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Pharmaceutical patents: reconciling the human right to health with the incentive to invent

Levon M. Khachigian
Vascular Biology and Translational Research, School of Medical Sciences, Faculty of Medicine, University of New South Wales, Sydney NSW 2052, Australia

In developed countries that protect core aspects of the fundamental human right to the highest attainable standard of health, how does that right intersect with intellectual property rights? Here, the human rights implication of providing access to all cancer drugs recommended by experts in a developed country is considered in the context of conflict between the incentive to invent and the rights of others to access medicines. Effective incentives to innovate in developed countries can lead to global improvements in access to medicine if the intellectual property system is calibrated to permit this. This depends partly on the usefulness of compulsory licensing and alternative mechanisms facilitating global access to drugs. This review considers tensions between fundamental rights to access essential medicines and rights of the inventor and investors, including the pharmaceutical industry.

Introduction

The Australian Government adds new medicines to the Pharmaceutical Benefits Scheme (PBS) [1] on the first day of each month as 'subsidized prescribed medicines'. For example, Symdeko® (tezacaftor with ivacaftor) was listed on the PBS in December 2019 for the chronic treatment of cystic fibrosis [2]. In April 2019 the immunotherapy Bavencio® (avelumab) was listed for metastatic Merkel cell carcinoma – a rare skin cancer [3]. Those who would have paid up to AU$250 000 or AU$150 000 per year for Symdeko® or Bavencio®, respectively, now pay AU $41 per script (or AU$6.60 for concessional patients, i.e., holders of a Pensioner Concession Card; Australian Seniors Health Card; Health Care Card; Department of Veterans' Affairs Gold, Orange or White Card) [2,3]. Last August, the government also made four other new listings (costing AU$56 million) including Sprycel® (dasatinib) for acute lymphoblastic leukemia (saving patients AU$51 900 per course) and extended its subsidy of Avastin® (bevacizumab) for refractory glioblastoma (saving AU$31 200 per course) [4]. Listing all cancer drugs recommended by experts on the PBS was a key federal election issue in May 2019 [5]. These and ~5000 other pharmaceuticals and products for most health conditions have been included in the PBS [6], which provides massive savings to Australians needing patented drugs. The PBS costs the government AU$9.1 billion (21% of funds administered by the Department of Health) with >200 million prescriptions subsidized in 2014–15 [7]. In 2018–19, the Government allocated AU$1 billion over the forward estimates to pay for drugs that have not yet been listed on the PBS [8] – a significant cost burden to government given Australia's position as a net importer of patented drugs [9]. Yet, medicines are regarded as unaffordable by some. One in eight Australians delayed filling a prescription or going without prescribed medicines in 2017 because of unaffordability [10,11].

Intellectual property (IP) protection and incentive theory

The essence of any granted patent is the bargain between the patentee and the public. The

E-mail address: L.Khachigian@unsw.edu.au.

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patentee is granted the exclusive right to exploit the invention in return for public disclosure of that invention. The invention eventually becomes part of the public domain, and its underpinning specifications are made available for others to understand. The Scottish IP scholar Boyle described the 'promise of patent' as a decentralized system that allows innovation through individuals and firms being able to satisfy a multitude of human needs [12]. A problem requiring a solution is selected and solved with the *quid pro quo* of a monopoly for that investment and risk. This prevents the innovation becoming dormant and brings knowledge to the public.

The Venetian Statute of 1474 influenced the subsequent development of the European patent system. It granted exclusive privileges of 10-year terms to inventors of 'new and ingenious device(s)' in return for the inventor disclosing the nature of the invention to the Venetian General Welfare Board. This was a reward of a monopoly for innovation intended to stimulate production of new devices and spread skills for 'utility and benefit'. Public discontent with restraints of trade associated with the 16th century system granting monopolies for new innovations in the UK prompted reform. The resulting 1623 Statute of Monopolies established the principle that a 'true and first inventor' should be granted a monopoly patent [13]. Moreover s 6 provided a limited term (up to 14 years) upon grant. The 14-year term was enshrined in the first Australian patent legislation several centuries later [Patents Act 1903 (Cth), s 64(1)] and is currently 20 years for a standard patent [Patent Act 1990 (Cth), s 67].

Incentive theory explains the patentee's right to exploit as a reward and motivation to innovate [13]. This can be easily understood in the context of modern pharmaceutical innovation involving high development, testing and regulatory costs. An important part of any patent system is to ensure the public benefits from access to innovation. However, it is crucial to effectively facilitate public access to medicines that result from this innovation. As access to essential medicines is a core minimum obligation for states to realize the human right to health, this objective has great weight [14].

A key factor in pharmaceutical access is IP protection. New pharmaceuticals, or the new use of existing pharmaceuticals, can be protected under IP laws around the world as patentable inventions as defined in relevant patent legislation [e.g., s 18 of Patents Act 1990 (Cth)]. The Agreement on Trade Related Aspects of IP Rights (TRIPS) requires WTO member states to adhere to international IP laws protecting patents and ensure their enforcement (the general obligation is at Article 41, as pointed out by others) [15]. Patent monopolies facilitate profits, new and improved medicines and drive knowledge-based economies. Cutting-edge translational research [16] leads to technology transfer [17] and celebrates local innovation. Monopoly granted through patent rewards inventor(s) [or assignee(s)] for often risky, lengthy and expensive innovation.

The right to health

The intersection between IP and pharmaceuticals has enduring human rights significance. The value of incentivizing innovation and providing access to it is recognized in the International Covenant on Economic, Social and Cultural Rights (ICESCR), which was ratified by UN General Assembly resolution in 1966 and came into force in 1976. ICESCR (signed and ratified by Australia in 1972 and 1975, respectively; signed by the US in 1977 but not ratified) [18] recognizes an individual's right to benefit from the moral and material interests as inventors of scientific creations [Article 15(1)(c)], a right integrated with the rights of individuals to access the benefits of science [ICESCR Article 15(1)(b)]. CESCR's General Comment No. 14 makes it clear that reference to the right to health 'is not confined to the right to health care' and extends to a broad range of socioeconomic factors such as healthy eating, housing and work health and safety. Tensions arise when the right to health intersects with IP rights (IPR); and protecting the interests of the inventors of scientific creations are balanced against rights to access science and rights to health. Prosperous countries are also obliged to support less prosperous countries to meet core minimum right to health standards including access to essential medicines. This is also an important public health issue. Almost 2 billion people do not have access to basic medicines [19]. Perehudoff et al. conducted a cross-national analysis of national medicines policy across 71 countries between 1990 and 2016 using criteria focusing on medicine affordability and financial support for vulnerable groups and found that good governance, measures to pool user contributions and international cooperation were absent or weak [20]. If IPR raised prices making drugs unaffordable, this could have serious consequences for the right to health of individuals. Low health standards can impact other human rights, such as productivity losses and negative economic consequences [21]. Although there is no human right to productivity, loss of productivity is likely to reduce maximum available resources that can be used to realize economic, social and cultural rights.

For comparatively wealthy countries like Australia, the PBS helps it meet its obligation to fulfil the right to health by making affordable a broad range of expensive pharmaceuticals underpinned by patents. Progressive realization of the right to health could benefit from any drug that improves wellbeing, alleviates suffering and reduces mortality, whether the drug extends life by a few months but does not necessarily cure [such as current immunotherapies for cancer) or can cure (such as Sovaldi®/sofosbuvir for hepatitis C (HCV)] [22]. This also includes drugs developed in a country's own backyard. In the Australian setting, this includes recombinant granulocyte colony-stimulating factor (Neulasta®/Neupogen® or pegfilgrastim/filgrastim) which stimulates neutrophil production to support chemotherapy regimens [23] and Venclexta® (venetoclax) for chronic lymphocytic leukemia [24], an invention the subject of a US$325 million deal [25,26]. Venetoclax, costing AU$165 000 per course of treatment over a 2-year period, was listed on the PBS in March 2019 [27].

Returns on investment in health R&D can deliver long-term health gains through prevention and treatment of disease and reduce public health expenditure. It has been estimated that every AU$1 in health R&D expenditure generates > AU$3 return in health, longevity and productivity gains [28]. However, the World Health Organization (WHO) does not include many targeted medicines (smart drugs) that are known to reduce morbidity and mortality on its current list of essential drugs [29] such as ipilimumab (CTLA-4 immunotherapy) and aflibercept [soluble decoy receptor that binds vascular endothelial growth factor (VEGF)]. Although it is unclear why ipilimumab and aflibercept are not listed, the 22nd WHO Expert Committee on the Selection and Use of Essential Medicines indicated that cancer medicines nivolumab, pembrolizumab and atezolizumab were not recommended for the Essential Medicines List (EML) for the management of non-small-cell lung cancer because more data with longer follow up are needed to better understand the magnitude of benefit [29]. Baxi et al. recently argued that consideration of EML inclusion should be given to generic or biosimilar versions of targeted cancer therapies losing patent exclusivity and that patent status is but one factor impacting access to essential cancer drugs [30]. Ipilimumab and aflibercept were recommended for listing on the PBS for metastatic melanoma

and retinal disease in 2012 [31] and 2013 [32], respectively. Aflibercept was the 3rd most costly drug (AU$304.2 million) to the Australian Government in 2017-18 [33], whereas there was a 38.9% increase in cost to government for ipilimumab from 2016-17 to 2017-18 (AU$64.4 million) [34].

What actually constitutes an essential medicine is seemingly open to interpretation despite WHO's definition of essential medicines that includes those that 'satisfy the priority health care needs of the population' and are 'intended to be available within the context of a functioning health system at all times' [35]. However, studies by Duong et al. found that stakeholder decision makers, leaders or advisors in essential medicines in Australia could not discern whether medicines that were nationally reimbursed were essential medicines and did not consider the EML concept in medicine reimbursement decisions or supply management [36].

Other comparatively wealthy countries have also put measures in place to ensure citizens are not deprived of access to medicines. A recent example is the Serious Shortage Protocols (SSPs) that arose from uncertainties around Brexit. The UK Government introduced new laws to deal with the possibility of drug shortages in the UK market. SSPs, that operate under The Human Medicines (Amendment) Regulations 2019, have allowed community pharmacists in the UK to replace drugs they cannot access with alternate drugs that might have 'different strength, quantity or pharmaceutical form of the prescription-only medicine' to that ordered by the prescriber (s 226A) [37]. Fluoxetine was the subject of an SSP in October 2019.

Tensions between rights to health and IPR regimes

Access to pharmaceuticals is part of the obligation of each ICESCR party to fulfil the right to health under CESCR General Comment No. 14. So how do new and expensive treatments that are not 'essential medicines' fit into state obligations to protect the right to health? This expands beyond essential medicines because it forms part of progressive realization of the obligation for states to provide individuals with the highest attainable standard of physical and mental health. This approach of progressive realization recognizes different economic capabilities between states. However, states are obligated not to regress from measures to protect economic, social and cultural rights, including the right to health once they are provided. Removal of a drug from the PBS might be considered a retrogression of the progressive realization of the right to health by Australia, which could constitute impermissible retrogression under CESCR General Comment No. 3, presumably unless the delisted drug is superseded by a comparable or more superior alternative. Drugs can be delisted in circumstances of failure or inability to supply [38] or where the supplier and the government cannot agree on price [39]. The alkylating anticancer agent thiotepa provides an example of a drug that was deleted from the PBS in 2011 [40]. Where providing additional treatments means the health budget expands, governments can reduce other social services that could restrict the realization of other economic, social and cultural rights. These are opportunity costs, where decisions are made between competing alternatives [41]. Consequently, cost considerations could limit human rights incentives to improve health through expanded access to cancer treatment.

Are there other ways to reduce the financial impact of providing new cutting-edge treatments? Australia is an innovator but also a net importer of medicines. The TRIPS Agreement means that access to pharmaceuticals can be expensive in Australia, even where it corresponds to right to health obligations. Here, 'access' is used as a proxy for affordability. It should also be acknowledged that access, from a health systems perspective, can also refer to barriers in both demand and supply, and be identified as geographic and financial accessibility, quality, acceptability and availability [42]. Non-governmental organizations, such as Oxfam and Médecins Sans Frontières, recognized that in less prosperous countries patent protection can increase pharmaceutical prices [43]. Moreover, the 17-year extension to the transition period (to 2033) for least developed countries to enforce global trade rules could be even further extended under Article 66.1 of the TRIPS Agreement [44].

Compulsory licenses

Crosstalk between human rights and IPR regimes is fragmented. States have human rights obligations to improve access to medicines in less prosperous countries under CESCR General Comment No. 14. There is no explicit recognition of human rights or an individual's right to health in the TRIPS Agreement. Although TRIPS Articles 8 and 27 are relevant to human rights they do not incorporate human rights obligations and the dispute settlement body is not obliged to refer to them [45]. There are mechanisms built into TRIPS that permit states to recognize public health as relevant considerations to domestic IP policy. Yet, despite recent recognition that such considerations provided support for Australian tobacco plain packaging legislation, mechanisms supporting flexible implementation of TRIPS are not widely used [46]. This is problematic where it limits access to essential medicines in less economically prosperous countries because ICESCR requires wealthier states to act where other states cannot meet core minimum obligations to provide access to essential medicine. A 2018 study suggests that use of TRIPS flexibilities could be more frequent than previously thought. There were 176 cases of possible use in 89 countries between 2001 and 2016, the majority (100) involving compulsory licenses or public noncommercial use licenses [47]. Nevertheless, measures that could facilitate better exploitation of TRIPS flexibilities include streamlining procedures to obtain compulsory licenses and patent examiner training [48]. The potential disconnect between pharmaceutical access and patent protection was supposed to be addressed by the TRIPS Protocol comprising addition of Article 31*bis* together with the Annex to the TRIPS Agreement following Article 73 (added in 2005) [49] that allows pharmaceuticals produced under so-called 'compulsory licenses' to be exported to least-developed nations or other eligible importing member nations that have limited or no production capacity. Compulsory licensing can potentially facilitate global access to essential drugs and technologies by permitting states to use patents without the authorization or consent of patent holders. Under TRIPS Article 31, states can authorize use by third parties under certain circumstances such as when attempts have been made to obtain 'authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time'. In India, under ss 84 and 92 of Patents Act 1970 any person can apply to the Controller to license a patent 3 years after the patent is granted on grounds that, in relation to the patented invention, the reasonable needs of the public have not been satisfied, the invention is overpriced precluding public use, is not being worked in India or in circumstances of national emergency or extreme urgency [50]. In March 2012, India's Patent Office granted the nation's first compulsory license to Natco Pharma (Hyderabad) to produce a generic version of Bayer's anticancer agent Nexavar® (sorafenib), a kinase inhibitor. Only 2% of cancer patients had easy access to the drug. Moreover, Bayer sold the drug at an exorbitant price of INR280 000 for a month's

supply. Because Nexavar® was being imported into India, Natco's compulsory license enabled the generic medicine to be sold for INR8880 per patient per month [51]. Natco paid Bayer 6% of net sales of the drug in line with TRIPS Article 31 (h) and s 90 (1) of Patents Act 1970. This is after Bayer rejected Natco's earlier request for a voluntary license [51].

Article 31 does not permit the export of pharmaceuticals by generic manufacturers in one nation to nations in need but without manufacturing capability. Hence, the need for the TRIPS Protocol which formalized paragraph 6 [52] of the DOHA declaration enabling countries unable to produce drugs domestically to import patented drugs under compulsory licensing, described by WTO at the time as a 'decision (that) removes final patent obstacle to cheap drug imports' [53]. The TRIPS Protocol came into effect on 23 January 2017 and Australia passed legislation incorporating the Protocol from 25 August 2015 [Intellectual Property Laws Amendment Act 2015 (Cth), Chapter 12 Part 3, ss 136B–136 M]. But the problem of access to affordable medicines remains unresolved and some have described the amendments as 'regulatory ritualism' and 'an unworkable solution to provide affordable access to medicines to patients in poorer countries' [54]. For example, bilateral and regional trade agreements have constrained TRIPS flexibilities [54]. Beall and Kuhn identified that two-thirds of compulsory license episodes between 1995 and 2011 involved HIV/AIDS, the remaining involved other communicable diseases (e.g., flu, anthrax) and noncommunicable diseases (e.g., cancer, CVD). Interestingly, even the threat of a compulsory license can prompt more-aggressive negotiation by developing nations and can lead to voluntary licenses and significant drug discounts [55]. However, there remain significant obstacles in compulsory licensing use that prevent individuals accessing the benefits of science to realize the highest attainable standard of health. Son and Lee identified 108 attempts to issue compulsory licensing for 40 drugs in 27 countries from 1995 to 2014. The proportion of middle-income countries attempting compulsory licensing grew from 35% to 63%; the proportion of low-income countries fell from 47% to 15%, with 70 of the 108 attempts being made for HIV/AIDS drugs [56]. In Australia there has been no compulsory licensing of patents [57]. While aligning with the TRIPS Protocol, the process for obtaining a compulsory license is onerous, lacks clarity and is open to judicial discretion of the host country [58,59]. Others have argued that flexibilities provided by the TRIPS Protocol are procedurally complex and burdensome and not in line with the original intent of flexibility as discussed elsewhere [54].

Potential alternatives to compulsory licensing

There is need for alternate mechanisms of improved global access to medicines on the back of the patent system, building on TRIPS and humanitarian principles set out in a range of international treaties and conventions. This requires vision and commitment by governments, policy makers and the pharmaceutical industry alike. Putting aside foreign aid, governments could leverage capacity in industry by providing tax breaks or market exclusivities for health R&D in medicines more specific to developing countries noting that diseases specific to the developing world are less lucrative.

Pharma is naturally biased toward medicines for chronic diseases of the developed world. It is estimated that only ~1% of the >1500 drugs approved in the period 1975–2004 relate to neglected diseases [60]. Indeed, only 10% of the world's R&D relates to diseases affecting 90% of the world's disease burden [61]. Australia already has an attractive tax-refundable offset scheme for health R&D of 43.5% [62]. Registered expenditure for this scheme grew by 50% from 2012 to AU$1.6 billion in 2015 [63]. Governments might also reward companies that invent prioritized medicines for the third world [64] or expedite or fast track the drug approval process allowing manufacturers to recoup costs more rapidly. For example, under the US Federal Food, Drug and Cosmetic Act (FFDCA) orphan drug product developers are guaranteed a market exclusivity term of 7 years after FDA approval [65]. Any plan to provide broader access to essential medicines is admirable. However, given the human rights implications identified, such plans need to be considered within a holistic, rights-based strategy to incentivize pharmaceutical innovation. Existing programs that can be built upon include the Orphan Drug Act that promotes drug development for rare diseases [66]. Priority Review Vouchers awarded by the FDA to sponsors of product applications relevant to tropical diseases [67], US President's Emergency Plan for AIDS Relief, which has already awarded US$85 billion [68], and the Qualified Infectious Disease Product program that facilitates fast-track designation [69]. On the other hand, the prospect of higher drug prices could trigger novel drug development, particularly in circumstances where pharmaceutical companies (such as GSK, Merck, Pfizer and Takeda) have reduced R&D spending [70] yet numbers of drugs being approved is growing (59 in 2018 compared with 21 in 2010), many being orphan drugs [71]. The Orphan Drug Act has been criticized for enabling firms to charge higher prices for orphan drugs in 'salami sliced' disease indications [72]. Another model is the Medicines Patent Pool (MPP) [73], a public health organization founded in 2010 backed by the UN that relies on the willingness of pharma to make their patents available on a voluntary basis. Patents are licensed to the MPP and generic versions of new medicines are made available to low- and middle-income countries. Companies already engaged in the program covering HIV and HCV medicines include Abbvie, Bristol-Myers Squibb, Gilead, MSD and ViiV Healthcare [73]. As 't Hoen, inaugural MPP Executive Director, indicated in 2012: 'this demonstrates a willingness of drug companies to move from conflict to collaboration' [74].

Patent commercialization: low strike rate but need to keep the balls coming

Costs for developing a new drug are staggering. In 2014 The Tufts Center for Study of Drug Development surveyed the R&D costs of >106 new drugs from ten pharmaceutical firms and estimated the mean pre-tax out-of-pocket cost per new approved compound was US$1395 million in 2013 [75]. They found that costs for abandoned compounds were linked to costs of approved compounds. It is little wonder that drugs are so expensive when companies seek to recoup costs of drugs failing to progress to market. Success rates for developing a marketable drug are dismally low. It is estimated that of 5000–10000 candidate chemical compounds 250 will show promise for experimental testing and just ten will qualify for human trials [76]. Clinical drug development pipelines start with a Phase I trial evaluating safety and tolerability. Biotechnology Innovation Organization (BIO) found that the overall likelihood of market approval from Phase I for all drugs was 9.6%, and 11.9% for indications beyond oncology (which was 5.1%) [77]. Bringing to market a drug takes roughly 12 years compared with a device taking ~3–7 years [78]. With such formidable barriers to market, it is vital that basic research feeding the pool of candidate drugs and devices remains vibrant.

How can incentive theory-fueled IPR in medical research be better exploited?

An unresolved paradox in reconciling the human right to health with the incentive to invent is that new and improved medicines are

typically driven by IPR, which increases cost and reduces accessibility. Policy makers need to balance short-term benefits to patients of lower (or subsidized) prices for existing drugs with long-term benefits underpinning the development of novel drugs. So how can countries like Australia better harness its innovative capacity for long-term gain? First, there needs to be clear recognition that new discoveries stemming from increased investment in health R&D provides greater opportunity to exploit IP and fuel further R&D. This is especially important given the development of resistance in patients to certain new medicines such as immune checkpoint immunotherapies [79]. However, OECD figures released by Universities Australia indicate that gross expenditure on R&D as a percentage of GDP fell from 2.11% in 2013-14 to 1.88% in 2015-16. Australia sits under the OECD average of 2.38%. The government, through NHMRC, funds basic, translational and clinical research to the tune of ~AU$800 million per year through the Medical Research Endowment Account. It does so by way of a range of competitive grants, including those that promote interactions with industry based on demonstrable IP and commercial potential within a foreseeable timeframe. Opportunities to fund nontargeted blue-sky research must be preserved as many important discoveries and treatments have arisen from serendipity and curiosity-driven research. Fleming is quoted as saying 'I did not invent penicillin. Nature did that. I only discovered it by accident' [80]. Marshall said of his and Warren's discovery that Helicobacter pylori infections caused peptic ulcers, 'we were not looking for the cause of ulcers' [81]. The AU$20 billion Medical Research Future Fund (MRFF) represents visionary government recognition of the value of investing in research over the long term but this largely provides targeted funding. This includes funding calls in early 2020 to develop a COVID-19 vaccine(s), antiviral therapies for those infected with COVID-19 and trials to better manage severe acute respiratory distress in COVID-19 patients.

Second, more funding opportunities for early-stage R&D are needed to avoid promising drugs and devices disappearing in the so-called 'Valley of Death' – the pivotal period between preclinical validation and clinical translation where many drugs fail to advance for lack of resources and funding [82]. Enabling schemes in Australian universities and medical research institutes include the Medical Research Commercialization Fund [83] and Uniseed [84] – but these early-stage investment programs are largely restricted to partner research organizations. The government's Accelerating Commercialization scheme [85] provides up to 50% of eligible project costs and access to expert networks but necessitates matching funds, the lack of which necessitates grant funding in the first place. In late 2015, the Australian Government established the not-for-profit MTPConnect to improve collaboration and growth within the medical technology and pharmaceuticals sector to promote commercialization. MTPConnect operates the MRFF's BioMedtech Horizons Program and the Biomedical Translation Bridge Program [86]. Research co-development partnerships provide an alternate business model. In Australia, pharmaceutical investment from abroad particularly from China has enabled research co-development programs as an alternative to simply out-license technologies developed in-house. For example, Griffith University's Institute for Glycomics recently partnered with a Hong-Kong-based pharmaceutical company to jointly develop and commercialize a novel treatment for human parainfluenza virus with Griffith retaining ownership of the drug [87]. The biotech sector has recognized the value of investing in early-stage R&D. CSL recently launched its Research Acceleration Initiative to support discovery research with a view to developing innovative biotherapies in its areas of interest through collaborative partnerships with Australasian research organizations [88]. This recognition also extends to joint ventures between philanthropic and corporate entities with a common goal. The Bill & Melinda Gates Foundation, Wellcome and Mastercard launched the US$125 million COVID-19 Therapeutics Accelerator in March 2020, 'remov[ing] barriers to drug development' and 'de-risk[ing] the pathway for new drugs and biologics' including initial screens of candidate compounds [89].

Third, improved training programs would help researchers better understand IPR, translational research and commercialization. This is because, although researchers are trained to think, write grants and papers, and to experiment, they are typically not formally trained to protect or commercialize their discoveries. For example, the difference between novelty and invention might not be necessarily understood enough to be able to recognize and protect new IP when it is created. Cooperative Research Centres grants, which provide funding for industry-led research collaborations and link Australian industry organizations with Australian research organizations for up to 10 years, represent an excellent mechanism not just for pre-commercialization or proof-of-concept research but for industry-focused education and training [90].

Fourth, broader adoption of a more flexible approach to handling IP could help. Typically, patent owners or their agents go into the market place and seek to out-license their IP. However, many inventions and IP developed in universities and medical research institutes are simply not used or are underutilized. Around 20% of patents in Australia are granted and 35% lapse without grant [91]. This can have human rights implications, if the relevant inventions and IP have social utility the failure to use them could impact on the realization of economic and social rights such as the right to health. Traditional intersections between public health and IP can be more nuanced when viewed from a human-rights perspective. 'Easy Access IP' provides an alternative system, which in general terms offers to license, at no cost original research discoveries, inventions and IP to accelerate new opportunities with simple agreements [92]. For example, the UTS Centre for Autonomous Systems provided Mobility 2000, a mobility equipment company, free access to relevant IP, giving powered wheelchairs capacity to climb stairs [93]. This notionally improves partner engagement based on goodwill and fits with the ideal of a university or large research institute bringing inventions with potential societal benefit to the community. On the other hand, it is difficult to imagine that IP holders and their institutions would pass up the opportunity of making a fortune on a promising blockbuster. In any event, the notion of making IP freely available is not confined to academic institutions. A similar strategy was announced by Tesla in respect of its electric car technology [94]. Rival Toyota announced a few months later that it would freely share its 5680 patents on fuel-cell cars for free to help promote hydrogen-powered vehicle technology [95].

Concluding remarks

New medicines arise from health R&D, which itself arises from the incentive to invent. Whereas health R&D must remain a national priority in countries that can afford it, states have human rights obligations to improve access to medicines in less prosperous countries. Instruments that more effectively meet human rights standards of assessment would enable wealthier countries to more effectively share the fruits of human ingenuity in health R&D beyond its own citizens.

Conflicts of interest

L.M.K. is an inventor on granted patents noting that none relate to a PBS listing.

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L.M.K. is a Professor and NHMRC Senior Principal Research Fellow in the Faculty of Medicine, UNSW and a molecular biologist with interests in drug discovery, translational research and IP. He is a former President of the Australian Society for Medical Research. This work was conceptualized by L.M.K. who wrote the manuscript with input from those acknowledged.

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