May and Baker (India) Limited Vs Union of India

Writ Petition No. 2667 of 1982

Court: Bombay High Court

Date of Decision: June 21, 1989

Acts Referred:
Central Excise Rules, 1944 â€" Rule 8

Citation: (1989) 24 ECR 338 : (1989) 43 ELT 411

Hon'ble Judges: S.P. Bharucha, J

Bench: Single Bench

Judgement

1. The petitioners manufacture Flagyl tablets in two strengths, 200 mg. and 400 mg. The composition thereof is as follows :

2. On 3rd May 1979 a notification [Note : This presumably refers to Notification No. 116/69-C.E., dated 3-5-1969. Hence the date here should

read 3rd May 1969.] was issued under Rule 8 of the Central Excise Rules, 1944, whereby the Central Government exempted patent of

proprietary medicines falling under Item No. 14E of the First Schedule to the Central Excises and Salt Act, 1944, and containing one or more of

the ingredients specified in the Schedule thereto from so much of the duty of excise leviable thereon as was in excess of 2 1/2 per cent ad valorem.

Metronidazole was one of the ingredients specified in the Schedule. The notification stated that the exemption thereby conferred would not apply

to any medicine which contained any ingredient that was not specified in the Schedule unless the ingredients in the medicine were pharmaceutical

necessities such as diluents, etc. There was a proviso to this latter provision whose interpretation is relevant for the purposes of the petition. The

proviso read :

Provided that such pharmaceutical necessities are therapeutically inert and do not interfere with the therapeutic or prophylactic activity of the

ingredient or ingredients specified in the Schedule.

3. The petitioners submitted a classification list wherein they claimed the benefit of the exemption given by the said notification. The list was

approved and Flagyl tablets were cleared upon payment of the concessional excise duty provided for under the said notification.

4. On 21st April 1981 and thereafter the petitioners received notices which alleged that they were not entitled to clear Flagyl tablets at the

concessional rate under the said notification because Flagyl tablets contained Calcium Carbonate Light, I.P. Calcium Carbonate was categorised

as an antacid. It could not be said to be therapeutically inert. As such, the exemption under the said notification was not applicable to Flagyl

tablets. The petitioners were required to show cause why the differences in the duty amounts for different periods should not be recovered from

them.

5. The petitioners showed cause. They contended that Flagyl 200 mg. tablets contained 49.5% Metronidazole, 13.86% Calcium Carbonate and

36.63% other excipients and the 400 mg. tablets contained 80% Metronidazole, 4.21% Calcium Carbonate and 15.79% other excipients. It was,

therefore, clear that Metronidazole was the only active ingredient in Flagyl tablets which had therapeutic efficacy. The Calcium Carbonate in the

Flagyl tablets did not overtake the strength and activeness of Metronidazole. Calcium Carbonate therein was a pharmaceutical necessity which

acted as a diluent and was therapeutically inert.

6. It appears that the Collector of Central Excise, Bombay, referred the matter to the Central Board of Excise & Customs, New Delhi. He noted

that Calcium Carbonate had been categorised as an antacid when its dosage ranged between 1 and 4 grams, but in the Flagyl tablets the presence

of Calcium Carbonate was in a much smaller quantity. It was, he said, therefore, doubtful whether the addition of Calcium Carbonate therein was

pharmaceutical necessity or, because of its negligible content, it could be considered as therapeutically inert so that Flagyl tablets conformed to the

requirements of the said notification. On 20th July 1982 the Central Board informed the Collector of Central Excise, Bombay that the issue had

been examined and it had been decided that Flagyl tablets were not eligible for the concessional rate of duty under the said notification and that

steps should therefore, be taken to realise the amount of excise duty. No reasoning was set out.

7. The show cause notices were thereupon adjudicated upon and confirmed. The petition impugns the order, Exh. N to the petition, confirming the

show cause notices.

8. It was contended by Mr. Andhyarjuna, learned Counsel for the petitioners, that Calcium Carbonate found a place in the composition of Flagyl

tablets only as a diluent, that is to say, it was added to the formulation of the tablets to increase their bulk and make them convenient to handle.

Calcium Carbonate was well-known to be a diluent. In that behalf reference was made to Hussa''s book on ""Pharmaceutical Dispensing"", 5th

edition. Calcium Carbonate had antacid properties but only if used in doses ranging from 1 to 5 grams. In this behalf, reference was made to the

British and Indian Pharmacopoeias and Martindale''s Extra Pharmacopoeia. The presence of Calcium Carbonate in Flagyl tablets was as a diluent

or a pharmaceutical necessity. It was therapeutically inert therein and did not interfere with the therapeutic or prophylactic activity of the

Metronidazole which was the only effective ingredient.

9. Mr. Lokur, learned Counsel for the respondents, submitted that the mere presence of Calcium Carbonate in Flagyl tablets, regardless of

whether it was active as an antacid or not, precluded Flagyl tablets from the benefit given by the said notification. He submitted that, in any event,

the Calcium Carbonate in the Flagyl tablets was bound to have some effect as an antacid and, therefore, the tablets would fall outside the scope of

the said notification.

10. Mr. Lokur''s submission would appear to be thus : If a medicine contains as a pharmaceutical necessity, e.g. as a diluent an ingredient which is

capable of therapeutic activity, the medicine falls outside the scope of the said notification regardless of whether or not that ingredient is, having

regard to be formulation of that medicine, therapeutically inert. In other words, the proviso in the said notification, must be interpreted as saying

that the pharmaceutical necessity must be (a) therapeutically inter and (b) it must not interfere with the therapeutic or prophylactic activity of the

ingredient specified in the Schedule to the said notification.

11. It does not appear to be the correct construction of the proviso. If an ingredient is therapeutically inert it cannot ipso facto interfere with the

therapeutic or prophylactic activity of the ingredient specified in the Schedule. The requirement in the proviso that the pharmaceutical necessity

must be ""therapeutically inert and does not interfere with the therapeutic or prophylactic activity of the ingredient or ingredients specified in the

Schedule"" must, therefore, be read as a whole; that is to say, the pharmaceutical necessity must, having regard to the formulation of the medicine,

be therapeutically inert and not interfere with the therapeutic or prophylactic activity of the ingredient or ingredients specified in the Schedule.

12. There is no material to bear out the submission that the Calcium Carbonate is bound to have some antacid effect even in the formulation of

Flagyl tablets. In fact, the material that is on record, namely, the pharmacopoeia referred to, shows that to have an antacid effect, Calcium

Carbonate must be used in the doses ranging between 1 and 5 grams. There is also the certificate of the Commissioner, Food and Drug

Administration, Maharashtra, that the only active ingredient in the Flagyl tablets is Metronidazole.

13. Accordingly, Calcium Carbonate, though it may have antacid properties in the prescribed doses, must be held to be therapeutically inert in the

formulation of Flagyl tablets so that it does not interfere with the therapeutic or prophylactic activity of the Metronidazole therein. Flagyl tablets,

are, therefore, entitled to the benefit of the exemption conferred by the said notification.

14. Having regard to this, it is not necessary to consider Mr. Andhyarjuna"s submission that the authority in passing the order on the show cause

notices acted only upon the instructions of the Central Board and the order is bad on that account.

15. Accordingly, the order, Exh. N to the petition, is quashed and set aside. The bank guarantee furnished by the petitioners pursuant to the interim

order shall stand discharged. No order as to costs.

16. Upon Mr. Lokur"s submission, the bank guarantee shall not stand discharged as aforesaid until after the expiry of 2 weeks from today.