

Hazel Tau & others v. GlaxoSmithKline, Boehringer Ingelheim & others, 2002
(South African Competition Commission, Competition Commission Case No. 2002Sep226)

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Summary

The *Hazel Tau* case provides an example of how competition law can be used to facilitate access to affordable medicines. In 2002, a group of HIV/AIDS patients initiated a complaint against GlaxoSmithKline (hereinafter “GSK”) and Boehringer Ingelheim (hereinafter “BI”) with the South African Competition Commission (hereinafter “the Competition Commission”), alleging that the two firms had abused their dominant positions by charging excessive prices for their patented antiretroviral medicines (hereinafter “ARVs”).¹ After investigating the complaint, the Competition Commission concluded that GSK and BI had abused their dominance and decided to bring the case to the Competition Tribunal. The case was finally settled by an agreement between GSK and BI on the one hand and the Competition Commission on the other, in terms of which GSK and BI agreed to license their patented ARVs to local generic manufacturers.

The facts

According to the South African National Department of Health, approximately 4.74 million South Africans were infected with HIV in 2001.² The Medical Research Council reported that AIDS was the main cause of mortality in the early 2000s in South Africa.³ It is in this context that a group of HIV-infected individuals, doctors and several organizations filed a complaint in September 2002 against GSK and BI, two pharmaceutical firms, with the Competition Commission. The complainants alleged that the respondents had both abused their dominant positions by charging excessive prices for their patented ARVs to the detriment of consumers, in violation of section 8(a) of the South African Competition Act (Law No. 89 of 1998, as amended; hereinafter “the Competition Act”).

GSK and BI held patents in South Africa and elsewhere on certain ARVs used to treat HIV/AIDS. Specifically, GSK held patents in South Africa on AZT (branded as Retrovir), Lamivudine (branded as 3TC) and AZT/Lamivudine (branded as Combivir). BI held a patent in South Africa on Nevirapine (NVP) (branded as Viramune). The original complaint in this matter was filed by Ms. Hazel Tau and similarly situated HIV/AIDS patients (and HIV/AIDS patients' groups) and their doctors, alleging that GSK and BI were charging excessive prices to the detriment of consumers for their patented ARV medicines. GSK and BI had refused to issue licenses to local generic manufacturers to produce these ARVs for the local market.

The legal issues

¹ ARVs are drugs used to treat HIV/AIDS.

² National HIV and Syphilis seroprevalence survey of women attending public antenatal clinics in South Africa 2001, Summary Report, South African National Department of Health, 2001, p. 12.

³ The impact of HIV/AIDS on adult mortality in South Africa, Technical Report, Medical Research Council, 2001, p. 6.

In order to establish the dominant position of GSK and BI within the meaning of section 7 of the Competition Act, the complainants identified South Africa as the relevant geographic market for each ARV given the national medicines regulatory system and the patents on these ARVs that are national in nature.

Regarding the relevant product market, the complainants raised two alternative arguments, the first being that each ARV constituted its own market and the second being that the relevant markets to be considered were the therapeutic classes to which the ARVs belong. In either event, the complainants argued that GSK and BI were dominant.

As for the first argument, defining the relevant product market narrowly, the complainants advanced that there was no alternative on the market to the branded ARVs of GSK and BI. Because of the respondents' reliance on patent protection, patients had no access to generic versions of the ARVs. Moreover, no other ARVs available in South Africa could be substituted for the respondents' ARVs. Relying on the affidavit provided by a technical expert, the complainants explained why access to all the ARVs available was essential for patients' HIV treatment: "In general, ARVs cannot be considered as substitutable for each other. In order to access HAART⁴, a person living with HIV/AIDS must at a minimum be able to have access to all of the ARVs that are the subject of this complaint. This is because HAART requires the commencement of at least three ARVs simultaneously, with alternative regimens being necessary to meet specific requirements at initiation of treatment and to substitute for regimens in the case of unmanageable side effects or treatment failure".⁵ Under this approach, GSK and BI were alleged to be dominant, namely to control 100% of market share, in respect of the South African market for each particular ARV.

As for the second argument, the complainants argued that the respondents were dominant firms with respect to each therapeutic class of ARVs. They alleged *inter alia* that the market shares of GSK and BI exceeded the 45% threshold prescribed by Section 7 of the Competition Act that determines whether a firm is dominant in a relevant market or not.

After defining the relevant market and establishing respondents' market dominance, the complainants alleged that GSK and BI engaged in excessive pricing of their ARVs. Section 8(a) of the Competition Act prohibits a dominant firm to charge a price for a good which bears no reasonable relation to the economic value of that good. However, before assessing the prices charged by the respondents, the complainants clarified that the existence of a patent on a particular drug did not constitute an exception to the rule that would justify charging a price that bears no reasonable relation to the economic value of that drug. Thereafter, the complainants demonstrated through a pricing analysis that there was "at least powerful prima facie evidence that grossly excessive prices [were] being charged" by GSK and BI, in violation of the Competition Act.⁶

⁴ HAART or highly active antiretroviral therapy, also known sometimes as "triple drug cocktail", is a treatment regimen that consists of three or more ARVs. The introduction of HAART in the 1990s represented substantial progress in the treatment of HIV-infected patients.

⁵ Para. 55 of the complaint.

⁶ Para. 65 of the complaint.

To determine whether there was a reasonable relationship between the price and the economic value of the ARVs in question, the complainants based their analysis on the cost-based approach adopted by the Competition Commission.⁷ The complainants took into consideration the following factors:⁸

1. The hypothetical price of the good in a competitive market (i.e. in the absence of patent protection) including a normal rate of profit.
2. A reasonable allowance for the recovery of research and development (hereinafter R&D) costs. The role of public funding in R&D should, however, be clarified.
3. Some allowance for additional profit as an incentive for innovation and any unusual entrepreneurial risk.
4. The nature and extent of the detriment to consumers that results from the high price.
5. The impact of the high prices on constitutionally protected and internationally recognised rights (i.e. right to life, dignity and access to health care services).

The complainants first estimated the economic value of the ARVs by adding: (1) the prices charged by manufacturers of WHO pre-qualified generics⁹, treating these prices as if they were manufacturing costs; (2) an allowance for R&D, licensing fees and profit; and lastly, (3) the average rate of return on revenue in the pharmaceutical industry. The estimated economic value of each ARV was thereafter compared to the actual prices charged by GSK and BI. Given the lack of information provided by the respondents, in particular regarding the R&D costs and the actual rates of return of the ARVs in question, it is noteworthy that the complainants adopted a method of calculation that was particularly generous to the respondents. The complainants found however that the prices charged by the respondents in South Africa were from 1.72 to 4.01 times higher than the estimated economic value of the ARVs. As the complainants stated, “[i]n each case, actual price is grossly in excess of the estimated “economic value”.”¹⁰

The complainants further advanced that the high prices for ARVs charged by GSK and BI were directly responsible for premature, predictable and avoidable deaths of people living with HIV/AIDS, including children and adults. Moreover, they claimed that patients should not receive less efficient treatment when life is at stake and where patent protection precludes access to generics. In these circumstances, the complainants concluded that there was no reasonable relation between the prices charged by the respondents and the economic value of each ARV. They affirmed thus that GSK and BI engaged in excessive pricing of ARVs to the detriment of consumers, an abuse of dominance prohibited by section 8(a) of the Competition Act.

⁷ Competition Commission of South Africa, Competition News, Edition 5, September 2001, p. 7: “It may be necessary to take a pragmatic approach to the analysis of excessive pricing. Such an approach may be as follows: in order to establish economic value, a cost-based approach should be followed, taking the manufacturing costs of the particular product into account, with an industry norm profit margin added. It may also be necessary to add premiums for special circumstance, i.e. risk, cost of innovation or intellectual property, etc.”. Available at: <http://www.compcom.co.za/2001-newsletters/>.

⁸ Para. 60 of the complaint.

⁹ WHO pre-qualification means that the product has been found to meet stringent standards of quality, safety and efficacy. The prices charged for these pre-qualified generics include a profit margin for the generic manufacturers that would have been appropriate to deduce in order to obtain the respondents’ manufacturing costs. However, because information about the generic rate of profit was not available, no deduction was made. This means that the values attributed to the respondents’ manufacturing costs were more than generous.

¹⁰ Para. 66 of the complaint.

The complainants requested the Competition Commission to investigate the case and gather information from the respondents, especially regarding the actual R&D costs, in order to further substantiate the complaint.

The key points

- The *Hazel Tau* case was initiated in 2002, at a time when South Africa was facing an extremely high level of HIV/AIDS cases.
- The *Hazel Tau* case was heard before the South African Competition Commission, which is charged with the implementation of the Competition Act. Competition authorities are usually the initial venue for arguing cases under competition law claims and include the potential to hear competition-based cases related to the abuse of IP rights. In this case, the investigation was triggered by the excessive pricing of ARVs by GSK and BI and by their refusal to license at royalty rates affordable to generic South African manufacturers.¹¹
- Following the complaint and after conducting an investigation, the Competition Commission agreed with the complainants and found that GSK and BI abused their dominant positions in their respective ARV markets. The Competition Commission concluded that GSK and BI violated not only section 8(a) of the Competition Act by charging excessive prices for their ARVs, but also sections 8(b) and (c), by denying competitors access to an essential facility and by engaging in an exclusionary act. The Competition Commission therefore decided to refer the case to the Competition Tribunal for determination. It requested the Competition Tribunal *inter alia* to make “an order authorising any person to exploit the patents to market generic versions of the respondents patented medicines [...] in return for the payment of a reasonable royalty”.¹²
- Before the referral and prosecution of the case, GSK and BI concluded separate settlement agreements with the Competition Commission. They agreed to:
 - grant licenses to generic manufacturers;
 - permit the licensee’s to export the relevant ARV medicines to sub-Saharan African countries;
 - where the licensee did not have manufacturing capability in South Africa, permit the importation of the ARV medicines for distribution in South Africa only, provided all the regulatory approvals were obtained;
 - permit licensees to combine the relevant ARV’s with other ARV medicines; and
 - not require royalties in excess of 5% of the net sales of the relevant ARV’s.¹³

¹¹ Generally, decisions of the competition authorities are appealable to the courts. This happened in 2010 in Indonesia, for example, when Pfizer and Dexa Medica successfully appealed a fine issued by the Indonesian Competition Commission for price fixing, cartel, illegal agreements with foreign parties and abuse of dominant position, concerning a branded hypertension drug that had come off patent.

¹² South African Competition Commission, Media release No. 29 of 2003, 16 October 2003. Available at: <http://www.cptech.org/ip/health/sa/cc10162003.html>.

¹³ OECD, 2014, Generic Pharmaceuticals: Note by South Africa, 5 June 2014, DAF/COMP/WD(2014)68. Available at:

- The *Hazel Tau* case provides valuable guidance on how cases of excessive pricing are built and argued to competition authorities, and the standard of proof that is needed to have a chance at succeeding in making such claims.
- This case also sets a good example of how competition law can be used to facilitate access to affordable medicines. The settlement agreements contributed to decrease significantly the prices of ARVs in South Africa and enabled the entry of generic manufacturers into the market.
- A threshold issue for competition authorities to consider such cases is the question of dominance in the market. Medicines differ widely in their characteristics, with some easier to build cases showing dominance and others more difficult. In the *Hazel Tau* case, the unique features of ARVs were used to show that one ARV cannot simply be replaced by another, thus helping to establish dominance. Patent status is relevant but not necessarily determinative, as even patented medicines may have a readily available alternative treatment.

Key Words: Competition, abuse of dominance, market definition, excessive pricing, refusal to license, access to medicines, settlement agreement.

Available at:

<http://www.section27.org.za/wp-content/uploads/2010/10/TauvGSKEvidenceAndLegalSubmissions.pdf>