22
The law and ethics of access to medicines in developing countries

Paul Ogendi and Peter Munyi

22.1 Background

Lack of access to essential medicines has led to untold suffering and loss of many lives, particularly in developing countries (Yamin 2003), and was rightly termed by Yamin as a ‘horrific injustice’ (2003: 370). Notwithstanding this, the World Medicines Situation report continues to identify inequality and discrimination in access to essential medicines as the key public health challenge of our time (Hogerzeil and Mirza: 2011). The situation is exacerbated by the increasing demands for existing and new medications to mitigate the HIV/AIDS, tuberculosis (TB), and malaria burden in developing countries. Today, the World Health Organization (WHO) estimates about one-third of the world’s population lacks access to essential medicines (Hogerzeil and Mirza 2011: 1; UN Human Rights Council 2011: 4). In some areas, the figures project that more than 100 million people endure high financial burdens to fund their healthcare due to high costs (UN Human Rights Council 2011: 4). In developing countries, patients pay approximately 50 to 90 per cent of the cost of medicines, while 20 to 60 per cent of these costs are accounted for in the country’s healthcare budget (UN Human Rights Council 2011: 4). Therefore, increasing access to affordable medicines in resource-poor settings and finding new ways to promote the development of new medicines and vaccines to treat diseases of the poor remain a top priority (Leach et al. 2005).

Indeed, measures to address the current public health challenges of access to medicines, particularly in developing countries, must be sustainable (Klug 2008). These measures must take into account the complex interplay of macro-economic development, disease patterns, and healthcare needs and provision (Attridge and Preker 2005). Notably, the recognition of access to medicines as a fundamental human right under the right to health is the foundational argument for universal access to essential medicines (Kenyan Constitution 2010, article 43(1)(a); South African Constitution 1996, section 27).

22.2 Legal framework regarding access to medicines

22.2.1 Overview of the right to health and access to essential medicines

In 1946, the preamble to the WHO Constitution was the first document to recognize the fundamental right to health. It defined health as ‘a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity’ (WHO 1946, preamble).
Arguably, the WHO Constitution paved the way for the recognition of the right to health in various international treaties and instruments (Torres 2002). In the recent past, the regional and national protection of the right to health has also gained traction among WHO actors.

The right to health is extensively protected at the international level. Article 25 of the Universal Declaration of Human Rights 1948 (UDHR) enshrines, amongst other socio-economic rights, the right to health. This is important since the UDHR is the first universal authority and statement on human rights (Dimitrijevic 2006). In fact, some parts of the UDHR are believed to be customary law, meaning they are legally enforceable (Dimitrijevic 2006).

The UDHR provision on the right to health was subsequently incorporated in article 12 of the International Covenant on Economic, Social and Cultural Rights 1966 (ICESCR). Unlike the UDHR, the ICESCR is legally binding and enforceable. Other binding and enforceable international instruments include article 12 of the Convention on the Elimination of All Forms of Discrimination against Women 1979 (CEDAW), and article 24 of the Convention on the Rights of the Child (CRC) 1989. The CEDAW and the CRC are predominantly concerned with the rights of women and children respectively.

Notwithstanding the importance of each instrument enshrining the right to health, the ICESCR is of particular importance since it led, through treaty-body interpretation, to the classification of access to essential medicines as a core obligation under the right to health (UN Economic and Social Council 2000, para. 43(d)). Thereby a state party to the ICESCR cannot derogate from this obligation whatsoever. Currently, there are 160 state parties to the ICESCR and 70 signatories (UN Treaty Collection 2013). It is also in the context of the protection of the international right to health that the UN Special Rapporteur on the Right to the Highest Attainable Standards of Physical and Mental Health has been able to publish various reports on this issue. In particular, the Special Rapporteur’s report entitled ‘Expert Consultation on Access to Medicines as a Fundamental Component of the Right to Health’ is significant, as it asserts that since ‘access to medicines is an integral and fundamental part of the right to health, Governments and the international community as a whole have a responsibility to provide access to medicines for all’ (UN Human Rights Council 2011, para. 44).

Recent news indicates that the UN Human Rights Council may actually consider a resolution on access to medicines as a human right, to be submitted to it by India, Brazil, South Africa, Egypt, and Thailand upon recommendations from the Special Rapporteur (Don’t Trade Our Lives Away 2013). This would expand the access to medicines discourse beyond the list of drugs to the ‘essential medicines’ in use for decades (Don’t Trade Our Lives Away 2013).

Secondly, regional instruments have also contributed to the protection of the right to health. In Africa, article 16 of the African Charter on Human and Peoples’ Rights 1981 (African Charter), article 14 of the Protocol to the African Charter on Human and People’s Rights on the Rights of Women in Africa 2003, and article 14 of the Protocol to the African Charter on the Rights and Welfare of the Child 1999 all provide for the right to health. At the regional level, the African Commission on Human and Peoples’ Rights put in place a resolution on access to health and needed medicines (Resolution 141 2008). On the legislative front, the Pan-African Parliament called for the

3 Kenya signed the Protocol on 12 December 2012 but has yet to ratify it. South African ratified it on 17 December 2004.
'development and/or review of national medicines policies to ensure that all the key elements that ensure access to medicines are covered …' (2011: 2).

With regard to the Inter-American human rights system, article 26 of the American Convention on Human Rights 1969 requires the progressive realization of the socio-economic rights provided for under the Charter of the Organization of American States 1948, as amended by the Protocol of Buenos Aires 1970. The American Convention on Human Rights, however, does not specifically provide for enforceable socio-economic rights in its text. Similarly, the Charter of the Organization of American States only commits its members to certain socio-economic goals including ‘[u]rban conditions that offer the opportunity for a healthful, productive, and full life’ (article 34(1)).

In 1999, the Inter-American human rights system adopted the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights [Protocol of San Salvador]. Article 10 of the Protocol of San Salvador enshrines the right to health. This article has been relied on by litigants, in addition to article 4 of the American Convention on Human Rights, to demand access to antiretroviral medications (Jorge Odir Miranda Cortez et al. v. El Salvador 2001). Finally, the European Convention for the Protection of Human Rights and Fundamental Freedoms 1950, like its counterpart, the American Convention on Human Rights, does not explicitly mention the right to health. However, the European Social Charter (Revised 1996) was later adopted in 1961 and provided for socio-economic rights, including the right to health under article 11. These rights are not legally enforceable and rely on ‘a supervisory mechanism based on a system of collective complaints and national reports’ to ensure their respect and the implementation of the European Social Charter (Secretariat of the European Social Charter 2009: 1).

Third, there is an increasing protection of the right to health at the national level. Kenya and South Africa are leading the way, codifying a justiciable right to health in their respective Constitutions. Kenya guarantees the right to health under article 43(1)(a) of its 2010 Constitution, while South Africa protects the right to health by virtue of article 27(1)(a). As a result of this constitutional protection of the right to health, both the Kenyan and South African constitutional courts have been able to enforce access to medicines. In Patricia Asero Ochieng and others v. The Attorney General, Petition No. 409 of 2009 (popularly known as the Patricia Asero case), the Kenyan Constitutional Court addressed access to generic drugs in the context of national anti-counterfeit legislation. In Minister for Health and others v. Treatment Action Campaign and others 2002 (5) SA 703 (popularly known as the TAC case), the South African Constitutional Court discussed expectant mothers’ access to Nevirapine for the prevention of mother-to-child-transmission of HIV. Both cases upheld the government’s obligation to provide access to essential medicines unconditionally.

These cases add to the growing list of authorities on access to essential medicines, particularly in developing countries. India is leading the world in protecting the right to health through judicial interpretation, even though the right to health has been listed outside of the country’s enforceable fundamental rights pursuant to article 37 of Part IV (Directive Principles of State Policy) of the Indian Constitution 2007.5 India has also developed progressive access to medicines jurisprudence as in Novartis v. Union of India and others, Civil Appeal No. 2606–2716 of 2013. In this case, the Supreme Court of India rejected Novartis’ patent renewal application for a popular cancer drug on the grounds that it did not meet the patentability criteria set out under the patent laws of India. In rejecting the appeal by Novartis, the judges, at para. 195 of the judgment, posited that the new invention claimed ‘fails in both the tests of invention and patentability as provided under clauses (j) and (ja) of section 2(1)

Paul Ogendi and Peter Munyi

and section 3(d) respectively of the Patent Act 1970. This decision has been lauded by various public health actors because of its potential impact in curbing the problem of ‘evergreening’ of pharmaceutical patents, which delays access to affordable generic medicines in the market (MSF Access Campaign 2013a).

22.2.2 WTO rules and access to medicines

The inclusion of intellectual property under the World Trade Organization (WTO) through the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement 1995 marked a new era of intellectual property (IP) rights protection globally, within a set of minimum standards. Unlike before, IP could now be treated as a trade commodity under international trade, meaning material interest in an intellectual creation is protected through an international property-based IP system (Yu 2007).

However, the main concern in developing countries currently under the TRIPS Agreement is the protection of public health, and economic and technological development generally (Commission on Intellectual Property Rights 2002). In particular, developing countries are concerned that by introducing patent protection, medicine prices will increase while the choice and supply of pharmaceuticals will decrease (Commission on Intellectual Property Rights 2002). In August 2000, Resolution 2000/7 of the UN Sub-Commission on the Promotion and Protection of Human Rights on intellectual property rights and human rights was the first international resolution to acknowledge the conflict between human rights and intellectual property (Sub-Commission on Human Rights Resolution 2000/7, para. 2). However, it was quick to also declare that the TRIPS Agreement is not equivalent to human rights, which are fundamental in nature and indivisible (Sub-Commission on Human Rights Resolution 2000/7, para. 2). The Resolution also sought to remind the governments of the primacy of human rights obligations over economic policies and agreements (Sub-Commission on Human Rights Resolution 2000/7, para. 3). In responding to the above report, Pakistan noted that developed countries were benefiting more from the TRIPS Agreement than developing countries. According to Pakistan’s reply, the cost-to-gain ratio borne by developing countries is disproportionate:

The experience of many developing countries with the implementation of the intellectual property agreements indicates that the fundamental objectives of these agreements are not being realized. There may perhaps be reasons to believe, at best on theoretical grounds, that in the long term, benefit could accrue in the form of increased investments, innovation and transfer of technology. However, it is painfully evident that in the short and medium term, the costs being borne by developing countries are higher than the gains, and that the balance between the rights holder (mostly from the developed countries) and the user of intellectual property has shifted dramatically in favour of the former.

(UN Sub-Commission on the Promotion and Protection of Human Rights 2001: 3)

Pakistan goes on to provide detailed reasons. Notably, the government of Pakistan posits that stronger intellectual property protection undermines the right to health, the right to education and the right to food (UN Sub-Commission on the Promotion and Protection of Human Rights 2001: 4). The government of Pakistan also argued that stronger intellectual property rights protection promotes monopolistic and anti-competitive practices (UN Sub-Commission on the Promotion and Protection of Human Rights 2001: 4). Lastly, the government of Pakistan further asserted that some developing countries have been unable to quickly respond to
epidemics such as HIV and AIDS (UN Sub-Commission on the Promotion and Protection of Human Rights 2001: 4). Notwithstanding the current stand-off, the TRIPS Agreement avoided the defects of the World Intellectual Property Organization (WIPO) and other IP treaties by insisting on ‘balance’ as the multilateral objective (He 2011: 831). In this regard, the ‘rules v. flexibilities’ dichotomy embodies an unprecedented level of international will (He 2011: 831). This is because the concrete and enforceable TRIPS Agreement flexibilities are also meant to give effect to the objectives and principles of articles 7 and 8.1 of the Agreement (He 2011: 832). Nevertheless, a ‘one-size-fits-all’ approach to IP protection is unadvisable since it is ‘unreasonable and unrealistic’ and may actually hamper rather than facilitate the achievement of an appropriate legal balance (He 2011: 833).

Recently, the TRIPS Council extended one of the flexibilities under the TRIPS Agreement to the least developed countries (LDCs), granting them a transition period. Article 66.1 of the TRIPS Agreement initially required LDCs to comply with the TRIPS Agreement’s minimum standards within a period of ten years. In 2005, the TRIPS Council extended this initial transition period to another seven and a half years. With regard to pharmaceutical patents, an extension was granted in 2002, until 1 January 2016, pursuant to para. 7 of the Doha Declaration on the TRIPS Agreement and Public Health 2001. The Doha Declaration is an important instrument in the access to medicines discourse since it grants developing countries the right to utilize the TRIPS Agreement’s flexibilities to promote public health initiatives. In June 2013, the transition period for LDCs was again extended to 2021, eight years away, in order to further promote innovation and technological development. This new extension received popular support from the UN, developing countries (including China, India, Brazil, and South Africa), academicians, and civil society organizations across the world (Saez 2013). Since the extension on pharmaceutical patents has yet to expire, LDCs will need to seek a separate extension in 2015.

This new extension of the transition period may have implications on access to medicines, according to UNAIDS, in that it will preserve the policy space for LDCs. Particularly, the extension will ‘conserv[e] the autonomy of LDCs to determine appropriate development, innovation, and technological promotion policies, according to local circumstances and priorities’ (UNDP and UNAIDS 2013: 4). A press release by Médecins Sans Frontières (MSF) stated that LDCs are ‘now in a position to roll-back existing level of IP protection to meet domestic policy objectives, and should do this in the years ahead’ (2013: 1a). However, while acknowledging that pharmaceutical patents were covered by this extension generally, MSF recommended that LDCs should insist, in 2015, on a ‘more comprehensive extension,’ which is not time bound and without any other conditions (2013b: 1). Notwithstanding, the EU pointed out that the 2021 extension is conditional on the country remaining an LDC and not gaining developing country status (Permanent Mission of the European Union to the World Trade Organization 2013). The EU further asserted that LDCs ‘have committed themselves not to reduce or withdraw the current protection that they give’ (Permanent Mission of the European Union to the World Trade Organization 2013: 1). From the above, it appears that the exact meaning of the ‘no-roll-back’ clause is contested and will form the basis of future engagement, particularly in the implementation of the decision in LDCs.

### 22.2.3 Threats to access to medicines

Free trade agreements (FTAs) animate a number of threats in the access to medicines movements by the impracticability of some amendments in the TRIPS Agreement and the Anti-Counterfeiting Trade Agreement 2011 (ACTA).
22.2.3.1 FTAs

Despite the TRIPS Agreement, international communities perceive a failed enforcement of IP in developing countries given the prevalence of counterfeiting and piracy (Kur 2009). In particular, members of the WTO have been accused of not adequately implementing the provisions of the TRIPS Agreement, and/or not investing enough resources to enforce the provisions enacted nationally in compliance with the Agreement (Kur 2009). The above reasons, coupled with unwillingness at the multilateral level to upgrade substantive obligations under IP law, led to the revival of bilateral strategies (Santa-Cruz 2007). In response, the United States, the EU, and Japan are offering favorable market conditions to specific trading partners for stronger IP protection. According to Musungu and Dutfield, this concession becomes critical when applied to areas such as public health, the promotion of domestic industries, and access to knowledge (2003: 4). For example, the presently negotiated EU-India FTA may restrict access to generic drugs for HIV/AIDS, while Indian manufacturers supply 80 per cent of these generic antiretroviral drugs to MSF for treating patients (MSF 2013b). In addition, ‘due to deficiencies of procedural fairness and equal standing of negotiating parties,’ the resultant IP provisions in FTAs are ‘ill-adapted to a member’s individual situation’ (Kur 2009: 33).

According to Correa (2006), FTAs generally require stronger protection of IP rights than what is internationally sanctioned under the TRIPS Agreement. In some cases, FTAs surpass the interests of the developed countries promoting them (Correa 2006). Ultimately, Correa concludes that the impact of these FTAs is to limit the capacity of states to realize their human right to health and to negate the Doha Declaration (2006: 402). FTAs may include what is often referred to as ‘TRIPS-plus’ provisions for requiring protection beyond the minimum requirements under the TRIPS Agreement. These provisions so far extend to the following: broadening patentability; restricting patent oppositions; extending patent duration; introducing test data exclusivity and a patent-registration linkage; and, lastly, IP enforcement requirements (UNDP and UNAIDS 2012: 3–4). According to UNAIDS and UNDP, countries should avoid entering into FTAs that contain TRIPS-plus provisions in order to benefit from the TRIPS Agreement flexibilities (2012: 5).

22.2.3.2 TRIPS amendments impracticability

The most contested flexibility seems to be in the area of compulsory licensing, where there has been considerable flip-flopping from WTO members. In particular, the Doha Declaration identified the difficulties WTO members experience in having insufficient or no manufacturing capacities to utilize the compulsory licensing provisions under the TRIPS Agreement (Doha Declaration, para. 6). Therefore the Doha Declaration instructed the Council for TRIPS ‘to find an expeditious solution and report to the General Council before the end of 2002’ (para. 6). On 30 August 2003, the General Council reached a decision on this issue and dubbed the ‘Implementation of Paragraph 6 of the Doha Declaration on TRIPS Agreement and Public Health’ (the Decision) (WTO General Council 2003). The Decision allowed for limited importation and exportation in countries with little or no manufacturing capacities. Baker described this outcome as a ‘cumbersome, but potentially important mechanism for allowing trade in low-cost generic medicines’ (2004: 7). In effect, both LDCs and developing countries are allowed to benefit from the Decision. For LDCs, they are automatically eligible, but eligibility for non-LDCs or developing countries is conditional on ‘insufficient or inefficient capacity in the pharmaceutical sector’ (Baker 2004: 16). Compulsory licensing is allowable where there is a patent in place to benefit from the Decision (WTO General Council 2003). In ‘good faith,’ all WTO
members can export under the Decision following stringent conditions (WTO General Council 2003). In practical terms, the real difficulties of the Decision concern post-1994/5 discoveries. It expands the 2005 product-patenting rights for countries like India that must become fully TRIPS compliant and must provide patent protection both for post-1994/5 pipeline/mailbox patent applications and for all post-2005 inventions. Of course, the Decision also applies to countries like Brazil, where most medicines are patented and intended to be exported under a non-competition-based compulsory license (Baker 2004: 30).

The complexities described above are arguably responsible for the limited number of countries adopting legislation implementing the Decision as an exporting country. These countries include Norway, Canada, India, the EU, Hong Kong, Switzerland, the Philippines, Singapore, Albania, Croatia, China, the Republic of Korea, Jordan, and Japan (WTO 2011). Similarly, only one importing country, Rwanda, has used the system to import drugs from Canada for its HIV patients despite the availability of similar drugs in India (South Centre 2011: 8). The overarching issue is the continued failures of the current system to improve access to essential medicines in developing countries because it is ‘unnecessarily burdensome and complicated’ (South Centre 2011: 8).

22.2.3.3 ACTA

Anti-counterfeiting is discussed under Part III ‘Enforcement of Intellectual Property Rights’ of the TRIPS Agreement. Thereby members are urged to apply border measures to combat, among other things, trademark counterfeits (TRIPS Agreement, article 51). With regard to willful trademark counterfeiting, criminal procedures and penalties are preferred in order to enforce IP rights (TRIPS Agreement, article 61). Nonetheless, industrialized countries appear dissatisfied with the enforcement provisions under the TRIPS Agreement: they are convinced that the current enforcement provisions cannot combat counterfeiting, urging for strategies beyond the TRIPS Agreement (Kur 2009). However, the problem lies in expanding anti-counterfeiting measures beyond what is provided for under the TRIPS Agreement as it has little benefit to the consumer: only willful trademark counterfeiting is potentially dangerous to the public since willful counterfeit medicines are not registered with the national drug regulatory authorities (Maybarduk 2010: 4).

This dissatisfaction with the enforcement mechanisms in the TRIPS Agreement is manifest in the proceedings, negotiations, and signing of the Anti-Counterfeiting Trade Agreement 2011 (ACTA). ACTA sought to fight counterfeiting, but failed to distinguish criminal activity and civil infringement by extending enforcement to patent and ordinary trademark infringements (Maybarduk 2010: 3). Consequently, it was believed that ACTA would create legal uncertainty, impose costs, taint commercial disputes with ‘the air of criminality,’ and ‘divert resources and attention away from more direct and comprehensive measures to protect the public from unsafe products’ (Maybarduk 2010: 3–4). Specifically, from an access to medicines standpoint, the following proposed measures are undesirable:

- **Border measures requirements** that expand the scope of authorized seizures to any case where a border agent ‘suspects’ a medicine’s label of being ‘confusingly similar’ to a brand.
- **Injunction provisions** that require all ACTA members to put in place the basic legal elements that were used in the ‘Dutch seizures’ cases in the EU, enabling authorities in one country to issue injunctions preventing goods from entering commerce in a third country without that third country’s officials ever passing on whether the item would infringe its own laws.
• **Third-party liability rules** that increase risks of erroneous injunctions and seizures of property from distributors, shippers, procurement agents, and component suppliers of any generic product suspected of having a ‘confusingly similar’ label.

• **Damages provisions** that over-deter lawful conduct by encouraging determinations of damages in poorer countries based on the ‘market price’ or ‘suggested retail price’ of a branded product, even where that price is intentionally set at a level that excludes the great majority of a population from access to the product.

• **Information disclosure requirements** that could be used by right holders to discover details on distribution chains of generic companies and mount aggressive and expensive litigation against suppliers and intermediaries to deter generic entry into key markets.

• **Expansion of criminal liability** to cases where a supplier did not intentionally create or use the counterfeit label itself, thus raising the (over-)deterrent effect of trademark law for importers, including those of generic medicines.

• **Expansion of seizure and destruction rules** to require that, for example, absent ‘exceptional circumstances,’ a medicine found to have a minor trademark infringement on a label be destroyed rather than re-labeled and re-sold.

(Flynn and Madhani 2011: 2–3)

In terms of the implications of ACTA, Flynn and Madhani contend that:

On the whole, ACTA negotiators created an agreement that shifts international ‘hard law’ rules and ‘soft law’ encouragements towards making enforcement of intellectual property rights in courts, at borders, by the government and by private parties easier, less costly, and more ‘deterrent’ in the level of penalties. In doing so, it increases the risks and consequences of wrongful searches, seizures, lawsuits and other enforcement actions for those relying on intellectual property limitations and exceptions to access markets, including the suppliers of legitimate generic medicines.

(2011: 1)

In this regard, numerous health actors have opposed the issue of anti-counterfeiting and patent linkage; for example, under the TRIPS Agreement, the subject of IP for which the term ‘counterfeiting’ is used is limited to trademarks and copyright, and is not extended to patents. According to Baker, if patents are excluded, the health risk under ACTA will be reduced (2010: 2). The effects of the anti-counterfeiting measures proposed in ACTA are evident, especially in Europe. In 2008 and 2009, Dutch customs officials detained multiple drug shipments, based on Council Regulation (EC) No. 1383/2003, applying a manufacturing fiction doctrine (Baker 2010: 3). The risk in linking patents to counterfeiting is not limited to border seizures alone. Baker argues that injunctions may be used against active pharmaceutical ingredients manufacturers, international shippers, and other participants in the global trade of medicines, thereby effectively crippling the trade of generic medicines (2010: 4). Because of the potential risks that ACTA portends, it is not surprising that the European Parliament rejected the Agreement in toto (European Parliament 2012).

In Kenya, some of the arguments above were borrowed and utilized successfully in the *Patricia Asero* case, dating back to when Kenya first enacted its *Anti-Counterfeit Act* 2008. In 2009, the three petitioners living with HIV and AIDS opposed the law on the grounds that it violated their constitutional right to health, life, and human dignity. The UN Rapporteur argued for the right to the highest attainable standard of physical and mental health, and some civil society organizations joined the case as *amicus curiae*. The petitioners singled out sections 2, 32, and 34 of
The Anti-Counterfeit Act as potentially restricting access to generic medicines in the country. In particular, they argued that section 2 on the definition of counterfeiting conflated ‘counterfeits’ with ‘generics.’ The petition was granted, but the decision has yet to be implemented. In response to the decision, UNAIDS observed that the ruling will safeguard access to affordable and quality life-saving generic medicines (UNAIDS 2012). The decision of the Kenyan High Court seems to have contributed to the delayed enactment of anti-counterfeiting legislations in the African region.

22.2.4 Domestic application of access to medicines concepts in developing countries

This section examines the domestic application of access to medicines concepts in developing countries, focusing on pre-grant opposition in India, parallel importation and anti-counterfeiting in Kenya, compulsory licensing in Indonesia, and compulsory licensing in Latin America.

22.2.4.1 Pre-grant opposition in India

Depending on the country’s intellectual property system, a pre-grant opposition and/or a revocation (also known as post-grant opposition) may be exercised by concerned parties to challenge a patent duly filed with the relevant government department. One reason may be due to, inter alia, failure to meet the patentability criteria. According to article 62(4) of the TRIPS Agreement, revocation, opposition, and cancellation of patents should be governed by the principles set out in article 41(2) and (3). Article 41(2) provides for fair and equitable procedures. Article 41(3) requires that all decisions be reasoned and in writing. Lastly, article 32 of the TRIPS Agreement allows for judicial review of any decision to revoke or forfeit a patent. Arguably, a post-grant opposition procedure is preferable in an incentive patent based system to a pre-grant opposition that may lead to unnecessary delays in patent protection (Tripathi 2013).

India provides for both pre- and post-grant opposition. Opposition of patents in India is provided for under section 25 of the Patents Act 1970. Section 25(1) deals with pre-grant opposition generally. Similarly, section 25(2) addresses post-grant opposition. There are various grounds to base an opposition, including obtaining an invention wrongfully (sections 25(1)(a) and 25(2)(a), Patents Act) and if the invention was published before the priority date (sections 25(1)(b) and 25(2)(b), Patents Act). In the case of a post-grant opposition, it must be filed within one year from the date of publication of grant of the patent (section 25(2), Patents Act).

In early 2013, India won a case it had successfully filed against the pharmaceutical giant, Novartis, with regard to its cancer drug Gleevec. The case was initially filed as a pre-grant opposition and was later decided by the Supreme Court of India. In Novartis AG v. Union of India and others, Civil Appeals Nos. 2706-2716 2013, the Appellant, Novartis, had filed a patent renewal grant on 17 July 1998 for Imatinib Mesylate in beta crystalline form at the Chennai Patent Office (para. 8). The Appellant claimed that the application was valid because the ‘new’ product had ‘(i) more beneficial flow properties; (ii) better thermodynamic stability; and (iii) lower hygroscopicity than the alpha crystal form of Imatinib Mesylate’ (Novartis, para. 8). However, due to section 3(d) of the Indian Patents Act, the Appellant was ultimately unsuccessful: the application for patent renewal failed. Section 3(d) of the Patents Act is part of the amendments adopted by Parliament and which came into effect on 1 January 2005 (Patents (Amendment) Ordinance 2004). According to this section, a higher patentability criterion was introduced, requiring that
any new form of a known substance must also enhance the known efficacy of that substance. If this criterion is not met, the application for patent renewal must fail, as in Novartis. As stated by the Supreme Court of India:

Thus, in whichever way section 3(d) may be viewed, whether as setting up the standards of ‘patentability’ or as an extension of the definition of ‘invention’, it must be held that on the basis of the materials brought before this Court, the subject product, that is, the beta crystalline form of Imatinib Mesylate, fails the test of section 3(d), too, of the Act.

(Novartis, para. 190)

Novartis expanded access to medicines by addressing the problem of patent renewals known as ‘evergreening’. The decision has been praised worldwide: according to MSF, it was a major victory for ‘patients’ access to medicines in developing countries’ (2013c: 1). Indeed, this would have not been possible without the patent reforms of 2004/5. Novartis failed in its attacks against section 3(d) of the Patents Act, which aims at safeguarding the public health system in India (MSF 2013c). Other developing countries can learn from India’s example and provide better protection in their public health system by amending their patent laws.

22.2.4.2 Parallel importation and anti-counterfeiting law in Kenya

By definition, parallel imports/trade ‘occurs when products produced under the protection of a patent, trademark, or copyright in one market are subsequently exported to a second market and sold there without the authorization of the local owner of the intellectual property (IP) right’ (Matthews and Munoz-Tellez 2007: 1429). Parallel importation in Kenya is provided for under section 58(2) of the Industrial Property Act 2001 (IPA). This section provides for an international exhaustion principle opening the widest avenue possible to exploit this flexibility in the country. This utilization of the TRIPS Agreement parallel importation flexibility by Kenya constitutes best practice (Lewis-Lettington and Munyi 2004). Some tangible benefits of utilizing parallel importation include ‘lower pricing, improved stability of supply, and generally enhanced competition’ (Lewis-Lettington and Munyi 2004: 18). Nonetheless, others have noted that the utilization of parallel importation flexibility in Kenya has failed to promote access to essential medicines to the general public (Pharmacy and Poisons Board (Kenya) 2006). However, not in doubt is the steady growth of parallel importation in Kenya since its inception in 2002 (Nyaga 2009).

The anti-counterfeiting situation in Kenya is nuanced. In 2008, it enacted the Anti-Counterfeit Act 2008 amid opposition from civil society actors working around access to medicines locally and abroad. The basis of the opposition was that the definition of ‘counterfeiting’ under the law was TRIPS-plus. Of particular concern was the inclusion of patent linkage for generic medicines, as well as the ambiguous ‘counterfeiting’ definition under section 2. This led to a High Court petition, the Patricia Asero case, where the three petitioners argued that sections 2, 32, and 34 of the anti-counterfeiting legislation violated their constitutional rights to health, life, and human dignity, as they relied on generic medicines which would be restricted if the anti-counterfeiting legislation was enacted as drafted. Ultimately, the case was decided in favor of the petitioners, affirming important principles. First, it determined that human rights (life, human dignity, and health) supersede intellectual property rights. Secondly, it established that the right to health also encompasses access to affordable generic medicines. Lastly, it confirmed that international law applies directly to Kenya.

6 This term is used to mean that the standard adopted is higher than what is found under the TRIPS Agreement.
22.2.4.3 Compulsory licensing in Indonesia and Latin America

Compulsory licensing is permitted under article 31 of the TRIPS Agreement. As such, several countries, including Indonesia, have managed to intervene in HIV and AIDS treatment programs. In 2004, for example, the President of Indonesia issued a decree enabling a local manufacturer of antiretrovirals to offer affordable prices in Indonesia (2004). Similarly, Brazil followed this example for the AIDS drug Efavirenz. After amending its laws (Decree No. 3,201 1999), Brazil appealed to the public interest as another ground for issuing a compulsory license under article 71 of Brazil Law 9.279 1996. The introduction of this new ground allowed the Minister for Health to declare that Efavirenz was a public interest drug for HIV and AIDS (Minister of Health, 2007), enabling the President to decree a compulsory license for Efavirenz (Presidential Decree No. 6.108 2007). The decree was extended in May 2012 for another five years. In conclusion, compulsory licenses work elsewhere in promoting access to essential medicines, particularly in fighting HIV and AIDS.

22.2.5 Some threats to access to medicines at the national level

National budgetary allocations for health and unreliable bilateral funding and unsustainability of funding from the Global Fund pose formidable threats to access at the national level and each are discussed in turn in the following sections.

22.2.5.1 National budgetary allocation for health

The allocation of public resources in most countries is predominantly decided by way of a national budgeting process. The importance of health budgeting lies in its direct effects on service delivery, particularly to the poor and the vulnerable segments of the society who depend heavily on the public health system (Save the Children 2012). All health services, including doctors, medicines, and hospitals, have a cost (World Health Report 2010: 4). In fact, the government pays both directly to the health sector and indirectly through addressing the social determinants of health (WHO 2010: 23). Total external assistance is usually minimal in most cases. In 2007, for example, external assistance to the health sector for low-income countries was less than 25 per cent (WHO 2010: 23).

In 2001, African Union (AU) members pledged to commit at least 15 per cent of their national health budgets to improve the health sector (Abuja Declaration on HIV/AIDS, tuberculosis and related infectious diseases 2001). To date, only South Africa and Rwanda have achieved the set target (WHO 2011). Despite a 9.9 per cent increase in the government budget from 2009 to 2011, the Kenyan health budget witnessed a 13.5 per cent reduction in the same years (Sealy and Rosbach 2011). Consequently, most AU member countries, including Kenya, are not on track to achieve the health-related millennium development goals, such as that of eradicating HIV and AIDS. Moreover, access to essential medicines has also suffered due to lack of adequate health financing.

22.2.5.2 Unreliable bilateral funding

The past half-century has seen unprecedented public attention paid to global health. Increased funding, among other things, has assisted in the effort to ‘successfully eradicate smallpox, decrease AIDS mortality, and raise average global life expectancy from forty to sixty five’ (Council on Foreign Relations 2013: 1). However, in a recent report published in Health Affairs, the study
results show that as a result of the global financial crisis, the development of assistance for health has slowed down from 17 per cent in 2007/8 to 4 per cent in 2009 to 2011 (Leach-Kemon et al. 2012: 230). Similarly, the growth rate of health financing from bilateral agencies has decreased from 12 per cent in 2009/10 to 4 per cent in 2010/11 (Leach-Kemon et al. 2012: 231). This situation is precarious considering that development assistance for health from bilateral agencies was the major driver of a 14 per cent annualized growth rate in health initiatives (Leach-Kemon et al. 2012: 231). The current slow-down is a result of the US decision to slow its development assistance for health due to the global economic crisis (Leach-Kemon et al. 2012: 232). In order to maintain growth, the World Bank’s International Bank for Reconstruction and Development increased its development assistance by 128 per cent in 2010/11 (Leach-Kemon et al. 2012: 230).

22.2.5.3 Unsustainability of funding from the Global Fund

Equally affected by the global economic crisis is the Global Fund, namely because health assistance channeled through it decreased by 16 per cent between 2010 and 2011 (Leach-Kemon et al. 2012: 232). Disbursements from donors also continued to decrease with tides of the global economic crisis. In 2009, donors disbursed about 94 per cent of their commitments, but only disbursed about 78 per cent of their commitments in 2010. In response, the Global Fund scaled back its funding (Leach-Kemon et al. 2012: 232).

22.2.6 Current and emerging legal and ethical issues pertinent to access to medicines

The following analysis discusses access to medicines as an emerging issue. In particular, it reviews recent developments through a financial and research lens, respectively.

22.2.6.1 Financing side

Generally speaking, research and development is driven by market forces. The market for medicinal development in developed countries is supported either through private consumption or public funding (Lexchin 2010: 1). Consequently, developing countries are bearing the brunt of developing medicines for neglected diseases. We discuss briefly three solutions suggested by Lexchin: paying for innovation; priority review vouchers; and public-private partnerships (2010).

Paying for innovation entails an ‘advanced scheme to promote research into neglected diseases that are based on paying the innovator from a prize fund,’ such as the Health Impact Fund (Lexchin 2010: 6). The idea is to ‘incentivize the development and delivery of new medicines by paying for performance’ through an alternative registration mechanism that would promote access to essential medicines, particularly in developing countries, through a system of reward based on the actual health impact of the drug and not profitability (Lexchin 2010: 6). Despite slight differences, other countries share the same idea by basing ‘their payments on the therapeutic value of the new products’ (Lexchin 2010: 6).

Secondly, the priority review voucher system was initiated by the United States in September 2008 to promote research in neglected diseases. The US Food and Drug Administration (FDA) gives priority (up to six months priority period from the previous 12 months standard period) to a company’s products presented for registration, provided that it also conducts research and development on new drugs for neglected diseases (Lexchin 2010: 7). In 2009, for example, the FDA granted its first voucher to Novartis for its combination product (artemether/
lumefantrine, trade name Coartem) (Lexchin 2010: 7). The priority review is usually worth millions of shillings because it depends on the sales potential of the product, which is a sufficient incentive for research and development on drugs for neglected diseases (Lexchin 2010).

Lastly, public-private partnerships (PPP) do not predominantly engage in drug development but ‘integrate multiple industry and academic partners and contractors along the drug development pipeline; allocate philanthropic and public funds to the “right” kinds of R&D projects; and manage neglected disease R&D portfolios’ (Lexchin 2010: 8). Despite its successes, one major challenge is the lack of representation of developing countries on relevant boards (Lexchin 2010).

Other strategies include: advanced market commitments (AMCs); patent buy-outs; and patent pools. To begin, AMCs mean advance donor commitment to purchase drugs or vaccines for poor-country diseases as a way of spurring research and development on these diseases and ensuring that, if developed, these drugs or vaccines reach those who need them (Kremer and Glennerster 2004). The central pillar is to provide incentives through guaranteed economic returns at the time of investment and not at the time of the sale (Basheer 2012). Second, patent buy-outs can potentially promote greater access to medicines, particularly where they are purchased and put in the public domain, becoming available for public use, or are licensed to generic manufacturers (Outterson 2006).

Lastly, patent pools have also been proposed to create new combinations and formulations of needed medicines, as patent holders voluntarily offer, under certain conditions, the IP related to their inventions to the pool. Any company wanting to use the IP to produce or develop medicines can seek a license from the pool against payment of royalties (Bermudez and ‘t Hoen 2010). A good example is the UNITAID patent pool financing mechanism established in 2010. The project is dedicated to scaling up treatment, particularly for AIDS, tuberculosis, and malaria. The first agreement was signed in July 2011 between the Medicines Patent Pool and Gilead Sciences for HIV and Hepatitis B medicines for developing countries (UNITAID 2011).

22.2.6.2 Research side (global frameworks to support medical R&D)

Another important development in access to medicines is the discussion at the WHO on global frameworks to support medical R&D. In 2006, the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) brought to the fore the need ‘for an international mechanism to increase global coordination and funding of medical R&D’ in its report on Public Health Innovation and Intellectual Property Rights (2006: 91). In adopting the CIPIH Report, the WHO also put in place a Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property to which are anchored elements for prioritizing and promoting medical and R&D needs. Whereas discussions and negotiations towards actualizing the Global Strategy and Plan of Action have been mired by differences of opinion among countries, recent World Health Assembly resolutions reveal consideration for a three-pronged approach towards its fulfillment: the establishment of a global health R&D observatory; the setting up of demonstration projects; and the development of norms and standards to better collect data on health R&D. The ultimate wish for most developing countries is the negotiations and adoption of a medical R&D treaty for it is believed that such a treaty would provide a concrete and tangible plan on which frameworks for promoting and supporting medical R&D would rest.

7 For more information, see http://www.medicinespatentpool.org/who-we-are2/partners/.
22. Conclusion

Throughout this chapter, we have canvassed the issue of limited access to essential medicine in developing countries. The legal framework on the right to health and access to medicines was discussed. The ICESCR General Comment No. 14 2000 is crucial in that it recognizes access to essential medicines as a compulsory obligation of states parties to the ICESCR. The next part addressed WTO rules including the Doha Declaration, which codified a right for WTO members, particularly from developing countries, to avail themselves of the TRIPS Agreement flexibilities for intervening in public health cases like HIV/AIDS, tuberculosis, and malaria. The third part of the paper focused on threats to access to medicines including ACTA. ACTA has been discredited, particularly because it introduces a number of controversial provisions that limit the ability of developing countries to utilize TRIPS Agreement flexibilities, and will hamper access to essential medicines. The subsequent section discussed the domestic application of access to medicines concepts, including the granting of compulsory licenses in Brazil on public interest grounds. Some threats to access to medicines were also discussed with the global economic crisis affecting a significant number of health programs. Lastly, this chapter reviewed contemporary developments in the area of access to essential medicines. The current discussion on global frameworks to support medical research and development at the WHO is of tremendous importance.

References


Minister of Health (2007) Ministerial Portaria, No. 886 (Ordinance No. 886) (Brazil).


Paul Ogendi and Peter Munyi


The law and ethics of access to medicines in developing countries


Legislation


Anti-Counterfeiting Trade Agreement (ACTA) 2011.

Brazil Law No. 9.279 (Industrial Property Law) 1996.


Council of the European Union, Council Regulation (EC) No. 1383/2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights.

Decree No. 3, 201 on Compulsory Licenses in Cases of National Emergency and Public Health 1999 (Brazil).


Indian Constitution 1950.

Industrial Property Act 2001 (Kenya).

Kenyan Constitution 2010.


Patents (Amendment) Ordinance No. 7 2004 (India).

Patents Act 1970 (India).


South African Constitution 1996.


Universal Declaration of Human Rights 1948.
Paul Ogendi and Peter Munyi

Cases


*Novartis AG v. Union of India and others*, [2013] Civil Appeals Nos. 2706–2716.

*Patricia Asero Ochieng and others v. The Attorney General* (2009), Petition No. 409 (the High Court of Kenya).