

Chapter 2

Intellectual property and medicine

Towards global health equity

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Introduction

The past thirty years have witnessed an explosion in the development of new biomedical and genomics technologies and other health innovations, advances in medical imaging, an evolution in information technologies and connectivity, as well as significant progress towards technological convergence between the North and some areas of the Global South. Countries such as Brazil, China and India have developed innovation capabilities in many areas including medicine. These developments bring considerable hope for long-term improvements in human well-being. However, this progress has not been realized to any great extent in many developing countries, and access to quality health care and related products and services is still lacking.

In poverty dynamics, limited access to health care and relevant technological progress stems from a combination of factors. These include the lack of public financing for health care infrastructure, along with the lack of economic incentives for the private sector to invest in such infrastructure and to provide medicines (particularly for diseases that are not endemic in higher-income countries), inadequate or inappropriate regulatory frameworks, and lack of awareness of legal options relating to intellectual property (IP). These factors are coupled in many developing countries with insufficient scientific, technological and industrial capabilities, including the inability to fully exploit technologies towards meeting users' needs. Many studies reveal, moreover, the strong relationship between poverty and disease burden (McCarthy, Wolf & Wu 2000; Marmot 2005, pp. 1099–1104; Mathers & Loncar 2006; Roffe, Tansey & Vivas-Eugui 2006).²

This chapter first provides an overview of issues and trends where IP intersects with access to health care and health-related products. In discussing the latter, it is necessary to point out the broad range of therapeutic drugs, diagnostics and medical devices which may be considered as health-related products and services. These include, for example, therapeutic and prophylactic vaccines, drugs and diagnostics derived from a range of biological materials (e.g. peptides, genetic materials, carbohydrates and cells), other synthetic or natural chemicals, and numerous methods of assessment or treatment. It should be noted, furthermore, that the overlap between IP and medicine is complex, going beyond issues of access to medicines and other health-related products to cover the impact of IP on medical research and exchange of related knowledge.

Although it is impossible within the scope of one chapter to discuss all these areas in detail, some issues and trends of key relevance to developing countries are highlighted in Section 1. This is followed by a discussion of important initiatives at the international and local levels to deal with the severe problem of resurgent and 'neglected' diseases (so called for the lack of research investment targeted at them) in developing countries and least developed countries

(LDCs). Strategies adopted at the international level, particularly at the World Health Organization (WHO), are discussed in Section 2, along with alternative innovation models developed largely through public-private partnerships for research and development (R&D) of new vaccines and medicines for HIV/AIDS and other diseases (see further Appendix B).³ In Section 3, some future scenarios published by international and regional entities in relation to IP and health are described, along with analysis of their implications for human development.

1. Overview of intellectual property issues and trends relating to health

Several recent studies analyse IP through the lens of human rights, raising relevant questions and perspectives about the balance between the rights of inventors and creators and the public interest (Petersmann 2000, pp. 119–125; Chapman 2002, pp. 861–882; Anderson & Wager 2006, pp. 707–747; Barbosa, Chon & Von Hase 2007, pp. 114–123; Helfer 2007, p. 971). Human rights perspectives are becoming more and more important in reforms of IP policies and laws, especially in balancing the grant of exclusive intellectual property rights (IPRs) over innovations with rights of access to the benefits of science and technology.⁴

International human rights law imposes on States an obligation to respect, protect and fulfil the right to health. The latter is enshrined in Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), adopted by the UN General Assembly in 1966.⁵ General Comment No. 14 (2000) of the Committee on Economic, Social and Cultural Rights (CESCR) regarding this Article clarifies that the right to health embraces, among other things, the right to ‘health facilities, goods and services’ (including ‘essential drugs, as defined by the WHO Action Programme on Essential Drugs’).⁶ The right to health is also emphasized in Article 24 of the Convention on the Rights of the Child (CRC),⁷ interpreted by the Committee on the Rights of the Child in its General Comments No. 3 (2003) on ‘HIV/AIDS and the Rights of the Child’ and No. 4 (2003) on ‘Adolescent Health’ (Ovett 2006).⁸

Health and development promotion are also central components of the United Nations Millennium Project, expressed by the eight Millennium Development Goals (MDGs)⁹ – a series of time-bound targets set out at the Millennium Summit in September 2000 – to be achieved by 2015 (Millennium Project 2005; see Chapter 6, Box 6.1). Several of these goals are directly or indirectly related to improving health; this includes, for example, the MDGs aiming to ‘eradicate extreme poverty and hunger’ (MDG1), to ‘reduce child mortality’ (MDG4) and to ‘improve maternal health’ (MDG5). The sixth goal under the MDGs explicitly addresses combating ‘HIV/AIDS, malaria and other diseases’. The Target for 2015 under this goal is to ‘halt and begin to reverse the spread of HIV/AIDS and the incidence of malaria and other major diseases’ (MDG6). Under MDG8, which is to ‘develop a global partnership for development’, one of the stated targets is to provide access to essential drugs in developing countries in cooperation with pharmaceutical companies.¹⁰

The linkage of intellectual property rights (IPRs) to the world trade regime through the Agreement on Trade-Related Aspects of Intellectual Property Rights (‘TRIPS Agreement’),¹¹ signed in 1994 by members of the newly established World Trade Organization (WTO), effectively introduced new minimum standards of IP protection for WTO members. Significantly, the Agreement required WTO members to extend patentability to inventions in all

technological fields. Although the TRIPS Agreement does not define what constitutes an ‘invention’ or a ‘technological field’, leaving these terms open to interpretation, countries that formerly did not grant patents to pharmaceutical products or processes have been under pressure to alter their legislation within the implementation deadlines provided by the Agreement.¹² Such implementation has had a worldwide impact on the entire structure of the generic and innovative medicines industries as well as on pricing strategies.

The impact of the TRIPS Agreement on health access in developing countries and LDCs has been a source of tremendous controversy. On one hand, there are proponents who argue that effective patent protection is necessary to encourage innovation and investment in pharmaceutical and related medical technology research; on the other hand, there are voices that emphasize alternative public-private models for R&D, and the promotion of the public interest through appropriate TRIPS revisions and/or the use of existing TRIPS flexibilities (including those with the potential to refuse to grant or enforce patents, or to otherwise weaken patent protection). The latter strategies include creating policies and/or structures that guarantee the use of all TRIPS exceptions and limitations without the threat of penalties or sanctions from WTO members.

A significant development in relation to TRIPS and public health was the adoption of the Declaration on the TRIPS Agreement and Public Health at the WTO’s Fourth Ministerial Conference in Doha, Qatar, on 14 November 2001 (the ‘Doha Declaration’).¹³ The latter Declaration followed much public scrutiny, activism by civil society, and demands by developing countries especially over the impact of TRIPS on issues such as access to essential medicines in developing countries. Confrontation on access to medicine and competition issues between the South African government and pharmaceutical companies (over legislative reforms in South Africa aimed at facilitating parallel importation of patented drugs and generic substitution of off-patent drugs) was partly responsible for catalysing the international mobilization that resulted in the Doha Declaration.¹⁴ Intended to ensure that TRIPS provisions would not prevent countries from protecting public health, the Doha Declaration clarifies that the TRIPS Agreement should be interpreted and implemented in favour of WTO members’ right to public health protection. Significantly, its provisions restate and reinforce some of the flexibilities contained in the TRIPS Agreement, such as freedom to grant compulsory licences for any reason (although under specified procedures) and freedom to establish parallel importation regimes. It emphasizes that practices related to the use of such flexibilities cannot be the subject of dispute settlement at the WTO. The Doha Declaration further provides that LDCs have the option to delay implementation until 2016, a time flexibility which these countries should make full use of. Other decisions at the WTO since the Doha Declaration have sought to clarify aspects of TRIPS flexibilities relating to public health and the implementation of the Doha Declaration.¹⁵

It is important for developing countries to be able to take full advantage of the exclusions from patent eligibility or patentability provided under the TRIPS Agreement. The law in this area is in flux. A number of court and administrative decisions (some pending) in the United States (US) and Europe concerning the scope of patent eligibility and the required level of inventive creativity could preclude or restrict patents on at least some drugs, genetic sequences and diagnostic methods even in developed countries.¹⁶

Some other areas that will receive increasing scrutiny include the potential for developing countries to make better use of compulsory licensing or refusals to enjoin infringement of health care-related patents (providing only compensatory remedies), and appropriate laws in relation to parallel imports in ensuring public health targets. These and other key issues and trends relating to IP and health, both within and beyond the TRIPS context, are briefly highlighted in the following sections, along with some projections on areas of growing significance.

1.1. Trends in pharmaceutical patenting and their implications for new innovations and generic production

It has been argued that IP protection (particularly patent protection) is essential to maintaining drug development efforts, especially in light of the rising costs and complexities in the development of new drugs. However, higher standards in patent protection do not necessarily induce the development of new pharmaceutical inventions. In recent years, there has been increasing emphasis in the R&D policies of many pharmaceutical companies on new therapeutic uses for known drugs and minor modifications to them. Firms now strive to obtain patents in the largest world markets to protect these new uses and modifications. For example, the United States Food and Drug Administration (FDA) has reported that new drug applications have increasingly been submitted for variations of existing drugs, rather than for more innovative molecules (FDA 2003, 2004; Taylor 2003, pp. 408–409). According to the FDA, increases in these so-called ‘me-too’ drugs have been paralleled by decreases in the development of new drugs more likely to be truly innovative (FDA 2003).

Some studies focus on the effectiveness of the patent as a means of appropriability (i.e. the ability to capture returns accruing as a result of innovation) for the pharmaceutical industry (Mansfield 1986, pp. 174–175; Levin et al. 1987, pp. 795–796; Cohen, Nelson & Walsh 2000). Appropriation regimes vary from industry to industry due to differing motivations, and few other industrial sectors place such a high strategic value on patents as the pharmaceutical sector. In practice, ‘appropriation’ in the pharmaceutical sector is sometimes achieved through the ‘evergreening’ of patents, where manufacturers extend the life of their patent monopolies by filing new applications on minor modifications to the invention disclosed in the original patent, and also by adopting aggressive marketing strategies to get doctors to switch their patients over from an original drug going off patent to a new ‘upgraded’ version sold under a different name that may offer little if any therapeutic advantage over the first drug.¹⁷

In 2006, the Canadian Supreme Court set a precedent against the practice of ‘evergreening’ in a ruling in favour of a Canadian generics manufacturer,¹⁸ but the issue is nonetheless highly case specific. India has also passed legislation that seeks to prevent this practice. The relevant provisions in this legislation were challenged by Novartis in the Indian courts on the basis that they were in conflict with India’s obligations under the TRIPS Agreement and in breach of the Indian Constitution.¹⁹ Novartis’s challenge failed. However, there was no decision on whether these legislative provisions are consistent with the TRIPS Agreement, because the Indian court held there was lack of jurisdiction.²⁰ The Brazilian Government has also taken an aggressive stance towards ending abuses related to ‘evergreening’. However, the Brazilian Government’s 2008 decision to ban the patentability of new uses for

known drugs and other trivial inventions is still under criticism from part of the pharmaceutical industry and the Brazilian Association of Intellectual Property.

With patents increasingly being used to protect new uses for old drugs (particularly for diseases for which reasonably effective treatments already exist) and small changes to existing compounds such as new drug dosages or forms, questions have been raised as to whether patents are doing enough to encourage the development of new chemical entities that are significant improvements on existing medicines.²¹ Perhaps the most significant factors contributing to the proliferation of ‘me-too’ drugs or new uses of existing drugs in the US are the elasticity of the novelty rules and the existing threshold for the test of ‘non-obviousness’ for patent grants. ‘Non-obviousness’ (or ‘inventive step’ in other jurisdictions including in Europe) is one of four traditional and internationally accepted requirements for the grant of a patent. The other three requirements are ‘novelty’ (i.e. that the invention be new), ‘utility’ (i.e. that it be useful or have ‘industrial applicability’), and that the ‘invention’ is adequately described in the proposed patent and thus ‘enabled’ (Barton 2003, p. 475). Barton explains that:

The novelty and non-obviousness principles are designed to work together to ensure that the patent monopoly is available only for genuinely new inventions. The novelty standard asks whether the invention has been previously described or practised; thus, it seeks to determine whether the invention is already within the existing state of the art. The non-obviousness principle asks whether the invention is an adequate distance beyond or above the state of the art; it clearly and unavoidably, therefore, involves an exercise of judgment. (Ibid., pp. 475–476)

Barton argues that ‘contemporary patent law has weakened [the] non-obviousness requirement, leading to the grant of many patents on trivial inventions’ which he considers to be ‘economically wasteful’ (ibid., p. 475). Examining the non-obviousness standard, he explores ways to set the standard at a level that rewards significant inventions and avoids a proliferation of economically undesirable patents (ibid.). While the TRIPS Agreement does not harmonize the level of creativity required to obtain a patent, economic theory suggests that a heightened non-obviousness requirement creates incentives for investment in more innovative – as opposed to ‘me-too’ – drugs and other relevant technologies. Since 2007, a significant US Supreme Court decision²² has been thought to raise the bar in regard to showing non-obviousness (particularly in regard to new combinations that do not have new functions or significantly improved efficacy), with implications for pharmaceutical patents.

The effects of patent grants for second and subsequent uses of drugs²³ have been observed to result in delaying entry of new generic medicines in local markets (Correa 2007).²⁴ By generic drugs we mean drugs that are produced and distributed without patent protection but with the same dosage, safety, quality and efficacy as the branded drug. Box 2.1 presents some recent trends in relation to world generics production and patent protection of pharmaceuticals.

Box 2.1. Generics and the price of medicines²⁵

The TRIPS Agreement requires WTO members to provide patent protection for inventions in all technological fields (Article 27).²⁶ The implementation deadline for developed countries was 1996. The Agreement provides additional time for developing countries and LDCs to put in place patent regimes for certain technologies and products, including pharmaceuticals. Developing countries that had already granted patents for pharmaceutical products had to implement the relevant provisions in TRIPS by 1 January 2000 (Article 65(2)). Developing countries that had not granted products patents for an area of technology could further delay the introduction of such legislation until 1 January 2005 (Article 65(4)). The Doha Declaration (para.7) has extended this deadline to 2016 for LDCs.

India has been one of the world's largest producers of generic medicines. It has a strong pharmaceutical industry, primarily in the production of generics, and it has taken significant advantage of its ten-year transition period under the TRIPS Agreement to consolidate this industry further. Bulk drug production in India increased by nearly 20% every year in the period between 1993 and 2003 (Joshi 2003). The country has been producing generic versions of essential medicines not just for its population but for patients in other developing countries and LDCs. Countries in Sub-Saharan Africa, for example, lacking their own pharmaceutical production capabilities, rely on imports of medicines and active pharmaceutical ingredients²⁷ from countries that produce them at low cost, including India and China. In 2001, an antiretroviral (ARV) therapy using branded medicines typically cost US\$10,000 or more in the developed world (Fleshman 2005). That same year, Cipla – one of the largest Indian generic pharmaceutical companies – offered the therapy to humanitarian groups for use in Africa at the much lower price of US\$350 per patient per year (ibid.). One estimate suggests that the price for first line generic ARV drugs procured for countries in Sub-Saharan Africa further decreased to US\$114 per patient per year by 2006 (Chien 2007).

China and Thailand are among other countries which have taken advantage of the TRIPS extension period to produce low-cost generic medicines. Now that the extension period for TRIPS compliance has expired for these developing countries, this freedom will be affected. The full impact of TRIPS compliance on the structure of global generic production remains to be evaluated. While a number of years have passed since India issued its presidential decree²⁸ to conform to the 2005 deadline, a study by Janodia et al. (2008) suggests that it is still too early to examine its full effect.²⁹ The Indian decree will affect the prices of first line medicines for patients. Of further concern to public health advocates, it will drive up the prices of second and third line drugs.³⁰

Some commentators suggest that compulsory licensing provisions in the TRIPS Agreement should be invoked by countries manufacturing generics in order to continue exporting to other countries (Kuanpoth 2007, p. 214; see Section 1.2). While the TRIPS Agreement requires that a compulsory licence be granted 'predominantly' for the supply of the domestic market, there is still some room for exports under Article 31(f) of the Agreement (ibid.). Moreover, in cases where a compulsory licence has been granted to remedy anti-competitive practices, there is no export restriction (ibid.). Kuanpoth (2007, p. 214) highlights that the Doha Declaration, along with the WTO Decisions of August 2003 and December 2005,³¹ permits the export of medicines to a country with insufficient or no manufacturing capacities in the pharmaceutical sector.

Developing countries and LDCs, especially those lacking these manufacturing capabilities, should explore flexibilities under the TRIPS Agreement to import generics from countries which produce them. Kuanpoth (2007, pp. 203–204) points out, for example, that the price of ARVs in Vietnam is generally 'much higher than current international best prices'; he adds that 'the

production and importation of several generic ARV drugs, needed in order to provide treatment in line with international and WHO standards at affordable prices, is not feasible without infringing patents' in Vietnam. He suggests that countries like Vietnam may need to avail themselves of the available legal options under the TRIPS Agreement and national laws to ensure the availability of these medicines, including through parallel imports and imports of drugs sold by other countries under compulsory licensing (ibid., pp. 213–215; see Section 1.2).

Many countries that until now have benefited from imports of inexpensive generic drugs are also increasingly dependent on international regulatory bodies to create other sources of inexpensive medicine. Further developments in this area will significantly impact IP regulations, the pharmaceutical market and public health decisions in all countries. Given competition from generics and the fact that many 'blockbuster' drugs under patents since the early 1990s are going off patent (e.g. the 'cholesterol-reducing' drug Lipitor® is going off patent in 2011), brand-name pharmaceutical companies are also under pressure to adjust their pricing policies,³² and are entering increasingly into generic production. In February 2009, the world's second largest pharmaceutical company, GlaxoSmithKline, allegedly announced that it would cut its prices for all drugs in the fifty LDCs to no more than 25% of the levels in the UK and US, while also taking steps such as placing any chemicals or processes over which it has IPRs that are relevant to finding drugs for neglected diseases into a 'patent pool'.³³ Some health campaigners are concerned, at the same time, that such moves may undermine the generics industry currently supplying the cheapest drugs in poor countries; Oxfam and Medecins Sans Frontières have suggested that any patent pools created should include the HIV/AIDS drugs (see Appendix B for an update on such patent pools).³⁴

Generics have to be contrasted with counterfeit medicine, as emphasized at the World Health Assembly (WHA) in May 2008. The WHO defines counterfeit medicines as 'deliberately and fraudulently mislabeled [medicines] with respect to identity and/or source'.³⁵ According to this definition: 'Counterfeiting can apply to both branded and generic products. Counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients, or with fake packaging'.³⁶ The use of counterfeit drugs can have negative consequences on the health of patients taking the drugs. Often the drugs contain no active ingredients and can therefore exacerbate the disease and cause resistances among wider sections of the population.³⁷

The WHO has developed international guidelines and recommended national strategies and measures to put a stop to the growing problem of counterfeit drugs.³⁸ Recognizing that international collaboration against counterfeits is an issue affecting both developed and developing countries, WHO organized a conference 'Combating Counterfeit Drugs: Building Effective International Collaboration' in 2006. The meeting was concluded with the 'Rome Declaration',³⁹ in which countries agreed that: 'Counterfeiting medicines...is a vile and serious criminal offence that puts human lives at risk and undermines the credibility of health systems...Because of its direct impact on health...[it] should be combated and punished accordingly' (Articles 1–2). The Declaration called for a concerted action from all relevant private and public stakeholders. It also called for the creation of the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) to raise awareness, coordinate efforts, and exchange information between countries to combat counterfeit medicines globally (Article 6 of the Declaration). The IMPACT approach has been heavily criticized, however, by many developing countries. There is also disagreement on the very use of the term 'counterfeit drugs', an issue which was discussed amongst others at the 124th Session of the WHO Executive Board,

in Geneva, on 19–27 January 2009.⁴⁰ It is relevant to highlight a recent seizure by the Netherlands authorities of losartan potassium (a drug used primarily to treat high blood pressure) in transit from India to Brazil on grounds that IPRs might be violated due to the existence of a patent right in the Netherlands. This seizure was considered a violation of WTO rules by the Brazilian government, as losartan was not patented in India or Brazil, among other reasons.

Indeed, there is a very real danger that anti-counterfeiting measures based upon unduly broad or vague definitions of ‘counterfeit’ medicines could inhibit the trade, supply and sale of perfectly legitimate generic drugs.⁴¹ According to legislation recently passed in Kenya (the Anti-Counterfeit Act 2008),⁴² counterfeiting refers to a range of actions which are done ‘without the authority of the owner of any intellectual property right subsisting in Kenya or elsewhere in respect of protected goods’ (Article 2).⁴³ This appears to go too far, blurring the meaning of the term and potentially enabling owners of patents not necessarily held in Kenya to have the importation, domestic manufacture and supply of otherwise perfectly legitimate generic drugs suppressed. It also reduces Kenya’s abilities to take advantage of the flexibilities of TRIPS, fails to address the possible problems of originator firms selling poor quality versions of their own drugs, and may possibly exclude those fakes that do *not* infringe on any IPRs.⁴⁴ Uganda has reportedly drafted similar legislation.

Issues have also been raised over the extent to which generic manufacturers are able to import, manufacture and test a patented product prior to the expiration of the patent in order that they may fulfil the regulatory requirements imposed by particular countries for marketing the drug as a generic. Such acts are now made legal in the US by the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the ‘Hatch-Waxman Act’), which overturned a landmark court decision (*Roche v. Bolar*, 1984)⁴⁵ by introducing what is now known as the ‘Bolar Exception’ or ‘early working exception’ to patent infringement. The WTO legality of a similar exception was confirmed in 2000 in a dispute settlement case brought by the European Union (EU) against Canada.⁴⁶ The Commission on Intellectual Property Rights (CIPR) notes these developments in its seminal 2002 report on *Integrating Intellectual Property Rights and Development Policy* (hereinafter ‘CIPR Report’). The report recommends that: ‘Developing countries should include an appropriate exception for “early working” to patent rights in their legislation, which will accelerate the introduction of generic substitutes on patent expiry’ (CIPR 2002, p. 50). Of the sixty-three developing countries whose legislation was examined by the CIPR study, only eight specifically included a Bolar exception (*ibid.*). Nevertheless, many countries have experimental use exceptions that may extend to experimentation for generating test data required to obtain regulatory marketing approval.

1.2. Compulsory licensing and government use

Given that a major purpose of the TRIPS Agreement was to require the extension of patents to pharmaceutical products and processes for their manufacture,⁴⁷ the generic production of drugs will be increasingly restricted as countries implement the Agreement. A substantial amount of focus has shifted to the authorization for exceptions to the exclusive rights that must be provided under the TRIPS Agreement, especially in relation to compulsory licensing and government use which may have an important role to play in maintaining a ‘pro-competitive IPR policy in the new environment’ (CIPR 2002, p. 42). TRIPS Article 31 does not prohibit the issuance of compulsory licences or governmental uses on any grounds, but rather imposes procedures

(including compensation) in the event of such licences or use. In cases of national emergency, extreme urgency and public non-commercial uses (under Article 31(b)), no prior efforts to obtain patent holder authorization are required. Although Article 31(f) required that such compulsory licences or government use be primarily for domestic markets, the Doha Declaration waived Article 31(f) in the case of countries seeking to export medicines to developing countries where production capacity does not exist.

Developing countries have yet to make full use of their retained compulsory licensing authorities, even though this is allowed under the TRIPS Agreement as clarified by the Doha Declaration. Concern by developing countries over reprisals from investors might be one reason. The CIPR Report notes that ‘ironically, it is the developed countries that have been the most active users of compulsory licensing (not only in the pharmaceutical field) for a number of purposes, including importantly in antitrust cases in the U.S.’ (CIPR 2002, p. 42). According to the report, Canada used compulsory licensing extensively in the pharmaceutical field from 1969 until the late 1980s, with the result of prices of licensed drugs being 47% lower than in the US in 1982 (ibid.).

More recently, two countries – Brazil and Thailand – announced compulsory licences for pharmaceuticals. Thailand issued compulsory licences on 26 January 2007 for the heart disease drug clopidogrel (Sanofi-Aventis’s Plavix[®]) and the HIV/AIDS drug lopinavir/ritonavir (Abbott’s Kaletra[®]) and on 29 November 2006 for the HIV/AIDS medicine efavirenz (Merck Sharp & Dohme’s Stocrin[®]) (Gerhardsen 2007). After declaring efavirenz a medicine of public interest, Brazil issued a compulsory licence for this patented AIDS drug on 4 May 2007, as price negotiations failed.⁴⁸ As expected, pharmaceutical multinationals strongly criticized these decisions. Since May 2007, efavirenz has been imported from India into Brazil through the United Nation’s Children’s Fund (UNICEF) and the Pan American Health Organization (PAHO). In September 2008, the Brazilian Minister of Health Jose Gomes Temporao announced that the ‘bioavailability’ tests were positive. The generic version of efavirenz is now being produced in Brazil. This generic version is expected to reach a final production cost close to the price that is paid for the Indian generic. Further analysis is required on the implications of these decisions for access to drugs in developing countries.

The approaches of Brazil and Thailand to ensure access to key ARV drugs had been different until recently. Ford et al. (2007, p. S24) note in the case of Brazil that ‘price negotiations, backed by the threat of compulsory licensing and local generic production, have been the main strategy used by the government to lower the price of patented antiretroviral drugs’. In contrast, direct negotiations with pharmaceutical companies have had mixed success in Thailand, where strategies to reduce the cost of antiretroviral drugs have focused on ‘patent challenges and compulsory licensing’ (ibid., p. S26).

The use of compulsory licences under the TRIPS Agreement is related to a larger trend towards wider use of alternative licensing techniques. Companies in South Africa and Brazil, for example, have obtained voluntary licences for AIDS drugs, sometimes with their government’s assistance. Patent pooling, in which patent holders agree not to assert certain patents against each other (usually by entering into cross-licensing agreements relating to a particular technology), is also used to reduce barriers to drug development (see Appendix B). This route is also being

explored for AIDS drugs by UNITAID, a WHO-hosted international drug purchasing facility. These innovative mechanisms can help to improve access to needed medicines and are likely to be used increasingly by developing countries, especially when associated with incentives for local production.

Similarly, significant potential exists for governments to make greater public, non-commercial uses of patented pharmaceutical technologies, as authorized under Article 31(b) of the TRIPS Agreement. Even without government-directed production actually resulting, the potential for such production may dramatically affect licensing behaviours or prices. For example, the US government has statutory authority to use any patented technology, subject to a potential lawsuit for the patent holder to obtain reasonable compensation.⁴⁹ In late 2005, in response to concerns about a possible avian influenza pandemic, the US government considered exercising this authority to authorize generic production of avian flu vaccine, following which additional production was voluntarily licensed by the patent holder.

1.3. Revisiting exclusions from patentability under the TRIPS Agreement

Discussions on flexibilities under the TRIPS Agreement sometimes ignore the significant flexibility WTO members retain over what they can exclude from patentability in the first place. Under Article 27(2) of the TRIPS Agreement, ‘members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment...’.

The patentability of biotechnological inventions gave rise to discussions on the application of moral grounds for refusing to grant patents. Article 27(2) of TRIPS only authorizes members to exclude (from patentability) inventions where preventing *commercial exploitation* ‘is necessary to protect *ordre publique* or morality’; Article 27(3)(a) further authorizes exclusions for medical, surgical and diagnostic methods for treating humans or animals. Many countries have adopted such exclusions. The Directive 98/44/EC of the European Parliament on the legal protection of biotechnological inventions says that ‘inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality’.⁵⁰ The Directive’s implementation in many EU countries was controversial due to the different positions of private and public sectors and non-governmental organizations. Outside the EU, many other countries either have laws with provisions on moral exclusions for certain biotechnology patents or exclude ‘immoral’ patents under a general morality exclusion authority, such as the Brazilian Industrial Property Law.⁵¹ Some kinds of subject matter such as embryonic stem cells and gene sequences are especially controversial, raising ethical and moral concerns. Further studies are needed to assess the current and potential scope of the morality criterion in various countries.

Countries thus have significant flexibility in the interpretation of these provisions and on what they choose to exclude from patent protection. In addition to flexibilities in the interpretations of ‘*ordre public* or morality’, the term ‘invention’ is not defined specifically in the TRIPS Agreement and Article 27(1) of the Agreement requires countries to authorize patents only for inventions that are ‘capable of industrial application’. Most countries explicitly or by interpretation exclude from the definition of an invention newly discovered scientific principles

and naturally occurring materials.⁵² A number of developing countries have sought to limit what constitutes a patentable invention by legislation or judicial interpretation. By way of example, the Common Industrial Property Regime of the Andean Community countries provides that the following shall not be considered as inventions: ‘Any living thing, either complete or partial, as found in nature, natural biological processes, and biological material, as existing in nature, or able to be separated, including the genome, or germplasm of any living thing’ (CIPR 2002, p. 115).

In contrast to the provision under the Andean Community mentioned earlier, genes and gene fragments may be covered within the scope of patentable subject matter in some other jurisdictions, including the US. Article 27(3)(b) of the TRIPS Agreement provides that members ‘may’ exclude from patentability ‘plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes’, but falls short of making it mandatory for WTO member states to exclude such plants, animals and processes from patentability. The future will likely see increasing debates in developed and developing countries over the scope and ethics of IPRs in regard to natural materials or medical and agricultural discoveries and inventions involving genes, gene fragments and genetically modified organisms (GMOs). Apart from ethical questions relating to the ‘patenting of life and life-forms’, there are debates as to whether such patents affect the advancement of research in the biomedical field, for example through restrictions on third-party use of research tools protected by patents. As highlighted in a report by Cornish, Llewelyn and Adcock (2003) entitled *Intellectual Property Rights (IPRs) and Genetics: A Study into the Impact and Management of Intellectual Property Rights within the Healthcare Sector*:

Genetic research into diagnosis and therapies for humans now grow out of our new knowledge of the structure of the human genome and that necessarily conditions the work which can effectively be undertaken. It is therefore a field in which the existing rules governing the validity and scope of patents need to be applied with a real awareness of the new conditions for research and commercial exploitation in this field. The scope of what is patentable in pharmacology has, as we have sought to suggest, expanded very considerably. It has to be asked at what points there should be some retraction for the biotechnology industry and those who make use of the results of its research.
(Ibid., p. 23)

One of the issues highlighted by Cornish et al. for further scrutiny is the concern that ‘the simple identification of genes and partial fragments does not disclose any requisite industrial application and are therefore discoveries rather than inventions’ (ibid., p. 30). For this reason, the European Biotechnology Directive requires identification of such an application to support patenting of genetic materials.⁵³ The authors also note that the enforcement of patent rights over genes which are used, for example, in diagnostic tests may require further scrutiny in terms of their impacts on costs for administration of such tests on patients, and on who has access to test results for future research (Cornish et al. 2003, p. 30). Concerning exclusions from patentability under the TRIPS Agreement, in the field of biotechnology the Brazilian Industrial Property Law does not consider as patentable living beings, in whole or in part, except transgenic

microorganisms meeting the three patentability requirements – novelty, inventive activity and industrial application⁵⁴ – and which are not mere discoveries.⁵⁵

1.4. Exceptions to exclusive patent rights

Article 30 of the TRIPS Agreement states that WTO members may provide limited exceptions to the exclusive rights conferred by a patent, provided that ‘such exceptions do not unreasonably conflict with normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties’.

There is significant debate over the scope of these exceptions, for example, in terms of the extent to which WTO members can provide for research exemptions including experimental use of an invention subject to a patent. The scope of such exemptions varies significantly with jurisdictions. Comparing the scope of research exemptions under European and US law, Holzapfel and Sarnoff (2008) highlight the uncertainties that remain in both contexts. They note that in the US, the Supreme Court has adopted a broad construction of the regulatory approval exception to patent law infringement (under 35 U.S.C. § 271(e)(1)) for experiments conducted at early stages of the pharmaceutical development process (ibid., 2008). While this was the decision in the case of *Merck KGaA v. Integra LifeSciences I Ltd.*,⁵⁶ Holzapfel and Sarnoff (2008) qualify that the Supreme Court in that case refused to determine whether that exception applies to patented ‘research tools’; a more recent appellate case, *Proveris Scientific Corp. v. Innovasystems, Inc.*,⁵⁷ limited application of the exception to patented inventions that are themselves potentially subject to regulatory approvals and thus could qualify for term extension provisions.

According to Holzapfel and Sarnoff (2008), the European experimental and regulatory approval exceptions may be subject to fewer interpretive uncertainties, particularly in light of decisions such as the UK *Monsanto* and German *Klinische Versuche (Clinical Trials)* cases.⁵⁸ However, they note that the nature and scope of the European exceptions may vary significantly among jurisdictions based on national legislative decisions to limit or extend patent protection – for example, the experimental use exception recently adopted in Belgian law⁵⁹ expressly applies to patented research tools. The authors assert that ‘determining the proper scope and application of experimental use and regulatory approval exceptions remains a pressing concern in the United States as well as in Europe’ (ibid., p. 127). These exceptions assure that patent laws intended to provide incentives for technological innovation do not unduly restrict scientific research, innovative medical product development and generic product competition.

A full discussion on research exemptions is beyond the scope of this chapter. In relation to biotechnological patents, Cornish et al. (2003) highlight that one major ambiguity about the experimental use exception concerns how far clinical tests can be regarded as ‘experimental use’ covered by a research exemption to patent liability, since treatment and the continuing search for further genetic knowledge often go hand in hand (Cornish et al. 2003, pp. 24–25). They note that as research on genetic diagnosis and therapy grows in volume and effectiveness the question of clinical testing, in particular resolving whether clinical trials fall within an ‘experimental use’ exception, will become an urgent issue (ibid., p. 32). While their discussion relates mainly to European law, it is highly relevant to other jurisdictions in resolving these difficult questions.

Other exceptions to the TRIPS requirements for exclusive patent rights also may be adopted. Little jurisprudence exists on the application of Article 30, or its correlate for exclusive copyrights in Article 13. However, it is clear that in determining whether national exceptions will conform to Article 30, contentious issues will arise in regard to the normative evaluation of such issues as ‘normal exploitation’, ‘unreasonably prejudice’, and the ‘legitimate interests’ of patent holders and the public (Holzapfel & Sarnoff 2008, p. 178).

1.5. Price controls, competition regulation and parallel imports restrictions

Additional concerns regarding affordable access to medicines pertain to the nature of the rights granted by patents, and how those rights relate to markets and to prices for patented products. There are significant policy questions for individual countries as to the extent to which the grant of patent rights should be subject to price and competition regulations. Given that a patent may convey monopoly economic power in the relevant product market for a pharmaceutical, it may also convey the ability to price medicines at supra-competitive rates, creating a dominant position for the patent holder in the relevant product market. The TRIPS Agreement simply does not address the relationship between the legal right to exclude and the ability of the government to regulate the prices of patented products. Many countries set the prices of patented medicines directly through government regulation or negotiate significantly lower prices through uses of formularies. Similarly, most competition laws impliedly or expressly apply to patent holders, and some countries have provisions in their competition laws that treat excessive price-setting among other practices as potential abuses of dominant position. Some jurisdictions also consider the use of patents to block all competition in a particular market under the essential facilities doctrine to give rise to such remedies as requiring competitors to be supplied with access on reasonable and non-discriminatory terms.

Article 31(k) of the TRIPS Agreement recognizes the relationship between IP and competition laws, providing that compensation of patent holders is not required when compulsory licences are issued to remedy anti-competitive practices. But there are no minimum international standards in the TRIPS Agreement or elsewhere on the substance of what competition laws must require or may permit. Article 40 of the TRIPS Agreement specifically recognizes national authority for members to adopt prohibitions on licensing practices that are thought to constitute an abuse of IPRs and to have adverse effects on competition.

Significantly, IP in general and patents in particular are normally understood to grant only rights to exclude competition.⁶⁰ Exclusive rights do not themselves authorize the sale or use of products or services (including medicines whose marketing requires prior regulatory approval). Nor do they provide any legal authority in regard to prices that may permissibly be charged for such products or services. However, countries differ significantly in their views regarding the extent to which IPRs may grant immunity from competition requirements (e.g. by authorizing exclusionary conduct that would otherwise violate competition laws), or the extent to which IP rights holders may leverage those rights in regard to additional markets or downstream users.⁶¹

Extensive regulation of price or extensive compulsory licensing of patented technologies to remedy broadly defined anti-competitive behaviours could theoretically be challenged either

on the grounds that doing so conflicts with expectations regarding mandatory Article 28 exclusive rights (beyond what is authorized under Article 30 exceptions authority) or denies the benefit of such rights, potentially rising to the level of a ‘non-violation’ complaint (although there is currently a moratorium in effect on such complaints in regard to TRIPS Agreement obligations). However, such challenges are unlikely to succeed without further development of consensus regarding the nature of the relationship of IP rights to price and competition policies. The relationship of patent rights to prices and competition concerns remains the subject of substantial dispute in some countries, and is likely to be the focus of significant attention in the near future.

A closer watch should be kept on an inquiry into competition in the pharmaceuticals sector launched in 2008 by the European Commission.⁶² There are indications that competition in European pharmaceutical markets may not be working well. Fewer new drugs are being brought to market, and the entry of generic pharmaceuticals seems to be delayed. The inquiry set out to investigate whether: ‘agreements between pharmaceutical companies, such as settlements in patent disputes, may infringe the EC Treaty’s prohibition on restrictive business practices (Article 81)’; ‘companies may have created artificial barriers to entry, whether through the misuse of patent rights, vexatious litigation or other means’; and if ‘such practices may infringe the EC Treaty’s ban on abuses of dominant market positions (Article 82)’.⁶³ The final report was published in July 2009 (see European Commission 2009a). In the Executive Summary of the Pharmaceutical Sector Inquiry Report, the European Commission (2009b, pp. 26–27) observes: ‘The sector inquiry confirms that generic entry does not always take place as early as it potentially could under the current relevant legal framework. It shows that company practices are amongst the causes and suggests that a variety of other conditions might play also an important role. The sector inquiry also confirms a decline of novel medicines reaching the market and points to certain company practices that might, amongst other factors, contribute to this phenomenon.’ The Commission will address the issues identified in the course of the sector inquiry ‘by applying increased scrutiny under EC competition law to the sector and by bringing [enforcement actions in] specific cases, where appropriate’ (ibid., p. 27). To reduce the risk that ‘settlements are concluded at the expense of consumers’, the Commission will also ‘consider further focused monitoring of settlements that limit generic entry and include a value transfer from an originator company to a generic company’ (ibid.). In January 2010, a new initiative was launched by the Commission. Patent settlements between originator and generic pharmaceutical companies will be monitored. The goal is to investigate ‘patent settlements where an originator company pays off a generic competitor in return for delayed market entry of a generic drug’ (see European Commission 2010).

Another area that is likely to be one of increasing scrutiny and contention in terms of the distribution of pharmaceuticals around the world is that of parallel imports of pharmaceuticals. Essentially, the question is whether national laws allow IP right holders to invoke their IP rights to prevent the importation and marketing of a product which they have placed on the market in another country. In legal terms, the question is whether the relevant IP rights have been ‘exhausted’ through first sale in another country. Article 6 of the TRIPS agreement on the ‘exhaustion’ of IPRs essentially leaves it up to individual countries to decide appropriate parallel imports regimes, provided the principles of ‘national treatment’ and ‘most-favoured-nation treatment’ under the WTO agreements are observed. The Doha Declaration, in sub-paragraph

5(d), clarifies that ‘the effect of the provisions in the TRIPS Agreement relevant to the exhaustion of [IPRs] is to leave each Member free to establish its own regime [on this front] without challenge’, subject to the latter WTO principles. On the issue of parallel imports, the CIPR Report (2002) notes that:

[D]eveloping countries should not eliminate potential sources of low cost imports from other developing or developed countries. In order to be an effective pro-competitive measure in a scenario of full compliance with TRIPS, parallel imports should be allowed whenever the patentee’s rights have been exhausted in the foreign country. Since TRIPS allows countries to design their own exhaustion of rights regimes (a point restated at Doha), developing countries should aim to facilitate parallel imports in their legislation. (Ibid., p. 41)

The issue of exhaustion of rights is closely related to the earlier discussion over the scope and nature of the grant of exclusive rights within domestic markets. Countries may differ regarding whether to regulate price and market conduct of rights holders who may otherwise seek to enforce their exclusive rights on downstream purchasers after a first sale (or by limiting the grant of rights that can be transferred with protected property, through restrictive licensing terms). The legal rules in this regard may not be clear, and also may not be absolute but rather default principles that can be adjusted by contract (as suggested within the US context).⁶⁴ Similar concerns may apply to parallel imports for goods sold in one country, where the sales are conditioned on restrictions on export or other international limitations on rights. Questions also arise in regard to whether an importing country will recognize another country’s law regarding the domestic exhaustion effect of sales of products that are subsequently imported, or whether exhaustion applies to products sold in jurisdictions where no IPRs attach (e.g. because a company did not seek patent rights in that jurisdiction or because the rules of that jurisdiction prohibited the grant of patent rights).

So far, discussions on parallel importing have tended to focus on the possibility of price differentiation between developed countries and developing countries or LDCs, perhaps out of a pragmatic approach towards resolving issues of access to essential medicines in the latter countries. The CIPR Report suggests that price differentiation of pharmaceuticals between different markets, for example, between a developing country and a developed one, will depend on developed countries being able to maintain and strengthen their legislative regimes to prevent imports of low-priced pharmaceutical products originating from developing countries where these drugs are first sold by the rights owner (ibid., p. 41).⁶⁵ Without such measures to prevent parallel imports, it is said that incentives of the rights owners to sell the drugs at a lower price in the developing country than in the developed country market may be removed, especially if the latter is a dominant one for the pharmaceutical company (ibid.). However, this area is ringed with controversies as the public interest might require further scrutiny even within developed countries of the reasons for high pharmaceutical prices, especially given that underprivileged classes who need access to low-priced drugs exist in both developed and developing countries. Both within developed and developing countries, the ability of rights holders to segment their markets and to enforce restrictions will remain an important issue.

1.6. Appropriate technology transfer

There may be increasing focus in the future on provisions within the TRIPS Agreement relating to technological transfer from developed to developing countries. Article 66(2) of the Agreement provides that: ‘Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base’. According to Article 67: ‘In order to facilitate the implementation of this Agreement, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed country Members’.

Effective implementation of Articles 66(2) and 67 of the TRIPS Agreement to improve North–South and South–South technological collaboration – both public and private, which can ultimately assist developing countries in updating their innovation systems and expanding their innovation base – will require an international commitment. Various options for such collaboration might be explored, including innovative contracting mechanisms for technology transfer, as well as expanded technical and financial cooperation to promote local pharmaceutical production and stimulate the development of new health products (Morin 2005; Correa 2006). A good example of a South–South technology transfer process is the first factory in Mozambique for producing ARV drugs. The factory is funded by the Brazilian government which is also providing know-how and training to local staff.

Some argue that Articles 66(2) and 67 of the TRIPS Agreement oblige industrialized country signatories to assist developing countries in IP management capacity building (Koepsel 2004, p. 167). It is suggested that strengthening IPR management capacity and related legal infrastructure in developing countries will stimulate technology transfer and domestic innovation, enhance the ability of developing countries to attract foreign direct investment, foster greater integration into the global economy and ultimately improve standards of living (Homere & Colum 2004, p. 277).

There is a tendency, however, for many industrialized countries to emphasize enforcement of the IPRs of their companies as a primary goal, even when ostensibly invoking Article 67, and this trend requires further scrutiny (Reichman 2000). Indeed, it has been noted that IP technical assistance programs from these developed countries may promote standards of IP protection and enforcement higher than those required by the TRIPS Agreement (see Sagar 2006). The mixed effects of IP enforcement on human welfare in developing countries is explored further in Chapters 1 and 7 of this book.

Studying the impact of the TRIPS Agreement on access to medicines in developing countries, Abbott and Reichman (2007a) have made several recommendations in a study commissioned by the EU to promote R&D directed towards people in need in developing and developed countries and at promoting access to medicines. Among other things, the recommendations in the study encourage the EU and its member states to support transfer of technology to LDCs and local production of pharmaceuticals in all developing countries, especially LDCs, in keeping with the objectives of Article 66(2) (*ibid.*, p. 55). They also

discourage the EU from pursuing higher intellectual property standards affecting pharmaceuticals in multilateral, bilateral and regional forums (ibid.). In a published article drawing on the commissioned study, the authors (2007b, pp. 984–985) add that: ‘The evidence suggests that the wealthy OECD nations are little inclined to promote the development of world-class pharmaceutical producers in poor countries, which might eventually compete with the existing originators. The rhetoric of “transfer of technology” does not extend to the reality of investment in plant and equipment, upgrading systems for compliance with OECD GMP quality standards, or to the licensing of important pharmaceutical compounds... We strongly encourage a more proactive role for OECD transfer of technology to the developing country pharmaceutical sector. At the very least, OECD governments should not stand in the way of South-South cooperation’.

1.7. Proliferation of regional and bilateral trade agreements

Free trade agreements (FTAs) are being negotiated and increasingly established at the regional and bilateral levels, and there is currently an effort to negotiate a multilateral Anti-Counterfeiting Trade Agreement outside of the confines of the WTO or WIPO. These trade agreements often introduce new commitments for protection and enforcement beyond the minimum standards established in TRIPS, i.e. so-called TRIPS-plus provisions.⁶⁶ The implementation of FTAs demands that partners conform to new legislation and standards (Abbott 2006). Several bilateral FTAs contain TRIPS-plus provisions limiting the grounds on which compulsory licences can be issued, whereas TRIPS does not restrict conditions for their use (see Khor 2007).⁶⁷ The coexistence of TRIPS and FTA standards has significant consequences for public health systems in both developing and developed countries, and produces further imbalances in IP regimes at the individual country level. Commentators (Morin 2005, pp. 37–53; Correa 2006) have identified the following as the most common TRIPS-plus provisions of relevance to health policies:

- (1) stronger protection for regulatory data;
- (2) extension of patent terms;⁶⁸
- (3) limitations to the exceptions of patent rights;
- (4) linkage between drug registration and patent protection;
- (5) establishment of conditions for use of compulsory or voluntary licensing;
- (6) limitation of international exhaustion; and
- (7) restrictions on patent revocation.

These TRIPS-plus FTA provisions may be on the way to becoming more wide-spread, as more and more countries become bound by FTAs which include some of them (particularly developing countries that lack the political or economic power to reject their inclusion in FTA negotiations). The diffusion of these provisions will likely create a less friendly environment for developing countries facing public health problems. In addition, recent FTAs (e.g. US–Australia and US–South Korea) have involved requirements of transparency for drug formulary registrations that affect price and other actions to limit government price regulation. It remains to be seen whether counter-pressures increasingly exerted by civil society against such provisions, and changes in the political composition of the US and EU, may limit TRIPS-plus developments in the future.

1.8. IP management and licensing for public-funded research

The management of IP stemming from public-funded research is an area of increasing significance for both developed and developing countries. Brazil is an example of a country that has an innovative law which gives universities the right to independently manage IP created with government funding. Other prominent examples include the US Bayh-Dole Act, which has been the source of much controversy. As explained by McManis and Noh in a conference paper,⁶⁹ the Bayh-Dole Act effected a major change in US policy with respect to the ownership of IPRs in federally funded research, and was designed to promote technology transfer by allowing universities, small businesses and other research institutions to retain ownership of the patent rights resulting from federally funded research, subject to an obligation on the part of universities and other non-profit institutions to share royalties with the actual inventor. According to the paper, prior to the Bayh-Dole Act, patent rights were in principle retained by the federal funding agencies themselves, though actual patent policies of federal funding agencies varied considerably, with some agencies allowing universities to patent publicly funded research discoveries in certain circumstances. McManis and Noh note the ongoing debate over the Act:

Proponents of the Bayh-Dole Act argue that the Act was necessary because prior to 1980 many inventions resulting from federally-funded scientific research were not being commercialized, and that the Act has provided an effective framework for federal technology transfer, producing tremendous economic benefits not just for universities and private industry, but for the U.S. economy as a whole. Critics of the Bayh-Dole Act, on the other hand, question the theoretical and empirical assumptions on which the Bayh-Dole Act is based, and go on to argue that the use of patents in such areas as basic biological research may frustrate basic norms of ‘open science’ in the research community, and that the failure to distinguish between downstream inventions that lead directly to commercial products and fundamental research discoveries that broadly enable further scientific investigation may hinder rather than accelerate biomedical research, creating the risk of both ‘blocking’ patents on foundational discoveries or indispensable research tools and ‘patent thickets,’ or a ‘tragedy of the anti-commons,’ where basic research discoveries necessary for subsequent downstream development are owned by a large number of entities, thus impeding downstream development.⁷⁰ (Ibid., pp. 2–3)

Although the Bayh-Dole Act governs the patenting of federally funded research in all fields of technology, university patenting and licensing pursuant to the Act have thus far overwhelmingly involved the life sciences (ibid.). Other countries are implementing or considering approaches to deal with IPRs from publicly financed research. South Africa, for example, considered recommendations in this direction, based on studies comparing provisions of the Bayh-Dole Act with other national legislation such as in Denmark.⁷¹ On 22 December 2008, it passed its Intellectual Property Rights from Publicly Financed Research and Development Act, following public consultations and significant revisions to the draft bill.⁷² The proposed ‘Indian Bayh-Dole Act’ – the Protection and Utilisation of Public Funded Intellectual Property Bill of 2008 being considered by the Indian Parliament – has been controversial and is under revision at the time of this writing.⁷³

How countries choose to legislate in the future on IPRs over public-funded research will have a significant bearing on research and development, including in the area of medicine. At the same time, changes in university licensing policies may make a difference in terms of retaining rights to conduct further research or to license inventions specifically with developing country needs in mind.⁷⁴ Some universities are exploring licensing practices that seek to make new innovation, including in biotechnology, readily available for ‘humanitarian access’ (see further Brewster, Chapman & Hansen 2005).

2. Strategies and public-private initiatives for research into new medicines and vaccines

Pharmaceutical innovation is not sufficiently dealing with diseases of primary concern to developing countries. Many chronic diseases and conditions typical of developed countries such as coronary disease and high blood pressure, attract significantly more private investment by pharmaceutical companies in developed countries (along with research investment into so-called lifestyle drugs). An important area of ongoing and future concern for developing countries and LDCs and their constituents is the development of drugs addressing diseases that are prevalent in these countries but less prevalent, or of decreasing incidence, in the developed world. These include ‘neglected diseases’ such as malaria, schistosomiasis and Chagas disease, as well as emergent and resurgent diseases such as HIV/AIDS and tuberculosis. These diseases present challenges for health surveillance systems and for government policy more generally. Local research agendas and purchasing arrangements must respond to the ‘neglected diseases problem’ and to shifting trends in disease incidence.

Several developments at the WHO deserve emphasis in relation to IP and health, especially for neglected and resurgent diseases. Significantly, in May 2003, the fifty-sixth WHA formed a time-limited body entitled the Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH) to analyse the role of IPRs in promoting research and innovation in public health, especially for diseases that disproportionately affect LDCs. Various studies ranging from the prevalence of diseases worldwide to the global IP landscape and alternative models of innovation were reviewed. These reviews formed the basis of the Commission’s final report in 2006, entitled *Public Health, Innovation and Intellectual Property Rights* [hereinafter ‘CIPRH Report’],⁷⁵ which was presented to the Executive Board of the 116th session of the WHA.⁷⁶ Some key findings and recommendations of the CIPRH Report are described in Box 2.2. In 2008, the sixty-first WHA adopted the ‘Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property’ (Resolution WHA 61.21) aimed at the removal of IP obstacles to R&D of new drugs and vaccines for public health (see New 2008). The global strategy recognizes that the price of medicines can impede access to treatment and recalls the flexibilities contained in many international IP agreements.⁷⁷ Although these flexibilities were inserted in the text of instruments such as the TRIPS Agreement to facilitate access to medicines by developing countries, the global strategy points out that barriers to the use of such flexibilities may exist (*ibid.*, Annex, para. 12). The global strategy also incorporates a human rights approach by invoking and quoting Article 27 of the Universal Declaration of Human Rights (*ibid.*, para. 10).⁷⁸

Box. 2.2. Initiatives at the World Health Organization relating to intellectual property and public health⁷⁹

The CIPIH was a time-limited body created in May 2003 by the fifty-sixth World Health Assembly (WHA). The CIPIH's task was to analyse the role of IPRs in promoting research and innovation in public health, especially for diseases that disproportionately affect LDCs. According to the 2006 CIPIH Report, poor countries face a 'double' burden of disease: they are the victims of both communicable diseases (like HIV/AIDS and tuberculosis) and non-communicable diseases (like diabetes and cancer) (ibid., p. 15). The report also states that 'diseases of poverty (i.e. communicable, maternal, perinatal, and nutrition-related diseases) contribute to over 50% of the burden of disease in low income developing countries' and that the burden of disease in developing countries is 'nearly ten times higher than [the] burden in developed countries' (ibid.). The establishment and work of the CIPIH was intended as a step towards increasing access to medicines and alleviating the burden of disease in the world.

The 2006 CIPIH Report focused on Type III diseases – diseases that are overwhelmingly or exclusively incident in developing countries, such as African sleeping sickness (trypanosomiasis) and African river blindness (onchocerciasis). Type III diseases are often termed 'very neglected diseases'. In contrast to the situation with diseases such as HIV/AIDS which affect both the developed and the developing world, it is very challenging to get pharmaceutical companies to invest in R&D for diseases that only represent a very small and low-income market. As stated in the report, companies are not willing to invest in pharmaceuticals for developing countries because 'they are inherently unprofitable, or the relationship between investment and risk, in relation to potential profit, is unattractive to the private sector' (CIPIH 2006, p. 30). Consequently, pharmaceutical companies are doing much less than is expected to develop new drugs. The CIPIH report notes that 'while R&D spending by pharmaceutical companies based in the United States doubled between 1995 and 2002, the number of new molecular entities approved by the United States Food and Drug Administration (FDA) has not risen between the first half of the 1990s and the first half of this decade' (ibid., p. 65). According to the report, the majority of pharmaceutical companies' R&D resources are being directed towards minor improvements of existing drugs that simply aim to increase profits, instead of significant therapeutic advances that could potentially eradicate diseases (ibid., p. 30).

The CIPIH Report found that the existing IP model, as currently implemented, was not achieving the desired goals of promoting the development of products for treatment and prevention of diseases, specifically for developing countries (ibid., pp. 23–24). Based on this conclusion, the CIPIH Report considered a wide range of proposed alternative innovation models which might better address the current lack of incentives for pharmaceutical R&D that meets the needs of developing countries. Some alternative IP and innovation schemes that the CIPIH reviewed included: orphan drug schemes which offer limited additional market exclusivity to promote the development of drugs for Type II and III diseases;⁸⁰ tax credits for clinical trials; prize funds and other reward systems; guaranteed market commitments; modalities for transferring IPRs to developing countries; and open source approaches (see ibid., pp. 102–107). A common thread amongst the various alternative proposals was the CIPIH's recognition of a need for more public-private partnerships, with long-term and sustainable funding mechanisms guaranteed by the WHO, as well as a need for increased efforts to strengthen clinical trials and regulatory infrastructure in developing countries (ibid., p. 173).

The report's sixty final recommendations are directed towards governments, international agencies and pharmaceutical companies (see ibid., pp. 196–210). Recommendations for developed

countries include increasing funding for research and advanced purchase mechanisms. It is also recommended that developed countries refrain from seeking bilateral agreements with developing countries that undermine the spirit of the Doha Declaration and the goal of increasing access to medicines and improving public health (see *ibid.*, pp. 197–204). Recommendations for developing countries include ensuring that the infrastructure for market approval and delivery of medicines to populations is put in place. Developing countries are also encouraged to use the compulsory licence flexibilities available within the framework of the TRIPS Agreement (see *ibid.*, pp. 204–206). The report recommends that the WHO and other international agencies develop patent pools and secure sustainable financing schemes to ensure that access and delivery of medicines increases in the developing world (see *ibid.*, pp. 197–210). The report further draws attention to the special responsibility of pharmaceutical companies to increase access to medicines in poor countries, given that they work in and profit from public health needs. To that end, it recommends coming up with differential pricing policies between developed country markets and developing country markets (see *ibid.*, p. 205).

In May 2006, WHO Member States adopted a proposal to establish an Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG).⁸¹ The IGWG's task was to prepare a global strategy and plan of action based on the recommendations of the CIPIH Report. On 24 May 2008, following a week-long review of the eighteen months' work and final recommendations of the IGWG, the sixty-first WHA adopted the 'Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property' (Resolution WHA61.21). The global strategy reaffirms TRIPS flexibilities while aiming to 'promote new thinking on innovation and access to medicines' (*ibid.*, Annex, para. 13). Among other elements, the Plan of Action sets out to encourage R&D in 'traditional medicine' in developing countries, promote 'upstream research and product development in developing countries', and includes a paragraph on competition policy against the abuse of IP rights (*ibid.*, Appendix, paras. 1.3, 2.2, 6.3). A proposal with progress indicators for the Plan of Action was presented and approved at the sixty-second WHA in May 2009 (see WHO 2009). In terms of regional developments, the Pan American Health Organization (PAHO) is now organizing discussions on implementing the global strategy and action plan in the countries of the Americas.

Beyond the WHO, several international organizations and UN initiatives also deal with the intersection between IPRs and public health, including initiatives to facilitate research and access to medicines and vaccines. This includes, for example, the related work of the United Nations Development Programme (UNDP), WTO, WIPO, UNICEF, United Nations Conference on Trade and Development (UNCTAD) and the Joint United Nations Programme on HIV/AIDS (UNAIDS). While these multiple initiatives highlight the many dimensions and challenges posed for IP and public health, further information exchange and programme coordination is needed amongst these organizations. Section 3 of this chapter highlights two major scenario-planning processes undertaken recently by two organizations with implications for IP and health. Such planning processes can help bring together parallel initiatives by different organizations in search of coordinated and effective solutions in the public interest.

A variety of actors from the public, non-profit and private sectors have meanwhile come together to collaborate on new models of innovation for drugs and vaccines relevant to public health. In relation to the development of drugs for neglected diseases such as malaria and tuberculosis, product development partnerships (PDPs) present, for example, a significant opportunity for new and innovative collaborative research projects. Such partnerships have already started to yield results (Morel et al. 2005, pp. 401–404). As clarified by the Centre for

Management of Intellectual Property in Health Research and Development (MIHR) in its 2006 publication, *Academic Licensing to Global Health Product Development Partnerships* ('MIHR Report'), these PDPs receive R&D support, both financial and in-kind, from a variety of sources both public and private, and focus on acquiring, developing and managing a portfolio of candidate products (MIHR 2006, p. 5).⁸² According to the MIHR report, PDPs follow a non-profit business model, including a clearly articulated business plan based on market analyses, a portfolio management approach, and an access and advocacy strategy; their priorities are based on health inequities, social demand and considerations including the maturity of the science (ibid.).⁸³ Recent examples of partnerships include those for the development of a new antimalarial drug by the Drugs for Neglected Diseases Initiative (DNDI) and Sanofi-Aventis, and of OneWorld Health's new leishmaniasis drug.⁸⁴ The more general term 'public-private partnerships' (PPPs) has been used to describe some of the initiatives in this vein.

Some interesting examples of alternative, collaborative models for R&D into medicines and vaccines – though by no means an exhaustive summary – are provided in Appendix B. These include public-private partnerships and non-profit pharmaceutical companies, medical R&D treaty and prize funds, advanced market commitments, patent pools and open source options.

3. Future scenarios relating to intellectual property and health⁸⁵

Two main publications have been identified in the Public Interest Intellectual Property Advisors (PIIPA) literature survey as containing components directly related to IP and health. One of these is the European Patent Office (EPO) 2007 report entitled *Scenarios for the Future: How Might IP Regimes Evolve by 2025? What Global Legitimacy Might Such Regimes Have?* ('EPO Report').⁸⁶ The other is the UNAIDS report on *AIDS in Africa: Three Scenarios to 2025* ('UNAIDS Report').⁸⁷ The former is discussed in detail in Chapter 9 of this study. This section focuses on the 'IP and health' components of the EPO and UNAIDS scenario plans. Some of the major themes and trends introduced in Section 1 of this chapter are addressed in the scenario plans.

3.1. The IP and health component of the EPO scenarios

The EPO Report suggests a range of changes and outcomes for IP and health by the year 2025. According to the report: 'Scenarios are challenging, relevant and plausible stories about the future, used as tools to generate policy dialogue. They do not attempt to predict the future, but set out the landscape of a wider environment that encourages reflection on how the future might unfold' (EPO 2006, p. 13). While 'health' is one of the few sectors singled out by the report for direct comparison between scenarios,⁸⁸ it is given extended discussion only in one of the scenarios ('Trees of Knowledge'). Nevertheless, the EPO scenarios provide thought-provoking ideas and insights into some of the key technological and social driving forces for the future of IP and health. The following is a synthesis of the main elements relating to IP and health in the four EPO scenarios:

(1) Scenario 1: Market Rules

Under the 'Market Rules' scenario, stricter IP rules, enforced by bi-lateral agreements often surpassing TRIPS and the increasing high-level

harmonization of IP rights worldwide, are said to leave fewer ‘white spots’ (i.e. areas not covered by patent protection) on the ‘patent map’ by 2025. IPRs are furthermore strengthened using supplementary protection and data exclusivity. There is increasing emphasis under this scenario on preventive diagnostics and pharmacogenomics, leading to what is described as a ‘highly individualized’ medicine, i.e., the use of medicines tailored to individual needs (ibid., p. 105). Health is said to have become a private commodity, with individual responsibility for health as the ‘ground rule’ (ibid.). There is philanthropic funding of rare and neglected diseases under this scenario. As health becomes more of a private commodity, the split widens between privatized and publicly funded health care. For drug companies, marketing becomes a pre-eminent concern (ibid.).

(2) **Scenario 2: Whose Game**

Under the ‘**Whose Game**’ scenario (which foresees a development of the technological hegemony of Asian powers like China and India), the global gap between medical ‘haves’ and ‘have-nots’ widens (ibid.). New power blocs emerge in this scenario along the lines of geographic regions, shared histories, cultural habits and beliefs. Intellectual property is used differently in different regions, and remains a strong competitive tool in some of them. Some role reversal from the current world order is witnessed in this scenario, with new economies leading in innovation and older Western economies following and engaging in ‘copying’ of the latest technology (ibid.).⁸⁹ The fierce competition between the rising and existing powers permeates to the health sector. In the new powers, a mostly state-governed health insurance system tries to secure basic needs, while the traditional health care systems in the Western world are said to be increasingly unable to cope with rising costs. Ironically, it is the governments and health insurers in the Western world who are said to be unable to ‘afford to pay the rights to expensive patented medicines’ under this scenario (ibid.).

(3) **Scenario 3: Trees of Knowledge**

The two scenarios above assumed some continuation of patent rights over pharmaceuticals. In contrast, under the third ‘**Trees of Knowledge**’ scenario, affordable access to health becomes a ‘social clarion call’ leading to the abolition of patents in the pharmaceutical sector by 2025. This scenario witnesses the emergence of alternative funding models for drug research, relying on so-called ‘push’ and ‘pull’ mechanisms (ibid.).⁹⁰ Social activism operates as a dominant driver in this scenario, and funding from governments as well as non-profit organizations figures prominently in shaping innovation in the health sector. Public-private partnerships, prize funds, advance payment schemes and outright government grants are mentioned as examples of modalities for innovation. Rare diseases or lifestyle-related conditions are not given ‘first priority’ in this scenario (ibid., p. 80). At the same time, human

genes, stem cells and other parts of the human body become excluded from patentability under some jurisdictions, with research based on ‘ethically sensitive’ technologies (such as germ-line modification) moving almost entirely to less prescriptive jurisdictions (i.e. where the laws are less strict) (ibid., pp. 10, 80).

Dynamics in IP and health are discussed in greater detail under the ‘Trees of Knowledge’ scenario than under the other scenarios. Under this scenario, a disastrous flu pandemic (said to leave 20 million people dead) catalyses drastic changes in attitudes towards IP. During the initial flu outbreak, it is said that ‘companies refused to lower the prices of existing vaccines and refused to allow generic manufacturers into the market’ and ‘complicated overlapping IP rights on different mutant variants of the flu virus severely hampered research into vaccines and therapeutics targeted to the precise strain of the virus’ (ibid., p. 80). The delay of vaccine developments by several months ‘severely damaged people’s trust in the patent system’,⁹¹ with pharmaceutical companies also criticized for having prioritized ‘lifestyle’ drugs and ‘me-too’ drugs in their R&D (ibid.). Demonstrations eventually lead governments to grant compulsory licences for patented products in the interest of public health, while broadening research and clinical trials exemptions. In parallel, patent grant numbers are limited to ensure that ‘only the most inventive’ ideas receive monopoly protection (ibid.). As the pharmaceutical and health industry shifts its focus to less sensitive areas (where the perceived risks of not recouping its investments are smaller), gaps become filled by government-funded research, prize funds and PPPs. Under this scenario, many governments eventually replace the current patent system ‘with a government regulated system’ that allows companies performing clinical trials on drugs (said to be the really costly area of R&D) to ‘sell their results to other companies’ (ibid.). The price for such transactions is fixed in relation to the estimated public health benefit.

(4) **Scenario 4: Blue Skies**

Under the final ‘**Blue Skies**’ scenario, pharmaceutical companies still rely on patents, ‘albeit with restrictions that ensure research exemptions and access for poorer nations’ (ibid., p. 105). Underlying this scenario are ‘technofix’ solutions to problems in health, with a ‘globally positive attitude to technology’ leading to flourishing health-care R&D (ibid.). Areas such as genetic diagnostics are mentioned in this scenario, and companies operating in these areas are said to have adopted ‘a system of licensing, patent pools and clearing houses to ensure optimal use of available technologies’ (ibid.). Under this scenario, ethical objections to biotechnology have given way to ‘utilitarian’ cost-benefit appraisal – stem-cell treatments, advanced prosthetics and embryo screening are accepted, and the first attempts at genetic enhancement are supported by large parts of society (ibid.). It is said that ‘epidemiological, pharmaceutical and genetic research is helped by huge interconnected databases bringing genomic, clinical, familial and social data together on a

worldwide scale' (ibid.). The most major breakthroughs come, however, from information and communication technologies (ICTs) that enable new forms of disease prevention by combining 'sophisticated diagnostics, advice and the control of human behaviour using technology' (ibid.). This scenario assumes that targeted patent restrictions will help ensure research exemptions and access to medicines for developing countries.

3.2. The UNAIDS scenario planning on AIDS in Africa as it relates to IP

In the large-scale scenario planning on 'AIDS in Africa' spearheaded by UNAIDS, IP is seen as only one component in the complex rubric of socio-economic and cultural factors shaping health-related research, development and delivery on the African continent. The UNAIDS Report contains three scenarios, each of which describes a different, plausible way in which the HIV/AIDS epidemic could play out across the whole of the African continent between now and 2025. As clarified in the report, these scenarios are 'rigorously constructed accounts of the future that use the power of storytelling as a means of going beyond the assumptions and understandings of any one interest group, in order to create a shared basis for dialogue and action about critical and difficult issues' (UNAIDS 2005, p. 12).

(1) Scenario 1: 'Tough Choices: Africa Takes a Stand'

The first scenario, 'Tough Choices', suggests little likelihood that the attitudes of the rest of the world will change drastically to produce solutions for the HIV/AIDS situation in Africa. This scenario argues that much depends on African countries nurturing their domestic resources, including cultural strengths, to find their own way forward in the efforts to overcome the HIV/AIDS epidemic. The scenario emphasizes that, while there are enormous odds to overcome, there is much that countries in Africa can do on their own and collectively. It suggests that, with leadership and community mobilization, effective HIV/AIDS responses are possible without huge outlays of resources on stand-alone programming. This scenario ends with declining HIV incidence as over two decades of long-term investments in social, economic, and human capital begin to pay dividends (ibid., p. 178).

In relation to IP, the scenario contains a story where the unity shown by African and other G20 governments in the world trade rounds finally pays off and these governments succeed in extending the period for compliance with the provisions in the TRIPS Agreement relating to pharmaceutical products – from 2016 (as agreed under the Doha Declaration for LDCs) to 2026. Without the pressure of compliance deadlines, the countries are 'freed up to pursue pragmatic solutions' (ibid., p. 84). According to this scenario: 'The countries seized on the opportunities provided by the TRIPS Agreement and Doha Declaration and pursued whatever mix suited them best: importing from developing country generic manufacturers; locally manufactured products; or importing under voluntary or compulsory licenses' (ibid., p. 85). A number of publicly regulated low-cost manufacturing sites are established in East and West Africa (initially as subsidiaries of Brazilian, Indian, South African and other manufacturers). Leading a vigorous international debate on ways to make newly patented drugs available to developing countries, African governments soon make it clear that they are not interested in bilateral trade agreements favouring the interests of patent holders or restricting governments' capacity to produce

medicines as cheaply as possible (ibid.). According to this scenario, the new generation of bilateral trade agreements and multilateral agreements maintain ‘a balance between, on the one hand, the aspirations and safeguards of the Doha Declaration, and on the other hand, realizing the investment potentials of intellectual property’ (ibid.).

(2) Scenario 2: ‘Traps and Legacies: The Whirlpool’

An underlying message in the second scenario, ‘**Traps and Legacies**’, is that: ‘It will be difficult to make a difference to the AIDS epidemic if HIV is viewed in isolation from its root social, economic and political context; or if it is seen only as a medical problem or an issue of individual behavioural change, addressed via programmes that only consider the symptoms’ (ibid., p. 179). Under this scenario, the HIV/AIDS epidemic does catalyse people and institutions into some response, but they cannot make sufficient headway in the face of depleted capacity. In this less optimistic scenario, the continent is gripped in a ‘downward spiral of disunity, denial and stigma, contested knowledge, wasted resources, and competing sources of power and authority’ (ibid.). The capacity of systems, people and institutions to respond to the crises of AIDS and underdevelopment is ‘systematically diminished’ (ibid.). By 2015, the cost of financial obligations established by new patent regimes is ‘many times higher than the value of any tariff concessions given by developed countries under the world trade agreements’ (ibid., pp. 120–121).

According to this scenario, the agreement under the Doha Declaration to extend the grace period for LDCs’ compliance with the TRIPS provisions relating to pharmaceutical products is not extended beyond 2016. As a result, the ambitious efforts of some countries to take over from India as centres for manufacture of generic drugs come under legal challenge (ibid., p. 120). Problems of counterfeit or adulterated drugs plague small-scale manufacture of drugs in this scenario. While there are efforts by research-based industries and generics manufacturers in countries as diverse as Brazil, Canada, India and South Africa to transfer technology to – and develop manufacturing capacity in – Africa, continuing polarization of the global IP debate means that these efforts are ‘not well supported across the continent’ (ibid., p. 121). Under this scenario, developing countries would remain the net importers of technology, with the related IP protection for technology continuing to expand and become globalized (ibid.).

(3) Scenario 3: ‘Times of Transition: Africa Overcomes’

More optimistic and far-reaching than the first two scenarios, the third scenario, ‘**Times of Transition**’, describes a series of transitions in the way in which Africa and the rest of the world approach health, development, trade, security and international relations towards equitable outcomes. In relation to IP and health, the following transition is recounted:⁹²

As the new millennium unfolded, there was increasing consensus on the need to overcome the emotive opposition between access to life-saving medicines and the global extension of intellectual property protection. The spirit of social justice and collective global responsibility resulted in landmark arrangements to regulate the supply of medicines. African countries could keep access to low cost drugs! Over the next decade there was growing international interest in new models of medicine development that

maximized poor people's access, while supporting the innovation required to produce new medicines. (Ibid., pp. 160–161)

This scenario highlights the success of 'groundbreaking' campaigns – the DNDI and the Medicines for Malaria Venture (MMV) are given as examples – where civil society and public research institutes join forces with private research companies and governments to address the lack of R&D for medicines for some of the world's neglected diseases. Innovative public-private collaborations begin to tap Africa's research potential more effectively; this happens in many areas, including biodiversity, benefit-sharing agreements harnessing traditional knowledge and global drug and vaccine development partnerships (ibid.). The development of an HIV/AIDS vaccine is hailed as one of the greatest successes of the new international regime under this scenario. This is said to be spurred by PPPs in vaccine R&D, with collaborative initiatives extending into the manufacture of vaccines in burgeoning industrial facilities situated across Africa. Following the year 2020, an international treaty-based framework is established to provide the legal and financial infrastructure necessary to support the development and manufacture of affordable essential medicines. Many of the compounds of potential use in treating the diseases that most affect the poorest countries are taken forward as 'open source' projects which enable countries and individuals to offset costs and pool capabilities (ibid., p. 161).⁹³ Free online access initiatives for academic journals, including medical journals, become increasingly widespread (ibid.).⁹⁴

3.3. Some thoughts on the scenarios

It is impressive how the UNAIDS Report charts the many socio-economic and cultural influences shaping the future of the HIV/AIDS crisis on the African continent. This multidimensional approach is not forgotten in any of the scenarios described in the report. This presents an interesting contrast to some scenarios under the EPO planning exercise, in particular the 'Blue Skies' scenario which highlights the promise of a 'techno-fix' approach to problems of inequities, including in the health sector. Indeed, the UNAIDS Report emphasizes, rather, that technology is but one component in the challenge to overcome Africa's HIV/AIDS situation. It qualifies that the development and uptake of new technologies is shaped by different influences, and that 'successful development does not guarantee their effective deployment' (ibid., p. 54). Under the 'Traps and Legacies' scenario in the UNAIDS Report, the uptake of biomedical technology is described as increasingly inhibited by: limited access, frequent drug stock-outs, failure to address underlying beliefs, competition or ineffective integration with traditional healers, insufficient attention to the diversity of local languages and deteriorating education (ibid., pp. 54–56).

There is also acknowledgement in the UNAIDS Report of parallel systems of knowledge shaping the future of health in Africa. In the 'Times of Transition' scenario, it is noted that 'there is increasing integration between parallel systems and capacities, with greater inclusion of biomedical knowledge in traditional health systems and vice versa' (ibid., p. 56). The need to combine new technology with traditional know-how is emphasized in the report as part of the solution to the HIV/AIDS crisis on the continent, especially in building local capacity in R&D. An example of ongoing research involving traditional know-how of local communities in the Pacific region is the project for development of a new AIDS and cancer drug, Prostratin, derived

from indigenous uses of the mamala tree in Samoa. The University of California, Berkeley (UC Berkeley) has an agreement with the government of Samoa for conducting this research project with the collaboration of local communities (IEGBIIP 2008, p. 31; see also Chapter 4, Box 4.5).

Traditional medicinal knowledge (TMK) is an important area in health care and research. Recognizing that up to 80% of the world's population depends on traditional medicine for its primary health needs,⁹⁵ the WHO adopted a *WHO Traditional Medicine Strategy 2002–2005* which includes among its main objectives the integration of 'relevant aspects of traditional medicine within national health care systems by framing national traditional medicine policies and implementing programmes' (see further Chapter 4 and Appendix C).⁹⁶ The overlap between IP and traditional knowledge, including TMK, is addressed in Chapter 4 of this study and is not repeated here.

Many of the alternative innovation models for R&D of vaccines and medicines (such as PPPs and prize funds) described in both the EPO 'Trees of Knowledge' scenario and the UNAIDS 'Times of Transition' scenario are already witnessed in collaborative efforts to address HIV/AIDS (see Appendix B). The UNAIDS Report furthermore emphasizes the importance of changes in mindset, alongside questions of resources and structural reforms, as central to finding viable solutions to the current vicious cycle in the HIV/AIDS crisis. In the 'Times of Transition' scenario, for example, a 'socially responsible' mindset permeates to different stakeholders, including corporate players. As observed in the scenario:

Over this period, more companies were becoming more widely engaged in development. Those who ran the big companies moved from following a model of corporate philanthropy or social responsibility to a wider understanding of their role as agents of social change. By 2019, most multinationals had developed a 'foreign policy', which went beyond public relations to something far more extensive – far-reaching partnerships in a range of activities that helped build communities and even national governance capacities. (UNAIDS 2005, p. 161)

This part of the story may seem far-fetched given that the current socio-political reality more closely approximates the 'Market Rules' scenario in the EPO Report (which emphasizes a strengthening of patent protection and increasing harmonization of laws around the world, paralleled by increasing prioritization of 'marketing' by drug companies and R&D trends towards 'individualized' diagnostics and health care in rich countries). The UNAIDS story reflects, however, the growing public demand for greater scrutiny in areas such as corporate governance and corporate social responsibility in light of the extensive outreach of multinational corporations on the global map.

4. Conclusion

As discussed in this chapter, the overlap between IP and medicine is complex, going beyond issues of access to medicines to the impact of IP on medical research and exchange of related knowledge. As emphasized in the UNAIDS Report, IP is only one aspect of the many socio-economic and cultural factors affecting access to medicines and health care in both developed and developing countries. Developing countries (especially LDCs) still lag significantly behind

in terms of benefits from recent progress in medical research, including biomedical research. Improved North–South and South–South cooperation, better education and appropriate technical cooperation could lead to more convergence between developed and developing contexts in standards of health protection. Scrutiny is needed, however, on how trade and IP regimes are shaping that future.

There is a tendency for many developing countries and LDCs to engage in policy-making and legislative activities relating to IP without full consideration of baseline information and alternative visions in the public interest. The health-related scenario plans explored in this chapter provide only a glimpse of many alternative possibilities, and further scenario planning targeting the particular needs of developing countries would be useful. Within countries, linkages among IP policy, innovation and industrial policy need to be formulated with public health objectives in mind. The interaction among IP laws, price regulation and competition laws, particularly to promote affordable access and pro-competitive environments in relation to new drugs and generic production of relevance to developing countries, also needs to be further explored. The capacity building of developing country stakeholders, especially marginalized stakeholders, towards their informed decision-making and engagement in policies to address the overlap between IP and public health is important. Such capacity building is dependent on country and local contexts, so that a case-by-case analysis is needed. It has been said that there is no ‘one size fits all’ solution. As some of the future scenarios discussed in this chapter suggest, thinking beyond the ‘IP box’ is important in addressing access to health and medicines, and exploring new models of innovation to meet the demands of global health equity.

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Notes

- ¹ The authors are grateful to Claire Comfort, Graham Dufield, Sean Flynn, Michael Gollin, Stan Kowalski, Roy Widdus, Claudia Trezza and Tzen Wong for their invaluable comments towards this chapter.
- ² See also Commission on Macroeconomics and Health 2001; World Health Organization (WHO) 2008.
- ³ According to a WHO definition: 'Human Immunodeficiency Virus (HIV) is the retrovirus that weakens the immune system, particularly by causing the death of many CD4+T cells, which coordinate the human immune system's response to intruders. This weakening of the immune system leaves the body open to attack from opportunistic infections, eventually leading to the development of Acquired Immune Deficiency Syndrome (AIDS)'. WHO 'Glossary of globalization, trade and health terms', available at: <http://www.who.int/trade/glossary/story051/en/index.html> (accessed 11 March 2010).
- ⁴ See further Sub-Commission on the Promotion and Protection of Human Rights, Intellectual Property Rights and Human Rights (17 August 2000), Sub-Comm. Human Rights Res. 2000/7, UN Doc. E/CN.4/Sub.2/RES/2000/7 (2000), available at: <http://www.unhchr.ch/Huridocda/Huridoca.nsf/0/c462b62cf8a07b13c12569700046704e?Opendocument> (accessed 5 February 2010).
- ⁵ International Covenant on Economic, Social and Cultural Rights (New York, 16 December 1966) 993 U.N.T.S. 3, 6 I.L.M. 360 (1967), G.A. Res. 2200A (XXI), UN Doc. A/6316 (1966) (*entered into force* 3 January 1976), available at: <http://www2.ohchr.org/english/law/pdf/cescr.pdf> (accessed 11 March 2010).
- ⁶ Committee on Economic, Social and Cultural Rights (CESCR) 2000, *General Comment No. 14: The right to the highest attainable standard of health* (art. 12), UN Doc.E/C.12/2000/4 (11 August 2000), available at: <http://www.unhchr.ch/tbs/doc.nsf/0/40d009901358b0e2c1256915005090be?Opendocument> (accessed 15 March 2010). See also WHO Model List of Essential Medicines, 16th edition (revised March 2009), available at: <http://www.who.int/medicines/publications/essentialmedicines/en/> (accessed 15 March 2010).
- ⁷ Convention on the Rights of the Child (New York, 20 November 1989), 1577 U.N.T.S. 3, 28 I.L.M. 1456 (1989), G.A. Res. 44/25, annex, UN Doc. A/44/49 (1989) (*entered into force* 2 September 1990), available at: <http://www2.ohchr.org/english/law/crc.htm> (accessed 3 February 2010).

- ⁸ See Committee on the Rights of the Child 2003, *General Comment No. 3: HIV/AIDS and the rights of the child*, UN Doc. CRC/GC/2003/3 (17 March 2003), available at: [http://www.unhcr.ch/tbs/doc.nsf/\(symbol\)/CRC.GC.2003.3.En?OpenDocument](http://www.unhcr.ch/tbs/doc.nsf/(symbol)/CRC.GC.2003.3.En?OpenDocument) (accessed 3 February 2010); Committee on the Rights of the Child 2003, *General Comment No. 4: Adolescent health and development in the context of the Convention on the Rights of the Child*, UN Doc. CRC/GC/2003/4 (1 July 2003), available at: [http://www.unhcr.ch/tbs/doc.nsf/\(symbol\)/CRC.GC.2003.4.En?OpenDocument](http://www.unhcr.ch/tbs/doc.nsf/(symbol)/CRC.GC.2003.4.En?OpenDocument) (accessed 3 February 2010).
- ⁹ See United Nations Millennium Declaration (8 September 2000), G.A. Res. 55/2, UN Doc. A/RES/55/2 (2000) [hereinafter 'UN Millennium Declaration'], available at: <http://www.un.org/millennium/> (accessed 22 June 2009).
- ¹⁰ For annual assessments on progress towards the Millennium Development Goals (MDGs), see 'Millennium Development Goals Reports' (published by the Statistics Division of the United Nations Department of Economic and Social Affairs), available at: <http://www.un.org/millenniumgoals/reports.shtml> (accessed 11 March 2010).
- ¹¹ Agreement on Trade-Related Aspects of Intellectual Property Rights (Marrakesh, 15 April 1994), Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter 'TRIPS Agreement'], available at: http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm (accessed 3 February 2010).
- ¹² While developing countries had to implement the relevant provisions in the TRIPS Agreement by 1 January 2000, those developing countries that had not granted product patents for an area of technology by that date were allowed to delay the introduction of such legislation until 1 January 2005. Under the TRIPS agreement, the least developed countries (LDCs) had to implement the relevant provisions by 2006. However, the Doha Ministerial Declaration (of 14 November 2001) subsequently extended the implementation deadline for LDCs to 2016 for pharmaceutical products.
- ¹³ World Trade Organization (WTO), Ministerial Declaration (Doha, 14 November 2001), 41 I.L.M. 746 (2002), Doc. No. WT/MIN(01)/DEC/W/1 [hereinafter 'Doha Declaration'], available at: http://www.wto.org/English/thewto_e/minist_e/min01_e/mindecl_e.htm (accessed 1 March 2010).
- ¹⁴ In 1997, the Republic of South Africa passed the Medicines and Related Substances Control Amendment Act, 90 of 1997, allowing parallel importation of patented drugs and generic substitution of off-patented drugs. In 1998, thirty-nine pharmaceutical companies filed a lawsuit against the South African government to block the new regulation. See *Pharmaceutical Manufacturers' Association of South Africa v. President of the Republic of South Africa*, Case No. 4,183/98 (filed 18 February 1998).
- ¹⁵ World Trade Organization (WTO), Decision of the General Counsel of 30 August 2003, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Doc. WT/L/540 (1 September 2003), available at: http://www.wto.org/english/tratop_E/TRIPS_e/implem_para6_e.htm (accessed 7 March 2010); World Trade Organization (WTO), Decision of the General Counsel of 6 December 2005, Amendment of the TRIPS Agreement, Doc. WT/L/641 (8 December 2005), available at: http://www.wto.org/english/tratop_E/trips_e/wtl641_e.htm (accessed 7 March 2010). See also World Trade Organization (WTO), 'TRIPS and Public Health' (briefings on TRIPS, patents and pharmaceuticals and public health), available at: http://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm (accessed 12 March 2010); see Abbott 2005 for detailed analysis and critique.
- ¹⁶ See, e.g. *Classen Immunotherapies, Inc. v. Biogen Idec*, 304 Fed. Appx. 866 (Fed. Cir. 2008), *cert. granted, vacated, remanded*, 2010 WL 2571877 (U.S. 29 June 2010) (No. 08–1509) for reconsideration in view of *Bilski v. Kappos*, No. 08–964, 2010 WL 2555192 (U.S. 28 June 2010); *Association for Molecular Pathology v. U.S. Patent and Trademark Office*, No. 09–CV–4515, slip opinion (S.D.N.Y. 29 March 2010, amended 5 April 2010) (Sweet, J.), appeal docketed, No. 2010–1406 (Fed. Cir. 22 June 2010) *Pfizer, Inc. v. Apotex, Inc.*, 488 F.3d 1377 (Fed. Cir. 2007). USPTO: 'Utility Examination Guidelines', 66 Fed. Reg. 1092, 1092–1099 (2001); *ICOSCorp/NovelV28 Seven Transmembrane Receptor* [2002] 6 OJ EPO 293; *Aeomica, Inc.* [2005] BL O/286/05. See Thambisethy 2008.
- ¹⁷ For examples of the latter practice, see Angell 2004, p. 79; Goozner 2004, p. 222; Law 2006, pp. 76–78.
- ¹⁸ On 3 October 2006, the Supreme Court of Canada ruled that Health Canada's regulatory regime, which allowed for the practice of 'evergreening', should not have been allowed. The case involved AstraZeneca's omeprazole drug whose patent had expired in 1999. After expiration, the company obtained a new patent for the drug despite not having incorporated new technology. *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, [2006] 2 S.C.R. 560, 2006 SCC 49, available at: <http://csc.lexum.umontreal.ca/en/2006/2006scc49/2006scc49.pdf> (accessed 12 March 2010).

- ¹⁹ See Affidavit Filed on Behalf of the Petitioner, *Novartis AG v. Union of India*, 2007) 4 MLJ 1153 (Mad) (W.P. No. 24759 of 2006), available at: <http://www.cptech.org/ip/health/c/india/novartis-v-india.doc> (accessed 12 March 2010).
- ²⁰ *Novartis AG v. Union of India*, (2007) 4 MLJ 1153 (Mad), available at: <http://www.mjlibrary.com/nominal-index/C1MF4PD2NH6RB0L.htm> (accessed 12 March 2010).
- ²¹ See US Government Accountability Office 2006.
- ²² *KSR Int'l. Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007).
- ²³ Second and subsequent medical uses of drugs may be expressed in different manners: (1) the composition of a known drug or drug formulation may be altered in order to acquire a new therapeutic effect; (2) a known composition may present new therapeutic effects when administered to patients in a different manner.
- ²⁴ See Pharmaceutical Sector Inquiry – Preliminary Report 2008, DG Competition Staff Working Paper, November 2008.
- ²⁵ This section was contributed by Claudia Trezza.
- ²⁶ Since the Agreement does not define what constitutes an ‘invention’ or a ‘technological field’, these terms are open to interpretation.
- ²⁷ There are companies in Sub-Saharan Africa with the facilities to manufacture drugs, but almost all of them must import the active pharmaceutical ingredients (APIs). For example, Danadams, a Ghanaian company, imports APIs for some AIDS drugs, which are then produced in its own laboratory.
- ²⁸ The Patents (Amendment) Ordinance, Ord. No. 7 of 2004 (Republic of India), available at: <http://lawmin.nic.in/Patents%20Amendment%20Ordinance%202004.pdf> (accessed 12 March 2010).
- ²⁹ Janodia et al. (2008) suggest that one of the reasons why it is difficult to tell what impact this will have relates to the so-called ‘mailbox’ system in India. The ‘mailbox’ system was established to receive and register patent applications in 1995, directly following the implementation of the TRIPS Agreement. Since then, approximately 9,000 applications have been filed and are pending approval (ibid.). For these applications, the twenty-year patent life begins on the date of the application, and the protection will be effective on the date that any patent is ultimately granted. On the WTO dispute settlement history regarding the India ‘mail-box’ system, see World Trade Organization (WTO), Appellate Body Report on *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, Doc. WT/DS50/AB/R, adopted 16 January 1998.
- ³⁰ It is important to make a distinction between first- and second-generation pharmaceuticals. The number of AIDS patients that now receive ARV therapy has grown since prices have dropped. Unfortunately, due to the highly mutative character of the virus, patients in many cases develop resistances to first-line drugs. Resistances are most complicated when patients do not adhere to the regimen of the therapy. Second-line drugs are necessary to prevent such resistances.
- ³¹ The relevant WTO decisions are cited in footnote 15; see the discussion in Abbott 2005.
- ³² ‘Big Pharma Besieged’, *The Guardian*, 5 September 2008.
- ³³ ‘World’s Poor and Ailing Promised Cheap Drugs’, *The Guardian Weekly*, 20–26 February 2009.
- ³⁴ Ibid.
- ³⁵ World Health Organization (WHO), ‘General Information on Counterfeit Medicines’ (fact sheet), available at: <http://www.who.int/medicines/services/counterfeit/overview/en/index.html> (accessed 1 June 2009).
- ³⁶ Ibid.
- ³⁷ Counterfeit drugs may not only cause harm to patients, but may also cause mistrust in the public towards health services and medicine; they can also lead to a waste of resources on the part of organizations or government(s) purchasing counterfeit medicines inadvertently. See Commonwealth Secretariat 2007.
- ³⁸ Department of Essential Drugs and Other Medicines, ‘Counterfeit Drugs, Guidelines for the Development of Measures to Combat Counterfeit Medicines’ (World Health Organization, Geneva, 1999), available at: http://whqlibdoc.who.int/hq/1999/WHO_EDM_QSM_99.1.pdf (accessed 1 June 2009). The proliferation of unregulated pharmaceutical industries and products is expected to continue into the future. Among the causes of counterfeit medicines are weak drug regulation, clandestine manufacturing, lack of sanctions and high levels of corruption, as well as high prices of medicines which force patients to look for cheaper substitutes. See WHO, ‘Counterfeit Medicines’, available at: <http://www.who.int/medicines/services/counterfeit/en/> (accessed 1 June 2009); see also Royal Pharmaceutical Society of Great Britain 2008.
- ³⁹ Declaration of Rome, Conclusions and Recommendations of the WHO International Conference on Combating Counterfeit Medicines (18 February 2006), available at: <http://www.who.int/medicines/services/counterfeit/RomeDeclaration.pdf> (accessed 1 June 2009).

- ⁴⁰ In the report on *Counterfeit Medical Products* (see WHO 2008), presented to the Executive Board by the Secretariat during the session, a revised IMPACT definition for counterfeit drugs was introduced. For an analysis on how the new definition might potentially extend the ambit of ‘counterfeits’, see South Centre and CIEL 2009, pp. 2–5.
- ⁴¹ This paragraph was contributed by Graham Dutfield, drawing on von Braun, J. 2009, ‘New Enforcement Mechanisms Challenge the Legality of Generics in the Name of Public Health’, a paper prepared for the WHO, United Nations Development Programme (UNDP) and University of Capetown (UCT) *Training Course on Intellectual Property Rights & Public Health: Towards an Intellectual Property Regime that Protects Public Health: A Course Directed at Policy Makers in the WHO African Region*, Cape Town, South Africa, 22–26 June 2009.
- ⁴² The official text of the Act is available at: http://www.kenyalaw.org/kenyalaw/klr_app/frames.php (accessed 15 February 2010). The Act is currently being challenged in Kenya’s Constitutional Court. See Anyangu-Amu, S. 2009, ‘Kenya: Anti-Counterfeit Law “Violates Right to Life and Health”’, *Inter Press Service*, 21 December 2009, available at: <http://ipsnews.net/news.asp?idnews=49764> (accessed 1 February 2010).
- ⁴³ The actions that amount to counterfeiting are described in Article 2.
- ⁴⁴ To the extent a fake drug does not contain any patented active ingredients, it is unlikely to infringe a patented invention. It may, however, infringe a trademark in given cases.
- ⁴⁵ *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d. 858 (Fed. Cir. 1984).
- ⁴⁶ WTO Panel Report on *Canada – Patent Protection of Pharmaceutical Products*, Doc. WT/DS114/R, adopted 7 April 2000, available at: http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm (accessed 9 April 2010).
- ⁴⁷ See Gervais 2008. The TRIPS Agreement does not on its face require pharmaceutical patents, and it remains an open question whether a country seeking to refuse such protection could treat some pharmaceuticals as not inventions or could discriminate by field of technology in a way that would also be valid under Article 30 (which authorizes national exceptions to patent rights meeting specified criteria). Thus, the Indian example is relevant – not all pharmaceuticals may be required to be potentially patentable. However, it is likely that a categorical exclusion of *all* pharmaceuticals would be found to violate these provisions, given the explicit major purpose to impose such requirements.
- ⁴⁸ Brazilian industrial property law recognizes compulsory licensing in cases of public interest. The Brazilian Government’s Ministerial Ordinance No. 886, of 24 April 2007, declared the patent rights relating to efavirenz to be of public interest, for the purposes of granting compulsory licensing for non-commercial public use.
- ⁴⁹ 28 U.S.C. § 1498(a).
- ⁵⁰ Council Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions, Article 6(1), OJ No. L 213, p. 18 (1998).
- ⁵¹ Article 18 of Brazil Industrial Property Law, No. 9,279, of 14 May 1996, available at: http://www.sice.oas.org/int_prop/nat_leg/Brazil/ENG/L9279eA.asp#grant (accessed 12 March 2010).
- ⁵² For example, European Patent Convention Article 52(2)(a) excludes from being considered an invention ‘discoveries, scientific theories, and mathematical methods’. See Convention on the Grant of European Patents (Munich, 5 October 1973), 1065 U.N.T.S. 199, 13 I.L.M. 271 (1974) (*entered into force* 7 October 1977), *as last revised* 29 November 2000 (*entered into force as revised* 13 December 2007) [hereinafter ‘European Patent Convention’], available at: <http://www.epo.org/patents/law/legal-texts/epc.html> (accessed 12 March 2010).
- ⁵³ Council Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions, Article 5(3), OJ No. L 213, p. 18 (1998). See Case C-428/08 *Monsanto Technology LLC v. Cefetra BV* [2010].
- ⁵⁴ Brazil Industrial Property Law, Law No. 9,279 of 14 May 1996, available at: http://www.sice.oas.org/int_prop/nat_leg/Brazil/ENG/L9279eI.asp (accessed 12 March 2010). Article 8 provides that: ‘To be patentable an invention must meet the requirements of novelty, inventive activity and industrial application’ (*ibid.*).
- ⁵⁵ *Ibid.*, Article 18.
- ⁵⁶ *Merck KGaA v. Integra LifeSciences I Ltd.*, 545 U.S. 193 (2005).
- ⁵⁷ *Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256 (Fed. Cir. 2008).
- ⁵⁸ *Monsanto Co. v. Stauffer Chemical Co.* [1985] R.P.C. 515 (High Ct. of Justice – Patents Court); *Klinische Versuche (Clinical Trials) I*, BGHZ 130, [1997] R.P.C. 623 (BGH); *Klinische Versuche (Clinical Trials) II*, BGHZ 135, 217, [1998] RPC 423 (BGH). According to Holzapfel and Sarnoff (2008, p. 198): ‘Europe’s experimental use exception as stipulated in Article 27 (b) CPC 1989 and corresponding national provisions

exclude from patent infringement acts of use that are carried out for experimental purposes relating to the subject-matter of the used invention. In this context, an experiment is defined as any systematic procedure aimed at discovering something unknown or testing a hypothesis. The motivation for gathering such information is irrelevant, as is whether or not the research has commercial application. Thus, e.g., pharmaceutical business interests may pursue clinical trials to assess effectiveness and a doctor may seek to identify a new drug indication, as long as the nature and scale of the acts of use reflect the purpose of obtaining new information. Similarly, the exception applies without differentiation between basic and applied research or between academic and commercial researchers.⁵⁹

⁵⁹ Belgium Patent Law, Art. 28(1)(b) (1997).

⁶⁰ *Bloomer v. McQuewan*, 55 U.S. 539, 549 (1852).

⁶¹ For example, in the US, see *In re Independent Serv. Orgs. Antitrust Litigation*, 203 F.3d 1322 (Fed. Cir. 2002); *Mallinkrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700 (Fed. Cir. 1992). In the European Union, see Case T-201/04 *Microsoft v. Comm'n* [2007] E.C.R. II-1; European Commission Decision of 24 March 2004 relating to a proceeding under Article 82 of the EC Treaty (Case COMP/C-3/37.792 *Microsoft*), COM (2004) 900 Final (21 April 2004). See generally Lemley 2007, pp. 1–8.

⁶² European Commission Decision of 15 January 2008 initiating an inquiry into the pharmaceutical sector pursuant to Article 17 of Council Regulation (EC) No. 1/2003 (Case COMP/D2/39.514), available at: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/decision_en.pdf (accessed 1 February 2009).

⁶³ EUROPA – Press Releases, ‘Antitrust: Commission Launches Sector Inquiry into Pharmaceuticals with Unannounced Inspections’, Reference No. IP/08/49 (16 January 2008), available at: <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/49&format=HTML&aged=0&language=EN&guiLanguage=en> (accessed 17 March 2010). For results of the preliminary research, see EUROPA – Press Releases, ‘Antitrust: Preliminary Report on Pharmaceutical Sector Inquiry Highlights Cost of Pharma Companies’ Delaying Tactics’, Reference No. IP/08/1829 (28 November 2008), available at: <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/1829&format=HTML&aged=0&language=EN&guiLanguage=en> (accessed 17 March 2010); for a press release regarding the Commission’s final findings, see EUROPA – Press Releases, ‘Antitrust: Shortcomings in Pharmaceutical Sector Require Further Action’, Reference No. IP/09/1098 (8 July 2009), available at: <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/09/1098&format=HTML&aged=0&language=EN&guiLanguage=en> (accessed 17 March 2010).

⁶⁴ For example, in a recent case the US Supreme Court reaffirmed that an unconditional first sale of a product embodying a patent exhausts the patent rights, but suggested that exhaustion may be avoided in some circumstances by clear contractual provisions limiting the scope of rights granted (at least to manufacturing licensees who would then lack authority to transfer those rights to purchasers by sale). See *Quanta Computer Inc. v. LG Elecs., Inc.*, 553 U.S. 617 (2008).

⁶⁵ The CIPR Report suggests that, to secure the segmentation of markets, it would also be desirable for developing countries ‘to act to prevent exports to developed countries of drugs that are part of a donation or differential pricing scheme’, noting that ‘it is especially important to avoid product diversion from those patients for whom the medicine is intended’ (CIPR 2002, p. 41).

⁶⁶ For example, in May 2004, the US signed the Central American Free Trade Agreement (CAFTA) with Costa Rica, El Salvador, Guatemala, Honduras and Nicaragua (the Dominican Republic was later added in August 2004). CAFTA requires both data exclusivity for five years and patent extensions to offset delays in the granting of a patent. See Westerhaus and Castro (2006), who note that TRIPS-plus measures have been included in similar US bilateral trade agreements with Singapore, Chile, Peru, Columbia and Morocco. The full texts for these agreements are available at: <http://www.ustr.gov/trade-agreements/free-trade-agreements> (accessed 15 March 2010).

⁶⁷ See Article 4, §20, of the FTA between the US and Jordan, available at: http://www.jordanusfta.com/free_trade_agreement_text_en.asp (accessed 3 February 2009); see also Article 16.7, § 6, of the FTA between the US and Singapore, available at: http://www.ustr.gov/Trade_Agreements/Bilateral/Singapore_FTA/Section_Index.html (accessed 3 February 2009). See Loy 2004; Khor 2007.

⁶⁸ For example, the US – Chile Free Trade Agreement provides that: ‘With respect to pharmaceutical products that are subject to a patent, each Party shall: (a) make available an extension of the patent term to compensate the

- patent owner for unreasonable curtailment of the patent term as a result of the marketing approval process' (Article 17.10(2)).
- ⁶⁹ McManis, C.R., & Noh, S. 2006, 'The Impact of the Bayh-Dole Act on Genetic Research and Development: Evaluating the Arguments and Empirical Evidence to Date', p. 2, paper presented at the conference on 'Commercializing Innovation', Washington University School of Law, 4–5 November 2005, available on the website of the Center for Research on Innovation & Entrepreneurship at: <http://law.wustl.edu/CRIE/publications/mcmaniscommercializinginnovationpaper.pdf> (accessed 19 October 2009).
- ⁷⁰ See further Eisenberg 1987; Heller 1998; Rai 2003; Rai & Eisenberg 2003; National Research Council 2005.
- ⁷¹ An example is the study conducted by the Republic of South Africa's Department of Science and Technology 2006, 'Framework for Intellectual Property Rights from Publicly Financed Research', available at: http://docs.google.com/Doc?id=dc39jv73_0cshk9pcb (accessed 17 March 2010).
- ⁷² The text of the Intellectual Property Rights from Publicly Financed Research and Development Act, No. 51 of 2008, is available at: <http://www.pmg.org.za/files/gazettes/090409propertyrightsregs.pdf> (accessed 15 March 2010).
- ⁷³ For a critique of the bill, see Kochupillai 2010.
- ⁷⁴ California Institute of Technology et al. 2007, 'In the Public Interest: Nine Points to Consider in Licensing University Technology', White Paper [hereinafter 'Nine-Point Report'], available at: <http://news-service.stanford.edu/news/2007/march7/gifs/whitepaper.pdf> (accessed 18 October 2008).
- ⁷⁵ Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) 2006, *Public Health, Innovation and Intellectual Property Rights* [hereinafter 'CIPIH Report'].
- ⁷⁶ World Health Assembly (WHA) Resolution WHA56.27 (28 May 2003), available at: http://apps.who.int/gb/archive/pdf_files/WHA56/ea56r27.pdf (accessed 17 March 2010).
- ⁷⁷ See WHA Resolution WHA61.21, Annex, paras. 11–12 (24 May 2008), available at: http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf (accessed 17 March 2010).
- ⁷⁸ See Universal Declaration of Human Rights (Paris, 10 December 1948), G.A. Res. 217A (III), UN Doc. A/810 (1948) [hereinafter 'UDHR'], Article 27, available at: <http://www.un.org/en/documents/udhr> (accessed 29 March 2010). The UDHR provides that 'everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits' and that 'everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author' (Art. 27).
- ⁷⁹ This section was contributed by Claudia Trezza and Claire Comfort.
- ⁸⁰ Type II diseases are diseases that 'are incident in both rich and poor countries, but with a majority of cases in poor countries – Type II diseases are often termed neglected diseases'.
- ⁸¹ See WHA Resolution WHA59.24 (27 May 2006), available at: http://apps.who.int/gb/ebwha/pdf_files/WHA59/A59_R24-en.pdf (accessed 17 March 2010).
- ⁸² Such PDPs have been funded, for example, by the Bill & Melinda Gates Foundation's Global Health Program and the Rockefeller Foundation, as well as by national governments and international organizations.
- ⁸³ The MIHR Report further states that PDPs are critical licensing and drug development partners for university technology managers as they strive to promote global health equity and formulate university-generated R&D and technology transfer alliances (2006, p. 5).
- ⁸⁴ It has been said that PDPs are most effective when partnerships are formed early in the drug development process. For further discussions, see Callan and Gillespie 2007, pp. 164–165.
- ⁸⁵ This section, synthesizing and analysing scenario plans relating to IP and health, was contributed by Tzen Wong.
- ⁸⁶ European Patent Office 2007, *Scenarios for the Future: How Might IP Regimes Evolve by 2025? What Global Legitimacy Might Such Regimes Have?*, EPO, Munich [hereinafter 'EPO Report'], available at: [http://documents.epo.org/projects/babylon/eponet.nsf/0/63a726d28b589b5bc12572db00597683/\\$file/epo_scenarios_bookmarked.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/63a726d28b589b5bc12572db00597683/$file/epo_scenarios_bookmarked.pdf) (accessed 26 February 2010).
- ⁸⁷ UNAIDS 2005, *AIDS in Africa: Three Scenarios to 2025*, UNAIDS, Geneva [hereinafter 'UNAIDS Report'].
- ⁸⁸ See Table 'Comparing health across the scenarios' (ibid., p.105).
- ⁸⁹ It is said that Western pharmaceutical industries have mostly turned into 'copy-cat' producers of drugs and treatments developed by the new, emerging powers (ibid., p. 105).
- ⁹⁰ In the context of pharmaceutical research, 'push' mechanisms generally refer to supply measures involving governments and other funding agencies or industry in actively encouraging certain R&D directions; 'pull'

mechanisms refer to the dynamics of market demand, which creates incentives for R&D in certain health-related innovations including pharmaceutical products.

⁹¹ Governments are blamed under this scenario for ‘allowing a patent system that reinforced this “immoral” behaviour of the pharma industry, and for not having established alternative public research programmes’ (ibid., p. 80).

⁹² The past tense is used by the storytellers in these scenarios, as if looking back from the future on past events. This is a narrative device often used in scenario planning.

⁹³ See Appendix B on some current open source initiatives relating to medicine. On the relevance of ‘open source’ in other fields, see Chapter 3 (Box 3.3) and Chapter 7.

⁹⁴ Online access initiatives for journals are further explored in Chapter 7 of this book.

⁹⁵ WHO, International Union for Conservation of Nature (IUCN) and World Wide Fund for Nature (WWF) 1993, *Guidelines for Conservation of Medicinal Plants*, IUCN, Gland, Switzerland.

⁹⁶ See WHO 2002, *WHO Traditional Medicine Strategy 2002–2005*, Doc. WHO/EDMTRM/2002.1, p. 5, available at: http://whqlibdoc.who.int/hq/2002/WHO_EDM_TRM_2002.1.pdf (accessed 26 November 2008).