TAC intervention leads to important legal advance: public interest concerns are relevant in determining interim interdict in patent cases

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On 26 July 2012, the Supreme Court of Appeal handed down its judgment in the matter between the Aventis group of pharmaceutical companies and Cipla?s group of generic pharmaceutical companies.

This is the first judgment to decisively say that public interest considerations must be taken into account when balancing the interests of the patentee and the infringer in determining whether or not to grant an interim interdict. The judgment is an important advance in the law that is in line with the values of the Constitution.

The dispute between Aventis and Cipla concerned the patent on Taxotere, a drug that treats various forms of cancer. Aventis holds the patent on the drug and sells Taxotere in both the public and private healthcare systems in South Africa. This patent is due to expire in November 2013, which will enable any generic company to introduce generic versions of the drug in South Africa. Cipla introduced such a generic in 2011, and at the same time challenged the validity of Aventis?s outstanding patent. Aventis opposed Cipla?s move to challenge the patent and launched an application for an interim interdict to prevent Cipla from selling its generic drug. The interim interdict was refused by the Commissioner of Patents Court. Aventis took this ruling on appeal to the Supreme Court of Appeal (SCA).

TAC was admitted by the SCA as an amicus curiae (friend of the court) in order to make submissions regarding the relevance of public interest concerns in disputes like this that ordinarily consider only the interests of the parties before the court. TAC argued that the court should consider the interests of the public broadly in making a determination about the balance of convenience, the test used by the courts in deciding whether to grant an interim interdict. Aventis expresed its view that the public interest is not important, notwithstanding the fact that the patent concerns a life-saving mecicine. Aventis stated that ?the public interest is not a factor to be taken into account when weighing the balance of convenience between the contending parties? (paragraph 55(a) of Aventis?s heads of argument).

It was only after the intervention of the TAC that Aventis conceded that the public interest was of relevance in such disputes. However, counsel for Aventis argued that in this particular case, there were no relevant public interest concerns that the court should take into account.

The SCA stated that TAC had strong arguments in suggesting factors to be taken into account by the court in deciding whether to grant an interim interdict (paragraph 46). TAC?s arguments centred on the Constitution, in particular section 27, which guarantees the right to healthcare services. TAC?s mission includes advancing access to medicines in the public and private health systems. TAC pointed to developments in the United States (US), where public interest concerns now play a significant role in the court?s determination of whether to grant an interdict. For example, the SCA judgment noted the US case that TAC referred to, in which the court took account of the fact that granting an interdict

and preventing the infringing company from selling its product could pose a serious risk to public health. In another case, the infringer?s product had superior medical qualities, which was clearly beneficial to the public.

The SCA held that the public interest factors identified in the US cases can and ought to be taken into account in the court?s decision. However, the court held that on the facts of this particular case, the public interest concerns did not weigh in favour of allowing Cipla to sell its generic cancer drug in violation of Aventis?s patent.

In weighing the public interest concerns raised by the case, the court considered the relative prices of the drugs marketed and sold by Aventis and by Cipla. One fact that played a significant role in this determination was that Aventis brought to the attention of the court the fact that it had introduced its own generic version of the drug as a result of Cipla?s entry into the market. Aventis had obtained authorisation to sell its generic drug in South Africa in 2007, but most likely had no intention of doing this until the patent expired - which is the normal practise. Aventis?s generic version of Taxotere is marketed at a cheaper price than its own patented version and very close in price to Cipla?s generic drug ? the 10% difference in the two prices was held by the court to be marginal. Aventis also had to give an undertaking to the court that it would not withdraw the generic or increase the price once judgment was delivered.

Consequently, the court found that in the particular circumstances of this case, the public interest concerns did not shift the balance significantly.

The court also considered the arguments that Aventis could potentially be compensated for the violation of its patent by an award for damages should the patent be found to be valid. The court took a very conservative view that by allowing the Cipla to market the drug while the dispute regarding the validity of the patent was being resolved - and to award damages to the patentee in the event that the patent is found to be valid - would amount to the granting of a compulsory licence. This is contrary to comparative law in US and India, which was brought to the court?s attention by TAC. It does not take into account that this was an interim interdict, not a final one.

Despite these findings with respect to the particular facts of the case, TAC?s intervention played a significant role in the decision of the court. Without the intervention made by TAC, the court would not have had the benefit of the detailed TAC submissions that led the court to make a significant pronouncement on the relevance of taking account of broader public concerns.

Judge Nugent?s comments relating to TAC?s intervention with regard to TAC?s involvement are thus unfortunate. Judge Nugent stated at paragraph 43 that,

?although purporting to act as an amicus curiae in truth it aligns itself with Cipla?s opposition to the grant of an interdict. Its objection to an interdict were more widely framed?.

It is not unusual that the arguments presented by an amicus curiae, which must be different from the contentions of the parties, are more favourable to one side of the dipsute. This does not diminish the value that an amicus curiae can and does bring to a matter before a court. One only has to look at significant rulings of the Constitutional Court to note the critically important role that the amicus curiae can play in assisting the court to come to a decision based on all the relevant considerations. TAC stands by its intervention as one that was based on the values of the Constitution and access to medicines.

This case sets an important precedent for future cases involving patents on medicines and on other products that impact on constitutional rights and the public interest more broadly. The change in South African law is an extremely important step, but leaves us behind the US courts, which are far more progressive in the way in which similar disputes are adjudicated.

A further challenge in South Africa is that our national legislation for the protection of intellectual property does not enforce the requirements that patented products and procedures are ?new? and ?innovative?. Additionally, it does not utilise important provisions allowed under the Agreement of Trade Related Aspects of Intellectual Property Rights (TRIPS) to protect public health. TAC will continue to campaign for an amendment of our laws to prevent excessive

patenting in South Africa from undermining the right to health.

ENDS

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