

## **Glaxo withdraws patent plea for asthma drug**

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NEW DELHI: Setting a kind of precedent, GlaxoSmithKline (GSK) has withdrawn its patent claim in India on a combination drug, used for treating asthma.

Glaxo has withdrawn its patent application on the combination of fluticasone and salmeterol after generic manufacturer Cipla filed a pre-grant opposition.

This is the second time that Glaxo has withdrawn its patent claim. In March, it was forced to withdraw its patent application on a fixed dose combination of zidovudine and lamivudine, an important AIDS medicine.

India's Patent Act allows room for any interested party to oppose an application that is awaiting a patenting decision, claims.

When contacted, Cipla joint MD Amar Lulla said "Yes, we have won the pre-grant opposition against Glaxo's asthma drug. Two years back, we had challenged the patent on the same drug in UK, and had won there too.

The development shows that public health safeguards as defined under the Indian laws are actually working well, legal experts pointed out.

This is because that most companies do not want a rejection of their patent claims as that would set a legal precedent which can be used by other developing countries in challenging these cases. So they instead decide to withdraw the claim, they added.

It is understood that the opposition by generic companies is based on a specific section of the Indian Patent Act which stipulates that patents should only be granted to medicines that are truly new and innovative, and not for drug combinations, new use, derivatives or form of an existing drug.

This was specifically targeted to prevent "frivolous patenting by drug companies, where manufacturers made minor variations in existing medicines in order to extend their monopolies for as long as possible.

An example of this is omeprazole: Sale of generic omeprazole in Canada was successfully blocked by the evergreening of patents by Astra Zeneca. As the basic patent on the drug was about to expire, the company switched the product from a capsule to a tablet, and acquired a new 20-year patent on the tablet form.

"The application was withdrawn by Glaxo, based on the evidence which was

overwhelming", Dr Gopakumar Nair, IPR consultant who represented Cipla, said.

In case of the asthma drug, both the individual drugs and their combinations are known and are being marketed, so there was hardly any ground for a patent