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

Abstract

This paper examines the value of human rights arguments in institutional, activist and doctrinal settings in reducing the access gap to patented medicines. Reliance on the human right to health to moderate patents ignores the source of the problem – the political moralism at the heart of the international human right to health and excessively technical decision-making in patent law that have purged reflexive spaces that might have aligned with the protection of human rights. Far from triggering meaningful intervention, the international human right to health functions as a placeholder, diverting attention away from greater ambitions of justice over current incentive structures around patented pharmaceuticals. The point is not that we should not limit patent rights; it is that we cannot significantly do so by using human rights thinking alone without retooling the patent system. The paper ends with a proposal for patent impact assessments as one way to explicitly include consequential reasoning in the grant and exploitation of patent rights.

In 2015 5.9 million children under the age of five perished, almost all in developing countries from preventable or treatable causes.[1] When and how does loss of life on

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such a scale become a human rights crisis? Tagging human rights to the lack of access to patented 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 society[3] and enough international political will to translate into legal arrangements[4] to ensure that patent monopolies do not get in the way of saving lives, at least when such large numbers are at stake.[5]

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[1] UN Inter-agency Group for Child Mortality Estimation, 'Levels and Trends in Child Mortality', (2015) Report *http://www.childmortality.org/files_v20/download/IGME%20Report%202015_9_3%20LR%20Web.pdf* [Accessed September 15th 2019]. See also Jeffrey Sachs, 'Saving the Lives of 6 Million Children a Year Wouldn't Cost Much' Market Watch Opinion (31 May 2006), *http://www.marketwatch.com/story/saving-the-lives-of-6-million-children-a-year-wouldnt-cost-much-2016-05-31* [Accessed September 15th 2019].

[2] In 2005 2 million Africans died of AIDS, but this year World Economic Forum reported that AIDS is no longer the leading cause of death in Africa. See [D Ng'ang'a 'HIV/AIDs is no Longer the LeadingCause of Death in Africa' (2017), *https://www.weforum.org/agenda/2017/08/hiv-aids-is-no-longer-the-leading-cause-of-death-in-africa* [Accessed September 15th 2019].

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

[4] Principally, the 2001 Declaration on the TRIPS Agreement and Public Health, *https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm* [Accessed September 15th 2019], 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

While the juxtaposition might seem natural in light of these developments, decades later how much have we actually achieved by associating human rights with the problem of access to medicines?

Over the last two decades since the AIDS crisis, drug companies are able to charge as much as they want for medicines that are patented, or so it has seemed. 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 USD 38,000 per patient per year.[6] The soaring cost of Mylan's life-saving Epinephrine pens is well documented – this old technology now costs over USD 600, 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. Even more revelatory is the variable pricing, based on market expectations even for life-saving drugs, rather than cost of production. For example, direct acting antiviral drugs that are crucial in the treatment of Hep C range in prices globally:

Paragraph 6 Decision: What Are the Remaining Steps to Protect Access to Medicines?' (2007) 3 *Global Health* 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* [Accessed September 15th 2019].

[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* [Accessed September 15th 2019].

> 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 to be 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 2 million new cancer cases a year.[10]

This 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

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[8] I 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* [Accessed September 15th 2019].

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

[10] Deena Beasley, 'Cancer Drug Prices Highest in US, Least Affordable in India, China: Study', *http://www.reuters.com/article/us-health-cancer-prices-idUSKCN0YS172* [Accessed September 15th 2019].

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 literature[13] and intervention[14] to argue that the scope and

[11] ER Gold, 'Patents and Human Rights: A Heterodox Analysis' (2013) 41 *The Journal of Law, Medicine and Ethics* 185, 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 A von der Ropp and T Taubmann, 'Bioethics and Patent Law: The Cases of Moore and the Hagahai People' (2006) 5 *WIPO Magazine*. 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, *http://www.wipo.int/export/sites/www/meetings/en/2009/wipo_ls_biot_ge_09/pdf/2_picworkshop_report_12_07.pdf* [Accessed September 15th 2019], 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 Literature, 2002) on the struggle to improve access to patented drugs which details civil society movements (comprising, amongst others, NGOs, health professionals and grass-roots 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, *https://www.mpg.de/8132986/Patent-Declaration.pdf* [Accessed September 15th 2019], which declares that the Trade Related Intellectual Property Rights Agreement (1994) and the Paris Convention for the Protection of Industrial Property (1884) are both part of, and should be interpreted in the light of, a wider set of international rules and principles, including regimes dealing with human rights and biological diversity.

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 the context of 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 tempered by human rights thinking where local affordability determines access. A related argument is advanced when public health needs or national emergencies arise in the context of granting compulsory licences for patented medicines.[18] In these kinds of arguments the human rights claim is often resorted to as

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[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, UK: CUP, 2011). An early version of the former is seen in D Beyleveld and R Brownsword, *Mice, Morality and Patents: The Onco-mouse Application and Article 53(a) of the European Patent Convention* (London: Common Law Institute of Intellectual Property, 1993), arguing that patent law must be read as a charter for human rights.

[16] World Health Organization (WHO), 'IPR, Innovation, Human Rights and Access to Drugs: An Annotated Bibliography' (2003), WHO Essential Drugs and Medicines Policy Series no: 14, *http://apps.who.int/medicinedocs/pdf/s4910e/s4910e.pdf* [Accessed September 15th 2019].

[17] First clearly laid out in an 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* [Accessed September 15th 2019].

[18] See also EK Oke, 'Patent Rights, Access to Medicines and the Justiciability of the Right to Health in Kenya, South Africa and India' in A Diver and J Miller (eds), *Justiciability of Human Rights Law in Domestic Jurisdictions* (New York: Springer, 2016).

a generalisable backup that outdoes any other legal claim, including the claim to a legitimately prosecuted or granted patent (property) right. As Amy Kapczynski notes:

> Each year in Brazil, tens of thousands of people 'judicialize', asking courts to order the government to provide them with one or more specific medicines. They almost always win. In Colombia, from 1999–2014, an estimated 1.3 million right-to-health cases were litigated, many targeting medicines, with patients prevailing about 80 percent of the time. The trend is most prominent in these two countries, but not limited to them. Courts in Argentina, Costa Rica, Uruguay, India and South Africa have also ordered governments to provide medicines to individuals to vindicate rights to health and life. (footnotes omitted)[19]

Yet despite this limited success at creating 'a serious, judicially enforceable right – a socio-economic right'[20] there is cause for scepticism about the real impact of these cases on the ability to provide a systemic source of relief or access to patented medicines because access to courts remains a function of resources to litigate, and litigants may often end up with less than the best or ideal drug recommended in those circumstances.[21]

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[19] A Kapczynski, 'The Right to Medicines in an Age of Neoliberalism' (25 April 2019) *Humanity Journal*, *http://humanityjournal.org/issue10-1/the-right-to-medicines-in-an-age-of-neoliberalism/* [Accessed September 15th 2019].

[20] Ibid.

[21] See OF Norheim and S Gloppen, 'Litigating for Medicines: How Can we Assess Impact on Health Outcomes?', in AE Yamin and S Gloppen Eds *Litigating Health Rights: Can Courts Bring*

Given the relatively poor outcomes of the judicialised struggle to improve access to medicines so far, the UN Special Rapporteur in the field of cultural rights Farida Shaheed's statement ,[22] that 'where patent rights and human rights are in conflict, human rights must prevail', seems unhelpful. Implicit in her statement is the assumption that a hierarchisation of patent rights and human rights is possible, or that one system of rights can resolve the problems created by another system of law. In reality human rights and patent law have widely differing institutional dispositions, inclinations and reach. The two systems are governed by different domestic and international rules and there is no direct, formalistic overlap. Where it is suggested that human rights ends can be accomplished within flexibilities in patent law, solutions are predetermined by persistent institutional inadequacies. Limitations and exceptions – in the language of intellectual property law – often require sophisticated judicial and legal expertise to apply and enforce, lack of which in the same contexts it is most needed can frustrate the intellectual property/human rights interface.[23] The argument that one should prevail over the other is institutionally and intellectually incoherent.

More Justice to Health' (Cambridge, Massachusetts: HUP, 2011) 304, and AE Yamin, 'Power, Suffering, and Courts: Reflections on Promoting Health Sights through Judicialization', in in AE Yamin and S Gloppen Eds *Litigating Health Rights: Can Courts Bring More Justice to Health'* (Cambridge, Massachusetts: HUP, 2011) 365

[22] F Shaheed, Report of the Special Rapporteur in the Field of Cultural Rights 'Patent Policy and the Right to Culture and Science' (4 Aug 2015) UN Doc A/70/279.

[23] R Okediji, 'Does Intellectual Property Need Human Rights?' (2018) 50 NYU J of International Law and Politics 1

This paper presents the case that the uncritical juxtaposition of these separate legal orders by advocacy groups and legal scholars could be doing more harm than good, and we should dissociate patent law from human rights to focus on more productive avenues of reform internal to patent law. I do so by unspooling the link between patents, high prices, affordability, human rights moralism and the international human right to health; before then advocating a new tool within patent law that could help ameliorate the access to patented medicines.

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 – opportunities that are not always taken. Instead we see a heightening of technocratic decision-making as a response to uncertainty. As a result reflexive spaces in the law have been purged or are further shrinking.

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 that simply uses rationality and technology.[24] In other words, reflexivity requires an awareness of the conditions of action, as well as the competence and agency to contemplate changing those

[24] While it is 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. U Beck, *World at Risk* (Cambridge, UK: Polity Press 2009).

conditions.[25] 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.

Patent legislation 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 is dominated by documentary evidence, examination guidelines, and technical expertise and results in peculiar 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.[26] 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 implications, including for the human rights narrative and its interface with patent law.

Attempts to push for 'human rights thinking' in patent law therefore, without understanding the structural and technocratic disposition of patent law, risks

[25] For a general discussion see G Soros, 'The Human Uncertainty Principle' (2017), Lecture One, *https://www.georgesoros.com/wp-content/uploads/2017/10/the_soros_lectures-human_uncertainty_principle-2017_10_05.pdf* [Accessed September 15th 2019].

[26] I discuss these in detail in S Thambisetty, 'Construction of Legitimacy in European Patent Law' (2017) 3 IPQ 221.

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 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 the course of global patent law.

As Okediji argues:

> Ultimately, the current narrow construction of the IP/human rights interface provides reprieve from the grander, more contested, distributive justice-oriented vision of human progress and flourishing embodied in the economic, social, and cultural rights. To be sure, a human rights frame offers new language and a 'moral hegemony' that can be usefully leveraged to support important public welfare goals. Thus far, however, the practical outworking of these efforts has had limited effects on the real needs and interests of most of the world's population, while the agenda for stronger IP rights continues unabated.[27]

My argument differs from conventional thinking on the relationship between the two systems of law in at least three ways. First, the question whether intellectual property rights are genuine human rights has been studied in depth by many scholars.[28] These

[27] R Okediji, n 23 above.

[28] Art 27(2) of the United Nations Declaration on Human Rights.

debates are important to the main thrust of my argument only in so far as treating intellectual property rights as human rights emphasises 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.[29] 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 in domestic law and policy[30] 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.

Access to patented medicines: where does the problem lie?

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[29] LR Helfer, 'Toward a Human Rights Framework for Intellectual Property' (2007) 40 UC Davis Law Review 971.

[30] 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, UK: CUP, 2015).

Activism and advocacy that aim to improve access to medicines are often driven by the many ways in which the human right to health is impacted by the enforcement of patents including the entitlement to the patent itself as a human right.[31] 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 justifications[32] 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 are taken as a given.[33] Moreover present models used in economics support 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.[34]

Pharmaceutical companies that own patents clearly play a part in making medicines more affordable. Affordability, however, is a complex problem and access to drugs is

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[31] Art 27(2) of the UNDHR.

[32] See C Dent, 'The Purpose of Patents for Invention: Regulation of Exchange versus Incentive' (2017) 3 IPQ 245.

[33] K Maskus, *Intellectual Property Rights in the Global Economy*, 2000 (Washington DC: Institute for International Economics)

[34] W New, 'US Working to Block UN High-Level Panel on Access to Medicines Ideas in Geneva and Capitals' (22 Jan 2018), IP Watch, *https://www.ip-watch.org/2018/01/22/us-working-block-un-high-level-panel-access-medicines-ideas-geneva-capitals/* [Accessed September 15th 2019]

not simply a matter of price. 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'.[35] 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.[36]

While affordability might be particularly acute in the developing world,[37] erratic and hyper-inflationary pharmaceutical pricing is becoming increasingly common everywhere. In the UK, the Competition and Markets Authority recently alleged that

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[35] Goldstein et al., n 9 above, The study found that in the US the median monthly price of branded cancer drugs still protected by patents was USD 8,700 compared to USD 2,600 in the UK and USD 3,200 in China.

[36] https://accesstomedicinefoundation.org/access-to-medicine-index [Accessed September 15th 2019]

[37] 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* [Accessed September 15th 2019] Also see the Global Access Problem campaign page 'Health Gap' http://www.healthgap.org/accesstomeds [Accessed September 15th 2019]. One-third of the world still does not have access to essential medicines. See Medicins Sans Frontier Access to Medicines campaign, *https://www.msf.org.uk/issues/access-medicines* [Accessed September 15th 2019].

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.[38] A 2015 study in the US reports that the prices of anti-cancer drugs have increased 10% every year between 1995 and 2013.[39] New immunotherapies have price tags of more than £100,000 per patient per year.[40] Such pricing strategies increasingly threaten systemic affordability and the 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 control[41] over a variety of forms of the same drug, accompanied by

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[38] 'CMA Alleges Anti-Competitive Agreements for Hydrocortisone Tablets' *https://www.gov.uk/government/news/cma-alleges-anti-competitive-agreements-for-hydrocortisone-tablets* [Accessed September 15th 2019] Such collusion is coming under increased scrutiny by competition law authorities. See also European Commission 'Final Report: Pharmaceutical Sector Inquiry' (8 July 2009), *http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf* [Accessed September 15th 2019]

[39] DH Howard, PB Bach, ER Berndt and RM Conti, 'Pricing in the Market for Anti-cancer Drugs' NBER Working Paper 20867 (2015).

[40] As reported by Cancer Research UK, 'The Cancer Drugs Cost Conundrum' (2016) *http://www.cancerresearchuk.org/funding-for-researchers/research-features/2016-08-10-health-economics-the-cancer-drugs-cost-conundrum* [Accessed September 15th 2019].

[41] 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

cumulative increases in duration of monopoly pricing. Associated regulations were developed at various times to solve localised problems within the legal incentive structure. Yet, despite 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.[42]

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.[43] This claim, which lies at the heart of justifications by the pharmaceutical sector for high drug prices, is difficult to debunk because there is very little

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supplementary protection certificate for medicinal products [1992] OJL 182 1-5. 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. C Clift, 'Data Protection and Data Exclusivity in Pharmaceuticals and Agrochemicals' in A Krattiger, et al 2007 *Executive Guide to Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices*. MIHR (Oxford, UK), PIPRA (Davis: USA), Oswaldo Cruz Foundation (Fiocruz, Rio de Janeiro: Brazil) and bioDevelopments-International Institute (Ithaca, U.S.A.) 2007.

[42] WHO, 'Towards Access 2030: WHO Medicines and Health Products Program Strategic Framework 2016–2030' (2017) *http://apps.who.int/medicinedocs/fr/m/abstract/Js23222en/* [Accessed September 15th 2019]

[43] See OECD, 'New Health Technologies: Managing Access, Value and Sustainability' (2017), Report, *http://www.oecd.org/newsroom/new-approach-needed-to-tackle-rising-drug-prices.htm* [Accessed September 15th 2019] calling into question the pharmaceutical industry's pricing strategies.

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)[44] 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.[45]

Recently a study[46] 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[47]), 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. In a bid to rewrite the narrative that drug development is exorbitant, other platforms have tried to demonstrate alternative, open

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[44] 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.

[45] 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' (3 May 2017), ***http://www.iccr.org/pharma-companies-block-investor-requests-greater-transparency-drug-pricing*** [Accessed September 15th 2019]

[46] 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.

[47] JA DiMasi, HG Grabowski and RW Hansen, 'Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs' (2016) *Journal of Health Economics* (2016) 47 20-33.

innovation models[48] 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.[49] 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'.[50] Recently the United Nations Secretary General's High Level Panel (UNSGHLP) on Access to Drugs has sought to push 'delinkage'[51] between incentives to invest in research and prices of drugs globally as the single most important effort that can help narrow the access gap to medicines. There appears to be some international support for cautious measures aimed at progressive delinkage to transition away from the current system of monopoly linked

[48] 'New Research Aims to Unlock Power of Big Data and Open Innovation for Medicine' (February 2017) *http://www.oxfordmartin.ox.ac.uk/news/201702_New_research* [Accessed September 15th 2019].

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

[50] See J Love, 'Perspectives on Cancer Drug Development Costs in JAMA' ibid.

[51] UNSG, 'United Nations Secretary-General High Level Panel on Access to Medicines Report' (2016), *http://www.unsgaccessmeds.org/final-report/* [Accessed September 15th 2019].

high prices [52] but there is also considerable resistance to overcome, with US government initiatives suggesting that delinkage is dangerous to economic growth.[53]

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 internationally harmonised patent rights are not an unmitigated good but one that must be tied to levels of socio-economic development.[54] This thinking had difficult beginnings during the height of the AIDS controversy that led directly to the Declaration on the TRIPS Agreement and Public Health (Doha Declaration).[55]

Since then there have been calls for a mechanism over and above the so-called flexibilities associated with the Agreement on Trade Related Intellectual Property Rights (TRIPS) that would subject international trade agreements to review standards to protect and advance human rights. [56] Interventions such as over compulsory

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[52] 'Development of Medicines: Better, Faster, Cheaper' Netherlands Council for Public Health and Society (The Hague, Nov 2017),, *https://www.raadrvs.nl/uploads/docs/Recommendation_Development_of_New_Medicines.pdf* [Accessed September 15th 2019]. Also see in general Delinkage.org.

[53] W New, n 34 above.

[54] 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.

[55] Declaration on the TRIPS Agreement and Public Health, n 4 above.

[56] Ellen 't Hoen, 'Translating Principles into Action: Access to Medicines, Diagnosis, Vaccines and Treatment in the Context of the Right to Health', speech at the UN Social Forum convened

licensing standards in Canada and Thailand,[57] or the Indian Supreme Court's observation on prices in *Novartis v Union of India,*[58] remain sporadic and anecdotal – partial wins that are not seen as easily replicable or enforceable in the law minus scarce political will.[59] These are inadequate to counter scepticism around global patent rules' ability to make progress towards just outcomes. Indeed scholars like Ruth Okediji have warned that a lack of consensus on how global intellectual property rules can effectively serve both developed and developing countries would cause disproportionate harm to the Global South, calling instead for a moratorium on further harmonisation of laws at the regional and multilateral levels.

Human rights law and human rights morality

The problem of trying to use human rights to remedy monopoly pricing is handicapped by a lack of clarity around terminology. The term 'moral human rights'

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by the Human Rights Council, 4 Oct 2017, *https://www.ip-watch.org/2017/10/10/mechanism-access-trade-agreements-needed-un-forum-access-medicines-hears/* [Accessed September 15th 2019].

[57] KM Lybecker and E Fowler, 'Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules' (2009) 37 *The Journal of Law, Medicine and Ethics* 222.

[58] 2013 AIR SC 1311. Also see S Thambisetty, '*Novartis v Union of India* and the Person Skilled in the Art: A Missed Opportunity' (2014)4 Queen Mary J of IP 79.

[59] For instance, see the widely reported US response to India's decision in *Novartis* discussed in S Thambisetty, 'Novartis v UOI' ibid; LS Esmail and JC Kohler, 'The Politics behind the Implementation of the WTO Paragraph 6 Decision in Canada to Increase Global Drug Access' (2012) 8 *Global Health* 7.

is used by Alan Buchanan[60] to emphasise the strong moral justification for a legal human rights regime, and as capturing the prevailing thinking in the human rights movement at large. Yet it also intimates deep unease and confusion about the basis of human rights in general and of the human right to health in particular.[61] As Conor Gearty says, the ideal of human rights is an ethical aspiration, while human rights law is a producer of outcomes in real world situations.[62] A good place to start, then, is to unpick the different implications when we talk about human rights morality and human rights law.[63]

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'.[64] This can be seen, for instance, in the discussion of the role of modernity in the orthodox view, which tempers the notion of universal and timeless human rights; or in the

[60] A Buchanan, *The Heart of Human Rights* (Oxford, UK: OUP, 2013).

[61] See J Meyerfield, 'Human Rights' in *The Promise of Human Rights: Constitutional Government, Democratic Legitimacy and International Law* (Philadelphia, USA: University of Pennsylvania Press, 2016), p. 235.

[62] Ibid. p. 396.

[63] As J Tasioulas says, 'imagine how much confusion would be avoided if people distinguished clearly between human rights and human rights law', Tweet, 27 Feb 2017.

[64] J Tasioulas, 'Exiting the Hall of Mirrors: Morality and Law in Human Rights', Kings College London Law School Research Papers no 2017-19, p. 4.

recognition that even within philosophical discussions the political uses of human rights are an important subject of investigation.[65]

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.[66] 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'.[67] While human rights underpin commitment to the value of human life, in reality, this commitment leads to a visceral disconnect. As Susan Marks questions, 'how can we take the presumption of the universality of human rights as a given when the most conspicuous fact about

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[65] See J Tasioulas, 'On the Nature of Human Rights' in S Besson and J Tasioulas (eds), *The Philosophy of International Law* (Oxford, UK: OUP, 2010).

[66] J Raz, 'Human Rights in the Emerging World Order' (2010) 1 *Transnational Legal Theory* 31, 43.

[67] S Marks, 'Four Human Rights Myths' (2012) LSE Law, Society and Economy Working Papers 10, p. 5.

the current world order is that there exists no such commitment – some lives are endowed with very much more value than others'.[68]

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'.[69] However, when human rights have to contend with capitalism[70] or neoliberalism[71] – they enter an arena where 'political visions clash, hard choices are made and tainted compromises struck'[72] with profound implications for the universality of these rights.

The curious case of Article 27(2) of the Universal Declaration of Human Rights (UDHR),[73] which casts the material and moral rights of authors and inventors as a

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[68] Ibid. p. 6.

[69] S Moyn, *The Last Utopia* (Cambridge, Massachusetts: HUP, 2010), p. 5. Also see S Mark's discussion of Naomi Klein in S Marks, 'Human, Rights and Root Causes', (2011) 74 *Modern Law Review* 57.

[70] See discussion of N Klein, *The Shock Doctrine* (New York: Penguin, 2007), p. 118 in S Marks, 'Four Myths', n 67 above, p. 8.

[71] I prefer Will Davies' definition of neoliberalism as 'the state-led remaking of society around the model of the market'. W Davies, 'Moral Economies of the Future: The Utopian Impulse of Sustainable Prosperity' (2017), CUSP Working paper series no 5, *http://www.cusp.ac.uk/pub/wp5/* [Accessed September 15th 2019].

[72] S Moyn, *The Last Utopia* (Cambridge, Massachusetts: HUP, 2010), p. 217.

[73] J Tasioulas, 'Exiting the Hall of Mirrors', n 64 above, p. 13.

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.[74] Both Wendy Gordon[75] and Rochelle Dreyfuss[76] 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.[77] 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'.[78]

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[74] Ibid.

[75] W Gordon, 'Current Patent Laws Cannot Claim the Backing of Human Rights' in W Grosheide (ed.), *Intellectual Property and Human Rights: A Paradox* (Cheltenham, UK and Northampton, MA, USA: Edward Elgar Ltd, 2010).

[76] R 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 (2006).

[77] LR Helfer, 'Toward a Human Rights Framework for Intellectual Property' (2007) 40 *UC Davis Law Review* 971.

[78] F Shaheed, Special Rapporteur in the Field of Cultural Rights, 'Address to the UN Human Rights Council' (4 Aug 2015), *http://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=16788&LangID=E* [Accessed September 15th 2019]. 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 have human right dimensions. In that

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.[79] 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.[80]

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

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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 (2015).

[79] A Sen, 'Human Rights and the Limits of Law' (2006) 27 *Cardozo Law Review* 2913 and discussion of Sen in J Tasioulas, 'Exiting the Hall of Mirrors', n 64 above.

[80] See J Griffin, 'Human Rights and the Autonomy of International Law', in S Besson and J Tasioulas (eds), *The Philosophy of International Law* (Oxford, UK: Oxford University Press, 2010), pp. 354–355.

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'.[81]

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.[82] 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. 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 standards of physical and mental health'). Article 2 also sets out the general obligations of states in relation to

[81] This, in Tasioulas's words, is Griffin's main beef with the autonomous view. J Tasioulas, 'Exiting the Hall of Mirrors', n 64 above, p. 10.

[82] Principally as seen in the UNDHR and the International Covenant on Economic, Social and Cultural Rights (ICESCR).

the Covenant rights and includes elliptical phrases such as 'progressive realization', 'maximum available resources' and 'all appropriate means'.[83]

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 Rights.[84] It speaks of three principles – protect, respect and remedy, themselves an evolution from the deeply divisive debate on the Norms on Transnational Corporations [85] which sought to impose directly on companies under international law the same range of human rights duties that states have accepted for themselves under treaties they 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,[86] including access to medicines.

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[83] Art 2(1) ICESCR.

[84] UN, 'Guiding Principles on Business and Human Rights' (2011), *http://www.ohchr.org/Documents/Publications/GuidingPrinciplesBusinessHR_EN.pdf* [Accessed September 15th 2019].

[85] 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), *http://hrlibrary.umn.edu/links/norms-Aug2003.html* [Accessed September 15th 2019]

[86] See, for instance, K Bluestone, A Heaton, C Lewis 'Beyond Philanthropy: The Pharmaceutical Industry, Corporate Social Responsibility and the Developing World' Oxfam International, Save the Children and VSO Joint Research Report (2002); and A Kapczynski, 'Addressing Global

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' – where 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'.[87]

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.[88] 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, that obligate states to set up a territorial property right that can be owned by politically endowed international corporations often based in nation states

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Health Inequalities: An Open Licensing Approach for University Innovations' (2005) 20 *Berkeley Technology Law Journal* 1032.

[87] J Tasioulas, 'Exiting the Hall of Mirrors', n 64 above, p. 11.

[88] C Gearty, 'The State of Human Rights' (2014) 5 *Global Policy* 391, 393.

outside of the state that administers the patent right, is therefore one of the weakest links in this version of human rights. It exposes the collision of the ideal of human rights with human rights law.

In this view, recasting a moral 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.[89]

The Formative Aim Thesis has several implications for the effectiveness of intervention and advocacy of the international human right to health.[90] It explains how the right becomes a placeholder orchestrating political space, even monopolising it.[91] It only condemns particular manifestations of injustice or injury rather than providing analytically precise accounts of the structural forces of injury.[92] It is inclined to relieve

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[89] 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, J Tasioulas, 'Hall of Mirrors', n 64 above, p. 11.

[90] For a discussion on human rights myths that fuel advocacy, see Susan Marks, 'Four Myths', n 67 above.

[91] W Brown, '"The Most We Can Hope For ...": Human Rights and the Politics of Fatalism' (2004) 103 *South Atlantic Quarterly* 451, 453.

[92] W Brown, *Politics out of History* (Princeton: New Jersey: Princeton University Press, 2001), p. 37.

suffering, but not to develop insight into why it occurs.[93] As a result, instances of the purported abuse of human rights – for instance, the price tag of USD 89,000 a year for Emflaza,[94] 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 grant and impact of patents.[95] For instance, the Declaration on Regulatory Sovereignty[96] argues that

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[93] S Marks, 'Four Myths', n 67 above, p. 11.

[94] Currently set at USD 35,000 after a backlash. 'PTC Therapeutics' DMD drug Emflaza to cost USD 35,000 a year and Launch Within Coming Weeks' *https://www.marketwatch.com/story/ptc-therapeutics-dmd-drug-emflaza-to-cost-35000-a-year-and-launch-within-the-coming-week-2017-05-08* May 8 2017 [Accessed September 15th 2019].

[95] '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'. 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* (Oxford, UK: OUP, 2014) 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) 91 *Bulletin of the World Health Organization* 533. doi: http://dx.doi.org/10.2471/BLT.12.115865.

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 licences[97] to produce patented medical products forces a response to 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.[98]

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. Reading human rights imperatives into TRIPS flexibilities becomes a distraction from the 'serious and unrelenting attention by States' that is required to seek effective solutions for the aspirations embedded in the UDHR and ICESCR.[99]

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[96] Declaration on Patent Protection: Regulatory Sovereignty under TRIPS (2014), *https://www.mpg.de/8132986/Patent-Declaration.pdf* [Accessed September 15th 2019]

[97] JH Reichman, 'Comment: Compulsory Licensing of Patented Pharmaceutical Inventions – Evaluating the Options' (2009) 37 J Law Med Ethics 247. http://dx.doi.org/10.1111/j.1748-720X.2009.00369.x pmid: 19493070.

[98] KM Lybecker and E Fowler, 'Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules' (2009) 37 *The Journal of Law, Medicine and Ethics* 222. http://dx.doi.org/10.1111/j.1748-720X.2009.00367.x pmid: 19493068.

[99] R Okediji, n 23 above.

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.[100] 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 '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 pressures these rights face from global capital. It also severely underestimates the technocratic disposition of patent law and it is to this I now turn.

The technocratic patent system and the difficulty in accommodating human rights thinking

The 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,

[100] F Shaheed, n 22 above.

inventive and industrially applicable invention.[101] Patentability criteria are predicated on the legal tests being able to fathom adequacy of social utility and technical advance. In reality it is impossible to measure or be certain about the social bargain struck for individual patent applications during the examination process.[102]

Patentability criteria, such as inventive step or industrial application, are simply not designed to include complex analysis of the commercial or social impact of grants of individual patents, as these are likely to unfold further down the line, influenced by unpredictable and non-linear technical and commercial realities.[103] At the time of the grant of a patent, usually early on in the development phase, very little is known about the technical or commercial consequences of the grant. As such, the discovery of an invention and its transformation into innovation are economically and sociologically 'entirely different things'.[104] Yet, patentability criteria, once met, are deemed to ensure that the quid pro quo was met.

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

[101] BN Roin 'The Disclosure Function of the Patent System (Or Lack Thereof)' (2005) 118 *Harvard Law Review* 2007.

[102] JA Schumpeter and FM Scherer, *Innovation and Growth: Schumpeterian Perspectives* (Cambridge, Massachusetts: MIT Press, 1984).

[103] S Thambisetty, 'Patents as Credence Goods' (2007) 4 OJLS 707.

[104] JA Schumpeter, *Business Cycles: A Theoretical, Historical and Statistical Analysis of the Capitalist Process* (New York: McGraw-Hill Book Company, 1939) p. 85.

based on faith in the overall incentive structure[105] 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.

Additionally, the framework of most patent legislation, whether national or international, allows for interpretative ambiguity and even higher appellate court decisions carry an unusual level of incomplete theorising. Reacting to the recent US Supreme Court ('SC') decision of *Alice. Corporation vs CLS Bank International*,[106] 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 to the Galaxy*.[107] 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'. The decision

[105] 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. KG Huang and F Murray, 'Does Patent Strategy Shape the Long-run Supply of Public Knowledge? Evidence from Human Genetics' (2009) 52 *Academy of Management Journal* 1193.

[106] *Alice Corporation v CLS Bank International* 573 US 208 (2014)

[107] R 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-cls-bank/* [Accessed September 15th 2019]. Also see discussion in S Thambisetty, 'Alice and Something More: The Drift Towards European Patent Jurisprudence' (2016) 3 J of Law and Biosciences 691.

did not give further content to this idea of 'something more' – a task that is left to the US Patent and Trademark Office (USPTO).

While deliberating *Human Genome Sciences v Eli Lilly and Co*,[108] it was suggested to the UK Supreme Court (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'.[109] The court then went on to confirm multiple terms that echo the utility standard in the US by adopting 15 principles from the European Patent Office (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

[108] [2011] UKSC 51.

[109] Ibid. [40].

limited information within the framework of the specialist legislation being administered. This decision-making rationality does not lend itself easily, if at all, to intervention on grounds of public utility, ethics or human rights.

One of the greatest challenges 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.[110] Since those who discuss the norms for grant or denial of patents do not and cannot directly analyse the outcomes of such grants;[111] because there is very little appetite or ability amongst such bodies to take account of projected impacts sometime in the future;[112] and because the faith in the incentive effect of patents is so strong[113] (demonstrated in part by the fact that there is little or no

[110] The EPO 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. See discussion in S Thambisetty, 'Patent Litigation in the United Kingdom: Solutions in Search of a Problem?' (2010) 32 EIPR 238.

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

[112] 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 undergrid IP, see S Sell, *Private Power, Public Law: The Globalization of Intellectual Property Rights* (Cambridge, UK: CUP, 2003).

[113] See EE Johnson, 'Intellectual Property and the Incentive Fallacy' (2012) 39 *Florida State University Law Review* 623.

leverage on patent holders post grant), there is very little reflexive space for consideration of human rights in the patent system.

At least theoretically, 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 interstate treaties (such as the European Patent Convention). Many legislative provisions in patent law are ambiguous and open to industry- or technology-specific contexts.[114] Second, during the creation of norms, a substantive process that happens rarely and requires some form of international agreement.

1. Application of norms

The disposition of the agencies tasked with application and enforcement of patent norms are often determinative of balance in the regulatory regime.[115] For developing countries with relatively recently established patent systems, there is a more conventional movement of rules percolating down to local bodies involved in implementation and application. Within and without entities like the EPO or the

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[114] D Burk and MA Lemley, 'Is Patent Law Technology-Specific?' (2002) 17 *Berkeley Technology Law Journal* 1155.

[115] See discussion in RC Dreyfuss and C Rodriguez-Garavito, 'Conclusion: Balancing Wealth and Health in a Transnational Regulatory Framework' in R Dreyfuss and C Rodriguez-Garavito (eds), *Balancing Wealth and Health* n 95 above.

USPTO, however, we also see an upward mobility of norms in processes that are not subject to conventional policy oversight but carry agenda-setting power to international fora.[116] The technical cooperation between networked patent offices (such as the Trilateral Office – a grouping of (Japan Patent Office, USPTO and EPO),[117] for instance, gradually builds support for coordinated positions, which are not checked for the impact they would have on poorer economies where inaccess is rife.

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 and the appearance of knowledge, even though this knowledge may not be particularly well balanced.[118] The expertise of the patent office is captured best in patent examination guidelines, often in peculiar ways. At the EPO, for instance, such guidelines 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 expertise[119] and administrative attributes of the patent office give these legal positions particular form – they are 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

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

[117] Ibid.

[118] S Thambisetty, 'Construction of Legitimacy in European Patent Law' (2017) 3 IPQ 221.

[119] L Davies, n 116 above.

expertise barrier, and resources that are not often available to developing countries.[120] The guidelines are presented as ahistoric, 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 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'[121] 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.[122] 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 phases – all of these phases have to be present in the claim, with each being 'practised in or on the human

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[120] S Parthasarathy, 'Breaking the Expertise Barrier: Understanding Activist Strategies in Science and Technology Policy Domains' (2010) 37 *Science and Policy* 355.

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

[122] 'Patents and the Fourth Industrial Revolution' EPO Study Report December 2017 http://documents.epo.org/projects/babylon/eponet.nsf/0/17FDB5538E87B4B9C12581EF0045762F/$File/fourth_industrial_revolution_2017__en.pdf [Accessed September 15th 2019]

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.[123]

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 monopoly pricing.[124] The 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. 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 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

[123] S Thambisetty, 'Construction of Legitimacy' n 26 above 231–33.

[124] Ibid. 236–237; and could also become a problem in the case of personalised medicine.

specifically written as a manufacturing claim to escape the exclusionary effect of another provision.[125]

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 groups, new dosages 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 critical pain medication brings to the 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.[126]

To bring a human right perspective to bear in the application of patent norms requires a willingness to assess outcomes of the application of particular standards. Generally patent offices are the only supplier of norms in a complex system of rules and regulations.[127] This dominant position, shored up by an expertise barrier[128] and

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[125] Ibid.

[126] *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' in Z Babbar (ed.), *Pharmaceutical Policy in Countries with Developing Healthcare Systems* (New York: Springer International, 2017), pp. 394–395.

[127] C Long, 'PTO and the Market for Influence in Patent Law' (2009) 157 *University of Pennsylvania Law Review* 1965.

[128] S Parthasarathy, 'Breaking the Expertise Barrier: Understanding Activist Challenges to Science and Technology Policy Domains' (2010) 37 *Science & Public Policy* 355. Also see Arthur

technocratic reasoning,[129] militates against consequential 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 undergrid information law can easily be lost in the analysis.[130]

The UN has called for action in multilateral organisations like the WHO, World Intellectual Property Organization (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'[131] taking into account public health needs. This particular recommendation has received very little reinforcement. It is translated, for instance, in an EU parliamentary resolution as 'strict application of patentability

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Daemmrich, 'Epistemic Contests and Legitimacy of the World Trade Organization: The Brazil–USA Cotton Dispute and Incremental Balancing of Global Interests' (2012) 4 *Trade Law & Development* 200, discussing questions of expertise, and methods for bounding disputes over scientific facts at the World Trade Organization (WTO).

[129] See M Shapiro, '"Deliberative, Independent" Technocracy v Democratic Politics: Will the Globe Echo the EU?' (2004) 68 *Law and Contemporary Problems* 341.

[130] 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* n 95 above p. 13.

[131] United Nations Secretary General High Level Panel on Access to Medicines Report (2016).

criteria'.[132] Without spelling out what the strict application of criteria would look like, or how it differs from lax application of the criteria – this is a toothless missive. It presupposes that patentability criteria functionalise 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 S 3(d) of India's Patent Act has been presented as an opportunity to 'sharp[ly] reduce exclusivity in the domain of medicines', based on 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.[133] It seeks to do so by denying patents to new forms of known pharmaceuticals, which prevents an extended monopoly on an already patented pharmaceutical. Rather surprisingly, however, Sampat and Shadlen,[134] 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

[132] Options for Improving Access to Medicines (European Parliament) 2 March 2017 2016/2057 (INI)

[133] Amy Kapczynski 'Harmonisation and it's Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector' (2009) 97 California Law Rev 1571, Also see S Thambisetty, 'Novartis v UOI' n 58 above.

[134] BN Sampat and KC Shadlen, 'Secondary Pharmaceutical Patenting: A Global Perspective', NBER Working Paper 23114 (2017).

their learning needs,[135] as well as the presence of technical or legitimacy networks that may be working to undermine the real effect of the provisions.

As anthropologist Alexei Yurchak argues[136] 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.[137] Human rights thinking in the interstices 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

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[135] S Thambisetty, 'The Learning Needs of the Patent System and Emerging Technologies' (2014) 1 IPQ 13.

[136] A Yurchak, *Everything Was Forever until it Was No More: The Last Soviet Generation* (Princeton, New Jersey: Princeton University Press, 2005).

[137] TC Scottek, 'Judge Richard Posner Says there Are Serious Problems with the US Patent System' (2012), *https://www.theverge.com/2012/7/12/3155296/judge-richard-posner-patent* [Accessed September 15th 2019]. Also see K Maskus, n 33 above.

Cornish, as quoted by Rochelle Dreyfuss,[138] 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.[139] 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 WIPO'[140] is the Declaration on the TRIPS Agreement and Public Health, which affirms the principle of balanced intellectual property protection[141] 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 as the WTO has little appetite to overextend its own legitimacy in this way.[142] The swell 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

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[138] R Dreyfuss and C Rodriguez-Garavito, in R Dreyfuss and C Rodriguez-Garavito *Balancing Wealth and Health*, n 95 above, p. 40.

[139] Ibid.

[140] Ibid.

[141] LR Helfer, 'Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking' (2004) 29 *Yale Journal of International Law* 5.

[142] See A Lang, *World Trade Law after Neoliberalism: Reimagining the Global Economic Order* (Oxford, UK: OUP, 2011). Also see M Fakhri, 'Reconstruing WTO Legitimacy Debates' (2011) 2 *Notre Dame Journal of International & Comparative Law* 64.

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.

The WIPO norm-setting is often long, drawn-out and 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.[143] In the case of traditional knowledge[144] the issue has languished[145] at the WIPO since the first fact-finding effort carried out in 1998–1999.[146] 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

[143] See WIPO, 'Traditional Knowledge and Intellectual Property' (2015), Background Brief, *http://www.wipo.int/edocs/pubdocs/en/wipo_pub_tk_1.pdf* [Accessed September 15th 2019].

[144] 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), p. 25, *http://www.wipo.int/globalissues/tk/report/final/pdf/partl. Pdf* [Accessed September 15th 2019]. Also see Daniel Gervais, 'Spiritual but not Intellectual? The Protection of Sacred Intangible Traditional Knowledge' (2003–2004) 11 *Cardozo Journal of International & Comparative Law* 467.

[145] There is some support for the view that WIPO negotiations are a 'safety valve to shunt issues away from the WTO'. LR Helfer, 'Regime Shifting' n 141 above.

[146] For an initial consideration of traditional knowledge in the WTO see Graham Dutfield, 'TRIPS-related Aspects of Traditional Knowledge' (2001) 33 *Case Western Reserve Journal of International Law* 233, 250.

also discussed for several years at the WIPO before being rejected.[147] While the 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.[148] Yet until recently the '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'.[149]

The WIPO is prone to a maximalist rights culture[150] – an approach that sees promotion of intellectual property rights as an end in itself.[151] While the WIPO is the

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[147] 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, *http://www.wipo.int/export/sites/www/meetings/en/2009/wipo_ls_biot_ge_09/pdf/2_pic-workshop_report_12_07.pdf* [Accessed September 15th 2019].

[148] See RL Okediji, 'The Role of WIPO in Access to Medicines' in Dreyfuss and Rodrigues-Garavito (eds) pp. 307–22.[Please check the cross-reference]

[149] Ibid. p. 311

[150] Goals include "'promot[e] creative intellectual activity" and facilitat[e] the transfer of technology . . . to developing countries in order to accelerate economic, social and cultural development'; 'promote the protection of intellectual property throughout the world'. See discussion in J Boyle, 'A Manifesto on WIPO and the Future of Intellectual Property' (2004) 3 *Duke Law & Technology Review* 1

[151] While such rights can further creativity and innovation they are by no means the only way to do so, or even the best way to do so. Different sectors or technologies can require different approaches at different points in time. The WIPO due to its intergovernmental processes is

most successful self-funded UN agency (due to intellectual property registration services) there is a widely acknowledged tension between member state driven character and 'special relationship with private clients' and by extension to the subset of member states that are home to these clients.[152]

Perhaps as a consequence the WIPO failed to act on a WHO 2012 expert recommendation for a legally binding instrument on neglected diseases innovation, and access to medicines. Additionally the WIPO's role in the realisation of United Nations Sustainable Development Goals (UNSDGs) is fairly narrow and extends to 'provide factual, technical assistance upon invitation or request' to states.[153] A noteworthy development in a global context is the Marrakesh Treaty, which behoves

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generally not nimble enough to be flexible in this way. For instance, in copyright rule-making, it has been said to engage in a 'pathological norm-setting process'; and failed to take note of the open source movement as part of its digital agenda, focusing instead on intellectual property rights. This was done at the behest of countries like the US that insisted that to do otherwise would be anathema to the WIPO's mission to 'promote intellectual property'. R Okediji, 'Creative Markets and Copyright in the Fourth Industrial Era' (2018) ICSTD Issue paper 43, *https://www.ictsd.org/sites/default/files/research/creative_markets_and_copyright_in_the_fourth_industrial_era-okediji-ictsd_final.pdf* [Accessed September 15th 2019].

[152] C Chiarolla, 'The Work of the World Intellectual Property Organisation and its Possible Relevance for Global Ocean Governance' in DJ Attard and M Fitzmaurice (eds), *Comprehensive Study on Effective and Sustainable Global Ocean Governance: UN Specialized Agencies and Global Ocean Governance*, IMO (International Maritime Organization)/IMLI (International Maritime Law Institute) research report to the Nippon Foundation, 2016, *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3002489* [Accessed September 15th 2019].

[153] Ibid.

parties to address the rights of those who are visually impaired through the instrument of copyright law.[154] Although the preamble refers to human rights instruments,[155] the negotiations were framed by tightly interpreted copyright exceptions – a normative architecture that is inherently limiting.[156] The WIPO's perspective that it is national intellectual property offices that must implement the Treaty, and not human rights

[154] 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.

[155] To the Universal Declaration of Human Rights and the United Nations Convention on the Rights of Persons with Disabilities.[2006]

[156] 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.

authorities,[157] suggests that the Treaty dons the mantle of being at the intersection of intellectual property and human rights in a rather post-hoc way.[158]

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

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[157] 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 JH Reichmann and LR Helfer, *The World Blind Union Guide to the Marrakesh Treaty* (Oxford, UK: 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* (Oxford, UK: OUP, 2018) (outlining four periods within which the intersection between IP and human rights gradually evolved and became more entrenched), *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2832417* [Accessed September 15th 2019].

[158] See C Sez, 'Between Human Rights and IP: An Interview with Laurence Helfer, Co-author of Guide to Marrakesh Treaty Implementation' *IP Watch* (31 August 17) https://www.ip-watch.org/2017/08/31/human-rights-ip-interview-laurence-helfer-co-author-guide-marrakesh-treaty-implementation/ [Accessed September 15th 2019] Dr C J Ramirez-Montes, 'The Marrakesh Treaty: Study for the PETI Committee' 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* [Accessed September 15th 2019].

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. [159]

However, the strategic fortunes of this sort of regime shifting are uncertain and amorphous. One set of rules to do with patent rights related to international trade are 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. Much of the work done in a human rights context, for instance, remains soft law that cannot excuse non-compliance with the TRIPS Agreement. 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.[160]

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 United Nations Secretary General's High Level Panel on Access to Medicines report recommending 'delinkage' as a way of dissociating investment in

[159] '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.' LR Helfer, 'Pharmaceutical Patents and the Human Right to Health: The Contested Evolution of the Transnational Legal Order on Access to Medicines' in TC Halliday and G Shaffer (eds), *Transnational Legal Orders* (Cambridge, UK: CUP, 2015) p. 311.

[160] See L Helfer, 'Human Rights and Intellectual Property', n 157 above, pp. 79–81.

R&D from drug prices.[161] 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.[162]

The European Parliament adopted the text of a resolution on Access to Medicines,[163] 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.

The application of norms can also include technical workarounds that cater to human rights without breaking the law. For instance, reverse engineering is an 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.[164] Attempts to thwart reverse

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[161] See Delinkage.org. Also see @James_Love #SDG2030_India tweets 21 Nov [2017], 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 2017.

[162] See James Love, 'Perspectives on Cancer Drug Development Costs in JAMA' in *Bill of Health* (2017) n 49 above

[163] Options for Improving Access to Medicines (European Parliament) 2 March 2017 2016/2057 (INI).

[164] P Samuelson and S Scotchmer, 'The Law and Economics of Reverse Engineering' 2002 *Yale Law Journal* 1575.

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 applications where public health is a concern. This is a tool to prevent the grant of problematic patents anticipating aggressive exploitation, but it too has its detractors.[165]

The use of compulsory licences in Thailand as a strategy to close the access gap has also been widely reported on.[166] 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

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[165] It has contributed to a severe backlog problem in Brazil. See K Shadlen, 'The Politics of Pharmaceutical Patent Examination in Brazil' (2011), *http://personal.lse.ac.uk/shadlen/Pol%20of%20Pharma%20Patent%20Exam%20in%20Brazil%20_forthcoming_.pdf* [Accessed 'NHRC Asks GOI for Clarification on (Anti) CL Stance' [Accessed September 15th 2019].

[166] KM Lybecker and E Fowler, 'Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules' (2009) 37 *Journal of Law, Medicine and Ethics* 222. http://dx.doi.org/10.1111/j.1748-720X.2009.00367.x pmid: 19493068.

reassurances' to the India–US Business Council.[167] There are other interesting cases in domestic law such as the celebrated South African constitutional case of *Minister of Health v Treatment Action Campaign*[168] 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.

The anecdotal nature of these successes, however, is out of kilter with the acuity of the problem and the resources that have been put into the progressive project of trying to link human rights to patent law and intellectual property. Intellectual property norm-setting, is blighted by asymmetric power and inequality amongst nation states even as health has become a legitimate foreign policy concern.[169] It is also, as Lang establishes,[170] subject to a great deal of ambiguity because the content and aim of

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[167] National Human Rights Council, Press Release (1 April 2016), *http://nhrc.nic.in/dispArchive.asp?fno=23893* [Accessed September 15th 2019] and 'NHRC Asks GOI for Clarification on (Anti) CL Stance' (2016), *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* [Accessed September 15th 2019].

[168] (TAC) (2002) 5 SA 721 (CC). See JM Berger and A Kapczynski, 'The Story of the TAC Case: The Potential and Limits of Socio-economic Rights Litigation in South Africa' in Deena R. Hurwitz and Margaret L. Satterthwaite (eds), *Human Rights Advocacy Stories* (New York: Foundation Press, 2009).

[169] M Chon, 'Intellectual Property and the Development Divide' in Margaret Chon, 'Intellectual Property and the Development Divide' (2006) 27 *Cardozo Law Review* 2821, 2828. H Feldbaum, K Lee and J Michaud, 'Global Health and Foreign Policy' (2010) 32 *Epidemol Review* 82

[170] A Lang *World Trade Law After Neoliberalism* n 142 above

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 satisficing placeholder in its interactions with patent law.

Equipping patent law to deal with consequences

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 a century of incremental, sector-specific changes cobbled together to deal with emerging problems. As it stands the system is in dire need of a root and branch appraisal.

Many academic and activist commentators reach 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. Excessive pricing is embedded in the dominant property-based justifications for patents[171] that see no reason to exert control over how a patent is

[171] Hovenkamp suggests that historically 'property' itself was rhetorically less threatening than 'monopoly' because property comes with built in limitations on the power to exclude. Patent rights, however, have become property without such built in limitations that flow from explicit and clear boundaries. HJ Hovenkamp, 'Patents, Property and Competition Policy' (2008–2009) 34 J Corp L 1243. It is in this context that many have suggested post-hoc moderation of patent

used or exploited even in the case of life-saving medications. The change we really need, then, is not to tinker with patent statutes, but a systemic retooling of patent law. A retooling to make the patent system reflexive and competent to participate in its own consequences by regulating how patents are granted and how, once granted, they are used and moderated.

One promising avenue is provided by those who advocate moving away from the property right prism[172] that is not receptive to limitations on the use of patents towards a regulatory and instrumental view of patent rights.[173] Patent rights granted

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rights using competition policy or regulation. HJ Hovenkamp, 'Competition for Innovation' (2012) *Columbia Business Law Review* 799, and M Lemley, 'Taking the Regulatory Nature of IP Law Seriously', Stanford Law and Economics Olin Working Paper No. 455 (2014). However, also see R Merges, 'What Kinds of Rights are Intellectual Property Rights?' in RC Dreyfuss and J Pila (eds), *The Oxford Handbook of Intellectual Property Law* (Oxford, UK: OUP 2017).

[172] There are many who have tried to unpack whether the 'property' connotation is more than just an analogy that has been taken too far. MA Carrier, 'Cabining Intellectual Property through a Property Paradigm' (2004) 54 Duke LJ 1, 6–7; SL Carter, 'Does it Matter whether Intellectual Property is Property?' (1993) 68 Chi-Kent L Rev 715. Others like Lemley and Menell have argued the inaptness of the analogy and its consequences. MA Lemley, 'What's Different about Intellectual Property?' (2005) 83 Texas L Rev 1097 and PS Menell, 'The Property Rights Movement's Embrace of Intellectual Property: True Love or Doomed Relationship?' (2007) 34 Ecology LQ 713.

[173] Sichelman argues that the private property element should not feature in patent remedies which should be designed with public interest in mind. T Sichelman, 'Purging Patent Law of "Private Law" Remedies' (2014) 92 Texas L Rev 528, MA Lemley in 'Taking the Regulatory Nature of IP Rights Seriously' (2014) 92 Tex L Rev 68. MA Lemley, 'What's Different About

should be subject to exploitation in the pursuit of innovation and well-being informed by the reformative moralism of human rights. Patent examiners would be discouraged from granting broad, or cumulative, rights over the same subject matter and patent applicants will learn that profit maximisation has to situate itself in moralism that is dissociated from current neoliberal conception and implementation of patent law.

One way to do both of these would be to develop a notion analogous to 'environmental impact assessment' before and after patents are granted. Patent applicants would have to survey the commercial context including divulging their own or other existing patent rights characterised by proximity to the technology they seek to protect, assess the impact of the patent right once granted and provide a potential exploitation plan that sits within any regulatory priorities set. There would have to be a way of distinguishing those inventions that needed such 'patent impact assessments' (PIAs) from those that do not, because patent examiners are severely constricted in the information they have access to and are presented with, when examining and granting patents.[174] A delay between grant and PIA may be needed to distinguish significant patents from the vast majority that may not require such assessments. PIAs would initially selectively augment this process in particular technology sectors.

Intellectual Property?', n 172 above, argues that the public interest element can continue to find a place even in the private right nature of patents.

[174] MA Lemley, 'Rational Ignorance at the Patent Office' (2001) 95 NWU L Rev 1495, 1495, and S Thambisetty, 'Patents as Credence Goods', n 103 above.

We currently have an international patent classificatory system (IPC) that has eight sections and as many as 70,000 subdivisions, established by the Strasbourg Agreement, 1971.[175] This sophisticated, language-independent retrieval system is used by inventors, and others concerned with research and development and the application of technology. Document retrieval does not fully represent the rationality of the IPC, because it is in essence a classificatory system for any and every technology developed and patented. It is therefore a significant source of information that lends itself well to being used for regulatory purposes.[176] The IPC specifies in a hierarchical way the relevant sectors in which technologies fall. Identifying sectors that require PIAs, would be a first step. This would not be dissimilar to the kinds of assessments research councils make when deeming it necessary to grant more funds to a particular sector, or when governments decide that units that manufacture particular products, for instance, prosthetic limbs, deserve a tax break.

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[175] A guide to the IPC (2018) is available here *https://www.wipo.int/classifications/ipc/ipcpub/?notion=guide&version=20190101&symbol=C12N00012 10000&menulang=en&lang=en&viewmode=p&fipcpc=no&showdeleted=yes&indexes=no&headings=yes &notes=yes&direction=o2n&initial=A&cwid=none&tree=no&searchmode=smart* [Accessed September 15th 2019].

[176] For instance, see N Goldschlag, TJ Lybbert and NJ Zolas, 'An 'Algorithmic Links with Probabilities' Crosswalk for USPC and CPC Patent Classifications with an Application towards Industrial Technology Composition' (1 March 2016), US Census Bureau Center for Economic Studies Paper No. CES-WP- 16-15, *https://ssrn.com/abstract=2749287* [Accessed September 15th 2019], which uses the classification system to highlight changes to the composition of industrial technologies in different sectors.

It is often stated that it is impossible to speculate on the ways in which a patent right may or may not be used in a commercial sense.[177] While this may be right with the current tools we have, we also know from competition law and policy that it is possible to divide up markets and analyse the impact of particular products and services on such markets and project market loss and gain.[178] Patent law would benefit from similar assessments that can feed into the regulatory and narrative governance. In fact it beggars belief that, for such monopolistic measures, patents are granted without any formal knowledge or assessment of how these rights will interact with markets. The monolithic vision of patents as property has prevented us from disaggregating these rights in terms of their impact and potential exploitation. If we can muster the political courage to move away from this unyielding view, we might be able to talk about the kinds of reflexive thinking we need to include effective human rights shaped spaces in patent law.

Conclusion

Asking for patent rights to be moderated by human rights is not just ineffective: it orchestrates intervention, and dampens the possibility of any deep change being effected. Patent law's epistemic barriers also mean 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

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177 MA Lemley and C Shapiro, 'Probabilistic Patents', n 111 above.

178 Although this process is not straightforward the tools used can provide a start. See L Kaplow, 'Market Definition, Market Power' (May 2015), *International Journal of Industrial Organization*, *SSRN: https://ssrn.com/abstract=2605179* [Accessed September 15th 2019].

them. As a result, the human right to health has a disappointing impact on campaigns that call for the reform of patent rights including negation or moderation. Instead, to uncouple human rights from patent law is to take patent law on its own terms and seek normative coherence informed by consequential reasoning. The proposal for PIAs is immodest in scale because it requires changes to the structural and systemic defaults of the patent system – but this is the sort of rethink we need to allow human rights to truly play a part in facilitating access to patented pharmaceuticals.