GROWTH OF BILATERAL TREATIES AS INTELLECTUAL PROPERTY POLICY IN GLOBAL SOUTH

***AKASH CHATTERJEE**

ABSTRACT

Historically bilateral patent agreements clearly play a pivotal role in today's intellectual property governance. Such agreements are frequently more like complements to trade—but are also sometimes very effective tools for enforcing the scope of patent protections beyond the minimum required by most multilateral agreements, particularly in the pharmaceutical industry. It focuses here on the legal and normative implications of bilateral patent treaties for Global South countries in which providing access to medicines is a development, and constitutional issue. It claims bilateral agreements frequently promote a policy space that is reduced with respect to essential domestic measures, generic competition is further delayed, and the inequalities between national and international markets in drugs are further exacerbated. This article demonstrates that, while the existence of patent protection is problematic, in international IP law, public health doctrine, and from a development perspective in legal literature, the way the bilateral bargaining arrangements and the treaty are designed can reinforce inequity. The manuscript argues that a more balanced approach is needed that recognizes innovation incentives and that which gives developing states regulatory authority, in the name of public health.

Keywords - Patent, laws, health, innovation, public health, bilateral, TRIPS.

*Research Scholar, University of Calcutta, Department of Law.

PATENT LAW AND POLICY INTERSECTIONS -

Patent law is located at the intersection of the three policy areas of innovation, market control and welfare. Its impacts are most significant for the pharmaceutical industry in which the patented product is likely to be a lifesaving, health and dignity medicine. In recent years, the envelope of pharmaceutical patents has shifted from the multilateral World Trade Organization (WTO) framework to bilateral and regional patent agreements with more enforcement focused than TRIPS alone to substantiate the copyright ideas of big pharmaceutical firms (Sell, 2003; Drahos, 2001). These are a large investment resulting in many important agreements for exporting patent standards to Global South.

This change is significant, especially as the Global South is not a geographically determined region, but a structurally defined place in the global legal order. Numerous developing nations acceded to the patent regime in a context of unequal influences, less industrial capabilities and great public health concerns. Accordingly, the implementation of more stringent patent requirements can be expected to generate distributive harms to the extent that domestic health care systems are poorly resourced or that individuals are responsible for paying a large proportion of the price of the medicine out of pocket (OOTP) (Kapczynski, 2008).

The main argument in this paper is that bilateral patent agreements are sometimes used as law-asymmetric instruments. In the realm of pharmaceuticals, they can put up obstacles to generic access and cause monopoly prices and prevent lawful flexibilities, like compulsory licensing and parallel importation from being used. They are often argued to be needed to boost investment and innovation, but can also have a negative impact on health and the development agenda. The issue before the court in the legal case can thus be stated as trying to maintain the incentive system of a patent law, while at the same time not permitting it to breach the public interest commitments.

BILATERAL NORM -

Bilateral patent agreements are those agreements between states, or between a state and a regional entity that govern standards of intellectual property protection, enforcement and resolution. In many instances these agreements contain provisions that extend beyond those under TRIPS. These agreements have been referred to as ‘TRIPS-plus agreements' because

they impose greater than multilateral baseline patent protection, in terms of scope, duration or effectiveness (Correa 2006; UNCTAD-ICTSD 2005).

From the literature of global intellectual property governance several facts are well known: Bilateralism is not neutral. It provides strong states with a way to negotiate unbalanced legally binding agreements with market-access, aid or diplomatic support-seeking states (Drahos, 2001). In this manner, bilateral patent treaties serve as tools of norm exportation, spreading the terms of a patent accord clauses from legal regimes under high-pressure economic incentives or concerns towards the policy priorities of other systems, which may have different public policy objectives in mind.

It can particularly be seen in the pharmaceutical sector. In the Global North, innovators in the pharmaceutical industry would like increased protection for test data, a longer period for which the drugs remain patented in the market, and better enforcement tools for violations. Their interests are then adapted into bilateral agreements which include potential legal reforms in the Global South. This leads to a system of government in which formal equality is accompanied by real inequality. But developing countries can negotiate to accept more robust patent protection in return for tariffs, development assistance or other diplomatic benefits if this means access to medicines is restricted (Sell, 2003).

PHARMACEUTICAL INDUSTRY AND IP POLICY -

Pharmaceutical patents are such that violate fundamental human needs different from many other patents. A patent on a new drug is not simply a promise of a return on investment, but can mean the difference between whether a health system can get a hold of a new drug or not. In many developing countries, the budgets of public procurement are restricted and there is a lack in private purchasing power. In such a situation, patent-based monopoly pricing can result in a situation where the price for patented drugs excludes a large portion of the population (Heller & Eisenberg, 1998).

During the HIV/AIDS crisis the link between patent exclusivity and access to medicine was put on the international map. There was then a significant absence of access to antiretroviral therapy for the Global South as a consequence of patent protection, which was followed by a significant drop in price as a result of generic competition. In an attempt to address this crisis, the Doha Declaration on the TRIPS Agreement and Public Health reaffirmed that TRIPS “can and should be interpreted and implemented in a manner supportive of WTO Members' right to

protect public health" (WTO, 2001, para. 4). This declaration accepted the validity of flexibilities like compulsory licensing, and parallel importation.

But that Promise of Doha has yet to be realised in the same way for everyone. These flexibilities have many times become less useful in practice with the help of bilateral patent agreements. By doing so they develop a graded exclusivity system which is more than TRIPS, and which challenges the policy equilibrium that the multilateral system aimed to maintain (Abbott & Reichman, 2007).

THE BILATERAL PATENT AGREEMENTS HAVE THE FOLLOWING TRIPS-PLUS ELEMENTS:

Bilateral patent compact deals tend to be associated with a bunch of TRIPS-plus measures that together add to the exclusivity of the pharmaceutical patent. Their importance is accrued not just from a particular treaty clause, but from the interplay of the treaty package in its entirety.

1. Patent Term Extensions

Patent term extensions add years to the end of the patent term, to compensate the patent holder if there has been regulatory delay. Such provisions are often put in place as a means of "fair" treatment for the innovator, yet they have been seen to greatly delay generic competition. Pharmaceutical industry: If the duration of extension is a relatively short time, it can be significant, because the most significant drop in price is likely to be in the post-expiry period.

2. Data Exclusivity

Regulators are prevented from relying on the clinical trial data in the originators' drug approval application for a certain amount of time, a period known as data exclusivity. This level of protection is not a patent, and may be implemented even if there is no patent. For developing countries data exclusivity is especially problematic because it forecloses access to the market for generic manufacturers, while failing to benefit anyone else from usage of the drug, if the drug is not otherwise covered by patent law (Abbott & Reichman, 2007).

3. Patent Linkage

Under patent linkage, drug regulators will have to take into account the patent status before they grant marketing approval to a generic drug. But this is not the case, making a regulatory

process an arm of patent enforcement. This can make it harder for generic entry, and enable the patent owner to pre-empt competition by simply going to court instead of an administrative process.

In its decisions and judgments, the ECHR has, broadly speaking, restricted the scope of compulsory licensing, as have the OECD countries. Compulsory licensing is one of the most important “public health” flexibilities of the patent regime. In some cases, TRIPS permits the users to use a patent without the consent of the owner. However, there may be certain restrictions on this right, such as the bilateral agreements which may create excessive procedures, establish limitations on grounds for patenting, etc., which may push the limits of TRIPS. This can be a significant constraint in cases of a sudden onset of any illness as well as when affordability is a concern (Bala, 2010).

Remedial Measures provide for exclusivity, for example through border measures, which should be strengthened. Enforcement can be an objective but can also have the effect of chilling the activities of generic products and discouraging use of TRIPS compliant flexibilities. It's not about enforcement, it's about how we do it and how we do it differently when it comes to access and access to solutions to access problems.

WHAT IS THE IMPACT OF THAT ON THE GLOBAL SOUTH?

The implications of bilateral patent accords vary between the two sides. These agreements can have an immediate and a long-term effect on health policy, industrial development and fiscal issues for the developing countries. The most obvious impact is access to inexpensive medications is postponed. With delayed generic entry comes the need for both governments and households to pay higher prices for longer to afford treatment access which frequently has repercussions on coverage and public health outcomes.

This is especially important in countries where there is a heavy burden of infectious diseases, and a shortage of pharmaceutical production facilities. Patent rights in these contexts may lead to rationing, delayed access and/or to using donor-funded procurement. Problems in patients don't just occur as a legal issue; it's also a treatment issue.

The wider development impact is also key. Having a robust local generic manufacturing sector can help to ensure employment, a transfer of technology, and medicine security. Yet, TRIPS-plus requirements can slow down market entry, and further regulate the establishment of such

capacity. Bilateral patent pacts can thereby have an impact on access to medicines, and the national industrial policy (Maskus, 2012).

But there is a constitutional aspect as well. There is a right to health, or duty to promote public welfare, in a large number of countries in the Global South. A bilateral patent situation that restricts the state's ability to use its patent rights creates a tension between treaty and constitutional law. Questions then present themselves about the requirement for patent exclusivity, and how to exercise that exclusivity in an adversarial manner to the state's obligation towards its people. A rights-based approach does not imply that it should (Cullet, 2016).

India is a telling example of opposition to patent Override. It had historically legislation that facilitated generic manufacture and access to medicines; and recent intellectual property legislation changes still allow some of the key protections like Section 3(d) which links with the TRIPS agreement and limits evergreening by mandating providing therapeutic efficacy for some pharmaceutical inventions. Success stories from the Indian side have demonstrated that, despite international pressure, a country's own legislation can maintain policy options (Kapczynski, 2008).

On the other hand, where a bilateral agreement with stringent TRIPS-plus terms has been negotiated, there has been a potential for a more restrictive regulation of pharmaceuticals in some countries. Case studies of the U.S. bilateral agreements with Jordan, Morocco and other countries suggest that both patent term extensions and data exclusivity provisions can provide an artificial boost to monopoly rights and end up delaying generic competition (El-Said, 2005). These examples are but a small sample of the results of bilateral treaty design when it comes to changing medicines access in the country.

South Africa, not necessarily under the most far-reaching TRIPS-plus restrictions, is a major battleground in the international debate on access to HIV drugs and patent changes. However, civil society mobilised there and showed that challenging exclusionary pharmaceutical regimes is possible by using the tools of domestic law, litigation and public pressure. The larger point here is that patent law is not in a vacuum by itself, it is litigated via institutions, politics, and social movement.

Legal and policy measures have also been adopted in Brazil to balance patent protection with access to medicines, such as robust public health procurement policies, and in some instances

the very possibility of compulsory licensing. These are examples of why they need to bear in mind that the Global South is not passive. In even the most unequal treaty contexts, the legal design and bargaining strategy of developing States allows them to consider the protection of public health.

SUBURBAN DEVELOPMENT AND POLICIES-

Under the international legal system, States are not obliged to give patent, as opposed to any other right, an absolute priority. The Doha Declaration is still a key interpretive declaration which reinforces the public health aspect of TRIPS (WTO, 2001). It acknowledges that WTO members can exercise TRIPS flexibilities and that each member exercise their freedom of choice when deciding on circumstances under which compulsory licenses may be issued.

Human rights obligations should also be, however, read in parallel with patent law. The right to health as set out in the International Covenant on Economic, Social and Cultural Rights entails steps to be taken by states to progressively achieve the full realization of the right to health which includes access to essential medicines (United Nations, 1966). As long as bilateral patent commitments obstruct that goal, they establish a normative tension with human rights law. Systemic integration suggests that treaty interpretation should not take patent rules out of context.

That doesn't mean that patents don't have their place. Instead, it is a conditional and instrumental patent protection, rather than absolute. The public benefit, like the private reward, must be reasonable. A balance between private reward and public benefit must be maintained if the patent system is to be legitimate. States should strive for interpretative and substantive safeguards in bilateral agreements where it contradicts that relationship.

BILATERAL PATENT AGREEMENTS WILL BE REFORMED

1. Reform demands a variety of action which should take place at various levels. First there is need to take a coordinated and technically backed position in the bilateral negotiations by the developing countries. Fragmented bargaining is likely to be advantageous for more powerful states and more sophisticated pharmaceutical lobbyists. Council countries on sharing legal strategies and being spared of over-obligations through South-South cooperation.

2. Secondly, bilateral agreements should contain clear provisions for state's regulatory autonomy, robust compulsory licensing provisions, and strong public health exemptions. Should not be required to implement data exclusivity, nor patent linkage, unless a public interest basis exists and is proportionate to the data. They should also ensure the continuation of the role of Governments to fight against evergreening by imposing stringent requirements on patentability.
3. Thirdly, transparency needs to be enhanced. Commitments should be put to the test in parliament and to the public – the commitments could last for years or decades and be pertinent to the affordability of medicines. This should not be a closed technocratic approach towards treaty-making.
4. Lastly, effort should be made to bolster international institutions' guidance on IP and the right to health. A potentially more effective way to avoid quietly undermining policy gains through multilateral public health advocacy is to put in place a more coherent framework.

REFERENCES –

Abbott, F. M., & Reichman, J. H. (2007). The Doha round's public health legacy: Strategies for the production and diffusion of patented medicines under the amended TRIPS provisions. *Journal of International Economic Law, 10*(4), 921–987. https://doi.org/10.1093/jiel/jgm023

Correa, C. M. (2006). *Trade related aspects of intellectual property rights: A commentary on the TRIPS agreement*. Oxford University Press.

Heller, M. A., & Eisenberg, R. S. (1998). Can patents deter innovation? The anticommons in biomedical research. *Science, 280*(5364), 698–701. https://doi.org/10.1126/science.280.5364.698

Kapczynski, A. (2008). Harmonization and its discontents: A case study of TRIPS implementation in India's pharmaceutical sector. *California Law Review, 97*(6), 1571–1648.

Maskus, K. E. (2012). *Private rights and public problems: The global economics of intellectual property in the 21st century*. Peterson Institute for International Economics.

Sell, S. K. (2003). *Private power, public law: The globalization of intellectual property rights*. Cambridge University Press.

United Nations. (1966). *International Covenant on Economic, Social and Cultural Rights*. https://www.ohchr.org/en/professionalinterest/pages/cescr.aspx

UNCTAD-ICTSD. (2005). *Resource book on TRIPS and development*. Cambridge University Press.

World Trade Organization. (2001). *Declaration on the TRIPS Agreement and public health* (WT/MIN(01)/DEC/2). https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

Drahos, P. (2001). *Negotiating intellectual property rights: Between coercion and dialogue*. Macmillan.

Drahos, P., & Braithwaite, J. (2002). *Information feudalism: Who owns the knowledge economy?* Earthscan.
Dent, C. M. (2006). *New free trade agreements and intellectual property: Policy transfer, norm diffusion and the "global south"*. Edward Elgar.
Shaffer, G. (2011). *Transnational legal ordering and state change*. Cambridge University Press.
Sell, S. K. (2014). *Private power, public law: The globalization of intellectual property rights* (2nd ed.). Cambridge University Press.
Moon, S., & Ornelas, A. (2014). The 2013 World Health Organization policy on access to medicines and public health innovation. *Health and Human Rights Journal, 16*(2), 1–12.
Roffe, P., & Spennemann, C. (2006). The impact of the TRIPS agreement on public health. In *Intellectual property and sustainable development: Development agenda policy paper* (pp. 1–34). ICTSD.
Outterson, K. (2005). Patent buy-outs: A mechanism for encouraging innovation while promoting access to essential medicines in developing countries. *The American Journal of Law & Medicine, 31*(4), 479–511.
Abbott, F. M. (2009). The WTO medicines decision: World pharmaceutical trade and the protection of public health. *American Journal of International Law, 99*(2), 317–358.
Gopakumar, K. M. (2010). *Patent linkage and access to medicines: A global health perspective*. Research and Information System for Developing Countries.
Sell, S. K. (2003). *Private power, public law: The globalization of intellectual property rights*. Cambridge University Press.
Basu, N. (2014). *Patent law and access to medicines in India*. Oxford University Press.
Hunt, P. (2004). Economic, social and cultural rights: The right of everyone to the enjoyment of the highest attainable standard of physical and mental health. *Report of the Special Rapporteur*.