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Improving Access to Patented Medicines: Are Human Rights Getting in the Way?

Siva Thambisetty*

Abstract: This paper examines the value of human rights arguments in reducing the access gap to patented medicines. Great efforts continue to be poured into institutional, doctrinal and activist settings to bring human rights thinking to bear on the grant and exploitation of patents. Far from triggering meaningful intervention, however, the international human right to health functions as a placeholder, pointing to specific sites of injury or harm and diverting attention from larger ambitions of justice over current incentive structures around patented pharmaceuticals. Excessively technical, incomplete theorising and linguistically driven decision-making have purged reflexive spaces in patent law that might have accommodated purposive reasoning aligned with the protection of human rights. Reliance on the human right to health to correct the technocratic forces in patent law is doomed to fail, because doing so ignores the source of the problem. The point is not that we should not limit patent rights; it is that we cannot do so using only human rights thinking. It would be far better to uncouple human rights from patent law, so that we may systematically retool the latter to be a purposive and reflexive system of law that understands and participates in its own consequences.

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INTRODUCTION

In 2015 5.9 million children under the age of five died, almost all in developing countries from easily preventable or treatable causes¹ – but when and how does this become a human rights crisis? Tagging human rights to the exploitation of patent monopolies on medicines can be traced to the catastrophic event that was AIDS in Africa at the turn of the century. Millions of Africans lost their lives,² while some developed-country governments and pharmaceutical companies blocked access to low-cost antiretroviral drugs. That fiasco mobilised civil society³ and enough international political will to translate into legal arrangements⁴ to ensure that patent monopolies do not get in the way of saving lives, at least when such large numbers are at stake.⁵ While the juxtaposition might seem natural in light of these developments, how much have we actually achieved decades later by associating human rights with the problem of access to medicines protected by patent monopolies?

Over the last two decades since the AIDS crisis, it has seemed as though drug companies are able to charge as much as they want for medicines that are patented. Humira, the anti-inflammatory drug which is also the best-selling prescription drug in the world, rose 100% in price from 2012 and currently costs 38,000 USD per patient per year.⁶ The soaring cost of Mylan's life-saving Epinephrine pens is well documented – this old technology now costs over 600 USD, a price increase of 500% since 2007.⁷ As bad as these examples are, what makes them worse for the people who owe their lives to highly priced drugs or devices is that in many cases, if the patent was taken out of the picture, low-cost generic options are available or could be made available for a fraction of the cost.

¹ 'Levels and Trends in Child Mortality', Report by UN Inter-Agency Group for Child Mortality Estimation (2015)

http://www.childmortality.org/files_v20/download/IGME%20Report%202015_9_3%20LR%20Web.pdf. See also Jeffrey Sachs, 'Saving the Lives of 6 Million Children a year Wouldn't Cost much' Market Watch Opinion (May 31 2006). Available at <http://www.marketwatch.com/story/saving-the-lives-of-6-million-children-a-year-wouldnt-cost-much-2016-05-31>.

² In 2005 two million Africans died of AIDS, but this year WEF reported that AIDS is no longer the leading cause of death in Africa. See <https://www.weforum.org/agenda/2017/08/hiv-aids-is-no-longer-the-leading-cause-of-death-in-africa>

³ Portrayed in *Fire in the Blood: Monopoly, Malice and Medicines*, Directed by Dylan Mohan (2012).

⁴ Principally, the Declaration on the TRIPS Agreement and Public Health. Available at https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm. accompanied by a more intangible recognition of 'Doha principles'.

⁵ Despite being hailed as a watershed in international trade, the Doha Declaration has not solved the problem of access to medicines. VB Kerry and K Lee, 'TRIPS, the Doha Declaration and Paragraph 6 Decision: What are the Remaining Steps to Protect Access to Medicines?' 2007 Global Health 3:3.

⁶ D Hakim, 'Humira's Best Selling Drug Formula: Start at a High Price, Go Higher' <https://www.nytimes.com/2018/01/06/business/humira-drug-prices.html>.

⁷ C Duhigg, 'Outcry Over Epipen Prices Hasn't Made them Lower' https://www.nytimes.com/2017/06/04/business/angry-about-epipen-prices-executive-dont-care-much.html?_r=0.

The story is even more telling with the realisation that variable pricing decisions, even for life-saving drugs are based on market expectations, rather than cost of production. For example, direct acting anti-viral drugs that are crucial in the treatment of Hep C range in prices globally: Sofosbuvir from \$300 (India, Pakistan) to \$20 590 (Switzerland); for daclatasvir from \$175 (Egypt) to \$14 899 (Germany); for simeprevir from \$241 (Egypt) to \$14 865 (Australia); for ledipasvir-sofosbuvir from \$400 (Egypt and Mongolia) to \$24 890 (Germany); and for ombitasvir-paritaprevir-ritonavir (or 2D regimen) from \$400 (Egypt) to \$20 215 (Switzerland).⁸

These disparities alone do not make drugs affordable in the countries where they are priced lower. A study on 23 cancer drugs for instance showed that once monthly drug prices were expressed as a percentage of domestic product per capita at purchasing power parity, cancer drugs were found less affordable in low-income countries.⁹ In India only 15% of the population has an annual income which is more than the baseline cost of treatment of a cancer and by 2020 there will be an estimated two million new cancer cases a year.¹⁰

The lack of access to patented medicines and the question of affordability remains a catastrophic question for many Third World countries, but it is by no means limited to them and extends to the relatively poor in the first world. Even as drug price increases are received by the public with a mixture of incredulity and moral outrage, what, if any, are the current strategies available to global civil society and legal advocacy groups?

There is an established propensity in academic commentary,¹¹ international negotiations,¹² advocacy literature¹³ and intervention¹⁴ to argue that the scope and

⁸ Andrieux-Meyer et al., 'Disparity in Market Prices for Hepatitis C Direct Acting Drugs'

[http://www.thelancet.com/journals/langlo/article/PIIS2214-109X\(15\)00156-4/fulltext](http://www.thelancet.com/journals/langlo/article/PIIS2214-109X(15)00156-4/fulltext).

⁹ Goldstein et al., 'A Global Comparison of the Cost of Patented Cancer Drugs in Relation to Global Differences in Wealth' 2017 *Oncotarget* 8(42) 71548-71555.

¹⁰ Deena Beasley, 'Cancer Drug Prices Highest in US, Least Affordable in India, China: Study' available at <http://www.reuters.com/article/us-health-cancer-prices-idUSKCN0YS172>.

¹¹ ER Gold, 'Patents and Human Rights: A Heterodox Analysis' (2013) *The Journal of Law, Medicine and Ethics* 41(1):185-98, identifying three broad approaches to the relationship between human rights and patents – the subjugation, integrated and co-existence.

¹² For instance, the appropriate linkages between consent arrangements and the patent system. See Anja von der Ropp and Tony Taubmann, 'Bioethics and Patent Law: The Case of Moore and the Hagahai People' (2005) WIPO Magazine Issue 5. See also M Temmerman, 'Human Rights in the Patent Procedure: The Issue of Prior Informed Consent of Human Donors to the Patenting of Inventions Based Upon their Genetic Material', NCCR-Trade Working Paper 2006/01 Available at http://www.wipo.int/export/sites/www/meetings/en/2009/wipo_ls_biot_ge_09/pdf/2_pic-workshop_report_12_07.pdf, labelling Art 26 of the EU Biotech Directive, which introduces an EU Prior Informed Consent requirement as being little more than symbolic at p. 8.

¹³ See P Benkimoun, *Morts sans ordonnance* (Hachette 2002) on the struggle to improve access to patented drugs. The book details civil society movements (comprising, among others; NGOs, health professionals and grass root movements) that, both in industrialised and developing countries, have set up alliances and networks to defend the principle that human dignity and health should come before private interests and profits.

¹⁴ See for instance the Declaration on Patent Protection: Regulatory Sovereignty under TRIPS, which declares that the TRIPS Agreement and the Paris Convention are both part of, and should be interpreted

remit of patent laws must and can be moderated by recourse to international human rights law, and human rights thinking.¹⁵ The argument, often raised in, but not limited to, the access to patented medicines,¹⁶ aims to moderate the terms on which patents are granted as well as limit post-grant exploitation. It extends to arguing that some kinds of patents on life-saving drugs must be negated due to their potential to impair human rights,¹⁷ and that the post-grant exploitation of patents could be or ought to be guided and tempered by human rights thinking where local affordability determines access. A different kind of argument is advanced when public health needs or national emergencies arise in the context of granting of compulsory licences for patented medicines.¹⁸ In all these kinds of arguments, the human rights claim is often resorted to as a generalisable back-up that outdoes any other legal claim, including the claim to a legitimately prosecuted or granted patent (property) right. In reality, however, there is cause to be sceptical of the impact of these arguments, if nothing else because of the persistence of the access gap and monopoly pricing. The resources poured into multiple international fora, activism and doctrinal tinkering are not commensurate with the insubstantial inroads made into patent law by international human rights law.

It is true both that human rights are important and that denial of access to patented substances in case of ill health, critical or otherwise, can lead to loss or blighting of life, and other impairment of human rights. Given the backdrop to the struggle to improve access to medicines, the UN Special Rapporteur in the field of cultural rights Farida Shaheed's statement¹⁹ that 'where patent rights and human rights are in conflict, human rights must prevail', seems more than just unhelpful. Implicit in this statement is the assumption that there is a common system of law inhabited by both patent rights and human rights, such that a hierarchy can be imposed, or that one system of rights can resolve the problems created by another. In reality, human rights and patent law have widely differing institutional dispositions, inclinations and reach. The two systems are governed by

in the light of, a wider set of international rules and principles, including regimes dealing with human rights and biological diversity. Available at <<https://www.mpg.de/8132986/Patent-Declaration.pdf>>.

¹⁵ Often human rights are raised as counterweights to the expansion of rights, as do those seeking such expansion. See L Helfer and G Autin, *Human Rights and Intellectual Property: Mapping the Global Interface* (Cambridge University Press, 2011). An early version of the former is seen in Beyleveld and Brownsword, *Mice, Morality and Patents: the Onco-mouse Application and Article 53(a) of the European Patent Convention* (London, 1993), arguing that patent law must be read as a charter for human rights.

¹⁶ IPR, Innovation, Human Rights and Access to Drugs: An Annotated Bibliography WHO Essential Drugs and Medicines Policy Series no: 14. Available at <<http://apps.who.int/medicinedocs/pdf/s4910e/s4910e.pdf>>.

¹⁷ First clearly laid out in influential 2002 Final Report of the UK Commission on Intellectual Property Rights, which states that fundamental human rights must not be subordinate to the requirements of intellectual property policy. Final Report <http://www.iprcommission.org/graphic/documents/final_report.htm>.

¹⁸ See Also see EK Oke, 'Patent Rights, Access to Medicines and the Justiciability of the Right to Health in Kenya, South African and India' in A Diver and J Miller (eds), *Justiciability of Human Rights Law in Domestic Jurisdictions* (Springer, 2016).

¹⁹ F Shaheed, Report of the Special Rapporteur in the Field of Cultural Rights 'Patent Policy and the Right to Culture and Science' A/70/279, 4 Aug 2015.

different domestic and international legal cultures, and there is no direct, formalistic overlap. The two systems of law are like oil and water; the argument that one should prevail over the other is intellectually incoherent. In fact, the juxtaposition of these separate legal orders by advocacy groups and legal scholars is doing more harm than good; and this paper presents the case that patent law should be dissociated from human rights.

My view is both a descriptive as well as a normative one, and uses pharmaceutical patents and access to medicines as a case in point. Over the last few decades patent law has had to respond to unprecedented and emerging technologies, presenting opportunities to re-examine the underlying justifications for the grant and maintenance of the patent system in its current form – opportunities that are not always taken. What we see instead is a heightening of technocratic decision-making as a response to uncertainty. As a result, reflexive spaces in the law have been purged or are shrinking.

Reflexivity requires more than a simple, instrumental problem-solving approach using rationality and technology. The reflexivity that is lacking in the patent system, to use Ulrich Beck's term, requires self-confrontation where the system might engage with the unintended, negative and systemic consequences of instrumental problem-solving.²⁰ In other words, reflexivity requires an awareness of the conditions of action, as well as the competence and agency to contemplate changing those conditions.²¹ In the patent system this would mean institutional processes that allow key actors in the system to step back from what they are doing to ask whether what they are doing procedurally is what they are supposed to be doing substantively. And if they do not know what they are supposed to be doing substantively beyond what they are doing procedurally, they need to reflect on how that might be changed.

Attempts to push for 'human rights thinking' in patent law without understanding the structural and technocratic disposition of patent law risk strengthening the placeholder effect of the human right to health – where instead of a systemic retooling of patent law, we focus on specific sites of injury and harm through a non-existent hierarchisation narrative. To make real strategic gains in public health and affordable medicines, we must understand and try to correct the many failings of patent law, including its epistemic weaknesses and instrumental reasoning. Relying on the human right to health indirectly undermines, and may even militate against, a radical correction of course of global patent law.

My argument differs from conventional thinking on the relationship between the two systems of law in at least three ways. First, the question whether

²⁰ While it's beyond the scope of this paper to fully unpack what modern reflexivity might mean for patent law, Beck's analysis of the meaning of the term is useful and relevant. Ulrich Beck, *World at Risk* (Polity, 2008?).

²¹ For a general discussion see G Soros, 'The Human Uncertainty Principle' Lecture One Available here <https://www.georgesoros.com/wp-content/uploads/2017/10/the_soros_lectures-human_uncertainty_principle-2017_10_05.pdf>.

intellectual property rights are genuine human rights has been studied in depth by many scholars.²² These debates are important to the main thrust of my argument only in so far as treating intellectual property rights as human rights exemplifies the instrumental nature of the moralism behind international human rights law. Second, much of the scholarship around intellectual property rights and the human right to health refers to the apparent paradox that arises when two human rights collide.²³ My argument draws out the incoherence in laying them out together by unpacking the false promise of an apparent hierarchisation, when neither the moralism nor legality behind each of these human rights can justify such arrangements.

Third, my argument is related to, but different from, that made under the transnationalisation framework. The debate on transnationalisation with respect to the human right to health and patent law exposes the diminution of choice available to domestic policy-makers²⁴ and law-makers and argues that it is this constriction in rule-making powers that is at the heart of our inability to improve access to patented medicines. The transnationalisation debate does not, however, fully grapple with all the ways in which reflective spaces are lost in a technocratic patent system that values predictable, engineered outcomes over messy or ambiguous legal positions.

Patent legislations cannot cater for all scenarios due to the evolving, and non-linear nature of technologies. General principles and old rules often have to be remade and recast in the image of the new, unprecedented technology by patent offices. This process dominated as it is by documentary evidence, examination guidelines, administrative procedures and technical expertise, results in textual and rhetorical artefacts (such as claim formats or claim types). These are designed to guide expectations and give certainty to future patent applicants by presenting even deeply contested questions as axiomatic guidelines. The resultant shrinking of reflexivity coupled with uncertain and infrequent pathways to judicial review, is an enduring characteristic of national and international patent law that has serious and multiple repercussions, including for the human rights narrative.

PATENTS, HUMAN RIGHTS AND ACCESS TO PATENTED MEDECINES

Activism and advocacy that aim to improve access to medicines are often motivated by the many ways in which the human right to health is impacted by the

²² Art 27(2) of the UNDHR.

²³ LR Helfer, 'Toward a Human Rights Framework for Intellectual Property' (2007) 40 UC Davis Law Review, 971–1020.

²⁴ LR Helfer, 'Pharmaceutical Patents and the Human Right to Health: The Contested Evolution of the Transnational Legal Order and Access to Medicines' in TC Halliday and G Shaffer (eds), *Transnational Legal Orders* (Cambridge University Press, 2015).

enforcement of patents including the entitlement to the patent itself as a human right²⁵ The nature of the relationship between patents and high prices that inhibit access, and potentially impair human rights, however, is not self-evident. Monopoly-driven drug pricing is entrenched in the dominant property justifications²⁶ for patents that exert no post-hoc control over how a patent is used or exploited. Legislative frameworks set up the examination and grant of patents but never address commercial or technical use of the monopoly explicitly. This is despite or perhaps because, of the fact that many of patent law's presuppositions and assumptions remain untestable and many of the unproven benefits of the grant of property rights is taken as a given.²⁷ The Access to Medicines (A2M) movement is acutely contested because our present model of economics supports the belief that technological innovation supported by patents drives growth, so tinkering with the foundational ideas about the incentive effect of patents begins to seem like an ideological attack on economic growth.²⁸

Affordability is a complex problem, and both access to drugs and affordability is not simply a matter of price. Pharmaceutical companies that own patents clearly play a part in making medicines more affordable. When patent monopolies cover pharmaceutical compositions that are needed to treat particular conditions or save lives, the degree of exploitation including pricing becomes pivotal to access. National purchasing agreements, presence of national health services, market dynamics, and regulation of private insurers all have an important part to play in affordability metrics. Goldstein's study calculates the monthly price of drugs as a percentage of gross domestic product, which is a better indicator of 'affordability'.²⁹ The Access to Medicines Index is an initiative that ranks the world's 20 largest pharmaceutical companies in terms of their efforts to improve access in 107 middle- to low-income countries. But the fact of the matter is that one-third of the world still does not have access to even essential medicines.³⁰

While affordability might be particularly acute in the developing world,³¹ erratic and hyper-inflationary pharmaceutical pricing is becoming increasingly common. Recently in the UK, the Competition and Markets Authority alleged that

²⁵ Art 27(2) of the UNDHR.

²⁶ see Chris Dent, 'The Purpose of Patents for Invention: Regulation of Exchange versus Incentive' (2017) IPQ (3) 245–61.

²⁷ K Maskus, 'Intellectual Property Rights in the Global Economy' Institute for International Economics (2000).

²⁸ IP watch William New, US Working To Block UN High-Level Panel On Access To Medicines Ideas In Geneva And Capitals 22 Jan 2018. Available here <<https://www.ip-watch.org/2018/01/22/us-working-block-un-high-level-panel-access-medicines-ideas-geneva-capitals/>>.

²⁹ Goldstein et al, supra n 9, Rabin Institute. The study found that in the US median monthly price of branded cancer drugs still protected by patents was USD 8700 compared to USD 2600 in the UK and USD 3200 in China.

³⁰ See MSF Access to Medicines campaign <<https://www.msf.org.uk/issues/access-medicines>>.

³¹ Target 8e of the Millennium Development Goals acknowledges the need to improve the availability of affordable medicines for the world's poor.

<http://www.who.int/medicines/mdg/MDG08ChapterEMedsEn.pdf>. Also see the Global Access Problem campaign page 'Health Gap' <http://www.healthgap.org/accesstomedis>.

Actavis and Concordia had colluded to increase the price of hydrocortisone tablets supplied to the NHS by 80% in the period 2013–2016; a jaw-dropping price increase of 12,000% from 2008 when it was 70p a tablet.³² A 2015 study in the US reports that the prices of anti-cancer drugs have increased 10% every year between 1995 and 2013.³³ New immunotherapies have price tags of more than £100,000 per patient per year.³⁴ Pricing strategies increasingly threaten to overflow from pockets of inaccessibility in the developed world into a general systemic problem with obvious implications for human rights. It is not just loss of life that is of concern, but significant impairment to the quality of life due to inability to access treatment on financial grounds is a moral minefield.

Over the years, the rules that allow patents on different kinds of subject matter have seen incremental expansion resulting in the possibilities of multiple monopolies and other forms of control³⁵ over a variety of forms of the same drug, accompanied by cumulative increases in durations of monopoly pricing. The regulations and possibility of further monopolies on incremental innovations were all developed at various times to solve localised problems within the legal incentive structure. Yet, despite the regulatory and governance measures shoring up patent law and systems associated with it, we are seeing ‘rising prices of new pharmaceuticals, rapidly changing markets for health technologies, and a lack of market incentives for older medicines’ place increasing pressure on health systems.³⁶

Pharmaceutical companies often claim that the cost of drug development is so high that extending the duration of monopolies is essential to the competitive survival of the sector.³⁷ This claim, which lies at the heart of justifications by the pharmaceutical sector for high drug prices, is difficult to debunk because there is

³² <https://www.gov.uk/government/news/cma-alleges-anti-competitive-agreements-for-hydrocortisone-tablets>. Such collusion is coming under increased scrutiny by competition law authorities. See also Final Report: Pharmaceutical Sector Inquiry (8 July 2009)

http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf.

³³ DH Howard, PB Bach, ER Berndt, RM Conti, ‘Pricing in the Market for Anti-Cancer Drugs’ NBER Working Paper 20867 (2015).

³⁴ As reported by Cancer Research UK <<http://www.cancerresearchuk.org/funding-for-researchers/research-features/2016-08-10-health-economics-the-cancer-drugs-cost-conundrum>>.

³⁵ Such as data exclusivity, marketing approval and supplementary protection certificates (SPCs), which extend patent rights on pharmaceutical and plant products, ostensibly in the interests of public health and innovation. Council regulation (EEC) No 1768/92 concerning the creation of a supplementary protection certificate for medicinal products>. During a period of data exclusivity, pre-clinical and clinical trials data produced by the first applicant for approval of a new medicinal product may not be referenced in the data of another company (typically a generic company). Marketing authorisation is a period during which a generic company may not market an equivalent generic version of the originator’s pharmaceutical product. Charles Clift, ‘Data Protection and Data Exclusivity in Pharmaceuticals and Agrochemicals’ in Krattiger et al. (eds), *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (MIHR USA, 2007).

³⁶ *Towards Access 2030* WHO Medicines and Health Products Program Strategic Framework 2016-20130 WHO strategy, executive summary. <http://apps.who.int/medicinedocs/fr/m/abstract/Js23222en/>.

³⁷ See ‘New Health Technologies: Managing Access, Value and Sustainability’, OECD Report (2017) calling into question the pharmaceutical industry’s pricing strategies. Available at <http://www.oecd.org/newsroom/new-approach-needed-to-tackle-rising-drug-prices.htm>.

very little transparency around associated research and development expenditure. There are studies that attack this justification by showing how a large proportion of drug discovery (84% in one study)³⁸ is in fact paid for by public money; and many entities have tried to pin down the mechanism of pricing as the first step towards accountability.³⁹

Recently an important study⁴⁰ on ten cancer drugs in the US revised down the median research and development costs of these drugs to USD 0.6 billion (compared to USD 1.395 billion in the DiMasi study where sample drugs were kept secret)⁴¹, while total revenue from sales of these ten drugs was USD 67 billion compared to a total research and development spend of USD 7.2 billion. The boldness of the study's claims is already attracting intense scrutiny and controversy.⁴² In a bid to rewrite the narrative that drug development is exorbitant, other innovation platforms have tried to demonstrate alternative, open innovation models⁴³ that rely on a mix of public and private action to maximise innovative possibilities while maintaining commercial prospects.

It has been accepted for a long time now that drug prices are not tied to specific 'backward look on sunk research and development' costs.⁴⁴ However '*policies* that support high prices and investment decisions are very much influenced by perceptions of R&D costs, and for that reason, estimates are surprisingly contested and political'— a vexing problem that long-time advocate and Access to Medicines campaigner James Love calls 'a deliberate veil of ignorance'.⁴⁵ Recently the UNSG's High Level Panel on Access to Drugs has sought to push 'delinkage'⁴⁶ between incentive to invest in research and prices of drugs globally as the single most important effort that can help narrow the access gap to medicines.

³⁸ DW Light and JR Lexchin 'Pharmaceutical Research and Development: What do We Get for All That Money?' *BMJ* 2012;344:e4348 doi: 10.1136/bmj.e4348.

³⁹ An attempt by US shareholders of 13 drug companies, to force boards to provide the 'rationale and criteria used for these price increases' failed when the Securities and Exchange Commission asserted that the shareholder resolutions related to 'ordinary business matters' that are not subject to US federal securities law. 'Pharma Companies Block Investor Requests for Greater Transparency on Drug Pricing' May 3 2017 available at <http://www.iccr.org/pharma-companies-block-investor-requests-greater-transparency-drug-pricing>.

⁴⁰ V Prasad and S Mailankody, 'Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues After Approval' (2017) *JAMA International Medicine* doi:10.1001/jamainternmed.2017.3601.

⁴¹ JA DiMasi, HG Grabowski and RW Hansen, 'Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs' (2016) *Journal of Health Economics* 10.1016/j.jhealeco.2016.01.012.

⁴² See R Harris, 'R&D Costs for Cancer Drugs Are Likely Much Less than Industry Claims, Study Finds' on NPR.org (Sept 11 2017).

⁴³ 'New Research Aims to Unlock Power of Big Data and Open Innovation for Medicine', University of Oxford, available at http://www.oxfordmartin.ox.ac.uk/news/201702_New_research.

⁴⁴ H McKinnell, *A Call to Action: Taking Back Healthcare for Future Generations* (McGraw Hill, 2005), as quoted by James Love, 'Perspectives on Cancer Drug Development Costs in JAMA' in *Bill of Health* Harvard Law Petrie-Flom Center, September 13 2017.

⁴⁵ See James Love, 'Perspectives on Cancer Drug Development Costs in JAMA' *ibid*

⁴⁶ United Nations Secretary General High Level Panel on Access to Medicines Report (2016) Available at <http://www.unsgaccessmeds.org/final-report/>.

There appears to be some international support for cautious measures aimed at progressive delinkage to transition away from the current system of monopoly-linked high prices⁴⁷ but there is also considerable resistance to overcome, with US government initiatives suggesting that delinkage is dangerous to economic growth.⁴⁸

In this context it is also worth noting that the most significant way in which human rights thinking or human rights law has made inroads into patent law, is through evolution of the idea that patent rights are not an unmitigated good but one that must be tied to levels of socio-economic development.⁴⁹ This thinking had difficult beginnings during the height of the AIDS controversy, which led directly to the Declaration on the TRIPS Agreement and Public Health (Doha amendment).⁵⁰ The idea that patent laws can, or should be, tempered so as to inhibit the adverse impact they have on monopoly pricing or access to protected medicines has led to some loosening or questioning of legal standards in domestic laws (for instance the compulsory licensing standards in Canada and Thailand,⁵¹ or the Indian Supreme Court's observation on prices in *Novartis v Union of India*).⁵² There have been calls for a mechanism over and above the so-called TRIPS flexibilities that would subject international trade agreements to review standards to protect and advance human rights⁵³. However, many of these interventions remain sporadic and anecdotal – partial wins that are not seen as easily replicable or enforceable in the law minus political will.⁵⁴

The problem of trying to use human rights to remedy monopoly pricing is confounded by a lack of clarity around terminology. The term 'moral human rights' is used by Alan Buchanan⁵⁵ to emphasize the strong moral justification for a legal human rights regime. It is seen by many as the most appropriate term for the prevailing thinking in the human rights movement at large. Yet it also intimates

⁴⁷ *Development of Medicines – Better, Faster, Cheaper*, Netherlands Council for Public Health and Society (Nov 2017) Available at

<https://www.raadvn.nl/uploads/docs/Recommendation_Development_of_New_Medicines.pdf>

Also see in general Delinkage.org.

⁴⁸ IP watch <US Working To Block UN High-Level Panel On Access To Medicines Ideas In Geneva And Capitals> supra n 28.

⁴⁹ UK Commission on Intellectual Property Rights (2002) Final Report. The WHO's strategic statement pursues access to medicines as a development goal for all by 2030.

⁵⁰ Doha Declaration on the TRIPS Agreement and Public Health, supra n 4.

⁵¹ KM Lybecker, E Fowler, 'Compulsory Licensing in Canada and Thailand: comparing regimes to ensure legitimate use of the WTO rules' (2009) *The Journal of Law, Medicine and Ethics* 37, 222–39.

⁵² S Thambisetty, '*Novartis v Union of India* and the Person Skilled in the Art: a Missed Opportunity' (2014) *Queen Mary Journal of IP* 79–94.

⁵³ Ellen 't Hoen, speaking at the UN Social Forum, 'Translating Principles into Action: Access to Medicines, Diagnosis, Vaccines and Treatment in the Context of the Right to Health' convened by the Human Rights Council, Oct 4 2017. Available at <<https://www.ip-watch.org/2017/10/10/mechanism-access-trade-agreements-needed-un-forum-access-medicines-hears/>>.

⁵⁴ For instance, see the widely-reported US response to India's decision in *Novartis* discussed in S Thambisetty, n 51; LS Esmail and JC Kohler, 'The Politics Behind the Implementation of the WTO Paragraph 6 Decision in Canada to Increase Global Drug Access' 2012 *Global Health* Apr 3, 8:7.

⁵⁵ Allen Buchanan, *The Heart of Human Rights* (OUP, 2013).

deep unease and confusion about the basis of human rights in general and of the human right to health in particular.⁵⁶ As John Tasioulas says, ‘so much confusion would be avoided if people made clear whether they are talking about human rights morality or human rights law’.⁵⁷

HUMAN RIGHTS LAW AND HUMAN RIGHTS MORALITY

Broadly speaking there are two approaches to human rights, which go to the very heart of the universality and justiciability of these rights. The orthodox view sees these rights as moral rights that are possessed by all simply by virtue of being human; the political view sees human rights as triggers for intervention or benchmarks of political legitimacy. It is also noteworthy that ‘the debate between adherents of orthodox and political views has become somewhat less polarised over time’,⁵⁸ for instance, in the discussion of the role of modernity in the orthodox view, which often tempers the notion of universal and timeless human rights; or in the recognition that even within philosophical discussions the political uses of human rights are an important subject of investigation.⁵⁹

While the view that these rights are triggers for intervention, or that they specify duties on the part of governments or other entities, is central to the development of international human rights law, there are at least two questions of relevance for the orthodox view which feed into the human right to health: first, are human rights universal; and second, does accepting the universality of moral rights presumptively entail a commitment to their enshrinement in law? And conversely what does the lack of legal commitment mean for a particular human right?

Raz, from the political perspective, is keen to highlight that presuming universal values raises the bar for any claim that a particular human right exists.⁶⁰ The question whether a human right exists or not is the same as whether the supposed right exists as one that can be claimed by everyone – and ‘that requires showing that some other agent or entity is under a duty to secure the enjoyment of the right, at least to some degree and in some way that is plausibly fair and reliable’.⁶¹ While human rights underpin commitment to the value of human life, in reality, this commitment leads to a visceral disconnect. As Susan Marks

⁵⁶ See James Meyerfield, ‘Human Rights’ Ch 1 in *The Promise of Human Rights: Constitutional Government, Democratic Legitimacy and International Law* (University of Pennsylvania Press, 2016), 235.

⁵⁷ Tweet, Feb 27 2017.

⁵⁸ John Tasioulas, ‘Exiting the Hall of Mirrors: Morality and Law in Human Rights’, Kings College London Law School Research Papers no 2017-19 p 4.

⁵⁹ See J Tasioulas, ‘On the Nature of Human Rights’ in S Besson and J Tasioulas (eds), *The Philosophy of International Law* (OUP, 2010).

⁶⁰ Joseph Raz, ‘Human Rights in the Emerging World Order’ (2010) 1 *Transnational Legal Theory* 31, 43.

⁶¹ Susan Marks, ‘Four Human Rights Myths’ (2012) LSE Law, Society and Economy Working Papers 10 p. 5.

questions, ‘how can we take the presumption of the universality of human rights as a given when the most conspicuous fact about the current world order is that there exists no such commitment – some lives are endowed with very much more value than others’.⁶²

The orthodox view also performs a different kind of work in the current world order – of presenting a ‘pure’ aspiration that is unsullied by political commitments and bargains, and which is peddled as a low-threshold commitment that is easy to sign up to and desirable. The non-political creed of human rights allows it to be ‘widely understood as a moral alternative to bankrupt political utopias’.⁶³ However, when human rights have to contend with capitalism⁶⁴ or neoliberalism⁶⁵ – they enter an arena where ‘political visions clash, hard choices are made and tainted compromises struck’⁶⁶ with profound implications for the universality of these rights.

The curious case of Article 27(2) of the Universal Declaration of Human Rights (UDHR),⁶⁷ which casts the material and moral rights of authors and inventors as a human right, damages the orthodox view further. Intellectual property rights generate economic incentives to spur innovation rather than realise universal morality; they are alienable, can be held by corporations and can expire over time unlike other human rights.⁶⁸ Both Wendy Gordon⁶⁹ and Rochelle Dreyfuss⁷⁰ robustly challenge the claim that patent rights are human rights, arguing that such an approach has very little expression in national patent laws. They both address the question in the context of the apparent paradox that is said to arise when one human right is pitted against another.⁷¹ In 2015 the UN Special Rapporteur in the field of cultural rights, Farida Shaheed, rather controversially, given her remit, ‘flatly denied there is a human right to patent protection’.⁷²

⁶² Ibid. p. 6.

⁶³ Samuel Moyn, *The Last Utopia* (Harvard University Press, 2010), 5. Also see Susan Mark’s discussion of Naomi Klein in S Marks, ‘Human, Rights and Root Causes’, (2011) 74 *Modern Law Review* 57.

⁶⁴ See discussion of Naomi Klein, *The Shock Doctrine* (Penguin, 2007), 118 in S Marks, ‘Four Myths’ p. 8.

⁶⁵ I prefer Will Davies’ definition of neoliberalism as ‘the state-led remaking of society around the model of the market’. Will Davies, ‘Moral Economies of the Future: The Utopian Impulse of Sustainable Prosperity’ CUSP Working paper series no 5. Available at <<http://www.cusp.ac.uk/pub/wp5/>>.

⁶⁶ Samuel Moyn, *The Last Utopia* (Harvard University Press, 2010), 217.

⁶⁷ John Tasioulas, *Exiting the Hall of Mirrors*, p. 13.

⁶⁸ Ibid.

⁶⁹ Wendy Gordon, ‘Current Patent Laws Cannot Claim the Backing of Human Rights’ in Willem Groscheide (ed.), *Intellectual Property and Human Rights: A Paradox* (Edward Elgar Ltd, 2010).

⁷⁰ Rochelle Dreyfuss, ‘Patents and Human Rights: Where is the Paradox’ New York University School of Law Public Law and Legal Theory Research Paper Series Paper No. 06-29 Paper No. 06-29 (2006).

⁷¹ Laurence R Helfer, ‘Toward a Human Rights Framework for Intellectual Property’ (2007) 40 *UC Davis Law Review* 971–1020.

⁷² F Shaheed, Address to the UN Human Rights Council, Special Rapporteur in the Field of Cultural Rights, 4 Aug 2015. Available here

<<http://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=16788&LangID=E>>.

Dreyfuss has turned back on her prior position, that Shaheed may have got it wrong with respect to material rights. ‘While patent rights are not the only way or even a sufficient way to promote future technologies, science is expensive. And because the material interests protected by patents furnish significant support to innovations that improve social welfare, an argument can be made that patents do

On the second question, whether universal moral rights reflect and are reflected in legalistic human rights, many, including Amartya Sen, have long insisted that there is no one-to-one relationship between the universality of human rights and the commitment to turn them into law and that there may be all sorts of obstacles, both practical and principled, to the converting of a norm into a law.⁷³ There is much theorising about the converse as well – whether every existing human rights law enacted requires a counterpart in human rights morality, such that this latter is necessary or sufficient to justify the enactment of the former.⁷⁴

The general consensus seems to be that the law is autonomous in the sense that you do not need each legal right to be mirrored by a universal moral right, and indeed the existence of a universal moral right is not necessary or even sufficient to justify the legal right that it mirrors. This reasoning supposedly strengthens the legalistic approach by formalising a distinction between the moral and legal, in order to bolster the authority of the legal to trigger interventions. Indeed, many human rights lawyers are inclined to ‘bypass the question of whether something really is a human right, in the moral sense, by treating the law as dispositive of the matter’.⁷⁵

The indeterminacy in the legal form of the human right to health therefore suffers directly from two broad trends in critical thinking on human rights: first, the ambiguity in the legal form reflects the modern-day moderation of the presumption of universality; and second, the autonomy of the legal form distinct from the moral version of this right, with a view to strengthening the basis for intervention, leaves us with uncertain recourse to the ethical and normative underpinnings of this right. The human right to health idiolect is scattered over several indeterminate phrases that allow great latitude amongst states in giving enforceable shape and form to this human right.⁷⁶ So in case of contingencies such as scarce public resources or the involvement of private corporations, the legalistic indeterminacy becomes hostage to imbalances in power.

Article 25 of the UDHR speaks of the right of all persons to ‘an adequate standard of living including guarantees for health and well-being’. The human right to health is set out in Article 12 of the International Covenant on Economic, Social and Cultural Rights (‘the right to the enjoyment of the highest attainable

have human right dimensions. In that case thought must be given to ways to promote the right to share in scientific advancement within a globally coordinated patent system. R Dreyfuss, ‘Patents and Human Rights: The Paradox Reexamined’ New York School of Law Public Law and Legal Theory Research Paper Series Working Paper No: 15–35.

⁷³ Amartya Sen, ‘Human Rights and the Limits of Law’ (2006) *Cardozo Law Review* 27: 2913–2927 and discussion of Sen in John Tasioulas, ‘Exiting the Hall of Mirrors: Morality and Law in Human Rights’ Kings College London Dickson Poon School of Law Legal Studies Research Paper Series: Paper No. 2017-19 (2017).

⁷⁴ See James Griffin, ‘Human Rights and the Autonomy of International Law’, in S Besson and J Tasioulas (eds), *The Philosophy of International Law* (Oxford University Press, 2010), 354–55.

⁷⁵ This, in Tasioulas words, is Griffin’s main beef with the autonomous view. See Tasioulas, ‘Exiting the Hall of Mirrors’, p 10.

⁷⁶ Principally as seen in the UNDHR and the ICESCR.

standards of physical and mental health'). Article 2 also sets out the general obligations of states in relation to the Covenant rights and includes elliptical phrases such as 'progressive realization', 'maximum available resources' and 'all appropriate means'.⁷⁷

These phrases are used to draw support for a variety of approaches including those that demand radical inclusivity in how this right ought to be legally rolled out; and those who would include non-legalistic content, such as the current UN Guiding Principles on Business and Human rights⁷⁸ (2011). It speaks of three principles – protect, respect and remedy, themselves an evolution from the deeply divisive debate on the Norms on Transnational Corporations⁷⁹ which sought to impose on companies directly under international law the same range of human rights duties that states have accepted for themselves under treaties they have ratified to promote and secure human rights. That early effort divided the business community and human rights advocacy groups while enjoying little support from governments despite the view taken by many international and public global health campaigns that corporate responsibility and action are instrumental to achieving better standards of health and well-being,⁸⁰ including access to medicines.

THE PLACEHOLDER VIEW OF THE HUMAN RIGHT TO HEALTH

What we are left with then, is a generalisable view of human rights law which comes closest to explaining the difference between the object of the human right to health, which may well be universal, and the legal technique that assigns rights to individuals. John Tasioulas refers to this view as the 'Formative Aim Thesis' – wherein the integrity or coherence of international human rights law, as one part of the domain of international law, does not depend on specific universal norms that are mirrored in legal forms/rights but on the view that international human rights law is primarily concerned with giving effect to universal moral rights, in 'so far as it is appropriate for international law to do so through the technique of assigning individual rights to all human beings'.⁸¹

⁷⁷ Art 2 (1) ICESCR.

⁷⁸ UN Guiding Principles on Business and Human rights (2011). Available at <http://www.ohchr.org/Documents/Publications/GuidingPrinciplesBusinessHR_EN.pdf>.

⁷⁹ Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regards to Human Rights UN Doc E/CN.4/Sub.2/2003/12/Rev.2 (2003) Available at <<http://hrlibrary.umn.edu/links/norms-Aug2003.html>>.

⁸⁰ See for instance, Oxfam International, Save the Children and VSO, 'Beyond Philanthropy: The Pharmaceutical Industry, Corporate Social Responsibility and the Developing World' (2002); and Amy Kapczynski, 'Addressing Global Health Inequalities: An Open Licensing Approach for University Innovations' (2005) *Berkeley Technology Law Journal* 20(2) 1032–1114.

⁸¹ J Tasioulas, (2005) 'Exiting the Hall of Mirrors', p. 11. 'The only kind of 'mirroring' that the Formative Aim Thesis inherently involves is of a very limited, formal kind: the general form of human rights morality – universal (moral) rights possessed by all human beings – will itself be mirrored by the distinctive legal technique adopted by IHRL to realise those rights, i.e. universal (legal) rights possessed by all human beings.'

The Formative Aim Thesis is a reasonable function of the scepticism that follows the concession that the battle for an ‘idea of human rights functioning in a constitutionally overarching kind of way with genuine global reach, effective and enforceable’ was lost by 1945.⁸² National sovereignty and nation states were to become the functional units of enforceable human rights, not human beings. International treaties, such as the TRIPS Agreement, which obligate states to set up a territorial property right that can be owned by politically endowed international corporations often based in nation states outside of the state that administers the patent right, is therefore one of the weakest links in the subaltern life of human rights. It exposes the collision of the ideal of human rights with human rights law. As Conor Gearty says, the first is an ethical aspiration, the second a producer of outcomes in real world situations.⁸³ Recasting a goal – affordable medicines – as a human rights goal makes obvious philosophical, but little legal, sense for those seeking a specific change. Although Tasioulas contends that those persuaded by the orthodox view should accept the Formative Aim Thesis, clearly and unlike in the orthodox view, this sort of morality with its caveat of ‘appropriate’ is instrumental, contingent and pragmatic. It accepts the political creed as a given and dwells in the world of compromise, bargain and constraints.⁸⁴

The Formative Aim Thesis has several implications for the effectiveness of intervention and advocacy of the international human rights to health.⁸⁵ where the right becomes a placeholder orchestrating political space, even monopolising it.⁸⁶ It only condemns particular manifestations of injustice or injury rather than providing analytically precise accounts of the forces of injury.⁸⁷ It is inclined to relieve suffering, but not to develop insight into why it occurs.⁸⁸ As a result, instances of the purported abuse of human rights – for instance, the price tag of \$89,000 a year for Emflaza,⁸⁹ the new muscular dystrophy drug, or the fact that life-saving drug Humira is protected by over 100 patents, are seen as unfortunate delinquencies rather than the predictable result of a financial and regulatory system that grants and embellishes market monopolies.

The placeholder view is palpable in the evolution of the so-called TRIPS flexibilities. Legal commentators have long observed that the ambiguous language in the TRIPS Agreement allows for creative interpretation that can moderate the

⁸² C Gearty, ‘The State of Human Rights’ (2014) *Global Policy* 5:4 391–400 at 393.

⁸³ *Ibid.* 396.

⁸⁴ This is not to say that international human rights law has always maintained the integrity of its formative aim. If it had, according to Tasioulas, it would allow it to be more responsive to claims of the proliferation of norms, ‘Hall of Mirrors’, p. 11.

⁸⁵ For a discussion on human rights myths that fuel advocacy, see Susan Marks, ‘Four Myths’, *supra* n 62. ⁸⁶ Wendy Brown, ‘The Most We Can Hope For ...’: Human Rights and the Politics of Fatalism’ (2004) 103 *South Atlantic Quarterly* 451, 453.

⁸⁷ Wendy Brown, *Politics Out of History* (Princeton University Press, 2001), p. 37.

⁸⁸ S Marks, ‘Four Myths’, p. 11.

⁸⁹ Currently set at \$35,000 after a backlash. Available at <<https://www.marketwatch.com/story/ptc-therapeutics-dmd-drug-emflaza-to-cost-35000-a-year-and-launch-within-the-coming-week-2017-05-08>>.

grant and impact of patents.⁹⁰ For instance, the Declaration on Regulatory Sovereignty⁹¹ argues that such interpretations must be treated as necessary ‘differentiation’ rather than discriminatory of technologies, which would be ultra vires the Treaty. However, the focus on for instance, the interpretation of ‘public health needs’ or ‘local working’ while granting compulsory licences⁹² to produce patented medical products forces a response to particular architectures of specific harm rather than drawing attention to the imbalances in the way we fund innovation in medicinal products in the first place. Even these responses are severely contested and their legitimacy doubted.⁹³ As Ellen ’t Hoen notes: ‘If we continue to rely on a system of exclusivities to finance innovation you will always have high drug pricing, rationing of essential medicines and growing inequalities and inequities in health ...’. While TRIPS flexibilities may moderate the consequences, it does not offer a solution to the deeper problem.

It is this ineffectual placeholder view of the human right to health that is rather paradoxically reflected in the UN Rapporteur’s statement that when in conflict, human rights must prevail over patent rights.⁹⁴ The word ‘prevail’ here could refer to superior legal character or superior moral authority. The first is palpably false, given that internationally intellectual property rights are tied to international trade, a relatively hard-edged dispute settlement authority and the possibility of trade-related sanctions. In terms of moral authority then, Shaheed must be implicitly referring to the generalisable moral view or a version of the Formative Aim Thesis. However both as a descriptive and normative proposition, her statement is utopic as it ignores the historic and incremental strengthening of patent rights, fuelled by disparities in economic power amongst nation states, focusing instead on those specific instances of ‘where patent rights and human rights are in conflict’. In this sense, Shaheed’s statement constricts our ambition to gain any credible, real relief from the systemic imbalances of trade-related intellectual property rights, and the inflationary pressures these rights face directed by global capital. It also severely underestimates the technocratic disposition of patent law and it is to this I now turn.

⁹⁰ ‘Most importantly, TRIPS does not define key terms. For medicines, the absence of definitions for new and inventive step provides a great deal of leeway’. Dreyfuss and Rodriguez-Garavito, p. 13. A recent WHO paper tasks rich countries with creating robust and workable legislative frameworks to facilitate the delivery of essential medicines to their poorer neighbours within TRIPS flexibilities. D Nicol and O Owoeye, ‘Using TRIPS Flexibilities to Facilitate Access to Essential Medicines (2013) *Bulletin of the World Health Organization* 91:533-539. doi: <http://dx.doi.org/10.2471/BLT.12.115865> (18 April 2013).

⁹¹ Declaration on Patent Protection: Regulatory Sovereignty under TRIPS. Available at <<https://www.mpg.de/8132986/Patent-Declaration.pdf>>.

⁹² JH Reichman, ‘Comment: compulsory licensing of patented pharmaceutical inventions: evaluating the options’ (2009) *J Law Med Ethics* 37: 247–63 <http://dx.doi.org/10.1111/j.1748-720X.2009.00369.x> pmid: 19493070.

⁹³ KM Lybecker, E Fowler, ‘Compulsory licensing in Canada and Thailand: comparing regimes to ensure legitimate use of the WTO rules’ (2009) *The Journal of Law, Medicine and Ethics* 37: 222–39 <http://dx.doi.org/10.1111/j.1748-720X.2009.00367.x> pmid: 19493068.

⁹⁴ F Shaheed, supra n 71.

THE TECHNOCRATIC PATENT SYSTEM AND THE DIFFICULTY IN ACCOMODATING HUMAN RIGHTS THINKING

In this section I detail the many different ways in which reflexive spaces are non-existent or shrinking in a technocratically disposed patent system. The framework of most patent legislations, whether national or international, allow for regulatory and interpretative ambiguity. Even higher appellate court decisions carry a level of incomplete decision-making. Reacting to the recent US Supreme Court (‘SC’) decision of *Alice*, for instance, Robert Merges says the SC’s resolution of the question ‘is software patentable?’ was akin to the answer 42 in the *Hitchhiker’s Guide*. The SC said if ‘the claimed invention involves a prohibited category then under the second prong of the test, analysis shifts to whether the inventor has added “something more” which might constitute an “inventive concept” beyond an abstract idea, law of nature or (presumably) a product of nature’.⁹⁵ The decision did not give further content to this idea of ‘something more’ – a task that is left to the USPTO.⁹⁶

While deliberating *Human Genome Sciences v Eli Lilly and Co*,⁹⁷ it was suggested to the UKSC that the UK might adopt the ‘utility’ standard for industrial application – transplanted from US law. The court acknowledged the rapid evolution of new norms in US jurisprudence but said, rightly, ‘however, there are obvious risks in relying on US jurisprudence when considering the precise nature of the requirements of Article 57’.⁹⁸ The court then went on to confirm multiple terms that echo the utility standard in the US by adopting 15 principles from the EPO Technical Board of Appeal decisions. Not remarkable in itself, but astonishing when you consider that the EPO has been using these terms derived from US law from about 2002 onwards. The UKSC did not ask questions about the provenance of the terms in the EPO’s usage, satisfying itself only that they do in fact emerge from EPO decisions. Nor is there an exploration of the basis of the 15 principles that speak to one of the three most important patentability criteria.

This level of generality and incomplete theorising is not unusual for patent decisions, but has led directly to an extraordinary increase in the power of patent offices like the USPTO and the EPO. In many jurisdictions, they actualise legal decisions by courts, and fill interpretational gaps in legislation further tweaked in the course of granting or rejecting individual applications. Patent Office decisions are made mostly on the basis of documents, through office actions on the basis of limited information within the framework of the specialist legislation being

⁹⁵ Rob Merges, “Go ask Alice — what can you patent after *Alice v. CLS Bank*?” (20 June 2014), <http://www.scotusblog.com/2014/06/symposium-go-ask-alice-what-can-you-patent-after-alice-v-clsbank/>.

⁹⁶ See discussion in S Thambisetty ‘Alice and Something More: The Drift Towards European Patent Jurisprudence’ 2016 J of Law and Biosciences 691–696.

⁹⁷ [2011] UKSC 51.

⁹⁸ *Ibid.* [40].

administered. This decision-making rationality does not lend itself easily, if at all, to intervention on grounds of public utility, ethics or human rights.

A conventional view of patent law tells us that the grant of a patent is a *quid pro quo* – a bargain in return for the social utility of and information about a new, inventive and industrially applicable invention.⁹⁹ Patentability criteria are predicated on the legal tests being able to fathom adequacy of social utility. In reality it is almost impossible to measure or speculate on the merits of the social bargain with functional accuracy for individual patent applications during the examination process.¹⁰⁰

At the time of the grant of a patent, very little is known about the technical or commercial prognosis or other consequences of grant. Patentability criteria, such as inventive step or industrial application, are simply not designed to include complex analysis of the commercial or social impact of a grant of individual patents, as these are likely to unfold further down the line, influenced by non-linear technical realities.¹⁰¹ As such, the discovery of an invention and its transformation into innovation are economically and sociologically ‘entirely different things’.¹⁰²

Patent examiners are not equipped to collect data that might help inform decisions on social utility or commercial viability and patent applicants have no obligation or incentive to provide such information in individual cases. Stating that any given patent is justified because of the social utility imparted by the invention is therefore based on faith in the overall incentive structure¹⁰³ rather than an individualised evaluation at the time of the grant of a particular patent. The social utility of individual patents, and evaluation of the *quid pro quo* of the monopoly versus social benefit in any individual case, requires a radical retooling of patent law; to talk of one without the other, as substantive justifications of pharmaceuticals do, is duplicitous.

Therefore the single greatest challenge to the incorporation of ‘human rights thinking’ in domestic patent law is the way in which the grant of patents is separated from the consequences of the exploitation of patents, which is where there is most scope for the impairment of human rights.¹⁰⁴ Because those who

⁹⁹ BN Roin “The Disclosure Function of the Patent System (Or Lack Thereof).” *Harvard Law Review*, vol. 118, no. 6, 2005, pp. 2007–2028.

¹⁰⁰ Schumpeter. Scherer, FM *Innovation and growth: Schumpeterian perspectives* (MIT Press, 1984).

¹⁰¹ S Thambisetty, ‘Patents as Credence Goods’ (2007) *OJLS* Issue 4, 707–740.

¹⁰² JA Schumpeter, *Business Cycles – A Theoretical, Historical and Statistical Analysis of the Capitalist Process* (McGraw-Hill Book Company, 1939) 85.

¹⁰³ In fact, there are plenty of econometric studies that suggest that the impact of private knowledge strategies on public knowledge production may in fact be negative. K G Huang and F Murray, ‘Does Patent Strategy Shape the Long-Run Supply of Public Knowledge? Evidence from Human Genetics’ *Academy of Management Journal*, Vol. 52, No. 6, pp. 1193-1221, 2009.

¹⁰⁴ The EPO functioning under the European Patent Convention deals with grant of patents but not with infringement or post-grant exploitation of the patents, which is left to national courts or national and inter-state competition law authorities. See S Thambisetty, ‘Patent Litigation in the United Kingdom: Solutions in Search of a Problem?’ 2010 *EIPR*, 32, 238–246.

discuss the norms for grant or denial of patents do not and cannot directly analyse the outcomes of such grants;¹⁰⁵ because there is very little appetite amongst such bodies to take account of projected impacts sometime in the future;¹⁰⁶ and because the faith in the incentive effect of patents is so strong¹⁰⁷ (demonstrated in part by the fact that there is little or no leverage on patent holders post incentive), there is very little reflexive space for consideration of human rights in the patent system.

There are two major contexts in which human rights thinking in the sense of a generalisable political morality discussed above may infuse patent law. Broadly, these are: first, during the application of these norms through different degrees of granularity, such as domestic legislation and administrative processes like patent examination guidelines both domestic or under inter-state treaties (such as the European Patent Convention). Many legislative provisions in patent law are ambiguous and open to industry- or technology-specific contexts.¹⁰⁸ Second, during the creation of norms, a substantive process that happens rarely and requires some form of international agreement.

(1) APPLICATION OF NORMS

It is the resources and disposition of the agencies tasked with application and enforcement that determine the balance the regulatory regime has struck.¹⁰⁹ By and large for developing countries with relatively recently established patent systems, it is true that international rules percolate down to local bodies involved in implementation and application. Within and out of entities like the European Patent Office (EPO) or the US Patent and Trademark Office (USPTO), we also see an upward mobility of norms from local, technocratic entities that are not subject to conventional policy oversight but carry agenda-setting power to international fora.¹¹⁰ The technical cooperation between networked patent offices (such as the Trilateral Office – a grouping of JPO, USPTO and EPO)¹¹¹ that

¹⁰⁵ This is also reflected in the difficulty in valuing patents accurately. See MA Lemley and C Shapiro, 'Probabilistic Patents' 2005 *Journal of Economic Perspectives* 19(2) 75–98.

¹⁰⁶ While competition law has a sophisticated set of tools to analyse the consequences of actions on markets, patent law tends to assume the right outcomes flow from the incentive structure at the point of grant of property rights over information. For a discussion on the values that undergird IP, see Susan Sell, *Private Power, Public Law: The Globalization of Intellectual Property Rights* (Cambridge University Press, 2003).

¹⁰⁷ See EE Johnson, 'Intellectual Property and the Incentive Fallacy' (2012) 39 *Florida State University Law Review*, 623–80.

¹⁰⁸ Burk and Lemley, 'Is Patent Law Technology-Specific?' (2002) *Berkeley Technology Law Journal* 17(4) 1155–206.

¹⁰⁹ See discussion in RC Dreyfuss and C Rodriguez-Garavito, 'Conclusion: Balancing Wealth and Health in a Transnational Regulatory Framework' pp. 323–343 in R Dreyfuss and C Rodriguez-Garavito (eds), *Balancing Wealth and Health: The Battle Over Intellectual Property and Access to Medicines in Latin America* (Oxford University Press, 2014).

¹¹⁰ L Davies, 'Technical Cooperation and the International Coordination of Patentability of Biotechnological Inventions' 2002 (29) *Journal of Law and Society* 137–162.

¹¹¹ *Ibid.* Also see S Thambisetty, 'Learning Needs' (2014) *IPQ*.

gradually builds support for coordinated positions, driven by a model of patent law that is indifferent to outcomes, exacerbates the problem of global inaccess.

Ambiguous terms in patent legislation, including in the European Patent Convention (EPC), when combined with the expertise of the patent office, gives rise to choice. Linguistic devices that enable such choice can give rise to an appearance of knowledge.¹¹² Patent Examination Guidelines at the EPO for instance are not law per se, and so are not subject to oversight and do not bind the boards of appeal, yet they set up legitimate expectations amongst patent applicants because they are binding on patent examiners. The technical expertise¹¹³ and administrative attributes of the patent office give these legal positions particular form – artefacts of highly technical language that blackbox legal facts – such that dissenting from them requires a great deal of unpacking by an entity inside the expertise barrier.¹¹⁴ The guidelines are presented as ahistorical, relying on technical referents that appeal to allied authorities but ignore contrary legal positions. Over time, it results in the mainstreaming of remarkable legal positions barely supported by the conventional language in patent statutes.

For instance, it is now accepted that a ‘computer implemented method claim is not a claim in the category of computer programs’¹¹⁵ even though that method is put in place using a computer program. This is only the latest in a variety of cognitive gymnastics that give substance to different computer implemented inventions as a claim category. A recent report by the EPO on patents of the Fourth Industrial Revolution identifies ‘data exchange’ as the most significant defining characteristic of the underlying technologies.¹¹⁶ The range of inventions reported on must put to rest any notion of the continued unpatentability of computer programs, or as they are referred to, ‘computer implemented inventions’. In another example the EPO Guidelines define excluded ‘diagnostic methods’ as a series of multiple phases – all of these phases have to be present in the claim and each of them has to be ‘practised in or on the human or animal body’ for the exclusion to kick in; if even one of the phases could be described as ‘technical’ it will fall outside the exclusion and make the diagnostic method patentable. The result is an elaborately constructed claim category that provides several loopholes to the exclusionary clause, so much so that the only diagnostic claim that is unpatentable is one that is badly drafted.¹¹⁷

The transformation of the Swiss-use claim, for medical substances from ‘rhetorical oddity to substantive law’ is one such textual artefact that has had severe consequences for the access to medicines, and exacerbates the problem of

¹¹² S Thambisetty, ‘Construction of Legitimacy in European Patent Law’ (2017) *IPQ* 221–44.

¹¹³ L Davies, *supra* n 107.

¹¹⁴ S Parthasarathy, ‘Breaking the Expertise Barrier: Understanding Activist Strategies in Science and Technology Policy Domains’ 2010 *Science and Policy* 37(5) 355–367.

¹¹⁵ G 3/08 [2011] OJ EPO 10 at [11.2.7].

¹¹⁶ EPO 2017, Report ‘Patents and the Fourth Industrial Revolution’.

¹¹⁷ S Thambisetty, *IPQ* (2017) 231–33.

monopoly pricing.¹¹⁸ Swiss-use claims in the form of a manufacturing claim were designed to circumvent a provision that said that methods of medical treatment are not patentable because they are not industrially applicable. The Swiss-use claim is a representation of second or subsequent medical uses of a known substance, which is a use that is in effect a method of treating the new condition or disease.

The claim type allows for such uses to be patentable as a method of manufacture of a medicament; since this is explicitly an industrial application, the claim in that form escapes the method of medical treatment exclusion. The claim itself does not disclose any new method of manufacture of a medicament – it is merely a somewhat absurd device that makes hitherto unpatentable subject matter patentable. Swiss-use claims ‘derive novelty by analogy from the new therapeutic use rather than the process of manufacturing the medicament’ even though the claim is specifically written as a manufacturing claim to escape the exclusionary effect of another provision.¹¹⁹

These claims are at the heart of what is euphemistically called pharmaceutical lifecycle management where certain claim types can lay the foundation of new patents on incremental innovations surrounding the original patent – such as use of the same substance for new diseases, new patient group, new dosage and even new information about how the pharmaceutical works. The recent Pregabalin litigation in the UK on the implications of accepting Swiss-use claims for a prominent prescription medication brings to fore the shrinking ability to make root and branch evaluations in court, and exposes how over time contrivances like the Swiss-use claim accrue into axiomatic positions that are hard to deviate from.¹²⁰

To bring a human rights perspective to bear in the application of patent norms requires an understanding and willingness to enquire about the outcomes of the application of particular versions of the law. Generally patent offices are the only supplier of norms in a complex system of rules and regulations.¹²¹ This dominant position, shored up by an expertise barrier¹²² and technocratic reasoning,¹²³ functions as an epistemic firewall, militating against consequential

¹¹⁸ S Thambisetty, *IPQ* (2017) *ibid.* 236–37; and could also become a problem in the case of personalised medicine.

¹¹⁹ *Ibid.* 236–37.

¹²⁰ *Warner-Lambert Company LLC v Generics (UK) Ltd (t/a Mylan) & Ors* [2016] EWCA Civ 1006, see W Kaplan, ‘Repurposing Medicines: A Case for Low and Middle Income Countries’ at 383494 (394–395) in Z Babbar (ed.), *Pharmaceutical Policy in Countries with Developing Healthcare Systems* (Springer International, 2017).

¹²¹ C Long, ‘PTO and the Market for Influence in Patent Law’ (2009) *University of Pennsylvania Law Review* 1965.

¹²² S Parthasarathy, ‘Breaking the Expertise Barrier: Understanding Activist Challenges to Science and Technology Policy Domains’ (2010) 37 *Science & Public Policy* 355. Also see Arthur Daemrich, ‘Epistemic Contests and Legitimacy of the World Trade Organization: The Brazil – USA Cotton Dispute and Incremental Balancing of Global Interests’ (2012) 4(1) *Trade Law & Development* 200 discussing questions of expertise, and methods for bounding disputes over scientific facts at the WTO.

¹²³ See M Shapiro, ‘“Deliberative, Independent” Technocracy v Democratic Politics: Will the Globe Echo the EU?’ 2004 *Law and Contemporary Problems* 68, 341–56.

reasoning that is not explicitly called for in the statute. As Dreyfuss and Rodriguez-Garavito note:

[D]isputes over intellectual property and access to medicines can require specialized knowledge about chemical components and products, cost-benefit analysis, financial risk assessment, and the economics of generic competition. The values that traditionally undergird information law can easily be lost in the analysis.¹²⁴

The UN has called for action in multilateral organisations like the WHO, WIPO and WTO to strengthen the capacity of patent examiners at both national and regional levels to apply rigorous ‘public health-sensitive standards of patentability’¹²⁵ taking into account public health needs. This particular recommendation has received very little reinforcement. It is translated for instance in a EU parliamentary resolution as ‘strict application of patentability criteria’. Without spelling out what the strict application of criteria would look like, or how it differs from lax applications of the criteria – this is a toothless missive. It also presupposes that patentability criteria itself effectuate the social quid pro quo of patents, of which public health needs are one component.

There is also a significant resource dimension (cognitive, physical and political) that can prevent the construction of ‘other’ desirable values (such as human rights thinking). To give an example, India’s S 3(d) has been vaunted as the exercise of TRIPS flexibilities led by public health needs. Amy Kapczynski states that it could ‘sharp[ly] reduce exclusivity in the domain of medicines’, citing Articles 7 and 8 of the TRIPS Agreement, which set forth the ‘objectives’ and ‘principles’ of the TRIPS Agreement and lend support to India’s interpretation of it. It does so by denying patents to new forms of known pharmaceuticals, which prevents an extended monopoly on an already patented pharmaceutical.¹²⁶ Rather surprisingly, however, Shadlen and Sampat,¹²⁷ conducting the first systematic study of patents on secondary inventions in India, Brazil and Argentina, found that measures designed to inhibit secondary inventions are having little effect. There could be a number of reasons for this, including the competence of patent examiners and their learning needs,¹²⁸ as well as the presence of technical or legitimacy networks that may be working to undermine the real effect of the provisions.

¹²⁴ *supra* n 113 p. 13.

¹²⁵ UNSG High Level Access to Medicines report (2016).

¹²⁶ S Thambisetty, ‘*Novartis v UOI* and the Person Skilled in the Art: A Missed Opportunity’ 2014 *Queen Mary Journal of Law* 79–94.

¹²⁷ BN Sampat and KC Shadlen, ‘Secondary Pharmaceutical Patenting: A Global Perspective’ *NBER WP* 23114 (January 2017).

¹²⁸ S Thambisetty, ‘The Learning needs of the Patent System and Emerging Technologies’ (2014) *IPQ* 13.

As anthropologist Alexei Yurchak argues¹²⁹ in the context of the paradoxes of life in the Soviet Union before it collapsed, everyone knew the system was failing but no one could imagine any alternative to the status quo, and most people were resigned to keeping up the pretence of a functioning society. Over time the delusions become self-fulfilling and the pretence is accepted by everyone as real, an effect that Yurchak termed hypernormalisation. In many respects patent law's technocratic leaning has led to a widespread view that we cannot go on as we are, yet it seems impossible to imagine an alternative to the status quo.¹³⁰ Human rights thinking should no longer prop up the pretence of a well-functioning patent system.

(2) CREATION OF PATENT RULES AND NORMS

The WTO and WIPO are the two most significant institutions where norm-setting takes place but they are both subject to processes with variable margins for human rights thinking. Any norms set in these start out as 'soft law' but in the words of Cornish, as quoted by Rochelle Dreyfuss,¹³¹ they have 'Genevan bootstraps' which harden over time through incorporation in bilateral agreements, citation in Dispute Settlement Board reports and adoption by the WTO ministerial conference.¹³² While the WTO provides a forum on discussion about compliance, the Dispute Settlement Board resolves issues of interpretation and enforcement of the TRIPS Agreement.

One of the easily recognised 'harbinger[s]' of more broad-based efforts to revise, reinterpret, or supplement intellectual property protection standards adopted in the WTO and WIPO¹³³ is the Declaration on the TRIPS Agreement and Public Health, which affirms the principle of balanced intellectual property protection¹³⁴ already embedded in various clauses of TRIPS. The promised formal hierarchisation of rules that define the relationship between trade law and human rights law following the Doha Declaration, however, never materialised. According to Andrew Lang, this was never politically or practically feasible and the WTO has little appetite to over-extend its own legitimacy in this way.¹³⁵ The swell

¹²⁹ Alexei Yurchak, *Everything was Forever Until it was No More: The Last Soviet Generation* (Princeton University Press, 2005).

¹³⁰ TC Scottek, 'Judge Richard Posner Says There are Serious Problems with The US Patent System'. Available at <https://www.theverge.com/2012/7/12/3155296/judge-richard-posner-patent> >. Also see K Maskus, *supra* n 10.

¹³¹ R Dreyfuss and C Rodriguez-Garavito, 'The Battle over Intellectual Property Laws and Access to Medicines in Latin America' in R Dreyfuss and C Rodriguez-Garavito (eds), *Balancing Wealth and Health: The Battle Over Intellectual Property and Access to Medicines in Latin America* (OUP, 2014) 40.

¹³² *Ibid.*

¹³³ *Ibid.*

¹³⁴ Laurence R Helfer, 'Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking' (2004) 29 *Yale Journal of International Law* p. 5.

¹³⁵ See A Lang, *World Trade Law After Neoliberalism: Reimagining the Global Economic Order* (OUP, 2011). Also see Fakhri, 'Reconstructing WTO Legitimacy Debates' (2011) 2 *Notre Dame Journal of International & Comparative Law* 64.

of international political will that responded to developing countries unable to afford the patented pharmaceuticals needed to prevent hundreds of thousands dying of HIV/AIDS may mean that the success of the Doha Declaration is a one-off, a rejoinder to a sequence of events in the wake of the end of apartheid, and difficult to replicate.

WIPO norm-setting is often long drawn-out, bulked out with rhetoric, posturing and non-legalistic elements. Through its working groups and standing committees, it monitors developments and issues reports on a variety of technical matters. Discussions are often driven by developing countries.¹³⁶ In the case of traditional knowledge¹³⁷ the issue has languished¹³⁸ at the WIPO since the first fact-finding effort carried out in 1998–99.¹³⁹ The need for informed consent for patenting outcomes of biological prospecting from human subjects, perhaps one of the most significant issues that has a direct impact on human dignity and autonomy, was also discussed for several years at the WIPO before being rejected.¹⁴⁰ While WIPO cannot directly intervene in the TRIPS mechanism, it is also true that WIPO's 'technical assistance' in the form of model patent laws or training programmes for officials has shaped domestic understandings of patent norms profoundly.¹⁴¹ Yet until recently 'WIPO was conspicuously absent from global public policy debates about public health and as some may argue, it was curious if at all only for reasons of institutional self-interest'.¹⁴²

The dominance of trade-related intellectual property agreements and legal standards has led to an explosion in intellectual property law-making in multiple lateral fora,¹⁴³ reflecting the issue density and complex policy interfaces where

¹³⁶ See WIPO, 'Traditional Knowledge and Intellectual Property' Background Brief (2015) Available at <http://www.wipo.int/edocs/pubdocs/en/wipo_pub_tk_1.pdf>.

¹³⁷ Defined as a subset of 'heritage' in WIPO. 'Intellectual Property Needs and Expectations of Traditional Knowledge Holders' Report on Fact-Finding Missions on Intellectual Property and Traditional Knowledge (1998-99) (Geneva: WIPO 2001) 25 Available at <<http://www.wipo.int/globalissues/tk/report/final/pdf/part1.Pdf>>. Also see Daniel Gervais, 'Spiritual but not Intellectual? The Protection of Sacred Intangible Traditional Knowledge' 11 *Cardozo Journal of International & Comparative Law* 467 2003–2004.

¹³⁸ There is some support for the view that WIPO negotiations are a 'safety valve to shunt issues away from the WTO'. L R Helfer, 'Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking', 29 *Yale Journal of International Law* (2004) 79.

¹³⁹ For an initial consideration of TK in the WTO see Graham Dutfield, *TRIPS-Related Aspects of Traditional Knowledge* (2001) 33 *Case Western Reserve Journal of International Law* 233, 250.

¹⁴⁰ M Temmerman, 'Human Rights in the Patent Procedure: The Issue of Prior Informed Consent of Human Donors to the Patenting of Inventions Based Upon their Genetic Material' NCCR-Trade Working Paper 2006/01 Available at <http://www.wipo.int/export/sites/www/meetings/en/2009/wipo_ls_biot_ge_09/pdf/2_pic-workshop_report_12_07.pdf>.

¹⁴¹ See Ruth L Okediji, 'The Role of WIPO in Access to Medicines' in Dreyfuss and Robrigues-Garavito (eds) pp. 307–22.

¹⁴² *Ibid.* p. 311

¹⁴³ '[D]isputes over the regulation of access to medicines are occurring in multiple transnational, national and local venues, including the World Trade Organization (WTO), the World Intellectual Property Organization (WIPO), the UN Human Rights Council (UNHRC), the World Health Organization (WHO), bilateral negotiations, national parliaments, constitutional courts, and domestic administrative agencies. L R Helfer, 'Pharmaceutical Patents and the Human Right to Health: The Contested Evolution

intellectual property issues become relevant, including human rights. Helfer explains how actions in these fora lay the political groundwork needed to integrate new principles, norms and rules of intellectual property protection into the WIPO and other agencies. From there they gather political strength and can apply to re-enter the trade-related regime. However, the strategic fortunes of this sort of regime shifting is uncertain and amorphous. Much of the work done in a human rights context, for instance, remains soft law that cannot excuse non-compliance with the TRIPS Agreement; and WTO jurists are unwilling to give interpretive weight to soft law in interpreting the TRIPS Agreement while also being resistant to deciding when soft law may become a binding norm.¹⁴⁴ Simplistically, one set of rules to do with patent rights related to international trade are for the most part legally entrenched and backed by global rules that can be enforced in a dispute settlement process, while the other, ‘human rights thinking’, suffers from all the infelicities of political moralism. Recent concerted efforts that recast the access to medicines as a global problem, not just one that is suffered by low- or middle-income countries, may give further credence to regime-shifting strategies where political will in one forum is used to incubate legal positions that then become more mobile.

A noteworthy development in a global context is the Marrakesh Treaty, which behoves parties to address the rights of those who are visually impaired through the instrument of copyright law.¹⁴⁵ Although the preamble refers to human rights instruments,¹⁴⁶ the negotiations were framed by tightly interpreted copyright exceptions – a normative architecture that is inherently limiting.¹⁴⁷ WIPO’s perspective, that it is national intellectual property offices that must implement the Treaty and not human rights authorities,¹⁴⁸ also suggests that the

of the Transnational Legal Order on Access to Medicines’ in T C Halliday and G Shaffer (eds), *Transnational Legal Orders* (Cambridge University Press, 2015) pp. 311–339 at p. 311.

¹⁴⁴ Helfer, 79–81.

¹⁴⁵ The Marrakesh Treaty intended to encourage the creation, sharing and cross-border transfers of accessible-format materials for visually impaired persons is the first international agreement of its kind that builds on copyright exceptions for the blind in many countries. Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired, or Otherwise Print Disabled 2013.

¹⁴⁶ The Universal Declaration of Human Rights and the United Nations Convention on the Rights of Persons with Disabilities.

¹⁴⁷ For a discussion of limiting architectures see RL Okediji, ‘Legal Innovation in International Intellectual Property Relations: Revisiting Twenty One years of the TRIPS Agreement’ 36 *University of Pennsylvania Journal of International Law* 191.

¹⁴⁸ Reichmann and Helfer in their guide to the Treaty recommend that other institutions, including national human rights institutions and government agencies that oversee the rights of persons with disabilities, should be involved. See Reichmann and Helfer, *The World Blind Union Guide to the Marrakesh Treaty* (OUP, 2017). Also see L Helfer, ‘Human Rights and Intellectual Property: Mapping an Evolving and Contested Relationship’ in RC Dreyfuss and J Pila (eds), *The Oxford Handbook of Intellectual Property Law* (OUP, forthcoming) (Outlining four periods within which the intersection between IP and human rights gradually evolved and became more entrenched.) Available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2832417.

Treaty dons the mantle of being at the intersection of IP and human rights in a rather post-hoc way.¹⁴⁹

Increasingly EU institutions also function as sites of norm creation – with Brusselian bootstraps. In recent times, the most credible opportunity for the creation of norms has arisen from the UNSGHLP report recommending ‘delinkage’ as a way of dissociating investment in R and D from drug prices.¹⁵⁰ It is a broad norm with real potential to shine a light on some of the systemic inequalities that support dubious claims on the cost of drugs.¹⁵¹

The European Parliament adopted the text of a resolution on Access to Medicines,¹⁵² which restricts delinkage to antimicrobial drugs and ‘poverty-related’ diseases. This language narrows the problem of monopoly pricing to specific instantiations that cordon themselves off from an enquiry into the ills of monopoly drug pricing and inflated claims made by pharmaceutical corporations. The reference to ‘poverty-related’ diseases in particular discards the human rights element to the low-income country context. But the consequences of reduced resources and stripped-back public health services mean that systemic inaccess due to rising prices of drugs is a global problem.¹⁵³

The application of norms can also include technical workarounds that cater to human rights without breaking the law. For instance, reverse engineering is accepted practice with a long history. ‘Lawyers and economists have endorsed reverse engineering as an appropriate way for firms to obtain information’ about another firm’s product even if it is in direct competition.¹⁵⁴ Attempts to thwart reverse engineering through contracts or through technical obfuscation can be resisted through policy changes which would in effect have a human rights impact by making medicinal products available where there are no patents, and where they reduce the time taken to enter the market. There are other domestic inroads made by human rights thinking on patent law, although not always presented as such. Brazil’s ANVISA agency is tasked with approval of pharmaceutical patent

¹⁴⁹ See Catherine Sez, ‘Between Human Rights and IP: An Interview with Laurence Helfer, Co-Author of Guide to Marrakesh Treaty Implementation’ IP Watch 31/08/17. Post hoc rationalisations? Dr César J Ramirez-Montes, ‘The Marrakesh Treaty’ European Parliament Policy Department for Citizens’ Rights and Constitutional Affairs [http://www.europarl.europa.eu/RegData/etudes/STUD/2016/571387/IPOL_STU\(2016\)571387_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/STUD/2016/571387/IPOL_STU(2016)571387_EN.pdf). Also see Helfer’s presentation.

¹⁵⁰ See Delinkage.org. Also see @James_Love #SDG2030_India tweets Nov 21 reporting on the 1st World Conference on Access to Medical Products and International Law for Trade and Health in the Context of the 2030 Agenda for Sustainable Development 21-23rd November.

¹⁵¹ See James Love, ‘Perspectives on Cancer Drug Development Costs in JAMA’ in *Bill of Health* (2017) Harvard Law Petrie-Flom Center.

¹⁵² Options for Improving Access to Medicines’ (European Parliament) 2 March 2017.

¹⁵³ Ranjana Srivastava, ‘We Are More Likely to Get Cancer Than to Get Married: This is a Wake up Call’ (Sept 12 2017). Available at <https://www.theguardian.com/commentisfree/2017/sep/12/cancer-common-marriage-wake-up-call-macmillan>.

¹⁵⁴ P Samuelson and S Scotchmer, ‘The Law and Economics of Reverse Engineering’ 2002 *Yale Law Journal* 1575 -1663.

applications where public health is a concern. This is a tool to prevent grant of problematic patents anticipating aggressive exploitation, and it has its detractors.¹⁵⁵

The use of compulsory licences in Thailand as a strategy to close the access gap has also been widely reported on.¹⁵⁶ In India, the *Novartis* decision refers extensively to the public interest in rejecting certain kinds of pharmaceutical patents, even citing the informal role that the Indian pharmaceutical generic industry has played as ‘pharmacy of the Third World’ to support an eligibility rule that is at least implicitly designed to prevent trivial, incremental innovation over individual pharmaceuticals. Recently the Indian National Human Rights Commission queried the anti-compulsory licensing stance purportedly given by the Indian Government in the form of ‘private reassurances’ to the India–US Business Council.¹⁵⁷ There are other interesting cases in domestic law such as the celebrated South African constitutional case of *Minister of Health v Treatment Action Campaign*, which is seen as successful socio-economic rights litigation because it resulted in a direct order to the government to implement a comprehensive programme to prevent mother-to-child-transmission of HIV.¹⁵⁸ The anecdotal nature of these successes, however, is out of kilter with the intensity of resources that have historically been put into the progressive project of trying to link human rights to patent law and intellectual property.

As Helfer details, a lot of time and effort have been spent trying to develop norms in lateral regimes that interface with intellectual property law, including human rights, in an effort to modify or soften the effect of binding legal norms. But this ‘integrationist regime shifting strategy’ has encountered resistance from industrialised countries. Efforts poured into such regime shifting take important resources away from developing insights into how we can fix the patent system and make its ecosystem more amenable to consequential and purposive thinking. Intellectual property norm-setting, as Margret Chon argued, is blighted by asymmetric power and inequality amongst nation states¹⁵⁹ even as health has become a legitimate foreign policy concern.¹⁶⁰ It is also, as Lang establishes,

¹⁵⁵ It has contributed to a severe backlog problem in Brazil. See K Shadlen, ‘The Politics of Pharmaceutical Patent Examination in Brazil’ Available here <http://personal.lse.ac.uk/shadlen/Pol%20of%20Pharma%20Patent%20Exam%20in%20Brazil%20_forthcoming_.pdf>.

¹⁵⁶ KM Lybecker, E Fowler, ‘Compulsory licensing in Canada and Thailand: comparing regimes to ensure legitimate use of the WTO rules’ (2009) *Journal of Law, Medicine and Ethics* 37: 222–39 <http://dx.doi.org/10.1111/j.1748-720X.2009.00367.x> PMID: 19493068

¹⁵⁷ NHRC Press release here 1 April 2016. Available at <<http://nhrc.nic.in/dispArchive.asp?fno=23893>> and ‘NHRC Asks GOI for Clarification on (anti) CL stance’ Available at <<https://spicyip.com/2016/04/spicyip-tidbit-an-irked-nhrc-calls-for-report-from-the-union-health-and-commerce-ministry-on-no-compulsory-licensing-promise-to-usibc.html>>.

¹⁵⁸ See Berger and Kapczynski, ‘The Story of the TAC case: The Potential and Limits of Socio-Economic Rights Litigation in South Africa’ in Deena R. Hurwitz, Margaret L. Satterthwaite (eds), *Human Rights Advocacy Stories* (Foundation Press, 2009).

¹⁵⁹ M Chon, ‘Intellectual Property and the Development Divide’ in Margaret Chon, *Intellectual Property and the Development Divide* (2006), 27 *Cardozo Law Review* 2821, 2828.

¹⁶⁰ H Feldbaum, K Lee and J Michaud ‘Global Health and Foreign Policy’ *Epidemiol Review* 2010 Apr 32(1) 82–92.

subject to a great deal of ambiguity because the content and aim of trade regimes and human rights are internally intensely contested. The meagre gains made so far demonstrate that the path from the Formative Aim Thesis of international human rights law to intellectual property norms is uncertain and largely ineffective. Far from the progressive ideal, the human right to health is offered up as a sufficing placeholder in its interactions with patent law.

CONCLUSION

The idea that where patent rights and human rights are in conflict, human rights must prevail can lead to considerable harm. This view is more conceptually cluttered than it appears and locates the entire weight of the promissory project of human rights in an implicit hierarchisation of two formal systems of law. Asking for patent rights to give way to human rights is not just ineffective: it orchestrates intervention, and dampens the possibility of any deep change being effected. The indeterminacy of the human right to health and the contingent political moralism that gives it shape and form is no match for an unyielding and technocratic patent law backed by resistance to integrationist regime shifting from developed countries. The promise of human rights gives way to a far more limited placeholder function.

Patent law's epistemic firewall also means that it is very difficult for 'outsiders' such as human rights advocates to make a difference, because they do not work with the same toolkit and do not bring predictable forms of ultimatum with them. As a result, the human right to health has a disappointing impact on campaigns that call for the negation or moderation of patent rights. Instead, to uncouple human rights from patent law is to take patent law on its own terms and seek normative coherence and doctrinal fidelity informed by consequential reasoning.

Over the last three decades we have seen conventional rationales for the grant of patents severely tested by unprecedented subject matter such as living biological material and new methods of data exchange, and by the immateriality of software. We are heading into the Fourth Industrial Revolution impeded by a patent system burdened by centuries of incremental, sector-specific changes. Many academic and activist commentators reach out for human rights when it comes to access to medicines because of the same sense of unfairness that blights many other aspects of patent law. Monopoly-driven pricing, justified by spurious claims, is embedded in the dominant justifications for patents that exert no control over how a patent is used or exploited. We need new ways to justify and rationalise the grant and exploitation of patents that are principled, ethical and entrenched in the gains made by international law. These rationalisations must work for all of patent law, not just respond to specific technology sectors. The change we really need, then, is

not to tinker with patent statutes, but a systemic retooling of patent law, to make it reflexive and competent to participate in its own consequences.