

Shire Biochem vs BIOCARE

Glaxo SmithKline (GSK), the second named plaintiff in this case, objected to the sale of lamivudine by generic drug companies. At first instance the additional district judge granted an ex parte interim injunction preventing the manufacture and sale of lamivudine by the generic companies. The generic companies argued that their manufacturing process for lamivudine was different and submitted details of that process. They also argued that the basic patent had expired and subsequent patents were alleged to be patents of addition, which expired at the same time as the basic patent. They also took the stance that an injunction would operate against the public interest as they had won a tender to supply bulk quantities of lamivudine to the government programme to prevent hepatitis B. According to the documents submitted, the manufacture of the generic products began before the expiry of the base patent.

After a full hearing, the application for an injunction was dismissed.

Appeal in the High Court

GSK appealed to the High Court and Justice Umar Ata Bandial issued interim orders restraining BIOCARE from manufacturing, selling or supplying any lamivudine products.

During the arguments before the High Court, BIOCARE claimed that it should be allowed to supply generic drugs to the government under its tender as the supply deadline was due to expire – if the drugs were not supplied before that date, the tender would expire and a new tender would take place. This would result in public suffering due to an absence of drugs to treat hepatitis B. The High Court held as follows:

- Whether GSK's valid patents were patents of addition could only be decided by a full trial.
- The statutory presumption of infringement of process favoured GSK, at least to the extent of its valid patents
- BIOCARE could supply generic drugs to the government against the tender but, in order to secure GSK's interest, it first had to provide a bank guarantee for the amount of the tender.
- BIOCARE would be restrained from supplying lamivudine to the market for all other purposes.

- BIOCARE'S product was to be sent to reputable laboratories for analysis and to determine whether it was manufactured by the allegedly different process that BIOCARE claimed to use to manufacture its lamivudine product.

APPEAL IN THE SUPREME COURT

GSK was satisfied with the order. However, BIOCARE appealed to the Supreme Court against the order of the High Court requiring it to submit a bank guarantee for over PKR 8 million and against the order that its product be analysed.

After hearing full arguments, the Supreme Court dismissed BIOCARE'S appeal and held that the order of the High Court was just and proper.