

9 INTELLECTUAL PROPERTY, COMPETITION LAW AND ACCESS TO PHARMACEUTICALS: THE RELEVANCE OF A 'MARKET APPROACH' TO THE EXERCISE OF INTELLECTUAL PROPERTY RIGHTS

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ABSTRACT

This contribution wrestles with an intensely debated topic: intellectual property (IP) and its interface with access to pharmaceuticals.¹ Since the entry into force of the TRIPS Agreement, advocates for enhanced access to medicine have been pushing for a reading of TRIPS that focuses more on the users of IP-embodied product needs to have improved access to pharmaceuticals. In addition to the 'built-in' flexibilities within the IP system such as the compulsory licensing mechanism, efforts have been made to support a reading of the agreement that enhances access to pharmaceuticals, especially in developing countries. The developments in the framework of Doha, with the Doha Declaration on Intellectual Property and Public Health² and the subsequent Article 31*bis* that allows Member States to issue licences for export, are in line with that dynamic. Despite those efforts, access to pharmaceuticals is still an issue.

In addition, and complementary to the access mechanisms within the IP system, competition law, as a market regulatory tool, is another legal instrument with huge potential to correct abuses of intellectual property rights (IPRs). Competition law thereby fosters access to pharmaceuticals. Of

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¹ Mor Bakhoum, 'TRIPS, Patent Rights and Right to Health: "Price" or "Prize" for Better Access to Medicine?' Max Planck Institute for Intellectual Property, Competition and Tax Law Research Paper Series No. 10-07, available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1619215&download=yes

² *ibid*, for discussions on the developments in the framework of Doha.

course, the TRIPS Agreement recognizes the relevance of competition law as a balancing tool to the exercise of IPRs and allows its Members to use their competition laws as a correcting tool against potential abuses of IPRs.³ However, in the absence of a binding agreement, the effectiveness of this approach depends on the strength of each country's competition institutions. The prospects of an international agreement on competition that potentially addresses IP-related abuses are at best uncertain.⁴

I. INTRODUCTION

Two important developments with regard to IP and access to pharmaceuticals have taken place over the past years. First, in the United States and the European Union, competition authorities are taking a more active stand by using competition law as a regulatory instrument to foster access to pharmaceuticals. The EU Commission's 2009 Sector Inquiry Report⁵ showcases various strategies patent owners use to limit competition, which has had the effect of hindering access to pharmaceuticals. Those strategies include reverse payment settlements between originators' companies and generics manufacturers. These developments demonstrate that in the United States and the European Union, a market-oriented approach that subjects the owners of IPRs to the rules of an open and competitive market seems to be more relevant to the issue of access to pharmaceuticals. It is well accepted that IP does not grant monopoly power. It only provides 'market power'⁶ that should be exercised in accordance with competition law rules. The second relevant development is the spread of competition laws, especially in developing jurisdictions.⁷ This placed at the forefront of the debate the issue of how developing jurisdictions approach the delicate interface between IPRs and competition law.

³ In particular Article 40 of the TRIPS Agreement., Article 8(2), Article 31 TRIPS competition related provisions

⁴ For discussion, see, Josef Drexel, 'International Competition Policy after Cancún: Placing a Singapore Issue on the WTO Development Agenda' *World Competition* 27 (3), 419-457, 2004.

⁵ Commission, Pharmaceutical Sector Inquiry Final Report, Part I <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf> see also Communication from the Commission Executive Summary of the Pharmaceutical Sector Inquiry Report, available at:

<http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf>. See for comments, Josef Drexel, 'AstraZeneca and the EU Sector Inquiry: When Do Patent Filings Violate Competition Law?', Max Planck Institute for Intellectual Property, Competition and Tax Law Research Paper Series No. 12-02.

⁶ Josef Drexel, 'The Relationship Between the Legal Exclusivity and Economic Market Power: Links and Limits, in *Intellectual Property, Market Power and the Public Interest* (Inge Govaere and Hanns Ullrich eds 2008) 16-18

⁷ In sub-Saharan Africa an increased number of countries have adopted competition law over the last 20 years. For an overview, See ACF. Also, Singh, *Competition and Competition Policy in Emerging Markets*, G-24 Discussion Paper No. 18 (2002), p. 6; Mehta/Agarwal/Singh, *Politics Trumps Economics*, 2007, p. 1; Stewart/Clarke/Joekes, *Competition Law in Action*, 2007, p. iv.

This paper discusses the interface between IP, competition law and access to pharmaceuticals, with a focus on the situation in sub-Saharan Africa. The focus of this contribution is not on TRIPS flexibilities *stricto sensu*. It looks at the potential of using competition law as a market regulatory instrument, in order to provide improved access to pharmaceuticals, especially in developing countries. Although competition laws have been enacted in many jurisdictions, case-law dealing with these laws remains very scarce. Only in South Africa have cases been decided that are relevant to the issue of access to pharmaceuticals. COMESA's Competition Commission has recently approved a merger without imposing conditions that involved two pharmaceuticals companies. Those cases will be discussed, in order to show the potential of using competition law as an access tool following the developments in the European Union.

When it comes to pharmaceuticals, the debate often focuses on the regulations (balancing tool) embodied in the IP system such as compulsory licensing. This paper argues that competition law as a market regulatory tool is a more relevant instrument that should be used to supplement the flexibilities of the IP system. This is evidenced by the EU approach to the Sector Inquiry Report and the subsequent cases, which have had a direct impact on access to pharmaceuticals.

This paper is divided as follows: section II provides general remarks on the 'market-oriented approach' to access to pharmaceuticals. Section III briefly discusses TRIPS-related flexibilities with a focus on competition-related provisions. Their limits as flexibility tools will be highlighted. Section IV is devoted to the developments in sub-Saharan Africa with two cases in South Africa and a merger case cleared by the COMESA Competition Commission. Section V concludes by showcasing the relevance of competition law to accessing pharmaceuticals, with a special emphasis on the perspective of developing countries.

II. A MARKET-ORIENTED APPROACH TO ACCESS TO PHARMACEUTICALS

The application of competition law to IP-related restrictions of competition seems to be well established. Intellectual property owners are not immune from competition law liability when exercising their rights in the marketplace. The IP system rewards IP owners for their innovation or

creativity with the possibility to enter the market.⁸ Markets are not without rules. Competition law provides the rules for the marketing of IP rights. Even if IP protection provides IP owners with the right to enter the market, IP owners are required to exercise their rights while respecting the need to keep the market open and competitive. Competition law intervention is going as far as questioning the mere acquisition of an IPR as being potentially anti-competitive. From an institutional point of view, it has been argued that competition law intervention is only acceptable when IP owners exercise their rights in the market. However, some commentators go as far as arguing that, in the framework of discussions triggered by the *AstraZeneca*⁹ judgment of the General Court, 'patent law does not insulate filing strategies from competition-law liability'.¹⁰ This far-reaching conclusion showcases how competition authorities are becoming more and more active in monitoring the behaviors of pharmaceutical companies. In the absence of sound competition-law control, pharmaceutical companies could easily undermine certain flexibilities within the IP system, such as compulsory licensing, limited durations of patent protection, and parallel trade. For instance, patent protection gives a limited protection of 20 years to a patent owner, which allows for price-based competition by generic producers once the term of the patent has expired. If originators and generic companies settle, by agreement, for the generic company to delay its entry into the market, there will be a *de facto* continuation of a monopoly situation with the consequence of monopoly prices paid by the consumers. Given their detrimental effect on access to affordable pharmaceuticals, in the United States and the European Union, the issue of pay-for-delay may constitute a competition law offence.

In addition to the pay-for-delays agreement, the 2009 EU Commission Sector Inquiry Report has identified various strategies that pharmaceutical companies use that have the effect of limiting competition and charging monopoly prices. Amongst such practices are patent filing strategies¹¹ that intend to delay or block the entry of generic products into the market. Such strategies may be a legitimate exercise and use of the patent system. The question therefore arises as to 'under which

⁸ Josef Drexl, 'The Relationship Between the Legal Exclusivity and Economic Market Power: Links and Limits', in *Intellectual Property, Market Power and the Public Interest* 16–18 (Inge Govaere and Hanns Ullrich eds. 2008).

⁹ Case T-321/05 *AstraZeneca v. Commission* [2010] ECR II-0000.

¹⁰ Josef Drexl, 'AstraZeneca and the EU Sector Inquiry: When do Patent Filings Violate Competition Law?', Max Planck Institute for Intellectual Property, Competition and Tax Law Research Paper Series No. 12-02.

¹¹ *ibid*, at page 17 *et seq.*

conditions such as patent filings are no longer to be considered legitimate and enter the ambit of competition law liability'.¹² Filing strategies that target actual or potential competing originators' companies have also been uncovered by the Commission's report.

The increased focus on competition law as a market regulatory tool in order to identify and sanction anti-competitive practices initiated by pharmaceutical companies reveals the potential of the competition law dimension when dealing with IP-related matters. The bottom line of all the developments taking place in the European Union with regard to the behaviors of pharmaceutical companies is that, when it comes to access to medicine, there is a shift from an IP-centered approach (with a mere focus on IP flexibilities) to a 'market-oriented approach' that focuses on opening the competition channels and preventing foreclosure in order to allow improved access to pharmaceuticals.

The developments taking place in the European Union are relevant from an international perspective. Given the fact that sub-Saharan African countries, and IP-importing countries in general, rely heavily on the importation of pharmaceuticals, recent developments in the European Union and the United States could have a substantial impact on public health from an international perspective. Reliance on generic competition is part of the strategies that aim at improving access to pharmaceuticals in developing countries. Since patent settlement strategies aim at delaying the entry of generic substitutes to the patented products market, markets in which competition authorities are not well suited to address such strategies will have to pay monopolistic prices even after the expiration of the patent.¹³ For instance, if two pharmaceutical companies operating in the European Union and doing business in sub-Saharan Africa agree to settle in order to avoid competition by generics, it is very likely that competition authorities would not address such practices. Given the effect doctrine, such practices would not be prohibited for the absence of an effect on the EU market. This raises the issue of international cooperation in competition law enforcement.

The focus when discussing those issues is on the EU or the US markets, which reflects the territorial nature of competition law enforcement. However, such practices have international ramifications and

could potentially impact global public health, especially for medicines distributed across markets.

This hypothesis showcases how related the goals of competition law and the goals of IP law are. Anti-competitive practices, if not addressed, could undermine the built-in flexibilities within the IP system. From the perspective of developing countries, it is important to have a broad view when dealing with policy issues such as access to pharmaceuticals. A narrow focus on the IP-related mechanisms is not enough.

The systemic approach of the use of competition law as a market regulatory mechanism, which goes beyond the technology transfer approach of the TRIPS competition-related provisions¹⁴, may turn out to be an effective tool for fighting anti-competitive practices in the pharmaceutical industry. Competition law, as a public policy instrument, offers diversified intervention tools that go beyond the mere exercise of the right. Merger control, for instance, offers the possibility to block or to authorize with conditions an operation that could potentially limit competition or research and development efforts. Merger control has the potential to oversee the functioning of the market for pharmaceuticals and to prevent operations that could lead to market foreclosure. As we shall see, the newly functional COMESA Competition Commission has recently authorized without conditions a merger involving two pharmaceutical companies. Competition law vests public authorities (a Competition Commission) with the power to initiate proceedings and to impose fines in case of cartels or abuse of dominance that involve IPRs. Individuals do not necessarily trigger enforcement initiatives, although private enforcement is becoming more and more important.

If competition law has the potential to curb anti-competitive practices initiated by pharmaceutical companies, how does TRIPS address the issue? We are now turning to a brief discussion of the issue.

III. TRIPS AND THE RIGHT TO USE COMPETITION LAW AS A FLEXIBILITY TOOL: POTENTIAL AND LIMITS

TRIPS does not create a binding international framework that obliges signatory members to apply competition law to IP-related restrictions of competition. From a TRIPS perspective, using competition law as a balancing tool to the exercise of IPRs is only optional. TRIPS competition-related

¹² *ibid*

¹³ See generally the structural disadvantage of developing countries with regard to abuse of dominant position in the IP field, Joseph Drexel, 'Intellectual Property and Competition: Sketching a Competition-Oriented Reform of TRIPS', in *Festschrift till Marianne Levin*, 2008, p. 261, 267.

¹⁴ Joseph Drexel, 'Intellectual Property and Competition: Sketching a Competition-Oriented Reform of TRIPS', in *Festschrift till Marianne Levin*, 2008, p. 261.

provisions give a leeway to signatory Members to define their own policies when it comes to applying their competition laws to IP-related restrictions. Therefore, the effectiveness of competition law as a balancing tool depends on the enforcement institutions of each Member's competition law. This situation creates an unbalance from an international perspective. On the one hand, there is a harmonization, from the top, of the protection of IP. On the other hand, the use of competition law is 'deregulated' and left to the choice of each Member to define its own policy.

The development of competition laws in developing countries is a positive sign of the use of competition law as a balancing tool. However, the treatment of IP in competition legislation in developing countries is very diverse. Whereas some countries apply competition law to IP-related restrictions, others go as far as exempting IP from the application of competition law. This shows that developed jurisdictions that have strong competition law institutions and sophisticated enforcement records are more likely to be able to use competition law as a balancing tool, as permitted by the TRIPS Agreement.

But signs of positive developments in sub-Saharan Africa, especially in South Africa, have been noticed.

The limited remedies provided by the IP system justify a broader intervention of competition law whose scope and objective are more general than the IP system *stricto sensu*.

Competition law is a public policy tool that can be triggered by public authorities when the functioning of the market is affected by anti-competitive practices, even those resulting from the exercise of IPRs. Public authorities enforce remedies under competition law issued after juridical adjudication, whereas private parties enforce some IP-related flexibilities.

IV. DEVELOPMENTS IN SUB-SAHARAN AFRICA RELATED TO INTELLECTUAL PROPERTY, COMPETITION LAW AND PUBLIC HEALTH

This part discusses the developments in sub-Saharan Africa with regard to the issue of access to pharmaceuticals, with an emphasis on how competition authorities have dealt with the issue so far. Although an unprecedented development has taken place over the past years in competition law in sub-Saharan Africa, the creation and effective functioning of competition authorities are still

lagging behind.¹⁵ Efforts have been made at the national, as well as at the regional level, to enact and enforce sound competition laws. COMESA, WAEMU, SADC and possibly ECOWAS are regional integration groups that deal with competition matters.¹⁶ At the national level, South Africa is by far the most advanced country with sound competition institutions and enforcement authorities. Other countries such as Mauritius, Zambia and Seychelles are catching up and are developing their institutions. When it comes to the interface between IP and competition law, some competition laws directly address the issue, whereas others exempt IP from competition law application.

From a practical point of view, cases have been rare. Only the South African Competition Commission dealt with a case, which was eventually settled. This case relates to the issue of IP, competition law and access to medicine. Another merger case that was eventually authorized with conditions is also of relevance for the discussion. Finally, the newly functioning COMESA Competition Commission has recently cleared a merger that involved two pharmaceutical companies. Those cases will be discussed subsequently. They are referred to as a pretext to demonstrate the relevance of competition law as a public policy instrument for access to pharmaceuticals.

A complaint was lodged before the South African Competition Commission against GlaxoSmithKline South Africa (Pty) Ltd ('GSK') & Boehringer Ingelheim (Pty) ('BI')¹⁷, (hereinafter *GSK/BI* case), initially for high pricing but later extended to include an alleged violation of Sections 8(b) and (c) of the Competition Act, which deal respectively with the essential facilities doctrine and exclusionary conduct.¹⁸ The case was eventually settled. In particular, GSK and BI were accused of the following anticompetitive conduct:

¹⁵ According to a need assessment conducted by the African Competition Forum, no fewer than 24 countries have competition laws at all, Mor Bakhoun, 'Balancing Incentive to Innovate and Freedom to Compete: an African Perspective on IPRs and Competition Law', p. 16, p. 15.

¹⁶ Generally on competition law and policy in regional integration, see 'Competition Policy and Regional Integration in Developing Countries', Joseph Drexler/Mor Bakhoun/Eleanor Fox/Michal Gal/David Gerber (Eds.) Edward Elgar, Northampton 2012.

¹⁷ The case was settled. See the Commission's comments on the case at South African Competition Commission, Newsletter, edition 15, March 2004, at pp. 1-2, available at:

<http://www.compcom.co.za/assets/Uploads/AttachedFiles/MyDocuments/March-04-Newsletter.pdf>

¹⁸ For a discussion of the case, see Mfundo Ngobese and Liberty Mncube, Competition Policy in South Africa's Pharmaceutical Sector: Balancing Competition and Innovation (2011) on file with the author).

- GSK abused its dominant position in the market for anti-retroviral drugs (ARVs) by charging excessive prices on the product;
- making the product inaccessible to the general public;
- refusing to supply a competitor access to an essential facility;
- dramatic difference in the price of ARVs sold in South Africa and generic alternatives sold outside South Africa;
- the existence of patents prevented sale of generic substitutes in South Africa;
- patent protection did not entail a firm to charge high prices.

The Competition Commission concluded its investigation with a finding that GSK and BI abused their dominant position by charging excessive prices, refusing to grant access to essential facilities to a competitor, and engaging in exclusionary conduct. The matter did not come before the Competition Tribunal, as GSK and BI accepted a settlement, which resulted in a drastic reduction in the prices of pharmaceuticals in South Africa.

As part of the settlement, GSK and BI agreed to:

- Grant licences to generic manufacturers;
- permit the licensees to export the relevant ARV medicines to sub-Saharan African countries;
- where the licensee did not have manufacturing capability in South Africa, permit the importation of the ARV medicines for distribution in South Africa only, provided all the regulatory approvals were obtained;
- permit licensees to combine the relevant ARVs with other ARV medicines; and
- not require royalties in excess of 5 per cent of the net sales of the relevant ARVs.

Two aspects are worth highlighting in this case. First, the competition law offences that GSK and BI are accused of would have been difficult to tackle using only the IP flexibilities such as compulsory licensing. Charging high prices, refusing to grant access to essential facilities, or engaging in exclusionary conduct would be difficult to use as grounds for compulsory licensing under the TRIPS Agreement.

The second interesting aspect of this case are the conditions of the settlements and the commitments accepted by GSK. The different commitments mirror the developments in the framework of Doha with regard to pharmaceuticals with the introduction of the mechanism of licensing for export for countries without sufficient manufacturing capacities. In Doha, in addition to the Declaration on Intellectual Property and Public Health, a new mechanism allowing countries without sufficient manufacturing capacities to issue compulsory licences for imports was introduced. Although in theory the mechanism would enhance access to pharmaceuticals, in practice it proved difficult to render operational, as the only instance in which it was tested displays.¹⁹

It is interesting to note in the GSK case in South Africa that the Doha mechanism set up for countries without manufacturing capacities, which allows countries to issue compulsory licences for exportation, was achieved through competition law. Hence, in its commitments, GSK agreed to permit licences to export the relevant ARV medicines to sub-Saharan African countries. In addition, GSK agreed that where the licensee did not have manufacturing capacity in South Africa, it would permit the importation of the ARV medicine for distribution in South Africa only, provided the regulatory approval was obtained. Those commitments, which constitute the essence of Article 31*bis* of the TRIPS Agreement, were obtained not through importing mechanisms, which turned out to be of difficult use, but by using competition law.

Moreover, a price cap of 5 per cent of the net sales of the relevant ARVs allows GSK to control the prices it charges licensees. The terms of the commitments go beyond what was agreed upon in the framework of Doha. In addition, enforcing the Doha measures involves a heavy administrative burden, whereas the Competition Commission can easily monitor that GSK actually respects its commitment.

This case displays the efficiency gains of using competition law in addition to IP flexibilities. Competition law control can turn out to be more effective and easier to enforce than IP *stricto sensu* flexibilities.

The *Aspen/GSK*²⁰ merger case dealt with by the South African Competition Commission is another example of the relevance of competition law intervention in order to keep the market open and

¹⁹ Only Rwanda has so far used the system.

²⁰ For comments on the merger see South African Competition Commission Newsletter, Edition 34, March 2010, available at: <http://www.compcom.co.za/assets/Uploads/AttachedFiles/MyDocuments/FINALfor-Web.pdf>

competitive. Aspen was a large generic pharmaceutical company that wanted to acquire the pharmaceutical component of GSK. During the merger, GSK announced its intention to license ARV to Aspen. The Competition Commission raised concerns about whether or not GSK would allow access of the ARV to other competing firms on the same conditions it had granted Aspen. In order to achieve a more competitive price the Competition Commission finally approved the merger on the condition that GSK granted licences to other competing firms on a non-exclusionary basis. The condition to grant licences to other competing firms allows price competition in the market that will eventually decrease the prices of pharmaceuticals. Price competition from an access point of view is very relevant for the consumer.²¹ However, one has to bear in mind that research and development (R&D) is very costly in the pharmaceutical industry. Mergers between competing firms can constitute a way to fund R&D. Therefore, when analysing the actual or potential effects of a merger in the pharmaceutical industry, the need to allow access to pharmaceuticals must be balanced with the need to ensure that future innovation will not be hindered.

Recently, the newly operative Competition Commission of COMESA approved unconditionally a merger between two pharmaceutical companies: Cipla India and Cipla Medpro South Africa Limited.²² Cipla India is a generic pharmaceutical manufacturing company that does business in various therapy areas. Cipla does not have manufacturing plants in the COMESA market. Cipla India supplies the Common Market primarily through distributors. As to Cipla Medpro, it manufactures and distributes various pharmaceutical products and provides health care solutions as well. After defining the relevant market as the supply of generic pharmaceutical products in the Common market, the COMESA Competition Commission determined that: (1) the same market concentration would remain post-merger as the parties did not compete in the common market before the merger;²³ (2) import competition was very rife in this market as most of the drugs sold in this market were imported. This would therefore give competitive discipline to the

merging parties and restrain them from behaving in an anticompetitive manner.²⁴

The Competition Commission added that 'the transaction would not result in the removal of any competitor from the relevant market as generally the parties were not competing pre-merger'.²⁵ Despite the absence of competition between the two firms and the openness of the relevant market to competition, the Commission reveals the existence of structural and regulatory barriers. Those relate to the cost of establishing a distribution network and the various registration processes the pharmaceutical companies need to take before they have the authorization to supply in the Common market. Regulatory barriers are common in the pharmaceutical industry business.

The Competition Commission:

concluded that the acquisition of Cipla Medpro by Cipla India was not likely to substantially prevent or lessen competition and it will not be contrary to public interest in accordance with Article 26 (1) and 26 (3) of the Regulations respectively. Further, the assessment of the merger revealed that it was compatible with Article 55 of the COMESA Treaty in that it did not negate the objectives of free and liberalized trade.²⁶

The merger did not raise competition-related issues that would have been detrimental to access to pharmaceuticals in the common market as importing competition was stifled and the merging firms were not competitors in the relevant market pre-merger. The analysis would have certainly been different if the merging companies were competing in the relevant market and held a dominant position in the distribution. This would have raised competition concerns.

The COMESA Commission hints to the issue of public interest, which is one criteria put forward by the COMESA Regulations when analysing a merger. This aspect goes beyond the scope of this paper, but it would be interesting to see how access to pharmaceuticals relates to the concept of public interest as defined in the COMESA Regulations.

²¹ Mor Bakhoum, 'Balancing Incentive to Innovate and Freedom to Compete: An African Perspective on IPRs and Competition Law', Max Planck Institute for Intellectual Property and Competition Law Research Paper No. 13-11, 2013.

²² Notification of a Merger under Article 24 of the COMESA Competition Regulations, available at: <http://www.comesacompetition.org/images/Documents/merger%20notice%20no%202.pdf>

²³ Press release on African Anti-Trust and Competition Law News and Analysis, available at: <http://africanantitrust.com/2013/08/07/comesa-publishes-explanation-of-first-two-merger-approvals-receives-4th-deal-filing/comment-page-1/>

²⁴ *ibid.*

²⁵ *ibid.*

²⁶ *ibid.*

V. CONCLUDING REMARKS

In line with the TRIPs Agreement, so far the focus has been limited to the use of the flexibilities within the IP system, including compulsory licensing. The developments in the framework of Doha, with the Doha Declaration and the subsequent scheme of exports, seem to be of limited effectiveness. So far only Rwanda has attempted to use the system, which turned out to be ineffective.

It is of course important to use the flexibilities within the IP system by carefully defining the patentability criteria or having an enhanced control over the requirements of patentability. This has been done in India with the Novartis case decided by the Supreme Court, which prevented ever-greening. Using the IP system should be the first layer of protection against strategic patenting that has a detrimental effect on access to medicine.
