+SECTION27 incorporating the AIDS Law Project
catalysts for social justice

SUBMISSION ON DISCUSSION PAPER ON COMPULSORY LICENSING

Introducing SECTION27

SECTION27 was established in South Africa in mid-2010 as a public interest law centre that seeks to influence, develop and use the law to protect, promote and advance human rights. Its main activities include research, advocacy and legal action to change the socio-economic conditions that undermine human dignity and development, prevent poor people from reaching their full potential and lead to the spread of diseases that have a disproportionate impact on the vulnerable and marginalised.[1]

Incorporating the AIDS Law Project (ALP) – which was established in 1993 – and retaining a strong focus on human rights in relation to HIV/AIDS and access to health care services, SECTION27 also recognises that the realisation of all rights (and socio-economic rights in particular) is fundamental to sustainable progress in reducing new HIV infections and ensuring sustained access to treatment. In conducting much of this broader work, SECTION27 recognises the centrality of HIV to its vision and mission.

SECTION27's work on access to medicines has thus far covered three main areas of focus: patents, pricing and sustainability of supply; public procurement and supply chain management; and drug regulation.[2] Much of this work was necessary in the absence of meaningful state intervention.[3] While a large part of our work has focused on medicines for the prevention and treatment of HIV infection and related opportunistic infections,[4] we have – by necessity – also had to focus on broader access concerns.

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[1] For more information on SECTION27, see http://www.section27.org.za/about-us/

[2] For further detail on this work, see http://www.section27.org.za/organisational-reviews/

[3] For example, the state has yet to amend patent legislation in South Africa to take full advantage of the flexibilities permitted under international trade law.

[4] Our access to medicines work began in earnest in early 2001 when the ALP filed a successful application on behalf of the Treatment Action Campaign (TAC) for the latter to be admitted as *amicus curiae* in *Pharmaceutical Manufacturers' Association and Others* v *President of the Republic of South Africa and Others*, case no. 4183/98, High Court of South Africa (Transvaal Provincial Division). For further detail on this case, see Mark Heywood, "Debunking 'Conglomo-talk': A Case Study of the Amicus Curiae as an Instrument for Advocacy, Investigation and Mobilisation" (2001) 5 *Law, Democracy & Development* 133.

Wherever possible, we have sought to raise the systemic issues when focusing on HIV, as well bringing an HIV angle to work focusing on the bigger picture. This approach has yielded mixed results: on the one hand a limited impact on legislative reform and jurisprudence, but on the other increased access to a range of important HIV-related medicines and a series of influential settlement agreements. It has clearly demonstrated both the benefits and limitations of using the law to increase access to medicines.

Purpose of this submission

In setting out possible options available to the Government of India to address concerns relating to drug pricing and availability, section IX of the discussion paper on compulsory licensing refers – amongst other things – to the Competition Act 2002.[5] Section XVII, which is entitled "Issues for Resolution" and in respect of which comment has been invited, expressly considers the relationship between compulsory licensing and anti-competitive behaviour. In this regard, issue 5 provides as follows:

> *The Competition Act 2002 does not explicitly provide for issue of Compulsory Licences as a remedy for anti competitive practices. However, Section 27(g) empowers the Competition Commission to pass 'such other order or issue such other directions as it may deem fit'. Further Section 90(ix) of the Patents Act recognizes that CLs can be granted to remedy a practice determined, after judicial or administrative process to be anti competitive. Should CLs be issued on the basis of anti competition law – if it is determined that companies have abused their dominant position in the market or engaged in unfair competition?*

While South Africa's Patents Act 57 of 1978 ("the SA Patents Act") makes no express reference to the term "anti-competitive conduct", it does make provision for the grant of compulsory licences where "the rights in a patent are being abused".[6] Amongst other grounds, section 56(2)(c) of that statute recognizes that "[t]he rights in a patent shall be deemed to be abused if … the demand for the patented article in the Republic [of South Africa] is not being met to an adequate extent and on reasonable terms". That being said, section 56 has never been successfully invoked.[7]

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[5] Section IX of the discussion paper provides as follows:

> The first short term option is invoking the Competition Act 2002 to scrutinize whether the price or availability of a drug is a consequence of an anti competitive agreement or a combination which has an adverse effect on competition; or the abuse of dominant position by a company and initiating suitable action.

[6] Section 56(1) of the SA Patents Act

[7] There are three reported cases dealing with section 56 and compulsory licensing in South Africa: *Syntheta (Pty) Ltd (formerly Delta G Scientific (Pty) Ltd)* v. *Janssen Pharmaceutica NV and Another* 1999 (1) SA 85 (SCA); *Afitra (Pty) Ltd and Another v Carlton Paper of SA (Pty) Ltd* 1992 BP 331; and *Sanachem (Pty) Ltd v British Technology Group plc* 1992 BP 276. None of these cases considered pharmaceutical products.

Like its Indian counterpart, South Africa's Competition Act 89 of 1998 ("the SA Competition Act") makes no express reference to the grant of a compulsory licence as a remedy for anti-competitive practices in respect of patented products or processes. Nevertheless, civil society organisations have successfully relied upon the abuse of dominance provisions in that statute effectively to compel exclusive rights holders in the pharmaceutical sector to license companies that manufacture in and/or import generic medicines into South Africa.

The purpose of this submission is threefold: first, to draw the attention of the Department of Industrial Policy and Promotion ("the DIPP") to the South African experience in using competition law to ensure the market entry of generic competition in the pharmaceutical sector; second, to draw to the DIPP's attention other examples of how competition law has been used in South Africa to increase access to medicines; and third, to share lessons learnt in South Africa regarding the appropriate role of competition law in the field of pharmaceutical patents and drug access.

Using competition law to ensure the market entry of generic competition

Acting on behalf of various clients, the ALP – now SECTION27 – was able to rely on the abuse of dominance provisions in the SA Competition Act to ensure the market entry of generic competition in respect of four patented antiretroviral (ARV) medicines: zidovudine (AZT), lamivudine (3TC), nevirapine (NVP) and efavirenz (EFV).[8] The first case, *Hazel Tau and Others v GlaxoSmithkline and Boehringer Ingelheim*, concerned allegations of prohibited excessive pricing. The second, *Treatment Action Campaign v MSD (Pty) Ltd and Merck*, focused on the circumstances within which an exclusive rights holder may be forced to license competitors. Both, in essence, were conceptualised with licensing remedies in mind.[9]

The *Tau* case, which took the form of a complaint lodged with South Africa's Competition Commission in late 2002,[10] gave rise to settlement agreements between the complainants and respondents which directly resulted in the market entry of a wide range of affordable generic AZT, 3TC and NVP products for use in the public and private health sectors. The case is discussed in some detail in Tenu Avafia, Jonathan Berger and Trudi Hartzenberg in "The ability of select sub-Saharan African countries to utilise TRIPs flexibilities and

[8] The South African patents on AZT and 3TC have since expired. However, South African Patent No 92/3544 specifically claims the combination of AZT/3TC and its use in the prevention or treatment of HIV infection. This patent is in force and will expire in the normal course on 15 May 2012.
[9] The legal papers in the *Tau* case did not expressly seek a licensing remedy.
[10] For further detail on the Competition Commission, see www.compcom.co.za.

competition law to ensure a sustainable supply of essential medicines: a study of producing and importing countries".[11]

The *Treatment Action Campaign (TAC)* case, which took the form of a Competition Commission complaint in 2007, resulted directly in MSD and Merck reaching agreement with multiple licensees – on reasonable terms – to bring a wide range of generic products containing EFV (an essential drug used as part of first-line ARV treatment in South Africa) to market. Unlike the *Tau* case, which was settled only after the Competition Commission had taken a decision to refer the matter to the Competition Tribunal for adjudication,[12] the *TAC* case was resolved before the Competition Commission completed its investigation on the matter. Further, whilst the *Tau* case resulted in a licensing remedy, only the *TAC* case expressly sought one.

For purposes of this submission, three documents are attached: first, a document that sets out the evidence relied upon and the legal submissions made in the *Tau* case; second, the statement of complaint in the *TAC* case; and third, the legal submissions advanced in the *TAC* case. All other documents referred to in these three documents are available upon request.[13]

Other examples of using competition law to increase access to medicines

For the sake of completeness, it is important to consider two other uses of competition law to increase access to medicines in South Africa: a successful challenge to an excessively priced off-patent drug used in the treatment of an HIV-related opportunistic infection; and a civil society intervention in merger proceedings that resulted in the grant of multiple licences for a key ARV medicine.

After receiving credible threats of litigation from the TAC and the Southern African HIV Clinicians Society in early 2005,[14] Bristol-Myers Squibb reduced the price of amphotericin B (AmB) – a key drug used in the treatment of cryptococcal meningitis – by 80 to 85%.[15] The matter did not even require the filing of a formal complaint to the Competition Commission. Unlike the ARV medicines discussed in the *Tau* and *TAC* cases above, AmB

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[11] This paper, published as Tralac Working Paper No 12 (University of Stellenbosch Printers, Stellenbosch: 2006), is attached to this submission. In addition, see Belinda Beresford, "The Price of Life: *Hazel Tau and Others vs GlaxoSmithKline and Boehringer Ingelheim* – a report on the excessive pricing complaint to South Africa's Competition Commission", available at http://www.aidslex.org/site_documents/T012E.pdf

[12] For further detail on the Competition Tribunal, see www.comptrib.co.za.

[13] For further information on each complaint, see http://www.tac.org.za/community/news_2003 and http://www.tac.org.za/community/node/2329.

[14] The ALP also acted on behalf of these two organisations in this matter.

[15] The private sector price was originally higher. After the reduction, one price was applied in both sectors.

was not under patent protection at the time the threat of litigation was made. The lack of patent protection had nevertheless not translated into generic market entry.[16]

In mid-2008, the Competition Commission invited interested parties to make submissions in respect of the proposed merger between Aspen Pharmacare – a South African-based generic pharmaceutical company – and GlaxoSmithKline (GSK). A joint ALP/TAC submission was instrumental in ensuring that, as a condition of the merger, GSK was required to grant non-exclusive licences to multiple companies in South Africa for the manufacture and/or import of generic abacavir "on terms and conditions no less favourable than those granted to Aspen." Prior to the merger, Aspen was GSK's *de facto* exclusive licensee in respect of abacavir.[17]

An appropriate role for competition law

The experiences described above have been useful in helping SECTION27 to develop a better understanding of an appropriate role for competition law to increase access to medicines that are ordinarily the subject of patent protection. In our view, competition law provides a useful set of complementary tools, with the primary set of tools being those that ordinarily fall within the scope of patent law. In part, this is based on our understanding that the mere exercise of exclusive rights cannot in and of itself provide a basis for using competition law tools.[18]

For example, a mere refusal to license – in the absence of anything else – cannot be considered as abusive and therefore actionable. However, there may well be circumstances – as we demonstrated in the *TAC* case – where an exclusive rights holder can and should be compelled to license. In the European Union, for example, a refusal to license may be considered unlawful where it prevents the market entry of an innovative product for which there is consumer demand. But in the United States, exclusive rights holders have the freedom to choose whether to license.[19]

The lack of developed country consensus provides great flexibility to developing countries. That said, there is no basis in law for an overly broad definition of what constitutes anti-competitive conduct. In our view, competition law is an inappropriate vehicle where the conduct of an exclusive rights holder is not abusive. In such cases, which may include an

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[16] For further information on this matter, see http://www.tac.org.za/newsletter/2005/ns19_05_2005.htm. The matter is also discussed in Avafia et al, above note 11

[17] For further information, see http://www.tac.org.za/community/node/2744

[18] See generally, Jonathan Berger, "Advancing Public Health by Other Means: Using Competition Policy" in Pedro Roffe et al, *Negotiating Health: Intellectual Property and Access to Medicines* (Earthscan, London: 2005)

[19] The relevant case law is addressed in the legal submissions in the *TAC* case.

exclusive rights holder's real inability to bring affordable products to market, the set of tools that ordinarily fall within the scope of patent law – such as government-use orders or compulsory licensing in the public interest – should rather be invoked.

As SECTION27, we have found competition law to be particularly helpful in advancing our public interest mandate. Acting on behalf of organisations that are not ordinarily involved in the manufacturing or importation of medicines, we have made good use of the broad standing requirements under competition law to invoke the investigation powers of an independent organ of state. But the drug-by-drug approach adopted by the ALP and its partners, whilst successful in increasing access to many HIV-related medicines, may be too labour-intensive and costly to ensure access to a wide range of essential medicines. In addition, it is unlikely to result in jurisprudence as respondent companies are likely to settle in the face of a strong case brought by a vocal, informed and mobilised civil society.

Conclusion

We thank you for the opportunity to make this submission. Should you have any questions in this regard, please revert to us using the contact details provided below.

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