principle for treaties, but also in order for international law in general to function properly²¹: “*every treaty in force is binding upon the parties to it and must be performed by them in good faith*” (article 26). In addition, article 31 of VCLT clearly determines that treaties “*shall be interpreted in good faith*”. Thus, applying TRIPs rules and the health-related 2001 Doha Declaration in accordance with the VCLT reasonably imposes certain limitations on WTO members. A contrary application may constitute an abuse of rights²².

¹⁸ See T. TRAINER, “Intellectual Property Enforcement: A Reality Gap (Insufficient Assistance, Ineffective Implementation?)”, 8 *John Marshall Law School Review of Intellectual Property Law* (2008): 74.

¹⁹ See *European Parliament legislative resolution of 4 July 2012 on the draft Council Decision on the conclusion of the Anti-Counterfeiting Trade Agreement* (12195/2011 – C7-0027/2012 – 2011/0167(NLE)).

²⁰ C. CORREA, *Implementation of the WTO General Council Decision on paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health*, World Health Organization, 2004, p.8.

²¹ See generally J.F. CONNOR, *Good Faith in International Law*, Aldershot, Dartmouth Publishing, 1991.

²² For a study on abuse of rights as a ceiling to patent protection see in particular M. TEMMERMAN, “The Legal Notion of Abuse of Patent Rights” *NCCR Trade Regulation Working Paper No 2011/23* (May 2011), pp.5-10.

26. In addition, TRIPs+ schemes with regard to pharmaceuticals can technically infringe WTO law by producing an annulment or denial of WTO benefits. These TRIPs+ schemes are to be read by their own nature as TRIPs-Minus with regard to the balance of benefits and concessions resulting from WTO law: a body of law made up of a series of complex trade-offs involved among WTO Members (i.e: more market access in exchange for stringent patent standards).

27. In consequence, TRIPs+ schemes invalidate the flexibilities provided by the TRIPs agreement and, as such, could be challenged as WTO non-compatible under the WTO Dispute Settlement Body (DSB)²³. In fact, any WTO Member may request a panel if any measures from other Members (including treaties) is denying or annulling those benefits²⁴. As a result, the negotiation or implementation of TRIPs+ schemes by WTO Members (treaties *external to* WTO) could *nullify or impair benefits* deriving from WTO law.

28. The compatibility of these schemes could be challenged not only by *IP violation complaints* but also by the so-called *non-violation* complaints, provided the present moratorium on the latter is finally lifted²⁵. However, it is also true that technology-exporting countries are probably those who would benefit most from the lifting of the moratorium, as they have more resources to invest on speculative legal claims²⁶.

29. In any case, the substantive rules are already in place (TRIPs flexibilities) to be properly adjudicated as violation complaints. This generous standing has been part of the legal *acquis* of the multilateral trading system almost since GATT was originally conceived²⁷.

30. However, those who manage the inner functioning of WTO processes are trade ministers, not health ministers. Arguably, some health ministers would see a legal case here, irrespective of whether or not they represent a developing country. However, they are not on board of the WTO ship. In practice, ministers or trade are those responsible for the final decision on whether to file WTO complaints, or not.

31. Promoting stringent patent standards for pharmaceuticals outside WTO, once these rules are in place, is playing against the rules and traditional inner functioning of the world trading system. In fact, it is also playing above those rules (playing a meta-game) against the interest of WTO itself as a global institution responsible for progressive trade liberalization.

32. The balance between rights and obligations resulting from the trade-offs negotiated in the Uruguay Round should be honoured. In this regard, there is a strong case for a legal ceiling on health-related patent protection in the benefit of the developing world. In fact, it could probably be critical to the success of the ongoing Doha Development Round.

²³ F. ABBOTT "The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health", 99 *American Journal of International Law* (2005): 357.

²⁴ In fact, the DSU standing is very open, and in practice close to an *actio popularis*. See P.J. KUIJPER, "The Law of GATT as Special Field of International Law. Ignorance, further refinement or self-contained system of international law?", *Netherland Yearbook of International Law*, Vol XXV(1994): 239-241.

²⁵ The moratorium is being extended from one ministerial conference to the other, the latest being the extension from the 2011 Geneva Ministerial Conference to the ministerial meeting agreed to hold in 2013. For the last extension see WT/L/842, *TRIPs non-violation and situation complaints, Decision of 17 December 2011* (19 December 2011).

²⁶ Non-violation complaints allow WTO Members to challenge a measure in WTO dispute settlement procedures that is not infringing WTO law, but nullifying or impairing the trade benefits that WTO members could have reasonably expected to obtain from WTO law. See ABBOTT, F. *Non-violation nullification or Impairment Actions under the TRIPs Agreement and the Fifth Ministerial Conference: A Warning and Reminder*, QUNO Occasional Paper N11, 2003.

²⁷ For its critical evolution compare J.H. JACKSON, *World Trade and the Law of GATT. A Legal Analysis of the General Agreement on Tariffs and Trade*, The Boobs-Merrills Company Inc, 1969, pp.163-189, J.H. JACKSON, *Restructuring the GATT System*, New York Council on Foreign Relations Press, 1990, p.65 and, finally (and particularly) J.H. JACKSON, "The WTO Dispute Settlement Understanding: Misunderstandings on the Nature of Legal Obligation", 91 *American Journal of International Law* (1997): 60.

33. The WTO constituency should recall that the 2001 Declaration on Public Health (read Doha) helped to keep on track the first post-GATT (read WTO) Round of negotiations, after the (globally broadcasted) 1999 Millennium Round derailment (read Seattle).

34. In this sense, the existence (or non-existence) of *legal ceilings* for the global ratcheting up of patent protection is a structurally critical *trade* issue deserving consideration in the Doha Development Round.

35. In short, the TRIPs rules, together with the 2001 Declaration on Public Health, should reasonably be interpreted as a legal ceiling against stronger IP protection in health-related areas, but also as a legal floor to promote the consolidation of a global generics market to the benefit of developing countries.

III. Private regulatory captures

36. However there are vested interests involved. Nowadays, modern patent systems have created high returns on revenues, assets and shareholders' equity over decades, making the pharmaceutical industry annually ranked as among the most profitable industries in the world. These revenues are highly concentrated in the pharmaceutical markets of developed countries but the CEOs' and shareholders' expectations on high future returns from investments on R&D and marketing in this area have been fuelled by their increasing collaboration with trade representatives negotiating new global IP standards.

37. In practice, this phenomenon has produced a "global money illusion" on exponential increases of corporate profits. As a result, brand-name pharmaceutical companies are involved in aggressive strategies to secure worldwide monopoly rents²⁸, and are not open to other profitable but alternative wealth-enhancing strategies.

38. In this regard, brand-name pharmaceutical companies could easily obtain profits at least comparable to those of generic producers (profiting from off-patent medicines in developing countries) by selling their brand-name products to larger numbers of poor people at *very* low prices²⁹: price-based competition is the word. That was in fact the rationale of the government of Thailand, when it officially suggested shifting pricing strategies based on 'low-volume, high margin returns' to 'high-volume, low margin returns'³⁰.

39. However, brand-name companies are less focused on this aspect and more on derailing generic companies from global pharmaceutical markets through lobbying in order to ratchet global IP standards. In consequence, international legislation is perceived as a second level playing field for policy formation, and it is often more effective than merely lobbying domestic legislators.

40. For corporations operating in multiple state jurisdictions, it is more efficient to lobby collectively for international legislation (which is binding in at least two or more state jurisdictions) than to lobby merely for domestic legislation (binding in one state jurisdiction). In addition, as Correa bluntly recalls with regard to US bilateralism, by creating protection standards higher than those applied domestically, the pharmaceutical industry may be able to force an amendment of US domestic laws "in ways simpler and less costly than through lobbying in Congress"³¹.

²⁸ See particularly, S. PICCIOTTO, Private rights vs public interests in the TRIPs agreement: the access to medicines dispute: in *Proceedings of the annual conference of the American society of international law*, 2003, 167.

²⁹ J. REICHMAN, "Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options", 37 *Journal of Law Medicine* (2009): 247-263.

³⁰ See *Facts and Evidence on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand*, Ministry of Public Health and National Health Security Office, Thailand, February 2007.

³¹ C. CORREA, "Bilateralism in Intellectual Property...op.cit. p.93.

41. The point applies to any technology-exporting country. These modern rent-seeking strategies are amplifying socially wasteful public law on a multi-state scale. As a result, nowadays, some international rules are almost by-products of corporate regulatory captures.

42. The enhanced and increasing leverage of special interest groups on global decision making has critical consequences for international law. These processes, which are currently shaping global politics cannot be understood or explained through a simple and traditional state-centric approach to international rule-making³². Therefore, traditional approaches need to be revisited, to combat or avoid the capture of public international law by special interest.

43. In this regard, it is also reasonable to argue that the pharmaceutical business model itself requires a major revision. In fact, the WHO Commission on Intellectual Property Rights, Innovation and Health (CIPIH) has already made some clear recommendations on this issue: “companies should adopt patent and enforcement policies that facilitate greater access to medicines needed in developing countries. In low income developing countries, they should avoid filing patents, or enforcing them in ways that might inhibit access. Companies are also encouraged to grant voluntary licenses in developing countries, where this will facilitate greater access to medicines, and to accompany this with technology transfer activities”. And last but not least: “companies should not lobby government for more stringent standards than those contained in TRIPs agreement”³³.

44. These are basic key ideas. However, the socially wasteful rent-seeking strategies of the industry in developing countries cannot be inhibited through mere (voluntary) initiatives of corporate social responsibility (CSR) but by reforming some modern legal institutions. The reason is simple: these companies are run by publicly inefficient incentives structures, and not merely by unethical persons who could be convinced to act (read manage) differently. In essence, these companies do what they do because their CEOs are tied too tightly to the mast of profit maximization as a direct result of the incentives structure in modern corporate law (the corporate form itself) and financial markets.

IV. Public interest coalitions

45. Nowadays, global policymaking occurs through nodes of closely connected actors in a diversity of networks³⁴. In the world of “nodal governance”, both public interest and private interest coalitions battle in multiple fora, without equal footing, to regulate critical public issues such as access to medicines³⁵.

46. Fortunately, transnational advocacy networks have an essential role to play here³⁶, as direct result of the growing research and legally-oriented function of NGOs in global politics³⁷. As Shaffer suggests, developing countries could critically enhance their prospects of success with regard to access to medicines if they worked together with US and European constituencies such as NGOs³⁸.

³² See K. ALTER and S. MEUNIER, “The Politics of International Regime Complexity” / *Perspectives on Politics* (2009): 13-24.

³³ See *Public Health, Innovation...* op.cit, paragraph 4.16, p.181.

³⁴ P. DRAHOS “Intellectual Property and Pharmaceutical Markets: a Nodal Governance Approach”, 77 *Temple Law Review* 2004: 401-424.

³⁵ See S. BURRIS, P. DRAHOS and C. SHEARING, “Nodal Governance”, 30 *Australian Journal of Legal Philosophy* (2005): 30-58.

³⁶ On the use of law for empowering and legitimating transnational advocacy networks see SIKKINK, K. “Transnational Advocacy Networks and the Social Construction of Legal Rules” *Global Prescriptions: The Production, Exportation, and Importation of a New Legal Orthodoxy*, Y. Dezalay and B. Garth (Eds.), The University of Michigan Press, 2002, pp.37-64.

³⁷ See generally M. KECK, and K. SIKKINK, *Activists Beyond Borders: Advocacy Networks in International Politics*, Cornell University Press, 1998.

³⁸ G. SHAFFER, “Recognizing public goods in WTO Dispute Settlement: Who participates? Who Decides? The case of TRIPs and pharmaceutical patent protection”, 7 *Journal of International Economic Law* (2004): 479–80.

47. In fact, global campaigns had a major impact on the WTO decision-making processes regarding both the 2001 Doha Declaration³⁹. The policy momentum would certainly not have been reached without global campaigns such as the so-called *PMA case* in South Africa⁴⁰. These and other events provided the window of opportunity for developing countries and civil society to obtain the first special session of the TRIPs Council to discuss health-related TRIPs issues in April 2001. The rest is already part of modern world history (i.e: 2001 Doha Declaration)⁴¹.

48. The 2001 Doha Declaration on public health is, as Drahos refers to it, ‘a case of a weak coalition making a gain that an observer would not have predicted given the power resources of the US-led coalition’⁴². In the brave new world of TRIPs+ schemes, however, developing countries/NGOs coalitions are forced to take action in multiple battlefields almost daily: the ongoing cycle of action and reaction with regard to global IP standard setting takes place in a wide variety of fora⁴³.

49. Since early 1980s, advocates seeking to ratchet up IP protection have shifted fora both vertically and horizontally to achieve their goals. They have shifted vertically, from multilateral to regional to bilateral levels, and they have shifted horizontally across diverse international organizations⁴⁴.

50. As Sell suggests, international politics are far messier than is generally assumed⁴⁵. In fact, the game is never over, as all actors involved continuously cycle through fora to find one at a moment in time where their power will be optimized⁴⁶. In the words of Chorev, institutions have interactive effects in any given policy space⁴⁷: as a result, the repositioning of one piece in one of those institutions (i.e: adoption of a rule) may result in the repositioning of more pieces in other institutions. This phenomenon has been also defined as “chessboard politics”⁴⁸.

51. Securing pro-health law and policy at global scale is directly dependent on the relative efficiency of the strategies deployed by developing countries/NGOs coalitions.

52. Susan Sell employs an illustrative “cat and mouse” metaphor to explain the arena in which public interest coalitions struggle for success today: in the 1980s, IP advocates (the “cat”) made the first move moving “trade-related” intellectual property from WIPO into the GATT regime. However, once the Developing countries/NGOs coalition (the “mouse”) mobilized in the WTO, IP advocates (the “cat”) moved again to TRIPs+ bilateral and regional treaties, the Anti-counterfeiting Trade Agreement (ACTA) or a Substantive Patent Law Treaty (SPLT). The “mouse” is nowadays certainly trying to chase the “cat” out of the WTO⁴⁹.

³⁹ See, for example, R. MAYNE, ‘The Global Campaign on Patents and Access to Medicines: An Oxfam Perspective’ in Peter Drahos and Ruth Mayne (Eds.), *Global Intellectual Property Rights: Knowledge, Access and Development*, Palgrave Macmillan (2002): 244-259.

⁴⁰ See *The Pharmaceutical Manufacturers’ Association of South Africa and Others v. The President of the Republic of South Africa and Others*, Case no. 4183/98, High Court of South Africa (Transvaal Provincial Division).

⁴¹ On the impact of events such as the PMA case see S. K. SELL, “TRIPs and the Access to Medicines Campaign” 20 *Wisconsin International Law Journal* (2001–2002): 511

⁴² P. DRAHOS “Four lessons for developing countries from the trade negotiations over access to medicines” 28 *Liverpool Law Review* (2007): 11-39.

⁴³ See F. ABBOTT, “The Cycle of Action and Reaction: Developments and Trends in Intellectual Property and Health” Pedro Roffe, Geoff Tansey and David Vivas-Eugui (Eds.), *Negotiating Health: Intellectual Property and Access to Medicines*, Routledge, 2006, p.31.

⁴⁴ See S. SELL, “Cat and Mouse: Forum shifting in the battle over intellectual property rules and enforcement”, Paper presented the *International Studies Association Montreal*, March 16-19th, 2011.

⁴⁵ S. SELL, “Cat and Mouse... op.cit, p.31.

⁴⁶ P. DRAHOS, “Four lessons ... op.cit, p.33.

⁴⁷ N. CHOREV, “Political and Institutional Manoeuvres in International Trade Negotiations: The United States and the Doha Development Round” in Wolfgang Blaas and Joachim Becker (Eds.), *Strategic Arena Switching in International Trade Negotiations*, Ashgate, 2007, pp.33-34.

⁴⁸ K. ALTER and S. MEUNIER “The International Politics of Regime Complexity”, 7 *Perspectives on Politics* (2009): 13-24.

⁴⁹ S. SELL, “Cat and Mouse... op.cit, p.30.

53. The ongoing global battles over generic medicines are taking place in parallel on multiple fronts, both in and outside the WTO. Under this scenario, public interest coalitions need to adopt a longitudinal, broad perspective of multiple moving parts on global IP negotiations⁵⁰. Otherwise, as Drahos suggests, these coalitions risk winning battles (2001 Doha Declaration) yet finally losing the war⁵¹.

54. In this sense, as resources are limited on their side, it would be reasonable to argue that public interest coalitions should consider forming a coalition to veto the continuous ratcheting up of IP standards⁵². A veto coalition on TRIPS+ schemes should certainly fight the major battle in the corridors of the William Rappard building in Geneva, speaking the language of WTO law and TRIPS flexibilities.

55. Interestingly, in May 2006, ten South American Ministers of Health (Argentina, Bolivia, Brazil, Chile, Colombia, Ecuador, Paraguay, Peru, Uruguay and Venezuela) adopted *the Declaration of Ministers of South America over Intellectual Property, Access to Medicines, and Public Health* to establish a united position against TRIPS+ schemes...

56. In this regard, an efficient and reasonable strategy for the developing countries/ NGOs coalition, in order to avoid battling continuously on every front (to finally lose the war), would be to obtain a formal WTO Declaration confirming that TRIPS flexibilities constitute a legal ceiling with regard to pharmaceutical protection in the developing world.

57. Promoting a new Declaration on TRIPS as a legal ceiling for pharmaceutical patent protection would be a major move, complementing the historic 2001 Doha Declaration on public health. In addition, such a critical initiative could provide some extra leverage towards the final completion of the Doha Development Round. Alternatively in any case, multiple global institutions with concurring competences in this sensitive social area are already available to promote a similar legal solution.

⁵⁰ P. DRAHOS, "Four lessons ... op.cit, pp.35-37.

⁵¹ P. DRAHOS, "Winning Battles, Losing the War: Lessons for the Weak from the Negotiations over the Doha Declaration on TRIPS and Public Health", paper presented at *Trade Negotiation and Developing Countries: The Doha Round, International Workshop*, Griffith University, August 12-13, 2005.

⁵² See P. DRAHOS and J. BRAITHWAITE, *Information Feudalism...* op.cit. pp.204-205 and pp.208-209.