**Cipla Ltd. and anr. Vs. Cce**

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**SooperKanoon Citation** : sooperkanoon.com/36169

**Court** : Customs Excise and Service Tax Appellate Tribunal CESTAT Mumbai

**Decided On :** Aug-06-2004

**Reported in** : (2004)(117)LC59Tri(Mum.)bai

**Judge** : K Kumar, S T C.

**Appellant** : Cipla Ltd. and anr.

**Respondent** : Cce

**Judgement** :

1. Heard both sides at length. The appellant company, M/s Cipla Limited, developed a new drug named "Deferiprone" for treatment of Thalassemia and after successful clinical trials, the results of which were monitored by the Drugs Controller, obtained a licence to manufacture and market the same subsequently. It is not in dispute that after approval by the Drugs Controller, M/s Cipla regularly manufactured and marketed the drug on payment excise duty on the same.

The impugned order relates to the period during which M/s Cipla manufactured and supplied the drug for clinical trials free of cost.

The question that has been raised in this appeal is whether such manufacture and supply attracts central excise duty. It has been contended on behalf of M/s Cipla that during the impugned period, they had no licence from the Drugs Controller to manufacture and sale the drug and hence it was not marketable. They further contend that all the new drugs have to necessarily undergo successful clinical

trials before even the Drugs Controller can issue a licence to manufacture and sale.

They further cite the following case laws to support their claim that at the stage of clinical trial, the drugs which were manufactured and freely distributed cannot be considered as goods for the purpose of levy of excise duty: 1) Union Carbide India Ltd. v. UOI and Ors. To become 'goods' an article must be something which can ordinarily come to the market to be bought and sold.Bhor Industries Ltd. v. Collector of CE An article not liable to excise merely because of its specification in the Tariff Schedule unless it is "goods" known to the market -Marketability an essential ingredient for dutiability.Collector of CE v. Ambalal Sarabhai Enterprises - The burden is on the department to prove that the goods are either marketed or marketable. - Captive consumption no evidence of marketability.

The appellants also state that the demand of duty is hit by limitation of time as they were under the bona fide impression that manufacture for clinical trial does not attract excise duty and hence the extended period of limitation cannot be invoked. They further state that in the very first budget after they started production, the impugned goods have been exempted totally from excise duty in view of the fact that the same was an essential life saving drug developed indigenously in India for a disease which is not very common in the western word.

2. We have also heard Shri Vimlesh Kumar, learned S.D.R. for the Department who supports the order passed by the lower authority and states that the appellants had not given any information to the department when they manufactured the impugned goods for clinical trial.

3. After hearing both sides, we find substance in the contentions made by the appellants. Under the law of the land, no drug can be manufactured and sold without approval and licence from the Drugs Controller. Issue of such licence is also subject to prior and satisfactory clinical trial of the drug. As such, it is not possible to hold that the drug manufactured and supplied free of cost for clinical trial meets the marketability test, laid down by the Apex Court decisions cited above, to become excisable goods as the same could not have been bought and sold at that stage. Hence, we are of the view that the duty demanded under the

impugned order cannot be sustained.

Accordingly, we set aside the impugned order including the duty demand and consequently, the imposition of penalty also. The appeal is allowed with consequential relief to the appellants.