After long years of negotiation, the Uruguay Round finally culminated in 1994 with the signing in Marrakesh of the controversial TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreement, aimed at extending worldwide the type of intellectual property protection that had up until that point been granted to firms established in the most developed countries.

All the while, the AIDS virus, which had infected an ever-greater number of victims throughout the 80s, was spreading across the world, hitting the poorest and least protected regions the hardest – and Sub-Saharan Africa worst of all.

The coexistence of these two series of events is obviously coincidental. Yet, they have become closely intertwined - to such an extent that the fight against the AIDS epidemic is in fact largely predicated on the totally different issue of the new global intellectual property rights regime. Extended so that it now covers drugs, this regime has raised a number of barriers impeding poorer nations’ access to treatment. These conflicting interests have become more critical with the HAART therapies that began to develop in the mid-90s. Such treatments may not offer a definitive solution but they do represent real progress, giving hope to millions of AIDS victims across the world by extending their life expectancy by several years.

The chapters making up this section of the book focus on the conflictual interactions between drugs-related intellectual property rights and access to treatment. As we will see, each of these chapters deals in depth with one of the issues at stake. As such, the current introduction is no substitute for reading
these chapters, nor does it provide a summary of them. The aim here is different; it is to highlight the significance of some of the largely transversal themes running through the various chapters on offer. It is also to attract the reader’s attention to what seems to be a growing tension between the dimension of the collective good of public health and profit-seeking by private firms involved in that domain. In this book we address this central issue and see how it affects the differential life chances of millions of HIV-infected persons.

Three themes will be emphasised. The first relates to the nature of the new legal framework that has governed drugs and healthcare access ever since TRIPS was first adopted. The second relates to the rich and varied lessons we can learn from different national generic drugs production experiences. This involves presenting and analysing the policies being pursued in Thailand, and especially in Brazil with its pre-eminent role in international issues pertaining to these topics. The third theme, which to a certain extent encompasses the first two, relates to actors’ behaviour and to pricing mechanisms that have been observed in the world market for ARVs. As we will see, this theme is closely connected to the institutional conditions determining the trading of ARVs (whether generic or not) between the countries of the North and the South.

_The new constraints that TRIPS has generated_

To measure the significance of the Public Health changes that TRIPS has introduced, one has to remember that before the TRIPS Agreement was signed in 1994 the various Treaties that used to oversee Intellectual Property agreements at an international level authorised multiple protection systems [1-3]. In particular, it was acceptable that countries marked by weaker levels of economic and technological development could adapt systems that were much more conducive to the diffusion of technology than to incentives to innovate [4]. For example, it was perfectly legal to copy existing molecules (even ones that had been patented in the countries of the North). This enabled many countries to build up a local pharmaceutical industry based on copying molecules that had been developed elsewhere – making it possible to offer such products in the local market at much lower costs, a necessary albeit insufficient precondition for providing the poorest members of society with access to healthcare.

The old system may come as a surprise to many people today, but less so if we recall that these very same principles (free copying enabled by an absence
of patents on pharmaceutical molecules) had originally been a key driving forces behind the growth of the pharmaceutical industry in the countries of the North. It was only from the 60s onwards, and sometimes much later (i.e., 1977 in Switzerland) that patents were introduced for pharmaceutical molecules. Until these late dates, law-makers throughout the world were unanimous in affirming that the public nature of health necessitated a special treatment for all of the products and services comprising this good.

One may observe that the absence of patents on pharmaceutical molecules in no way hindered innovation-driven progress. Quite the contrary, reciprocal imitation and free copying fostered waves of innovation for several decades. Nor was this earlier regime damaging to companies: in addition to the market growth enabled by the low cost production of an increasing number of molecules, firms had a whole range of tools and instruments they could use to optimise their investments. These included “first mover advantages” plus the development of brands and reputation effects – all of which usually allowed innovative firms to make a return on their investments.

There is little question therefore that the TRIPS agreement constituted a real break with the past – a shift that was all the more pronounced since not only did it align the least developed countries’ IPR regimes with those found in the more developed ones (withdrawing the copying rights that the latter had used to build up their own base) but also because this alignment was only implemented once the North’s own protection regime had been strengthened.

The change was so sudden that TRIPS’ initiators, aware of the problems such agreements could cause, made sure that the Treaty incorporated and encompassed a variety of exemptions and exceptions, including certain stipulations (often drawn from the Basel and Paris agreements that had historically been viewed as the world’s leading Intellectual Property Rights treaties). These stipulations specifically authorised copying, notably in the event of a health emergency.

1. One particularity of the pharmaceutical industry is that until recently process-related patents were the only ones to be accepted. Since in chemistry many different pathways can usually be used to synthesise a given molecule, process patents were no obstacle to the production of identical molecules obtained via other pathways.

2. In a study of the decline of the Italian pharmaceutical industry, Scherer shows that this coincided in fact with the advent of a patenting system.

3. For example, patent protection coverage rose on average from 16 to 20 years in recent times, first in the United States and then in Europe.

4. See Zhang, for details on this point.
The implementation of so-called “compulsory licensing” clauses were designed specifically to deal with these kinds of situations. Introduced into the system as a kind of cushion or shock absorber, this clause would nevertheless generate enormous problems for those countries that lacked research capabilities. States have supposedly retained room to manoeuvre that will provide them with the means to ensure the primacy of public interests over those of patent-holders in the event of health crises; or else the means to regulate competition, thereby preventing pharmaceutical companies from abusing their dominant positions. However, much greater room to manoeuvre has been granted to the countries of the North than to those of the South, specifically to Southern nations lacking in industrial production capabilities. Indeed, TRIPS Article 31f de facto prohibits countries of the South lacking in the requisite technological capacities from importing any drug which they cannot produce themselves. To some extent, this stipulation runs contrary to the spirit of the TRIPS agreement, which was intended to reduce barriers to international trade. Moreover it clearly emphasises monopoly protection as opposed to free trade and levies harsh penalties on the countries of the South. It is no surprise then that this issue is currently the subject of major international disputes. The chapter by ’t Hoen that opens this section of the book retraces the history of these conflicts in detail.

As for the present article, it is enough for us to indicate that when faced with the AIDS pandemic and the needs arising from the fight against this disease, TRIPS has in many circumstances been used by the pharmaceutical multinationals (and/or their representatives) to erect a panoply of barriers undermining any attempts by actors from the countries of the South (NGOs, State organisations, etc.) to develop anti-AIDS policies based on the use of generic ARV-based treatments. There is little doubt but that TRIPS, if maintained in its current form, constitutes a major institutional hurdle that the fight against the pandemic will have to overcome.\footnote{For a different view on this issue see \cite{7} which expresses the pro-patent arguments.}

**Thailand, Brazil:**

*what we can learn from Southern generics producers*

Both Thailand and Brazil in their own way exemplify the preceding conclusion. They also provide matter for further reflection, involving an exploration of other dimensions and areas involved in the fight against AIDS.
A key observation to begin with is that the successful generic ARV production in both countries has only concerned ARVs that are not protected under TRIPS, i.e. that were already being traded when the two countries first introduced legislation to ensure that their domestic intellectual property rights laws complied with TRIPS-introduced stipulations protecting patented molecules. It is essential to note here that the production of ARVs in both countries was not being de facto limited to the oldest generation of ARVs due to some lack of technological competency. On the contrary, both Thailand and Brazil possess skills that could allow them to produce the whole range of the ARVs used today against the disease. The obstacles are definitely of a legal, as well as political nature. In particular, the United States has made it clear that it is prepared to use a variety of instruments to pressurize countries (including reprisals, if need be) if post-TRIPS ARVs were to be produced locally in a generic form. For instance, Thailand and Brazil have been named in US article 301 Special procedures, threatening them with serious reprisals because the US Trade Representative has deemed their national laws to be a threat to American corporate interests. Worse still, local producers are being increasingly squeezed. In the case of Thailand for example, a sort of “Super-Trips” is being applied under the aegis of the Safety Monitoring Program adopted in the country to satisfy some US demands (cf. the chapter by Guennif and Mfuka).

This is only one of the lessons we can learn from these countries’ experiences. Others, some of which are more optimistic in outlook, are just as important.

First of all, copying molecules may not be all that easy, but it is quite possible for a large number of countries. Better still, since outright copying is apparently difficult (because patents reveal little about a product), the fact that something must be created if the same molecules are to be produced (cf. note 1 on the many different pathways that can be followed in manufacturing a particular

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6. Those trading before 1996 for Brazil and before 1994 for Thailand, respectively the years when new TRIPS compliance-ensuring patent legislation was first introduced in each country.

7. The "301 Special" section is a whole set of U.S. trade law stipulations specifically devoted to the defence of intellectual property rights and used to justify the unilateral actions this country takes (i.e. not recognising the authority of the WTO dispute resolution mechanism) whenever its national firms' interests are deemed to be under threat. To study these stipulations, which have been a main driver behind the adoption of TRIPS, see [3] and [8]. For a criticism thereof, see Baghwati [9].

8. SMP consists of a whole set of stipulations introduced in Thailand under pressure from the U.S. It has resulted in 2-year "exclusive market rights" being granted to multinational companies, covering new chemical entities, new combinations plus new recommendations and delivery systems.
molecule) could engender drugs featuring a number of improved properties over the patented drugs’ characteristics (cf. the chapter by Cassier and Correa).

Above all, it has been shown that production costs on generics thus obtained allow for significantly lower treatment prices (from $10-12,000 per person/year to about $300-350). A dollar a day: thanks to generic drugs, this is what the life of an AIDS sufferer costs; a figure that the international community could easily pay, if it decided to do so; and a figure that allowed Brazil to set up its remarkable universal and free public healthcare access programme, the effects of which have been spectacular (see the chapter by Texeira et al. for details of this programme).

Other less optimistic lessons can also be learned from these experiences, particularly from the fact that the provision of generic ARVs, the only ones whose price allows them to be used effectively to stem the pandemic, is still very dependent on the provision of low-priced active principles. For the moment, these continue to be mainly manufactured by Asian (notably Indian and Chinese) generics producers. It should be remembered that active principles amount to 90% of the cost of an ARV. Inasmuch as India and China have largely postponed their compliance with TRIPS until the year 2005, the active principles currently being used in ARV production are those being freely traded internationally between countries where they do not come under the aegis of patent protection. What will happen tomorrow if this trade is rendered impossible because of a restrictive application of TRIPS? If Brazil cannot develop its domestic active principles production capabilities, its remarkable universal and free healthcare access programme will be under threat and might have to be curtailed (cf. the chapter by Orsi et al.).

This is a crucial issue. Without the preservation of free trade in active principles, low-cost generics production could be threatened, even in those countries that have acquired the greatest experience and expertise in this domain (i.e. Brazil, Thailand).

Another key issue is generics provision in countries lacking in technological capabilities. In this crucial area, American intransigence (the U.S. being the only country to reject the intricate but successful compromise accepted by the 143 other participants in the 2002 Geneva Conference (cf. the chapter by ‘t Hoen) has hindered implementation of the advances achieved in the 2001 Doha protocol. Clearly the intransigence manifested until now by the US representative poses a grave threat to the fight against the pandemic.
Pricing and markets

The paragraphs above offer a sufficient reminder that ARV production and delivery pricing issues will be a key factor in the fight against AIDS. But how are these prices determined? How have the main protagonists in this field been behaving? What can we expect for the future? The final chapters focus on these questions.

The first observation is that the market for ARVs is complex and atypical in nature, being one of those markets which is described in economic analysis as based on forms of “imperfect competition”. There are at least two reasons why this market can be termed atypical. Firstly, the products traded there (ARVs) are covered by patents that are tantamount to monopolies being granted to the firms owning such goods. Secondly, and partially as a consequence of the preceding fact, there are very few participants in this market. Seven firms deliver the 17 ARVs being used today, clearly indicative of an oligopolistic situation. These characteristics explain why we are so far from any of the “equilibrium prices” formed in competitive markets as a result of supply and demand mechanisms.

The main issue here is that the existence of patents is what guarantees monopoly pricing. The legitimacy of such patents has long been discussed in the literature on this subject (cf. the chapter by Combes, Pfister and Zuniga summarising some of the main arguments). Economic theory states that, due to some uncertainties attached to production of the good “knowledge”, a number of transfers will have to be made in order to aid the actors ready to take on the risk of entering into research activities. There is an agreement (among theorists) that there must be incentives to reward firms taking on such risks. It is extremely difficult, however, to ascertain the form that such incentives should take, and previous responses have not been particularly conclusive [10]. For example, even if the solution chosen involves a patent (paving the way for a monopoly rent to reward the research investments that have been made), questions still remain as to the level at which this patent-generated rent should be fixed. Although it should be large enough to incentivize and reward the inventor, it should not be too heavy a burden for the consumer and/or (if s/he belongs to a

9. Since the seminal paper by Arrow [11], many studies have discussed the relevancy of patents as a way of creating incentives for research. The merits of other forms (subsidies, paying "bonuses" to inventors, etc.) have been thrown into the equation as well. However, theoretical literature has not been able to come up with any definite conclusions on this subject.
State health scheme) for the taxpayer. Between incentives to innovate and the cost of well-being, any equilibrium (if indeed one does exist) will be difficult to identify, especially since people’s ability to pay (the factor that should define the “reservation price” beyond which consumers will no longer purchase a good) varies greatly from one part of the world to the next.

In addition to these theoretical questions, there are others that come from observing the market’s actual modus operandi. At least three phenomena have helped to make this a particularly complex situation:

1) the market for patented drugs and the market for generic products are not completely cut off from one another. To a certain extent, the two types of products compete (this is the case for ARVs not covered by patents in Brazil and Thailand, and also certain Indian generics that might be in competition with some of the patented drugs on offer);

2) the market possesses a “political” dimension. A number of pharmaceutical firms have got together with international organisations and worked under the auspices of specific programmes to deliver patented ARVs at negotiated prices. The latter are much lower than current prices in countries of the North guaranteeing full compliance with patent laws. The so-called Accelerated Access Initiative (AAI) which brings together 5 organisations from the United Nations and 6 large pharmaceutical companies into programmes targeting the countries of the South is of special importance here. Lucchini et al. (cf. chapter in this book) have called this practice “political philanthropy”. It is one that raises serious questions about the future of the ARV market;

3) the coexistence of these “negotiated” price programmes with bilateral forms of transactions (the purchasing country, operating in general via its “central pharmacy”, develops a sourcing relationship with one or several firms which it forces to compete with one another) means that we are dealing with different market configurations and structures in which “suppliers” and “demanders” negotiate in very different ways, influencing the price of the transactions.

The chapter by Lucchini et al. (based on an exceptionally large and representative database), centred on the analysis of price mechanisms, provides valuable lessons. Three of them deserve special attention.

a) Up until now, North/South transactions have involved very small quantities of ARVs compared with the needs that have been identified. This fact attests in its own way, and irrespective of the underlying causes, to the weak commitment of national State authorities and international donors to the fight against the pandemic. This observation is particularly true for the African continent as a whole.
b) The second is the sharp fall in the constant market price of internationally traded ARVs over the past few years. There are two explanatory elements:

i) the generic producers’ massive entry into this market. Brazilian generics production, starting with the 1997 implementation of the country’s national treatment access programme, has clearly driven prices down – as have the widely-reported proposals of Indian generics producers;

ii) the launch of the AAI programme. Prices negotiated as part of such programmes since 2001/2002 have had a major impact on world prices.

c) The prices of the different types of ARVs have tended to converge towards the prices of their generic equivalents and/or towards AAI programme prices. This means that we are moving towards a sort of “dual market” for ARVs, characterised by high prices in the North and lower prices in the South. It should be remembered, however, that the programmes currently being run in the South treat an extremely small number of patients compared to the needs that have been identified.

The preceding observations stress the fact that in this field, as in many others, the main instruments moderating and controlling prices are the forms of competition that have been introduced (however diluted and often indirect they might be in the case of ARV markets). Hence, the authors’ conclusion that what we need to ensure is the ability of such principles to fulfil their role more completely in the future in order to encourage the transition from “politically philanthropic” behaviour (whose opportunistic dimension constitutes an undoubted problem) to clearly regulated markets guaranteeing a long-term downward pressure on the market prices of ARVs destined for the countries of the South – as well as access to treatment for insolvent patients in these countries. This sort of regulatory presence, even if it is insufficient to cope with the epidemic, is at least a prerequisite for this to happen.

For the moment we face a situation in which the absence of any clear willpower on the part of regulators and legislators (compounded by the weak bargaining power of the poorest countries) keeps the needs of developing countries from becoming the focal point of international dealings. The market for ARVs will probably remain imperfect for quite a while, being largely subject to the strategic behaviour of the different actors, and notably to the actions of the world’s large pharmaceutical companies, still the main actors in this field.

Given this situation, by highlighting three possible development scenarios, the final chapter (Dumoulin et al.) provides some useful keys for the future.
A brief presentation of these scenarios will help us to identify some of the key elements characterising the complex dynamics running through the issue of access to HIV/AIDS care.

1) The first scenario extrapolates the “status quo”. If unamended, TRIPS would guarantee multinationals considerable control over the pharmaceuticals sector, leaving generics producers with little room to work in. This scenario maintains and extends the great inequalities in access to treatment that we are experiencing today, and for this very reason would lead to a great deal of tension.

2) The second scenario is similar to the first, differing only in that it is predicated on the formation of a wider and more extensive market for ARVs. This would specifically result from the pharmaceutical multinationals undertaking a clear and confirmed price differentiation and market segmentation strategy, leaving some room for Southern market generics producers to operate in. This scenario, which extrapolates the current “market-orientation” of treatment, is unsustainable due to the same kinds of limitations as those mentioned above. At best, it extends healthcare access whose needs can at least partly be afforded, slightly broadening the target populations without providing any overall solution to the spread of the epidemic.

3) The third scenario differs in two respects. First of all, international organisations play a key role here, given their ability to regulate markets by redefining IPRs and authorising the international copying, distribution and circulation of low-priced generic ARVs, at least between countries of the South. In addition, funds can be collected and reallocated (again via international organisations) to allow patients without financial resources to access healthcare. This is an ideal scenario of course, but the only realistic one if the real aim is to eradicate the epidemic completely. This sort of scenario clearly infers the success of initiatives like those being implemented by the Global Fund to Fight AIDS, Tuberculosis and Malaria.

Finally, as regards the overall scene, marked by the confrontation of, and cooperation between, actors with conflicting interests and goals, the future depends on two questions:

– the status of ARV (i.e. the nature and scope of the intellectual protection they are granted) vs. the right to produce generic drugs and to trade them freely between the countries of the South;

– the role attributed to markets vs. allocation and transfer mechanisms guaranteeing healthcare access to patients without financial means, (currently the vast majority of recorded cases).
It is undeniable that these issues are interrelated, and that no sustainable solutions can be found if regulators and legislators do not enforce the type of measures able to provide the legal instruments required to tackle the situation. Nearly 20 years after the epidemic first broke out, the contributions made in the first section of this book, constituting the current state of knowledge, show that pathways do exist. It is up to the policy makers to flesh them out.

REFERENCES
