



MEMORANDUM

SUMMARY OF THE SOUTH AFRICA COMPETITION COMPLAINT AGAINST MERCK, FILED NOV. 6, 2007

Sean M. Flynn
Associate Director, PIJIP
November 6, 2007
202-294-5749

At noon today South Africa time, the AIDS Law Project and Treatment Action Campaign filed a competition complaint against the multinational pharmaceutical company, Merck & Co., and its South African subsidiary, alleging that its refusal to grant sufficient licenses to generic producers to import and sell the anti-AIDS medicine efavirenz (“EFV”) (branded as Stocrin®) violates the South African Competition Act.

This is the second competition complaint filed by ALP and TAC against an AIDS drug supplier, and is part of a new wave of action by developing country activists to use competition law to force open access to essential medicine patents. (For more on this topic, see www.wcl.american.edu/pijip/CompetitionPolicyProject.cfm). Competition law appears especially promising in this regard. The same standards that have required Microsoft to open access to its operating software and electricity and telephone monopolies to open access to their wires are justifiably being invoked by the world’s poor to force open access to the most important property rights in the world today – patents that are blocking access to millions in need of cheap and effective AIDS treatment to keep them alive. The South Africa complaint is amply supported by the principles and doctrines of competition law and, more importantly, will build upon South Africa’s existing precedent to chart a course for other developing countries to use their competition laws to promote access to needed medicines.

Summary of the Complaint

The legal submission supporting the complaint alleges:

“In refusing to license on reasonable and non-discriminatory terms, the respondents have – without good cause – threatened access to comprehensive treatment for HIV/AIDS in both public and private sectors, and in so doing have engaged in exclusionary acts where the anti-competitive effects of those acts outweigh their technological, efficiency or other pro-competitive gains, as prohibited by section 8(c) of the Competition Act 89 of 1998 (“the Act”).”

Section 8(c) of the South African Competition Act states:

“It is prohibited for a dominant firm to ... engage in an exclusionary act ... if the anti-competitive effect of that act outweighs its technological, efficiency or other pro-competitive gain”

Case law in South Africa instructs that the assessment of the anti-competitive effect of an exclusionary act must consider (1) “evidence of actual harm to consumer welfare” and (2) the degree to which “the exclusionary act is substantial or significant in terms of its effect in foreclosing the market to rivals.”

In reference to the second criteria, the submission refers to European Community case law (especially the “Magill” case, involving a refusal to license a copyright that prevented a combination television guide from coming to the market), and argues that grounds for a compulsory license should be found whenever the refusal to license prevents a new product from coming to the market, such as a new combination product using the patented material as one component.

The complaint provides the factual basis for the argument that Merck’s refusal to license additional generic suppliers unreasonably harms consumer welfare and prevents new products coming to market.

Merck has granted two licenses in South Africa (to Aspen Pharmacare Holdings and Adcock Ingram) to sell generic versions of EFV. But those companies do not offer the lowest global prices for EFV and their licenses do not allow the two companies to create combination products using EFV (e.g. single pill formats that combine EFV with other antiretrovirals). The complainant states that Merck has refused to license

“a) Any existing company in South Africa (other than Aspen and Adcock) to import into, manufacture, use, offer to dispose of and/or dispose of in South Africa, generic EFV products; and

“b) Any existing company in South Africa (including Aspen and Adcock) to import into, manufacture, use, offer to dispose of and/or dispose of in South Africa, co-formulated and/or co-packaged generic products containing EFV and at least one other ARV medicine.”

Merck sells EFV in South Africa at its best international price, which is currently US\$394.20 per adult per year for the 200mg formulation. The lowest price for generic 200mg EFV is US\$185 per adult year – less than half the current Merck price.

Importantly, the complaint notes that “generic companies have been able to reduce their prices without having access to significant economies of scale.” South Africa’s market is significant, projected have between 700,000 and 930,000 people using EFV in the public sector by the end of 2011. Thus, the compliant states:

“If generic companies had access to this already substantial and increasingly expanding market, the marginal costs of production could drop significantly. With sufficient competition, this would likely result in further price reductions.”

The refusal to license is also blocking new products using EFV from entering the South African market. The complaint states:

There appears to be no scientific reason why EFV could not be combined in a single pill with other ARV medicines that are also taken once daily and ordinarily form part of treatment regimens containing EFV. If this were done, FDCs such as FTC/EFV, 3TC/EFV, ddi/FTC/EFV and ddi/3TC/EFV could theoretically reach the market. But as indicated above, the respondents’ refusal to license any generic company to import and/or manufacture FDCs containing EFV and at least one other ARV medicine is an absolute bar to products such as TDF/3TC/EFV reaching the South African market.

Finally, the complaint states that consumer welfare is harmed by the limited number of suppliers through shortages in the supply of EFV in the local market. The complaint documents “a number of occasions when there have been ex-manufacturer shortages of the essential ARV medicine in the region,” including shortages of EFV in at least two SADC countries: South Africa and Botswana.

According to the complaint, in a letter denying the Indian pharmaceutical company Cipla-Medpro a license to sell efavirenz in South Africa, Merck stated:

“We are monitoring the demand for Stocrin both in public and private sectors, and have concluded that at this stage MSD SA is in position to adequately meet all of the demand for this product. In addition, we expect Aspen, another supplier, will be in a position to come to market in a few months to ensure multiple supplies for this medicine.”

The complainant also states that Merck has refused a request for a license from Sonke Pharmaceuticals (Pty) Ltd, a joint venture between Ranbaxy (SA) (Pty) Ltd and Community Investment Holdings (Pty) Ltd.

In summary, the complaint explains:

“By refusing to license further existing companies in South Africa, and by refusing to permit Aspen and Adcock to bring co-formulated and/or co-packaged generic products containing EFV and at least one other ARV medicine to market, the respondents have – without good cause – collectively threatened access to comprehensive treatment for HIV/AIDS in both public and private sectors by –

- a) preventing the market entry in South Africa of significantly cheaper generic EFV products;
- b) preventing the market entry in South Africa of a range of co-formulated and/or co-packaged products containing EFV; and
- c) placing the sustainability of supply of EFV products in South Africa under threat.”

The complainant requests a compulsory license as a remedy for the illegal acts of Merck. The complaint does not specify the requested terms of the license or whether such license should be an open license. In the previous case filed by TAC and the ALP, the Competition Commission found a violation of the Act by the companies’ refusal to license generics and sought an open license “authorising any person to exploit the patents to market generic versions of the respondents patented medicines or fixed dose combinations that require these patents, in return for the payment of a reasonable royalty.” A similar remedy would be appropriate in this case.

The Commission has one year to act on the complaint by either prosecuting the case in the Competition Tribunal or issuing an order allowing the complainants to prosecute the case privately.