

Advancing public health by other means: Using competition policy to increase access to essential medicines¹

INTRODUCTION

The “deepest violation of another person’s humanity is to deprive that person of the means to remain healthy, to fight off illness and to live – or die – in reasonable comfort and dignity”.²

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.”³

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” and “flexibilities” within TRIPS that permit the taking of “measures to protect public health”. Earlier this year, the WTO secretariat itself embarked on a series of regional capacity-building workshops, with a particular focus on these safeguards and flexibilities, as well as 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* (the Paragraph 6 decision).⁴

Yet despite the considerable flexibility accorded to WTO members in dealing with competition policy in general and anti-competitive practices in particular, coupled with the clear recognition in TRIPS that the latter are considered as particularly egregious, surprisingly little public attention has been accorded to the role of competition policy in advancing public health by increasing access to a sustainable supply of affordable essential medicines. While much has been said and written about the

¹ This paper is an updated and revised version of “Advancing Public Health by Other Means: Using Competition Policy to Mitigate the Impact of Patent Protection”, prepared for the ICTSD/UNCTAD Regional Dialogue on Innovation, Intellectual Property Rights and Sustainable Development in Eastern and Southern Africa (Cape Town, 29 June to 1 July 2004). Many thanks to the participants in the Cape Town meeting whose comments have influenced this revision. The original paper is available online at http://www.iprsonline.org/unctadictsd/dialogue/2004-06-29/2004-06-29_berger.pdf.

² Edwin Cameron, “Human Rights, Racism and AIDS: the New Discrimination” (1993) 9 *South African Journal of Human Rights* 22 at 26.

³ *Declaration on the TRIPS agreement and public health*, WT/MIN(01)/DEC/2 (20 November 2001) at paragraphs 1 and 4, available online at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

⁴ WT/L/540, 1 September 2003, available online at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm

policy options available in terms of patent legislation,⁵ surprisingly scant attention has been accorded to the interface between intellectual property (IP) and competition policy and the implications thereof for public health concerns.⁶

The purpose of this paper is therefore to consider the role that competition policy may play in developing countries in advancing public health by increasing access to a sustainable supply of affordable essential medicines. In particular, the paper will focus on a few key areas: the relevance of developed country experience in dealing with and academic scholarship on the interface between IP and competition policy; competition policy instruments to promote access; and considerations regarding the appropriateness of using competition policy within a developing world context. In addition, the South African experience in the field of patents, competition law and public health will be addressed insofar as it considers the key areas of focus.

The competition policy options discussed in this paper proceed on the assumption that developing country members of the WTO take full advantage of the IP policy options available in TRIPS – as clarified, in part, in the Doha Declaration – as well as the Paragraph 6 decision. In other words, this paper does not view competition policy options as an alternative to the public health safeguards and flexibilities ordinarily associated with TRIPS, but rather it sees such options as complementary and providing ‘added-value’.

It is important to understand what this paper is not. Essentially, it does not attempt to consider the ‘merits’ of high levels of patent protection, nor the role – whether positive or negative – of patent protection in economic development. Put another way, this paper proceeds on the basis that developing countries can and should take a wide range of measures to limit the potentially negative implications of patent protection and thereby advance public health. In short, it considers how and in what circumstances competition policy can be used to increase access to a sustainable supply of affordable essential medicines in developing countries.

THE TRIPS FRAMEWORK

But before doing so, it is important to reflect on the broader international trade law framework provided by TRIPS, not only to consider the extent to which the agreement limits the use of

⁵ See, for example, Jonathan M. Berger, “Tripping Over Patents: AIDS, Access to Treatment and the Manufacturing of Scarcity (2002) 17 *Connecticut Journal of International Law* 157; Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy* (London: Department for International Development, 2003), available online at <http://www.iprcommission.org>; Carlos Correa, “Chapter 22: Formulating effective pro-development national intellectual property policies” in Christophe Bellmann et al (eds.), *Trading in Knowledge: Development Perspectives on TRIPS, Trade and Sustainability* (London and Sterling, VA, USA: Earthscan Publications Ltd, 2003) at 209; Jerome H. Reichman, *Issue Paper No. 5 – Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA* (Geneva: International Centre for Trade and Sustainable Development (ICTSD) and the United Nations Conference on Trade and Development (UNCTAD), 2003), available online at <http://www.ictsd.org/iprsonline>; and Third World Network, *Manual on Good Practices in Public-Health-Sensitive Policy Measures and Patent Laws* (Penang, Malaysia: Third World Network, 2003).

⁶ The literature on policy options, whilst not investigating the IP/competition policy in any depth, clearly places the issue on the agenda. For example, see Reichman, above note 5 at 5, where he notes that in “negotiations on the intersection between trade and competition policy, developing countries must remain vigilant in order to preserve the autonomy they need to curb the excesses of overly protectionist IPR policies.” See also Commission on Intellectual Property Rights, above note 5 at 13, where, in dealing in Chapter 1 with intellectual property and development, the Commission recommends the “[e]stablishment of effective competition policies in developing countries”; and Third World Network, above note 5 at 95, where it is noted that a compulsory licence granted to remedy an anti-competitive practice “will have much room for flexibility with regard to its terms, and will be an important tool for ensuring access to affordable medicines.”

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 regulating the use of competition policy in this regard,⁷ but rather that it is the only international law framework that legally binds developing country members of the WTO at the moment.⁸

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 the potentially negative consequences of IP protection and concerns relating to issues such as public health and socio-economic development, 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, Article 1.1 permits significant flexibility regarding the exact manner in which the obligations under TRIPS are implemented. Thus, for example, some WTO members may choose to deal with all matters pertaining to IP in a single statute, including the abuse of exclusive rights in patents and remedying the anti-competitive practices of certain exclusive rights holders. Others may choose to separate out the various aspects of IP into stand-alone pieces of legislation, also choosing to deal with competition policy and anti-competitive practices elsewhere. Some may even decide to deal with the same issue, such as the abuse of exclusive rights in patents, in more than one statute.

The flexibility in Article 1.1 also extends to the institutional framework within which the obligations under TRIPS are implemented. Thus WTO 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, an administrative tribunal structure or within some form of hybrid system. At minimum, however, the TRIPS obligations must be incorporated into domestic law in a manner that facilitates some form of judicial or administrative process for the resolution of disputes.

In each option, member states 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

⁷ See, for example, UNCTAD, *The United Nations Set of Principles and Rules on Competition: The Set of Multilaterally Agreed Equitable Principles and Rules for the Control of Restrictive Business Practices*, (Geneva, 2000), originally adopted by the General Assembly at its 35th session in resolution 35/63 of 5 December 1980 and reaffirmed as valid by the Fourth Conference to Review All Aspects of the Set in resolution TD/RBP/CONF/10.Rev.2 of 4 October 2000.

⁸ Some limitations already exist and others may very well come at a later stage through regional and/or bilateral trade agreements that seek to impose TRIPS-plus standards of IP protection. See, for example, Correa, above note 5 at 211 – 212; and ICTSD/UNCTAD, *Policy Discussion Paper – Intellectual Property Rights: Implications for Development* (Geneva, Switzerland: ICTSD and UNCTAD, 2003), available online at <http://www.icts.org/iprsonline> at 52.

rules of procedure and evidence, provided this is exercised within the framework of “their own legal system and practice”.

Article 8

The second relevant provision, which is also particularly broad in its reach, provides that members may need to adopt certain measures in the public interest,⁹ as well take steps necessary “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.”¹⁰ All steps taken and measures adopted must be “consistent with the provisions” of TRIPS. In short, Article 8 recognises that WTO members are within their rights to take action to address these identified needs and concerns, and that other provisions of TRIPS do not prevent the taking of such action.

In essence, the measures permitted fall into two broad categories: measures in the public interest that may be taken irrespective of the conduct of the exclusive rights holder; and measures to prevent certain problematic conduct on the part of the IP holder. While not expressly mentioning competition policy, it is clear that Article 8 – when read in the context of TRIPS as a whole and in particular together with Article 1.1 – 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. What is less clear is whether competition policy may be used to give effect to both parts of Articles 8, or whether it is limited to the forms of problematic conduct identified in Article 8.2

On the face of it, only Article 8.2 seems to be of any relevance to competition policy. The well-recognised concept of abuse of market dominance fits well into the broader notion of abuse of rights in IP, as does anti-competitive conduct fall within the larger category of “practices which unreasonably restrain trade”.¹¹ But what then about Article 8.1? Much depends on the role ascribed to competition policy. In South Africa, for example, competition law seeks to “promote and maintain competition” for a range of purposes, including the promotion of “the efficiency, adaptability and development of the economy” and the advancement of social and economic welfare.¹² Thus the strengthening a domestic generic pharmaceutical industry that can compete internationally and ensure sustainability of supply for the local market seems an appropriate use of competition policy that falls within the reach of Article 8.1.

Article 8.2 also deserves much closer attention. In expressly stating 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, the provision implicitly recognises 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.” In addition, 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 taking of

⁹ Article 8.1

¹⁰ Article 8.2

¹¹ There is some degree of overlap between these two concepts. A refusal to grant access to an essential facility, a classic form of abuse of market dominance, is quite clearly a form of anti-competitive conduct. Prohibitions against excessive pricing, on the other hand, are not as easily recognisable as forms of anti-competitive conduct.

¹² Sections 2(a) and (c) of the Competition Act, 89 of 1998 (the SA Act)

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

In developing countries, 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, for the purpose of ensuring access to a sustainable supply of affordable medicines domestically and regionally.

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. The closest TRIPS comes to providing any direction in this regard is in Article 8.2, which permits the taking of steps “to prevent ... the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology” and in Article 40, which deals with the “control of anti-competitive practices in contractual licences” (and is discussed below).

It seems appropriate, therefore, that the concept of anti-competitive conduct must in some way be linked to these expressly identified and potentially problematic outcomes. However, given the discussion above regarding an appropriate role for the use of competition policy as a means for indirectly increasing access to essential medicines, what may be considered as anti-competitive for the purposes of compulsory licences issued in accordance with the provisions of Article 31 is almost certainly broader than conduct that has direct anticompetitive effect.

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,¹³ 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”. In the context of Article 40.1, which speaks of “some licensing practices ... which restrain competition [and] may have adverse effects on trade”, it seems appropriate to think of the concept of abuse as the use of exclusive rights in IP in an anticompetitive way that affects trade negatively. In other words, the focus must lie on the effects of the conduct and not the implications thereof for the exclusive rights holder. Further, while Article 40 provides some indication of what practices and conditions it considers as abusive,¹⁴ it does not go particularly far. In the result, members are left with much scope to determine for themselves which licensing practices or conditions to prevent or control through legislation.

IP/COMPETITION INTERFACE: LEARNING FROM THE DEVELOPED WORLD

Much has been written about the IP/competition policy interface.¹⁵ In its revised report on IP and competition policy, for example, 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.”¹⁶ On the face of it, assuming such experiences to be relevant to the developing world, 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.”¹⁷ 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”.¹⁸ 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.

¹³ 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.

¹⁴ Article 40 lists the following abusive practices: “exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing”.

¹⁵ See, for example, Robert D. Anderson and Nancy T. Gallini (eds.), *Competition Policy and Intellectual Property Rights in the Knowledge-Based Economy* (Calgary, Canada: University of Calgary Press, 1998), and in particular, Nancy T. Gallini and Michael J. Trebilcock, “Intellectual Property Rights and Competition Policy: A Framework for the Analysis of Economic and Legal Issues”, *ibid.* See also Organisation for Economic Co-operation and Development (OECD) Directorate for Financial, Fiscal and Enterprise Affairs Committee on Competition Law and Policy, *Competition Policy and Intellectual Property Rights*, available online at <http://www.oecd.org/dataoecd/34/57/1920398.pdf>.

¹⁶ 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

¹⁷ *Ibid*

¹⁸ UNCTAD, above note 16 at 26

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 by levels of IP protection significantly in excess of the TRIPS minimums, domestic regulatory environments that are generally more tolerant towards conduct that the developing world may regard as abusive, and a real concern that weakening IP protection in such economies would severely hamper innovation. Third, the approach to the IP/competition policy interface in certain developed countries has itself shifted over time.¹⁹ Thus even in the United States, the bastion of IP protection, the use of competition policy in this regard is hotly contested.

The academic debate,²⁰ which supports such a cautious approach to the developed world approach to the IP/competition policy interface, focuses primarily on the appropriate balance to be struck between IP protection and the promotion of competition as it seeks to find a theory that supports the optimal use of competition policy to keep IP abuses in check whilst at the same time promoting innovation. Such matters are not of much relevance in most parts of the developing world, where the existence or lack of strong levels of IP protection does little shift the balance either way. Thus the academic debate should largely remain academic when developing country governments seek to use competition policy to advance public health, provided they work within the limits of TRIPS.

REGULATORY MECHANISMS TO PROMOTE PUBLIC HEALTH

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, which IP law ordinarily does not regard 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.²¹ But, as has already been pointed out in this paper, there are various ways in which competition policy may appropriately be used to advance the public interest even where the conduct of the exclusive rights holder is neither abusive nor does it have any anti-competitive effect.

It therefore seems appropriate to characterise the various regulatory options available under competition policy into three groups: remedies, preventative measures and measures that serve the public interest by promoting competition, whether directly or indirectly. But as with public health, evident in struggles to contain the HIV/AIDS pandemic itself, this classic treatment/prevention dichotomy provided by the first two groups of policy options is a false one. The existence of measures to remedy anti-competitive practices, for example, may provide sufficient “incentive” for IP holders 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

¹⁹ In discussing the use of compulsory licensing as a remedy in non-merger “antitrust” matters, for example, 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.

²⁰ See, for example, above note 15.

²¹ See, in particular, Articles 7, 8, 27.2, 30 and 31 of the TRIPS Agreement, as well as the *Doha Declaration*, above note 3.

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.

Whilst recognising that TRIPS permits the taking of measures that serve the public interest by promoting competition, whether directly or indirectly, this paper nevertheless focuses on the two main competition policy instruments that can be used to prevent or control the abusive or otherwise problematic exercise of exclusive rights in IP: preventing and/or stopping the abuse of market dominance; and regulating IP licensing. In so doing, it does not consider various other policy instruments – such as merger control – in the promotion of competition. This is in part because jurisprudence in this field is relatively well developed in many jurisdictions and is not particularly controversial.

PREVENTING AND/OR STOPPING THE ABUSE OF MARKET DOMINANCE

While exclusive rights in IP do not necessarily in and of themselves result in market dominance,²² 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 which it and potentially competitive products (if any) are used. With this in mind, one might think that it would be particularly difficult to legislate so as to ensure sufficient certainty regarding the circumstances in which the mere existence of IP triggered prohibitions against market dominance.

This needn't be the case. The test of substitutability, which is central to any decision regarding dominance in a particular market, may be incorporated into legislation with relative ease. In addition, there is little in the way of lawmakers ensuring that the appropriate statute provides detailed guidance regarding the circumstances within which IP protection contributes towards market dominance, the factors to be considered in assessing the impact of IP protection on dominance, the definition of markets in relation to products protected by IP and what sort of market share is sufficient to confer dominance.

Having considered issues relating to proof of dominance and the relevant market to be considered, attention must now be placed on which types of practices may be considered as abusive. 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 and they target practices that in some way take unfair advantage of market dominance. 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. On the other hand, however, the ordinary exercise of exclusivity may – in certain circumstances – become abusive.

Excessive pricing

Legislators may choose to define an excessively high price as one that gives rise to an unfair advantage gained when the exclusive rights in IP 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. This would apply, for example, 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

²² 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.

unjustifiable, additional benefit. Justification is thus to be located within the context determined by the particular circumstances of the market concerned and the practical implications of the impugned conduct. Thus in a market that is largely irrelevant insofar as incentives to innovate are concerned, such as Africa, a price that would not ordinarily be viewed as excessive in North America or Europe may very well violate domestic prohibitions against excessive pricing.

Consider the following as one example of an unjustifiable pricing model. The private sector in a particular developing country provides pharmaceutical services for 20% of the population, with the remaining 80% reliant on the public sector for free medication. The state claims that drug P, which is used to treat diabetes, is too expensive to provide in the public sector. P is, however, freely available in the private sector at a particularly high price, in line with prices in the developed world. Economists show that if drug P were to be available for half of the price, private sector volumes would quadruple and profit margins would rise substantially. The manufacturers know this, but maintain the artificially high prices to prevent parallel importation from the developing country in question and the subsequent loss of profits in other wealthier markets.

Lawmakers may choose to narrow the scope of the prohibition somewhat so that it only deals with “excessive pricing to the detriment of consumers”,²³ in effect precluding pricing models that cannot be objectively justified within a particular market in relation to the negative impact of the high price or prices in question. This would serve to allay the “fears” of those who claim that such mechanisms may be used to cut into the significant profit margins of so-called “lifestyle” drugs. Further, prohibitions against excessive pricing should be located within a regulatory framework that promotes openness and accountability, ensuring that alleged abusers are required to justify their conduct in open judicial or administrative proceedings.

As the discussion of the South African experience regarding excessive pricing below shows, vagueness and lack of clarity may serve as a disincentive to use excessive pricing provisions as a tool to increase access to essential medicines. Legislators would thus be advised to provide clear guidance in respect of what can be considered as excessive, what would be expected of an exclusive rights holder in order to justify prices that are alleged to be excessive and what forms of relief may apply when a price has been determined to be excessive. For a good example of how not to regulate, consider the definition of “excessive price” in South African law,²⁴ which hinges on the reasonableness of the relation between the price in question and the “economic value” of a particular good or service, in the absence of any definition of economic value or any indication of how such value is to be determined.²⁵

Discriminatory and predatory pricing

In addition to excessively high prices, a company that is dominant in a market may choose to engage in either of two other forms of abusive pricing: unjustifiable price discrimination and predatory pricing.²⁶ The former, which is ordinarily understood to include discriminating between purchasers in

²³ See section 8(a) of the SA Act

²⁴ Section 1(1)(ix) of the SA Act

²⁵ After almost five years since the prohibition against excessive pricing came into effect, there is no South African jurisprudence on the issue.

²⁶ There are other forms of problematic pricing practices, such as price fixing and minimum resale price maintenance. These are ordinarily found in provisions dealing with restrictive horizontal and vertical practices and not abuse of dominance.

terms of the price charged for a particular good or services, is usually actionable when it results – or has the potential to result – in anti-competitive outcomes. It is particularly difficult to understand how this applies, for example, to patented products.

Consider, for example, where discriminatory pricing is used to secure a high-profit market by making it difficult for competitors to gain any share of the low-profit market without which access to the profitable market is not possible.²⁷ Similar concerns relate to the prohibition against predatory pricing, being the selling of a good or service at below marginal or average variable cost without justification.²⁸ With this in mind, lawmakers should be cautious when considering the prohibition of certain forms of price discrimination and 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 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 exclusivity, such as in a market for pharmaceutical products that are considered as therapeutically equivalent, prohibitions against price discrimination or predatory pricing may prove to be particularly effective in keeping abuse of market dominance in check. In addition, a patent holder that has been forced to grant “voluntary” licences may use price discrimination and predatory pricing to ensure that its licensees are unable to compete effectively.

Prohibitions against price discrimination and 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 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, such as an application for a compulsory licence under patent law. In such a case, 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, such selling below marginal cost, 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. In the result, it has no incentive to seek entry to the private sector, ensuring that the patent holder remains without competition.

With this in mind, legislators may choose to frame their prohibitions against price discrimination and predatory pricing so as to apply not only to actual but also potential competitors, even if they may be legitimately excluded by the ordinary exercise of the IP in question. This may be done by framing the prohibition so that what is guarded against is price discrimination or excessively low pricing that has – or is likely to have – the effect of either “preventing or lessening competition”,²⁹ rather than by limiting the reach to conduct that only lessens existing competition.

²⁷ See, for example, *Napp Pharmaceutical Holdings Ltd v The Director General of Fair Trading* [2002] CAT 1, [2002] CompAR 1

²⁸ See, for example, section 8(d)(iv) of the SA Act.

²⁹ Section 9(1)(a) of the SA Act

Refusals to license

While upholding the principle that a refusal to license cannot in and of itself constitute an abuse,³⁰ 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”.³¹ 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.”³² 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,³³ with US law generally not recognising “antitrust liability for the refusal to license intellectual property.”³⁴

There are many reasons to explain the significant divergence of opinion within the developed world, most of which lie beyond the scope of this paper. But perhaps most important is the fine balance sought to be achieved between promoting innovation and protecting against the “unintended” negative consequences of the exercise of exclusive rights. As has already been mentioned above, developing countries are not faced with the same dilemma. The extent to which competition policy is used outside of the north to mitigate the impact of IP protection will largely be irrelevant insofar as innovation in the developed world is concerned.

Thus policymakers and legislators in developing countries would be well advised to take advantage of this lack of consensus and develop a conceptual framework for the regulation of refusals to license based on at least two foundational principles. First, a refusal to license – in and of itself – cannot invoke the use of competition policy instruments. Second, a refusal to license may be considered abusive if it results in one of at least three outcomes: it stymies innovation, has anticompetitive effects in a secondary market, or is justified simply on the basis that it is permitted by the IP right in question.

Undermining innovation

In certain cases, a refusal to license allows the exclusive rights holder to extract a benefit from a product that is 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 in fact hinders innovation, preventing the market entry of a new product and thereby undermining the strongest rationale for the protection of IP. In this regard, developed country experience is useful, showing a concern with exclusive rights in IP being used “in a manner which impedes the very purpose for which they have been granted”.³⁵

³⁰ 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.”

³¹ *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. Delrahim (above note 19 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.”

³² *Radio Telefis Eireann*, above note 22 at para 54

³³ UNCTAD, above note 16 at 16

³⁴ Delrahim, above note 19 at 8

³⁵ See UNCTAD, above note 16 at 26.

Such an example of abuse has been highlighted by the development of fixed-dose combination (FDC) medicines for the treatment of HIV infection. Simplified treatment regimens are well known for improving levels of adherence to and thereby the efficacy of treatment. In countries where certain antiretroviral (ARV) medicines are not protected by patent, such as India and Thailand, generic manufacturers have developed three-in-one ARV FDCs that simplify chronic treatment for HIV infection to one pill taken twice daily.³⁶

Yet these innovative products, for which there is clear consumer demand, ordinarily cannot reach the market in those countries where the individual ARV components are protected by patent. The abuse in question thus results from two omissions: a failure to license generic manufacturers combined with a failure to co-operate with other exclusive rights holders to manufacture the desired FDC, either through cross-licensing or sub-licensing. In the result, innovation is stymied by the ordinary exercise of exclusive rights in a patent.

Anticompetitive effects in a secondary market

A refusal to licence may have anti-competitive effects in circumstances that may not necessarily be considered as abusive, such as when the potential licensor does not benefit from the refusal 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 a secondary market. This would ordinarily be a market other than that within which the licensor itself 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 the treatment of HIV infection. 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.

Unjustifiable refusals to license

In certain cases, patent holders have appeared to refuse the grant of voluntary licences simply on the basis that their exclusive rights in the patents concerned permit such refusals. Given that they have the right to exclude, they simply choose to do so. Consider the following example. As a result of public pressure, patent holder P decides to license generic manufacturer G1 to produce and market its drug D in certain developing countries. P also claims that it sells D in such countries at marginal cost and that G1's licence is royalty free. In other words, P is making no profit on the sale of D – or its generic equivalent – in the developing markets in question.

Generic manufacturer G2 is able to produce its version of D much more cheaply, primarily as a result of innovation in process, and is seeking to enter the market and offer its product at a price that substantially undercuts the prices of the both P's and G1's drug. But P refuses to license G2, stating

³⁶ These include Cipla's Triomune and the Thai Government Pharmaceutical Organization's GPO-VIR. The former is the first-line treatment regimen of choice in many parts of the developing world, while the latter forms the mainstay of the Thai public sector ARV treatment programme.

that it and G1 are able to satisfy demand on reasonable terms. In such a case, it is clearly “economically feasible”³⁷ and in the public interest for P to license more than a single generic manufacturer. In other words, P has no justifiable basis for refusing to license G2, being left to argue that its conduct is permissible simply because it is not extracting any unfair advantage to the detriment of consumers.

Exercising policy options regarding refusals to license

There are a wide range of regulatory tools that can be used to prohibit or control these – and other – examples of refusals to license. Some policy makers may choose to invoke the 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.³⁸ Others might wish to consider locating such provisions 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.

One concern that policymakers and lawmakers may wish to consider, relevant not only to the regulation of refusals to license but also IP licensing, is the potential negative impact of such intervention. Simply put, compulsory licensing in certain circumstances may unwittingly result in fewer rather than more licences being awarded. Thus, for example, the rational patent holder may decide not to deal with an exclusive licensee rather than risk having to be forced to license other manufacturers. In such cases, is a single licence not better than no licence at all, particularly if it brings a new product to the market?³⁹

Such a concern demonstrates the importance of developing and implementing a package of regulatory tools that work together to achieve the desired outcomes. Consider the FDC X/Y/Z example cited above, which considers the impact of an exclusive licence for drug X on the secondary market for drugs Y and Z. On its own, such a prohibition may well result in the failure to license at all. But, if read together with the prohibition of a refusal to license resulting in new innovative products being excluded from the market, the picture becomes much clearer. On the basis of the latter prohibition, the grant of the first licence cannot be refused. On the basis of the former prohibition, the grant of further licences is also required. Working in tandem, the two prohibitions result in the market entry of a new innovative product in respect of which there is direct competition.

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 what is perhaps ordinarily understood as abusive conduct, 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 licences were

³⁷ See, for example, section 8(b) of the SA Act, which defines a dominant firm’s conduct as abusive if it involves the refusal “to give a competitor access to an *essential facility* when it is economically feasible to do so”.

³⁸ In section 8 of the SA Act, for example, dominant “firms” are proscribed from engaging in a range of prohibited practices, including 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”.

³⁹ See also the text accompanying notes 40 to 44 below.

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 this field is seen as protecting potential “licensors’ willingness to license while enabling licensees to compete.”⁴⁰

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.⁴¹ In the US, on the other hand, the *Antitrust Guidelines for Licensing of Intellectual Property* (the US Guidelines)⁴² are based on the principle that the licensing of IP is generally considered as pro-competitive.⁴³ 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.”⁴⁴

One 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.

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

⁴⁰ UNCTAD, above note 16 at 25

⁴¹ Ibid at 7

⁴² Department of Justice and Federal Trade Commission, 6 April 1994, available online at www.usdoj.gov/atr/public/guidelines/ipguide.htm

⁴³ UNCTAD, above note 16 at 14

⁴⁴ Ibid at 15

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. In other words, the objects to be served by the regulation of IP licensing may be supported by the adoption of a comprehensive regulatory framework that sees the various competition policy tools as complementary to and an integral part thereof. As has been touched on above, it is important to manage the “fit” within and between the various legal frameworks. This IP licensing must be regulated in a way that complements the prohibitions against market dominance, all of which must support the public interest being advanced in patent law.

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 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.

CAN competition policy BE USED in the developing world?

Despite the significant regulatory flexibility regarding competition policy accorded to all WTO members under TRIPS, many developing countries may find that they have neither the level of expertise nor the institutional capacity to take full advantage, particularly insofar as state enforcement is concerned. With this in mind, such countries may decide against investing resources in giving effect to competition policy 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.⁴⁵

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 may require either the state to issue a compulsory license or an “interested person” to institute legal action for a licence to produce or import.⁴⁶ For good or bad reason, neither the state nor generic manufacturers or importers may decide to take such action. Thus leaving all decision-making powers in the hands of a single Minister or at the mercy of the softer face of the private sector may not necessarily result in the public interest being advanced.

⁴⁵ 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 minimum levels of IP protection, including patent protection for all 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.

⁴⁶ See, for example, section 56 of the South African Patents Act, 57 of 1978 (the SA Patents Act), which allows for such persons to apply to the Commissioner of Patents for a compulsory licence under the patent.

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.⁴⁷ 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 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, as well as possibly locating certain egregious forms of anti-competitive conduct within the ambit of the criminal law. While this may not be ideal, it may 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 only five years.⁴⁸ While it – perhaps unwittingly – 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 quite effectively to advance public health, most notably in the relatively recent civil society challenge to the pricing practices of two pharmaceutical giants.

Hazel Tau takes on GlaxoSmithKline and Boehringer Ingelheim

As part of a national campaign to increase access to treatment for HIV/AIDS, which includes the taking of steps to reduce the prices of essential medicines, a group of concerned individuals and civil society organisations lodged a complaint against GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI) with South Africa’s Competition Commission in September 2002.⁴⁹ Acting in terms of section

⁴⁷ To some extent, this 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 SA 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.

⁴⁸ While certain provisions of the SA Act came into force on 30 November 1998, the Act – as a whole – has been in force since 1 September 1999.

⁴⁹ 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 by the AIDS Law Project (see www.alp.org.za) on behalf of a number of PWHAs who are open about their status,

49B(2)(b) of the Competition Act, 89 of 1998 (the SA Act) that permits “any person” to “submit a complaint against an alleged prohibited practice”, the complainants argued 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 essence, 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”.⁵⁰ Deliberately adopting a conservative approach to the concept of prohibited excessive pricing, the complainants argued 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. Whilst argued on the basis of the statutory framework provided by the SA Act, the complainants located their arguments firmly within the broader context provided by the public health emergency faced by South Africa as well as the constitutional guarantee of a right of access to health care services.⁵¹

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,⁵² meaning that there were only three real options available to people in South Africa for accessing 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.”⁵³

Given the paucity of jurisprudence internationally on the use of competition law to increase access to patented medicines, the lack of clarity in the SA Act regarding the IP/competition policy interface and the risks associated with litigation of any form, the complainants decided to tread cautiously. Their goal was to make best use of the available legal framework to ensure access to a sustainable supply of affordable ARV medicines and to break the paralysis resulting from state inaction. After much internal debate and consultation, a decision was taken to focus on allegations of excessive pricing in respect of three particular drugs. If successful, the case would go some way towards achieving the goal of the campaign. But in and of itself, the complaint was never intended to be nor executed as the “magic bullet”.

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.

⁵⁰ See the Statement of Complaint at para 107, available online at www.tac.org.za/Documents/DrugCompaniesCC/HazelTauAndOthersVGlaxoSmithKlineAndOthersStatementOfComplaint.doc

⁵¹ See section 27 of the Constitution of the Republic of South Africa, 1996. In terms of section 39(2) of the Constitution, “every court, tribunal or forum”, when “interpreting any legislation ... must promote the spirit, purport and objects of the Bill of Rights.”

⁵² 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.

⁵³ 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.

The focus on excessive pricing was intentional. The South African experience in public interest lawyering has shown that public opinion matters in the ultimate resolution of any high profile case. This is not to argue that popular beliefs trump reasoned argument, but rather that the inherently conservative legal status quo cannot easily be changed. Judicial officers cannot be expected to take on powerful vested interests in the absence of compelling evidence that offers them no alternative. Rational profit-making entities with deep pockets may be more inclined to fight relatively small public benefit organisations in the courtroom if they have reason to believe that the matter is too technical for the public to care.

For these – and other – reasons, the focus on excessive pricing was identified instead of the essential facilities doctrine or the concept of exclusionary acts. The complainants believed that the manner in which they framed their case was most likely to bring the respondent drug companies “to their senses”, because answering an excessive pricing claim would very likely result in the forced public disclosure of costing models. This, the complainants believed, was something that GSK and BI would seek to avoid at all costs. Further, it was the one ground – if properly approached – that was most likely to elicit broad public support, because it could avoid having to challenge the patent system head on whilst still focusing on the abuse of exclusive rights in patents with which any person who has ever needed medical care can identify.

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 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.⁵⁴ In essence, the two groups of companies agreed to open up the market for these drugs to generic competitors.⁵⁵

Learning from Hazel Tau

The South African experience shows that competition policy instruments can indeed be used to great effect, particularly in a context where other key role-players – such as developing country governments – are either unwilling or unable to act. In this case, civil society was able to take the lead in advancing a public health agenda, not being constrained by the failure to take appropriate action on the part of both the state and generic pharmaceuticals companies.⁵⁶ To date, the state has

⁵⁴ The settlement agreements with the complainants are available online at www.alp.org.za/view.php?file=/camps/20030910_PatRights.xml

⁵⁵ As of 30 September 2004, both GSK and BI had apparently licensed 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. GSK has granted a third licence to a company that does not appear to be in any position to make use of the licence in the short to medium term, thus calling into question whether the granting of such a licence can indeed satisfy the requirements of the settlement agreement. To date, the only major generic player in South Africa that has yet to conclude licensing agreements with either GSK or BI is ironically the best placed to provide access to a comprehensive range of ARV products, including FDCs and paediatric formulations. The ALP has started to take initial steps in preparing to enforce the settlement agreements in the ordinary civil courts, if necessary.

⁵⁶ 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.

chosen not to invoke its powers under patent law to issue compulsory licenses,⁵⁷ with no court having issued a licence to a generic pharmaceutical company in terms of the third-party provisions in the same statute.⁵⁸

Faced with the adverse findings of an independent investigation, a protracted public hearing into its pricing practices and the potential for the strengthening of the legal framework through unfavourable jurisprudence, all of which were strong possibilities, GSK and BI acted as any rational corporation would do and decided to settle. 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. Knowing that the public sector ARV treatment plan was in the process of being finalised, that not only price but also sustainability of supply would become increasingly relevant, and that thousands of deaths could be averted if the matter was speedily resolved, the complainants had no reasonable alternative.

Through the use of the SA Act, civil society organisations in South Africa have recognised that the regulatory framework requires some work. One of the reasons that limited the scope of the complaint to a single ground is the complex set of hurdles that must be overcome before the substance of the matter could be addressed. The complainants thus had to deal with issues such as market definition and the establishment of dominance in the absence of limited statutory and no regulatory guidance. With each hurdle, the odds of a successful challenge to the unjustifiable pricing practices exposed were lowered. The statute needs fine-tuning to ensure that form does not stand in the way of substance.

Most crucial, however, 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, for example, the lack of express recognition is nevertheless problematic. Unless and until the Competition Tribunal rules favourably on the issue in any similar matter, the hand of both civil society and the Competition Commission remains weakened.

Hazel Tau has also focused attention on the need for a comprehensive legal framework that draws together the separate statutes dealing with competition policy, IP and the regulation of medicines in a cohesive and rational way. This requires the sort of political will, maturity and courage that has yet to surface. So for as long as the regulatory framework remains unchanged or undeveloped, either 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 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.⁵⁹

⁵⁷ See section 4 of the SA Patents Act. Of further concern is the state’s failure to take appropriate steps to remove problematic TRIPS-plus protections in the Act in accordance with the Doha Declaration.

⁵⁸ See above note 46

⁵⁹ 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 42.

CONCLUSION

This paper has focused on the role of competition policy in advancing public health by increasing access to a sustainable supply of affordable 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 appropriateness 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.

In countries where legal change is slow, where court processes are unduly time-consuming and not particularly user-friendly, and where laws often exist only on paper, the introduction and successful implementation of a complex and comprehensive competition policy framework will require a significant degree of political will and technical support. International institutions and organisations will most certainly have a significant role to play, but the debate must be framed by the very real needs and concerns of the developing world if competition policy is indeed to be used to increase access to essential medicines. Hopefully this paper has helped to place new ideas on the table and to identify research gaps, and in so doing, has stimulated creative thought and engaged debate.

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