

**17 April 2012**

## **Briefing Note for TAC on the issues involved in the case of Aventis Pharma v Cipla**

**The TAC National Council has resolved to seek admission in a legal dispute between the brand name drug company Aventis Pharma and the generic company Cipla, over a claim of patent infringement on a drug that treats cancer called Docetaxel. SECTION27 will act as attorneys for TAC. This briefing note sets out the background to the legal dispute and explains why TAC is arguing that the Supreme Court of Appeal must consider the right of access to health care services when it judges this dispute.**

### **Is cancer a problem in South Africa?**

Cancer is common in South Africa, particularly amongst poor people. This is because poor people are vulnerable to exposure to other illnesses that can lead to cancer, as well as exposure to environmental factors such as pollutants in the air, water and soil.

According to the Medical Research Council, in 2000, 41 691 people died from various forms of cancer. In women the most common cause of death was cervical cancer, but this has now been overtaken by breast cancer. In men the most common cause of death is lung cancer.

However, what is especially concerning is that experts say that cancer is greatly underreported, especially amongst poor and black people. They say that in fact the mortality rate could be twice as high as that reported and that there could be as many as 120 000 new cancer cases per year. Poor people present for and receive treatment for cancer late, if at all. One of the reasons for this is the prohibitive cost of medicines that treat cancer.

### **Is cancer a risk for people with HIV?**

People with HIV have a higher incidence of cancer than people without HIV. This is because of suppressed immune systems. The most common forms of cancer in people living with HIV are Kaposi's Sarcoma, cervical and breast cancer. People with HIV need greater access to cancer medicines and specialists, as well as better understanding and awareness of cancer – treatment literacy.

### **What is the name of the drug in the dispute and what does it do?**

Docetaxel is the active ingredient in a second line drug for cancer. Docetaxel is registered in South Africa and other countries for the treatment of non-AIDS-defining malignancies such as breast, prostate and lung cancers. Docetaxel has also been proven to be – and is indeed recognised as being – safe and effective as a treatment for advanced-stage AIDS-related Kaposi's sarcoma.

The patent on Docetaxel is held by Aventis and was registered in South Africa in 1993, which means that the patent has only one year to run. It expires in November 2013.

In countries such as India, Docetaxel is not patented and is available in various generic forms for cancer sufferers.

### **What is the case before the Supreme Court of Appeal (SCA) about?**

Despite Aventis' patent, Cipla, an Indian generic medicine company, has registered and begun to manufacture and market a generic version of Docetaxel in South Africa. It argues that the patent is ambiguous and therefore invalid and that it has a right to make and distribute the drug.

In response, Aventis sought an interdict from the Commissioner of Patents to stop Cipla from selling the drug in South Africa. However, the Commissioner refused to grant the interdict, ruling that their *"prospects of success at a trial are so slender that interim relief must be refused"* (Judgment, para 26). This finding supports Cipla's arguments about the alleged ambiguity of the patent.

After the ruling, Cipla continued to infringe the patent and began to make the medicine available in South Africa. Over 70 people with cancer in South Africa are already using Docetaxel.

Aventis is now appealing against the Patent Commissioner's decision to the Supreme Court, meaning it is trying once again to stop the use of this medicine in South Africa.

A major problem up to now is that the court has not considered the constitutional right of "everyone to have access to health care services" as a factor in the decision about whether to grant an interdict or not. It has heard only technical arguments, such as whether the patent is valid or not, that are to do with the interests of the drug companies – not patients.

### **Why is the case important for access to medicines in South Africa?**

Generally medicines in South Africa cost too much, particularly patented medicines. Most medicines for cancer are extremely expensive.

- One of the problems we face is that patents are granted without an examination of the substantive validity of the patent.
- Neither do we have a system such as exists in India where individuals and organisations are allowed to register opposition to patents, known as 'pre-grant opposition'.

Generics are cheaper than the patented originals. This drug is 50% of the price of the original drug. In addition once generics enter the market there is more competition which further helps to bring prices down.

### **What does TAC want to argue before the SCA?**

TAC is applying to be a 'Friend of the Court' (amicus curiae) in this case. TAC's Founding Affidavit is being signed by Nokhwezi Hoboyi, a TAC leader living with HIV who has herself had cancer.

TAC is arguing that when the SCA hears this case it should take into consideration arguments about the public interest and the constitutional right to health.

TAC is not leading evidence or making any arguments about how effective the drug is, or about the numbers of people who will benefit from the drug, or the types of cancers it may be useful for. Our intervention aims to establish as a principle something the Court has not considered before, and that is that Constitutional rights must be factored into the adjudication process when deciding patent infringements.

In this case TAC is arguing that it is in the interests of cancer patients that the generic drugs be available, and that the harm to patients will be greater than the harm to Aventis if they are granted the interdict. This is especially so given the fact that the patent only has one year left to run and the fact that there are questions about the patent's validity.

If TAC's argument is accepted by the SCA it will be an important advance for the rights of access to affordable medicines. It will mean that in future in any dispute over patents on life saving drugs, the courts will have to consider the public interest and the constitutional right of access to health care services.

It will be a small but significant step forward for people who need affordable medicines.

**ENDS**