

Govt may not act on Cipla's patent plea

Health Ministry Feels Waiver May Not Pass Legal Scrutiny

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New Delhi: In a setback to Cipla, the homegrown generics medicine company, the government has so far found little merit in its plea for waiver and cancellation of patent rights for five drugs over which Novartis has exclusive rights.

Sources told **TOI** that the health ministry has suggested that Cipla's proposal for a compulsory licence for the medicines under section 92 of the Patents Act—a rarest of rare provision to be used in case of national emergency or in extreme urgency or for public non-commercial use—may not be "fit" to pass legal scrutiny.

And, with several patent disputes related to Novartis' respiratory drug Onbrez already in court, the government is unlikely to use section 66 of the Patents Act, the other suggestion made by Cipla. In any case, the government has resorted to the use of section 66 only on two occasions—once in 1994 and a second time in 2012—as the provision is meant to be used if a patent is "mischievous to the State or generally prejudicial to the public".

Cipla had approached the department of industrial policy and promotion (DIPP) a few months ago

arguing that the patents should be revoked as Novartis imported small quantities of the medicine, estimated at around 54,000 units, allegedly depriving 1.5 crore patients who need the drug.

The move by the Indian generics firm was the latest demand before the government to use flexibilities available in the Patents Act to issue a compulsory licence, which effectively waives the pat-



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ent rights and allows a local player to manufacture the medicine and share a part of the revenue as royalty to the patent holder.

So far, compulsory licence has been issued only once in 2012, when Natco was allowed to manufacture a cancer drug whose patent was held by Bayer. Sources said in the case of Cipla's request, the health ministry has said if at all there is an argument for a compulsory licence, it should be considered under section 84. But, the government has no powers to use the provision.

Pactant