

## ADVANCING PUBLIC HEALTH BY OTHER MEANS: USING COMPETITION POLICY TO MITIGATE THE IMPACT OF PATENT PROTECTION

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### Introduction

Recognising "the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics", members of the World Trade Organization (WTO) agreed on 14 November 2001 that the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) "does not and should not prevent members from taking measures to protect public health", and that it "can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."<sup>1</sup>

The *Declaration on the TRIPS agreement and public health* (the *Doha Declaration*) has since been the subject of much public discussion and debate, with significant attention being placed on the so-called public health "safeguards" or "flexibilities" within TRIPS that permit the taking of "measures to protect public health". Recently, the WTO secretariat has embarked on a series of regional capacity-building workshops, with a particular focus on the flexibilities in TRIPS itself and the decision adopted by the General Council on 30 August 2003 on the *Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health*.<sup>2</sup>

Yet despite the considerable flexibility accorded to WTO members in dealing with anti-competitive practices, coupled with the clear recognition in TRIPS that such conduct is considered as particularly egregious, surprisingly little public attention has been accorded to the role of competition policy in advancing public health by mitigating the negative effects of intellectual property (IP) protection.

The purpose of this paper is therefore to consider the role of competition policy in advancing public health in Southern Africa, with a particular focus on increasing access to essential medicines. This will be done within the broader framework provided by TRIPS, focusing on a number of key areas: the relevance of developed country experience; regulatory mechanisms to promote access; and the limitations of using competition policy within a developing world context. In addition, the South African experience in the field of IP, competition law and public health will be addressed insofar as it considers the key areas of focus.

It is also important to understand what this paper is not. Essentially, this paper does not attempt to consider the merits of high levels of patent protection, nor the role of patent protection in economic development. Or put another way, this paper proceeds on the assumption that developing countries can and should take a wide range of measures to limit the potentially negative implications of IP protection and thereby advance public health. In short, the paper considers how and in what circumstances competition policy can and should be used to increase access to essential medicines in Southern Africa.

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<sup>1</sup> *Declaration on the TRIPS agreement and public health*, WT/MIN(01)/DEC/2, 20 November 2001, at paragraphs 1 and 4, available online at [www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm).

<sup>2</sup> WT/L/540, 1 September 2003, available online at [www.wto.org/english/tratop\\_e/trips\\_e/implem\\_para6\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm)

### **The TRIPS framework**

But before doing this, it is necessary to sketch the broader framework provided by TRIPS, not only to consider the extent to which the agreement limits the use of competition policy in respect of IP but also to seek guidance in determining in what circumstances it may be appropriate to invoke competition policy to increase access to essential medicines. This is not to imply that TRIPS is alone in limiting the use of competition policy, but rather that it is the only legal framework that legally binds Southern African countries at the moment. Other limitations may very well come at a later stage through regional and/or bilateral trade agreements.<sup>3</sup>

There are five key provisions in TRIPS that directly or indirectly provide the framework within which competition policy can operate. These range from broad principles regarding the need to deal with potential negative consequences of IP to specific provisions dealing with competition policy. While differing in focus, each of the five provisions underscore the proposition that TRIPS provides significant scope within which competition policy may be employed to advance a public health agenda that may be compromised if IP protection is left unchecked.

#### *Article 1.1*

The most general of these provisions is Article 1.1, which grants members the freedom to determine an "appropriate method of implementing the provisions of ... [TRIPS] within their own legal system and practice." In essence, the provision grants members significant flexibility regarding the exact manner in which they deal with all matters relating to IP, such as remedying anti-competitive practices. Thus members may choose to go the route of a regulatory authority, linked to a specialist court or tribunal and with extensive powers of investigation. Alternatively, they may choose to locate dispute settlement within the regular court system, or within some form of hybrid system.

In each option, they may choose the level and/or nature of state participation. This means, for example, that states that cannot participate actively in competition policy enforcement may simply choose to provide a forum and/or mechanism for dispute settlement by third parties. This flexibility is particularly important in a developing country context where resources for specific enforcement mechanisms may not necessarily be available. Further, members are free to determine appropriate rules of procedure and evidence, provided this is exercised within the framework of "their own legal system and practice".

#### *Article 8.2*

The second relevant provision, which is also particularly broad in its reach, provides that steps may need to be taken "to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology." In so doing, Article 8.2 expressly recognises that the exercise of exclusive rights in IP may result in up to three unwanted outcomes, only one of which is limited to the concept of abuse of rights in the IP concerned; that WTO members are within their rights to take action to prevent such problematic outcomes; and that other provisions of TRIPS do not prevent the taking of such action. While not expressly mentioning competition policy, it is clear that Article 8.2 of TRIPS contemplates regulatory frameworks other than IP law for dealing with problems that may arise from the exercise of exclusive rights expressly provided for in the agreement.

Implicit in Article 8.2 is that the exercise of the exclusive right concerned cannot in and of itself be considered as abusive, unreasonably restraining trade or adversely affecting "the international transfer of technology." Further, the provision also recognises that the simple exercise of exclusive rights – in circumstances that cannot be considered as abusive – may nevertheless be damaging to trade and technology transfer and therefore subject to regulatory control. In other words, the circumstances particular to a country may give rise to the need for and sanction the

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<sup>3</sup> For example, negotiators expect to finalise the United States/Southern African Customs Union Free Trade Agreement later this year.

taking of particular regulatory steps, regardless of whether the conduct of the rights holder is abusive.

In Southern Africa, for example, this may give rise to the implementation of competition policies that are responsive to developmental needs in general and possibly even public health needs in particular. This raises the possibility of using competition policy as an industrial policy that only has an indirect impact on public health needs. For example, the exercise of exclusive rights in IP may be regulated by competition policy in a manner that promotes the development of a strong domestic pharmaceutical industry. This would indirectly ensure access to a sustainable supply of affordable medicines.

#### *Articles 31(c) and (k)*

The third and fourth provisions of TRIPS that are relevant to competition policy, both of which deal with the granting of compulsory licences, recognise that anti-competitive practices involving patents are particularly egregious. These are Article 31(c), which limits the use of compulsory licensing in respect of semi-conductor technology to "public non-commercial use" or to remedy an anti-competitive practice; and Article 31(k), which exempts members from legislating certain conditions attached to the grant of compulsory licences where such licences are issued "to remedy a practice determined after judicial or administrative process to be anti-competitive."

In respect of the latter, members are exempt from requiring each of four particular conditions that ordinarily attach to the grant of compulsory licences. First they need not require that the state and/or prospective licensees engage in negotiations for the grant of voluntary licences. Second, they need not place limitations on exports of products manufactured under the licence. Third, they need not require the termination of the licence "if and when the conditions which led to such authorization are likely to recur". In addition, licences issued to remedy anti-competitive practices may be subject to particularly low royalty rates.

It is interesting to note that neither TRIPS in general nor Article 31 in particular defines what is meant by an anti-competitive practice. While members have significant flexibility to determine what they consider to be anti-competitive, TRIPS' failure to provide a definition in this regard cannot be understood as providing a blank cheque to determine what practices may be considered as anti-competitive, particularly in the light of Article 8.2 that permits the taking of steps "to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology." It seems appropriate, therefore, that the concept of anti-competitive conduct be linked to these expressly identified and potentially problematic outcomes.

#### *Article 40*

The fifth and final relevant provision, which comes closest to providing a definition of anti-competitive conduct, is Article 40. This provision, which is limited to certain anti-competitive practices that may arise in "contractual licences", permits WTO members to legislate so as to prevent or control "licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market." This is because TRIPS recognises that such practices or conditions may have "adverse effects on trade and may impede the transfer and dissemination of technology".

In general, Article 40 recognises that the exclusive rights holder is free to determine whom and under what circumstances to licence,<sup>4</sup> provided none of the terms and conditions of the licensing agreement – or the manner in which it is implemented – constitute an abuse of rights that has an "adverse effect on competition". While Article 40 provides some indication of what practices and

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<sup>4</sup> It would be counterproductive and certainly not in the interests of advancing public health to make it too difficult to licence. To the contrary, competition policy should encourage licensing.

conditions it considers as abusive,<sup>5</sup> it does not go particularly far. In the result, members are left with considerable scope to determine for themselves which licensing practices or conditions to prevent or control through legislation.

### **Relevance of developed country experience**

In its revised report on competition policy and IP, the United Nations Conference on Trade and Development (UNCTAD) secretariat notes that "[c]ompetition policies in major developed countries or regions generally take a favourable attitude to intellectual property rights", understanding that "intervention may be undertaken where a pragmatic case-by-case analysis indicates IPR-based market power is unreasonably restraining competition in relevant markets."<sup>6</sup> On the face of it, this would seem to suggest limited scope for intervention.

But the report further notes that notwithstanding "the general consensus in developed countries or regions about the appropriate treatment of the competition policy/intellectual property interface, there remain important differences with regard to specific issues."<sup>7</sup> In particular, the UNCTAD report notes that important differences remain in respect of issues such as "market definition, refusals to license IPRs or to sell IPR-protected products, the scope of the essential facilities doctrine in relation to IPRs, certain conditions in licensing ... [and] certain behaviour by dominant firms".<sup>8</sup> In other words, there is no consensus in the developed world on the exact reach of what is understood as anti-competitive in respect of crucial aspects regarding the exercise of exclusive rights in IP.

The developed world experience is relevant to developing countries in at least three important ways. First, it shows that there is no single approach to many of the important issues discussed in this paper. In the result, developing countries wishing to exploit the flexibilities under TRIPS in respect of competition policy have significant space within which to manoeuvre. Second, the developed world approach to the IP/competition policy interface is grounded in a context informed both by levels of IP protection significantly in excess of the TRIPS minimums as well as domestic regulatory environments that are generally more tolerant towards conduct that the developing world may regard as abusive. Third, the approach to the IP/competition policy interface in certain developed countries has itself shifted over time.<sup>9</sup> Thus even in the United States, the bastion of IP protection, the use of competition policy in this regard is hotly contested.

### **Regulatory mechanisms to promote public health**

#### *Introduction*

It is generally understood that the simple exercise of exclusive rights in IP cannot in and of itself provide a basis for using competition policy to advance public health. In such circumstances,

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<sup>5</sup> Article 40 lists the following abusive practices: "exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing".

<sup>6</sup> UNCTAD, Competition Policy and the Exercise of Intellectual Property Rights, TD/B/COM.2/CLP/22/Rev.1, 19 April 2002 at 3, available online at [www.unctad.org/en/docs/c2clp22r1.en.pdf](http://www.unctad.org/en/docs/c2clp22r1.en.pdf)

<sup>7</sup> Ibid

<sup>8</sup> UNCTAD, above note 6 at 26

<sup>9</sup> In discussing the use of compulsory licensing as a remedy in non-merger "antitrust" matters, for example, Makan Delrahim of the US Department of Justice's Antitrust Division writes of compulsory licensing as having "a long but contradictory history" in the US and a "history without a great deal of consistency" in both the US and the European Union. See Makan Delrahim, "Forcing Firms to Share the Sandbox: Compulsory Licensing of Intellectual Property Rights and Antitrust" at 3 and 9 respectively, presented at the British Institute of International and Comparative Law, London on 10 May 2004, available online at [www.usdoj.gov/atr/public/speeches/203627.pdf](http://www.usdoj.gov/atr/public/speeches/203627.pdf).

which IP law ordinarily does not understand as abusive, states are nevertheless permitted by the TRIPS Agreement to take a range of regulatory measures to increase access to essential medicines and other patented technologies.<sup>10</sup> Thus the freedom to determine the grounds upon which a compulsory licence can be issued cannot simply be translated into an unfettered discretion to define what is understood by TRIPS as being anti-competitive.

Further, the regulatory mechanisms permitted under TRIPS can only increase access to essential medicines and other patented technologies in response to abusive or problematic conduct on the part of the exclusive rights holder. In addition, such tools can only be used to prevent the further limiting of existing levels of access where necessary to prevent the establishment of "facts on the ground" that are likely to result in abusive or problematic conduct. That being said, the TRIPS framework nevertheless provides significant scope within which boundaries may be pushed and public health promoted.

In short, competition policy can only be used to advance public health in circumstances where access to health care products has been unfairly and unjustifiably limited, or to maintain access in circumstances where it already exists. This is primarily because competition policy is an inappropriate vehicle to promote access in circumstances where the exclusive rights holder's conduct is not in and of itself problematic. In the result, it may seem appropriate to characterise the various regulatory options available into one of two groups: remedies and preventative measures. But as with public health, evident in struggles to contain the HIV/AIDS pandemic itself, this classic treatment/prevention dichotomy is a false one.

For example, the existence of treatment for HIV infection is recognised as providing an incentive for a person to access HIV testing, with knowledge of one's negative status further providing an incentive to take preventative measures. Similarly, the existence of regulatory measures to remedy anti-competitive practices may provide sufficient "incentive" for holders of exclusive rights in IP to refrain from engaging in abusive or otherwise problematic conduct. This may be important for those countries without significant institutional capacity to regulate proactively. In contrast, those countries with capacity may choose rather to frame such measures in the language of prevention, such as by subjecting licensing agreements to prior approval processes of the sort ordinarily associated with merger regulation.

In essence, there are three main competition policy instruments that can be used to prevent or control the problematic – or potentially problematic – exercise of exclusive rights in IP: preventing and/or stopping the abuse of market dominance; regulating IP licensing; and controlling mergers. This paper does not consider mergers because jurisprudence in this field is well developed in many jurisdictions and is not particularly controversial. Further, it is well established and recognised that mergers are exceptionally difficult to undo, thereby requiring advance approval rather than ex-post facto remedial action. In the result, little is to be gained from seeking regulatory freedom where borders and boundaries are particularly well defined.

#### *Preventing and/or stopping the abuse of market dominance*

While exclusive rights in IP do not necessarily in and of themselves result in market exclusivity,<sup>11</sup> their existence may – in particular circumstances – be sufficient to confer market dominance. Much depends on the nature of the product protected by the IP in question and the manner in

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<sup>10</sup> See, in particular, Articles 7, 8, 27.2, 30 and 31 of the TRIPS Agreement, as well as the *Doha Declaration*, above note 1.

<sup>11</sup> According to the European Court of Justice (ECJ), for example, the "mere ownership of an intellectual property right cannot confer ... a [dominant] position". In this regard, see *Radio Telefis Eireann and Independent Television Publications Limited (Intellectual Property Owners Inc. intervening) v EC Commission (Magill TV Guide Limited intervening)* [1995] 4 CMLR 718 at para 46.

which it and potentially competitive products (if any) are used. With this in mind, it would be very difficult to legislate so as to ensure sufficient certainty regarding the circumstances in which the mere existence of IP triggered prohibitions against market dominance.

That said, however, there is little in the way of lawmakers ensuring that legislation provides detailed guidance regarding the circumstances within which IP protection contributes towards market dominance, the definition of markets and what sort of market share is sufficient to confer dominance. In addition, a wide range of practices may be considered as abusive, provided they involve the unfair advantage of market dominance. Under TRIPS, countries have some latitude in determining for themselves what would be considered as unfair in the circumstances, provided they do not regard the mere assertion of exclusive rights as abusive. In other words, a mere refusal to license competitors cannot in and of itself be seen as abusive or problematic conduct, nor can the setting of prices that are higher than what prospective licensees are either willing or able to charge.

### Excessive pricing

In respect of patents, for example, legislators may choose to define unfair advantage as that which would be gained when the exclusive rights in a patent are used to extract a benefit that does not necessarily flow from the exercise of such rights and is not necessary for creating or maintaining incentives to innovate. In other words, when an exclusive rights holder takes an unfair advantage by relying upon the market exclusivity that flows from the enforcement of the patent to extract an unjustifiable, additional benefit. Justification would have to be located within the context determined by the particular circumstances of the market concerned and the practical implications of the impugned conduct.

This would include a prohibition against “excessive pricing to the detriment of consumers”,<sup>12</sup> in effect precluding pricing models that cannot be objectively justified within a particular market. Central to the determination of what may be deemed abusive is the purpose served by the particular pricing model in question. In this regard, legislators would be advised to provide clear guidance in respect of what can be considered as excessive and what would be expected of an exclusive rights holder in order to justify prices that are alleged to be excessive.<sup>13</sup>

### Predatory pricing

On the issue of pricing, lawmakers should be cautious when legislating against predatory pricing by paying close attention to how rights in IP could be abused in this way, with the prohibition being framed accordingly. This is because rights in IP – in particular circumstances – can indeed create monopolies, providing little “incentive” to charge excessively low prices in any particular market as there would be no competitors to exclude from that or any other market. But where such rights do not in and of themselves create market dominance, such as in a market for pharmaceutical products that are considered as therapeutically equivalent, prohibitions against predatory pricing may prove to be particularly effective in keeping abuse of market dominance in check.

Prohibitions against predatory pricing may even be effective in certain circumstances where exclusive rights in IP create monopolies. In other words, the non-existence of actual – as opposed

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<sup>12</sup> See section 8(a) of South Africa’s Competition Act, 89 of 1998 (the SA Act)

<sup>13</sup> For a good example of how not to regulate, see the definition of “excessive price” in section 1(1)(ix) of the SA Act, which hinges on the reasonableness of the relation between the price in question and the “economic value” of a particular good or service. The SA Act provides no definition of economic value nor any indication of how such value is to be determined. After almost five years since the prohibition against excessive pricing came into effect, there is no South African jurisprudence on the issue.

to potential – competitors need not necessarily imply that no incentive exists for undercutting prices in an unsustainable manner. For example, a dominant company may use excessively low pricing to prevent action aimed at introducing competition.

This can be achieved in a number of ways. For example, a patent holder may choose to “sacrifice” the public sector market and thereby ensure a long-term hold on the lucrative private sector market. This could be achieved by using an exclusive not-for-profit public sector deal to generate sufficient economies of scale so that marginal costs in the private sector drop significantly. Without access to such economies of scale, a potential competitor’s private sector margins may not be sufficient to ensure the ability to compete effectively.

With this in mind, legislators may choose to frame their prohibitions against predatory pricing so as to apply not only to actual but also potential competitors. This may be done by framing the prohibition so that what is guarded against is excessively low pricing that has – or is likely to have – the effect of either “preventing or lessening competition”,<sup>14</sup> rather than by limiting the reach to conduct that only lessens existing competition.

### Refusals to license

While upholding the principle that a refusal to license cannot in and of itself constitute an abuse,<sup>15</sup> the European Court of Justice (ECJ) recently clarified – in a case concerning copyright – that a refusal to license will be considered as abusive if it prevents the market entry of an innovative product for which there is consumer demand, is not objectively justifiable, and excludes competition in a “secondary market”.<sup>16</sup> In an earlier case, the ECJ had held a refusal to license to be unlawful on the basis that it “prevented the appearance of a new product ... which the appellants did not offer and for which there was a potential consumer demand.”<sup>17</sup> In contrast, the bottom line in the US is that holders of exclusive rights in IP are ordinarily free to choose whether or not to license,<sup>18</sup> with US law generally not recognising “antitrust liability for the refusal to license intellectual property.”<sup>19</sup>

Given this significant divergence of opinion within the developed world, legislators in developing countries would be well advised to take advantage of the lack of consensus and protect against the unintended negative consequences of the exercise of exclusive rights. Thus a refusal to license may be considered abusive when it allows the exclusive rights holder to extract a benefit from a product considered to be inferior to what prospective competitors would be both willing and able to introduce to the market. In such circumstances, the exercise of exclusive rights in IP may hinder innovation, preventing the market entry of a new product and thereby undermining the strongest rationale for the protection of IP.<sup>20</sup>

Such an example of abuse has been highlighted by the development of fixed-dose combination (FDC) medicines, including three-in-one antiretroviral (ARV) medicines that simplify chronic

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<sup>14</sup> Section 9(1)(a) of the SA Act

<sup>15</sup> See *Volvo AB v Erik Veng (UK) Limited* [1989] 4 CMLR 122 at para 8, where the ECJ held that the mere refusal to grant a license “cannot in itself constitute an abuse of a dominant position.”

<sup>16</sup> *IMS Health GmbH & Co. OHG*, Case C-418/01 at paras 34, 38 and 53, available online at [www.curia.eu.int/jurisp/cgi-bin/form.pl?lang=en](http://www.curia.eu.int/jurisp/cgi-bin/form.pl?lang=en). Delrahim (above note 9 at 7) argues that a secondary market is best understood as a “market different from the copyright owner’s primary product line”, implying that “dominant firms can lawfully refuse to license any competitor who would operate in the same ‘primary market’ as the copyright owner.”

<sup>17</sup> *Radio Telefis Eireann*, above note 11 at para 54

<sup>18</sup> UNCTAD, above note 6 at 16

<sup>19</sup> Delrahim, above note 9 at 8

<sup>20</sup> Developed country experience shows a concern with exclusive rights in IP being used “in a manner which impedes the very purpose for which they have been granted”. See UNCTAD, above note 6 at 26.

treatment for HIV infection to one pill taken twice daily.<sup>21</sup> Simplified treatment regimens are well known for improving levels of adherence to and thereby the efficacy of treatment. The abuse in question results from two omissions: a failure to licence generic manufacturers combined with a failure to co-operate with other exclusive rights holders to manufacture the desired FDC. In this way, innovation is stymied, with the ordinary exercise of exclusive rights in a patent standing in the way of the market entry of better products.

A refusal to licence may also result in anti-competitive conduct in circumstances that may not necessarily be considered as abusive, even when the licensor does not benefit from the anti-competitive conduct in question. This may happen, for example, when the refusal to license follows the grant of an exclusive licence in circumstances where the licensee is effectively given an unfair competitive advantage in another market. This would ordinarily be a market other than that within which the licensor operates.

Consider the following example. Manufacturer 1, the holder of the patent on the ARV drug X, exclusively licenses generic manufacturer 2, which competes with generic manufacturers 3, 4 and 5 in the market for the ARV drugs Y and Z. Upon receipt of the licence, manufacturer 2 begins marketing the triple FDC X/Y/Z, one of the most common and recommended first-line regimens for ARV treatment. As a result of the availability of the triple FDC, which the other generic manufacturers would market if company 1 licensed them, sales of Y and Z plummet. In other words, the availability of the triple FDC gives manufacturer 2 an unfair advantage in the market for the other two drugs.

Legislators have a wide range of regulatory options that can be used to prohibit or control these – and other – examples of problematic refusals to license. Some may choose to invoke the hotly contested essential facilities doctrine, whereas others may choose to locate such prohibited practices within the ambit of a narrowly tailored prohibition against certain forms of exclusionary conduct or a simple refusal to deal.<sup>22</sup> In addition, lawmakers might wish to consider locating the provisions in question outside of the ambit of abuse of market dominance, focusing rather on the anti-competitive effects of the conduct instead of the abuse of exclusive rights in IP.

### *Regulating IP licensing*

While the previous section considered the various options available for controlling or preventing certain refusals to license IP, which may not necessarily involve the abuse of market dominance, this section focuses only on the conduct of the exclusive rights holder when it engages in the licensing of IP. It therefore focuses on the licensing practice itself, including the applicable terms and conditions of the license in question, regardless of whether other licence applications were granted or refused. But before doing so, it is helpful briefly to consider the general approach taken by the developed world, where the role of competition policy in the regulation of IP licensing is seen to protect potential "licensors' willingness to license while enabling licensees to compete."<sup>23</sup>

In the European Union, for example, "not every restraint of conduct in a licensing arrangement" is considered as a "prohibited restraint of competition", or anti-competitive.<sup>24</sup> In the US, on the other

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<sup>21</sup> These include Cipla's Triomune, Ranbaxy's Triviro LNS and the Thai Government Pharmaceutical Organization's GPO-VIR.

<sup>22</sup> In section 8 of the SA Act, for example, dominant "firms" are proscribed from engaging in a range of prohibited practices, including refusing "a competitor access to an essential facility when it is economically feasible to do so" and engaging "in an exclusionary act ... if the anti-competitive effect of that act outweighs its technological, efficiency or other pro-competitive gain". The SA Act further defines an "exclusionary act" as "an act that impedes or prevents a firm entering into, or expanding within, a market".

<sup>23</sup> UNCTAD, above note 6 at 25

<sup>24</sup> *Ibid* at 7

hand, the *Antitrust Guidelines for Licensing of Intellectual Property* (the US Guidelines)<sup>25</sup> are based on the principle that the licensing of IP is generally considered as pro-competitive.<sup>26</sup> Regarding restraints of conduct, the general approach under the US Guidelines is twofold: to determine whether the restraint in question is "likely" to have any anti-competitive effects; and if so, to determine whether the restraint is "reasonably necessary to achieve pro-competitive benefits that outweigh the anti-competitive effects."<sup>27</sup>

A possible approach that members may wish to consider in advancing public health, consistent with the understanding that the simple exercise of exclusive rights in IP cannot in and of itself be considered as abusive or problematic, is whether the licensing practice or condition concerned further limits – or has the potential further to limit – access to essential health products. In other words, does the grant of the licence make things worse, meaning that consumers actually or potentially had greater access prior to the grant of the licence? Such an approach would thus allow countries to prevent licensing agreements, for example, that permit the exclusive rights holder to extract more from certain markets by surrendering market exclusivity in others.<sup>28</sup>

Consider the following example. Manufacturer P, the holder of the patent on an essential antifungal medicine that is excessively priced, has been informed by the state that it is about to issue a compulsory licence for both public and private sectors to manufacturer Q, the only local generic manufacturer of the medicine in question. To avoid this action, manufacturer P "voluntarily" licenses generic manufacturer Q to produce the antifungal medicine for the public sector, on condition that it surrender its right under patent law to pursue legal action for a compulsory licence to supply the private sector.

As a result of the action, the state has no option but to abandon the idea of issuing the compulsory licence, leaving excessively high private sector prices untouched. It further decides not to issue compulsory licenses for the importation of the antifungal medicine in question, given that foreign-based generic companies have yet to register their products with the local drug regulatory authority. In the result, the grant of the limited voluntary license to manufacturer Q has had the effect of ensuring that consumers in the private sector will have to wait until patent expiry before seeing any generic competition.

Some may argue that preventing such a licensing agreement would be counterproductive in that it may potentially prevent even the public sector from gaining access to cheaper alternatives. In other words, it may result in the patent holder maintaining exclusivity in both markets. This may well be the case in circumstances where the state is unwilling to use its licensing powers under patent law, or where the third party compulsory licensing provisions under such a law offer TRIPS-plus protection, effectively precluding generic manufacturers from applying for licences themselves. But where a state has legislated to the full extent of the patent law flexibilities under TRIPS or is willing and able to issue licences, prohibiting the conclusion of such a licensing agreement may well serve to advance public health.

Once a decision has been taken to legislate in this regard, lawmakers must then decide whether to subject licensing agreements to prior approval or to regulate simply by prohibiting certain licensing practices, making provision for licensing agreements to be challenged by interested parties after their conclusion. In large part, this decision may depend on the institutional capacity of the relevant competition authority. Lawmakers may decide on a third hybrid approach, given

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<sup>25</sup> Department of Justice and Federal Trade Commission, 6 April 1994, available online at [www.usdoj.gov/atr/public/guidelines/ipguide.htm](http://www.usdoj.gov/atr/public/guidelines/ipguide.htm)

<sup>26</sup> UNCTAD, above note 6 at 14

<sup>27</sup> Ibid at 15

<sup>28</sup> While this may be regulated under the rubric of restrictive horizontal practices, ordinarily understood as agreements or concerted practices between competitors, it may be more appropriate to regulate IP licensing separately when prospective licensees are not yet competitors.

that many licensing agreements are often subject to competition authority approval. This approach could see countries deciding against automatic prior approval, whilst making provision (and charging) for a voluntary – but nevertheless binding – prior approval process.

### **Limitations of using competition policy within a developing world context**

Despite the significant regulatory flexibility regarding competition policy accorded to all countries under TRIPS, many developing countries may find that they have neither the level of expertise nor the institutional capacity to take full advantage. In addition, such countries may decide against investing resources in competition enforcement unless and until required to do so. Instead, they may prefer to focus attention on the public health safeguards and flexibilities under patent law, particularly given the requirement under TRIPS to provide a minimum level of IP protection.<sup>29</sup>

There are at least two reasons why this may prove to be an unfortunate and shortsighted approach to advancing public health. First, much of the IP regulatory flexibility under TRIPS requires either state or specific third party action. Take the example of the grant of a compulsory license to produce or import generic medicines. This would require either the state to issue a compulsory license or an “interested person” to institute legal action for a licence to produce or import.<sup>30</sup> For good reason, neither the state nor generic manufacturers or importers may decide to take such action.

Instead, not-for-profit organisations (NPOs) may wish to challenge the abuse of rights in the patent concerned, but may find that they are powerless to act, given the requirement under TRIPS that compulsory licences be non-assignable. Unless they are in the business of drug production or importation, NPOs might find that they are – legally speaking – powerless to act.<sup>31</sup> Under competition law, however, a consumer-driven complaint to the authorities may result in the issue of licences to third parties, such as generic manufacturers or importers, regardless of whether they participated in the proceedings.

Second, developing countries will most likely at some point in the not-too-distant future be required to commit to the enforcement of competition policy as part of the resolution of the “Singapore issues”, either as a result of the Doha Development Round or regional and bilateral trade agreements. It would be in their interests to enter such negotiations with relatively well-developed competition frameworks in place. This is both to ensure that the terms of the debate are not framed solely by developed countries, as well as to ensure that developing countries are fully aware of the implications of the competition policy framework under discussion.

If such countries are concerned about the allocation of resources for enforcement, they may decide against the creation of a dedicated competition authority, opting instead to dispense with all prior

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<sup>29</sup> Other than least developed countries (LDCs) that have until 1 January 2016 to provide patent protection for pharmaceutical products, all developing countries are required as of 1 January 2005 to provide the minimum levels of IP protection, including patent protection for technologies. Other than patent protection in respect of pharmaceutical products, LDCs must comply with the requirements of TRIPS by not later than 1 January 2006. In other words, all countries will have to invest resources in IP protection by not later than 2006.

<sup>30</sup> See, for example, section 56 of the South African Patents Act, 57 of 1978, which allows for such persons to apply to the Commissioner of Patents for a compulsory licence under the patent.

<sup>31</sup> To some extent, his explains why NPOs in South Africa have been slow to use the provisions of patent law to increase access to essential medicines. In 2003, two NPOs successfully threatened the use of section 56 of the South African Patents Act, with the result that they were granted non-exclusive royalty-free licences to import generic nevirapine products. The two NPOs were only able to threaten the use of the law on the basis that they are actually involved in the procurement and distribution of medicines. For more information on the settlement agreement between the two NPOs (the Generic Anti-retroviral Procurement Project and the TAC Treatment Project) and Boehringer Ingelheim, see [www.alp.org.za/resctr/other/pdf/20031215\\_GSKBI4.pdf](http://www.alp.org.za/resctr/other/pdf/20031215_GSKBI4.pdf).

approval procedures, outlawing certain anti-competitive conduct and practices and allowing for the private sector and NPOs – at this stage – to “enforce” the law in the ordinary civil court system. While this may not be ideal, it would certainly go some way in promoting a pro-public health agenda and laying the foundation for the law’s future development as and when circumstances allow.

### **The South African experience**

South Africa’s new competition law framework has been in force for less than five years. While it goes some way in taking advantage of the regulatory flexibility permitted under TRIPS, it is still relatively undeveloped, with little in the way of jurisprudence to give real meaning and content to its relevant provisions. Nevertheless, it has already been used to advance public health, most notably in the recent challenge to the pricing practices of two pharmaceutical giants.

#### *Hazel Tau and Others v GlaxoSmithKline and Boehringer Ingelheim*

As part of a national campaign to lower the costs of essential medicines for the treatment of HIV/AIDS, the AIDS Law Project (ALP) lodged the complaint against GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI) with South Africa’s Competition Commission in September 2002,<sup>32</sup> in essence arguing that the two groups of pharmaceutical companies were acting in violation of competition law by charging excessive prices for certain of their ARV drugs to the detriment of consumers. In short, the complaint alleged that the prices charged by GSK and BI for their essential medicines were directly responsible for the “premature, predictable and avoidable loss of life”,<sup>33</sup> arguing that even when full allowance was made for the costs of research and development, higher profits, licensing fees and the incentive to develop new drugs, the prices of these patented medicines remained excessive and unjustifiable.

At the time the complaint was lodged, the state had yet to commit itself to the development and implementation of a public sector ARV treatment programme,<sup>34</sup> meaning that there were only three options available to people in South Africa for accessing potentially life-saving treatment: out-of pocket purchase from private pharmacies; medical insurance cover; and workplace treatment programmes for uninsured workers. By challenging the high prices of drugs, the complaint sought “to ensure that people living with HIV/AIDS who are working can afford to buy medicines to save their lives; that medical ... [insurers] treat people living with HIV/AIDS without going bankrupt; and that employers are able to pay for the treatment of workers on a sustainable basis.”<sup>35</sup>

On 16 October 2003, the Competition Commission announced that it had decided to refer the complaint to the Competition Tribunal for adjudication. As a result of its year-long investigation, the Commission had found sufficient evidence to support the referral on the basis of prohibited excessive pricing as well as two additional grounds, both of which deal with the failure of GSK

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<sup>32</sup> In addition to the Treatment Action Campaign (TAC), South Africa’s most powerful and successful organization representing the interests of people living with HIV/AIDS (PWHAs), the complaint was lodged on behalf of a number of PWHAs who are open about their status, health care workers treating PWHAs, the Congress of South African Trade Unions (COSATU), the Chemical, Energy, Paper, Printing, Wood and Allied Workers’ Union (CEPPWAWU) and the AIDS Consortium. With approximately two million members, COSATU is the largest trade union federation in South Africa.

<sup>33</sup> See the Statement of Complaint at para 107, available online at [www.tac.org.za/Documents/DrugCompaniesCC/HazelTauAndOthersVGlaxoSmithKlineAndOthersStatementOfComplaint.doc](http://www.tac.org.za/Documents/DrugCompaniesCC/HazelTauAndOthersVGlaxoSmithKlineAndOthersStatementOfComplaint.doc)

<sup>34</sup> The *Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa* was adopted on 19 November 2003, some 20 days before the complainants entered into settlement agreements with both GSK and BI.

<sup>35</sup> See “The Price of Life: *Hazel Tau and Others vs. GlaxoSmithKline and Boehringer Ingelheim*” at page 5, available online at [www.alp.org.za/view.php?file=/camps/20030910\\_PatRights.xml](http://www.alp.org.za/view.php?file=/camps/20030910_PatRights.xml).

and BI to license generic manufacturers in certain circumstances. Simply put, the Commission found that GSK and BI were using their exclusive rights in the patents concerned to deny appropriate licences to other manufacturers, whilst simultaneously keeping their own prices high. By December 2003, within two months of the Commission's announcement, GSK and BI had entered into separate settlement agreements with the complainants and the Commission respectively.<sup>36</sup> In essence, the two groups of companies agreed to open up the market for these drugs to generic competitors.

To date, both GSK and BI seem to have licensed only two generic manufacturers on terms no less favourable than those contained in the settlement agreements, which require the grant of up to four and three licences respectively. The ALP has written to the two companies regarding its concern that they appear not to have complied fully with the terms of the settlement agreements. If and when appropriate, the ALP will seek the enforcement of the agreements in the ordinary civil courts.

### *Learning from Hazel Tau*

The South African experience highlights that competition law can indeed be used to great effect, particularly in a context where other key role-players are loathe to invoke the law. In this case, civil society was able to take the lead, not being constrained by the failure to take appropriate action on the part of both the state and generic pharmaceuticals companies.<sup>37</sup> To date, the state has yet to invoke its powers under patent law to issue compulsory licenses,<sup>38</sup> nor has it taken any steps to remove problematic TRIPS-plus protections in line with the *Doha Declaration*.

Faced with the adverse findings of an independent competition authority, a protracted Competition Tribunal hearing into its pricing practices and the potential for the strengthening of the legal framework through unfavourable jurisprudence, GSK and BI decided to settle with both the Competition Commission and the complainants. For their part, the complainants chose to abandon a particularly strong case in favour of a relatively speedy resolution of the matter, despite the historical complaint and the complex legal and regulatory issues remaining unresolved.

Through its use of the South African Competition Act, 89 of 1998 (the SA Act), the ALP has recognised that the regulatory framework requires a "little work". Most crucial is an amendment that would expressly recognise the grant of a compulsory licence as appropriate relief for certain forms of prohibited conduct. While there are strong arguments in favour of interpreting the provisions on relief to permit the granting of compulsory licences to prevent and control prohibited excessive pricing, the lack of express recognition is nevertheless problematic. Unless and until the Competition Tribunal rules favourably on the matter, the hand of both civil society and the Competition Commission remains weakened.

For as long as the regulatory framework remains unchanged, through lack of jurisprudence or legislative reform, the Competition Commission would be advised to invoke its powers in section 79(1) of the SA Act to "prepare guidelines to indicate the Commission's policy approach" to the IP/competition policy interface. Such guidelines, which must be published in the *Government*

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<sup>36</sup> The settlement agreements with the complainants are available online at [www.alp.org.za/view.php?file=/camps/20030910\\_PatRights.xml](http://www.alp.org.za/view.php?file=/camps/20030910_PatRights.xml)

<sup>37</sup> One generic company had in fact attempted to use the SA Act, but had not done so particularly effectively. It had argued that because it was both willing and able to provide certain ARV drugs at significantly lower prices than the exclusive rights holder was doing, the latter was unlawfully charging excessive prices to the detriment of consumers. In addition, no generic company had attempted to use the provisions of section 56 of the South African Patents Act to obtain compulsory licences on any essential medicines.

<sup>38</sup> See section 4 of the South African Patents Act.

*Gazette* and are not binding on anyone, would nevertheless provide much-needed guidance for all role-players, including both holders of exclusive rights in IP as well as consumers.<sup>39</sup>

## **Conclusion**

This paper has focused on the role of competition policy in advancing public health in Southern Africa by increasing access to essential medicines. This has been done by considering the broader framework provided by TRIPS, as well as the relevance of developed country experiences and the limitations of using competition policy within a developing world context. By focusing on the availability and nature of and the extent to which certain regulatory mechanisms may be used to promote public health, with a short analysis of the South African experience dealing with the IP/competition policy interface, this paper has sought to provide certain concrete recommendations. But more important, it has hopefully placed new ideas on the table and helped to identify research gaps. In doing so, it has sought to stimulate creative thought and engaged debate.

**21 June 2004**  
**Johannesburg, SOUTH AFRICA**

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<sup>39</sup> In publishing such guidelines, South Africa would not be doing anything particularly groundbreaking. In this regard, see the earlier reference to the US Guidelines, above note 25.