

MEDLEY PHARMACEUTICALS LTD.

v.

THE COMMISSIONER OF CENTRAL EXCISE AND
CUSTOMS, DAMAN

(Civil Appeal No. 3626 of 2005)

JANUARY 14, 2011

[D.K. JAIN AND H.L. DATTU, JJ.]

Central Excise Act, 1944:

Object of the Act – Discussed.

s.3 – “Physician Samples” manufactured and distributed as free samples – Liability to pay excise duty – Held: Liable to excise duty – Excise is a duty on manufacture, duty is payable whether goods are sold or not – Sale is not necessary condition for charging excise duty – The distribution of physician sample serves as a marketing tool in the hands of pharmaceutical company – It is not mandatory for the company to distribute the physician samples of every drug they manufacture – Prohibition on the sale of physician samples intended for distribution to medical practitioner as free samples by rule 65(18) of Drugs Rules shall have no bearing or effect on the levy of excise duty – Constitution of India, 1950 – Seventh Schedule, List I, Entry 84 – Drugs and Cosmetics Act, 1940 – Drugs and Cosmetics Rules, 1945 – r.96(1)(ix) – Central Excise Valuation Rules, 1975

Central Excise Valuation Rules, 1975:

s.6(b)(ii) – Valuation of Physician's samples – Held: To be valued on pro-rata basis – Central Excise Act, 1944.

Drugs and Cosmetics Act, 1940:

Object of the Act – Discussed.

- A *Prohibition on the sale of physician samples intended for distribution to medical practitioner as free samples by rule 65(18) of Drugs Rules – Effect on the levy of excise duty – Held: Shall have no bearing or effect on the levy of excise duty since excise is duty on manufacture and duty is payable*
- B *whether or not goods are sold – The Central Excise Act and the Drugs Act and the Rules made thereunder, operate in entirely two different fields having different objects, purposes and schemes – The conditions or restrictions contemplated by one statute should not be lightly and mechanically*
- C *imported and applied to fiscal statute for non levy of excise duty, thereby causing a loss of revenue – Interpretation of statutes.*

Drugs and Cosmetics Rules, 1945:

- D *Rule 96(1)(ix) – Labeling – Label “Physician Samples-Not to be sold” – Process of labeling is distinct or different from the overprinting on the label of a physician’s sample – Manufacture for the purpose of the Central Excise Tariff Act cannot be said to be incomplete until ‘Physicians Sample-Not to be Sold’ is printed on the label – Drugs and Cosmetics Act, 1940.*
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Precedent:

- F *Doctrine of merger – Held: In case, the appeal is dismissed without reasons, such order entail application of the doctrine of merger, wherein the superior court upholds the decision of the lower court from which the appeal has arisen – Doctrines.*

- G **The questions which arose for consideration in the instant appeals were whether “Physician Samples” manufactured and distributed as free samples are liable to excise duty in view of the fact that they are statutorily prohibited from being sold under the Drugs and Cosmetics Act, 1940 and the Rules made thereunder and**
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if physician's samples are held to be excisable, then what is the appropriate method of valuing physician samples for the purpose of excise duty. A

Disposing of the appeals and remitting the matter to adjudicating authority, the Court

HELD: 1. A duty of excise is a tax upon the goods and not upon sales or proceeds of sale of goods. In terms of Entry 84, List I of Seventh Schedule to the Constitution, taxable event in respect of excise is manufacture or production. Since excise is a duty on manufacture, duty is payable whether the goods are sold or not. Therefore, sale is not necessary condition for charging excise duty. Marketability is an essential criteria for charging duty. The test of marketability is that the product which is made liable to duty must be marketable in the condition in which it emerges. The word 'marketable' means saleable or suitable for sale. It need not in fact be marketed. The article should be capable of being sold to consumers, as it is without anything more. The essence of marketability of goods is neither in the form nor in the shape or condition in which the manufactured article is found. It is the commercial identity of the article known to the market for being bought and sold. The fact that the product in question is generally not being bought or sold or has no demand in the market, would be irrelevant. [Paras 7, 8] [753-A-C; 754-C-E] B
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Shinde Brothers v. Deputy Commissioner AIR 1967 SC 1512; *CCE v. Acer India Ltd.* 2004 AIR SCW 5496; *Indian Cable Co. Ltd. v. GCE* 1994(74) ELT 22(SC) – relied on.

Ram Krishna Ramanath Agarwal v. Secretary, Municipal Commissioner, Kamptee 1950 SCR 15; *Province of Madras v. Boddu Paidanna and Sons* (1942) FCR 90 – referred to. G

2.1. The main object or real purpose of the Drugs and Cosmetics Act, 1940 and Rules made thereunder, is to H

A regulate the manufacture of drugs in order to maintain the
standard or quality of drugs for sale and distribution as
a drug. Therefore, any requirement or condition imposed
by the Drugs Act and Rules made thereunder, is in
furtherance of its object of regulating and maintaining the
B quality of Drugs. The primary object of the Central Excise
Act, 1944 is to raise revenue by imposing duty on goods
that are manufactured. The scope of the Excise Act
extends to the event of manufacture of goods, for the levy
of excise duty. These two Statutes and the Rules made
C thereunder, operate in entirely two different fields having
different objects, purposes and schemes. The conditions
or restrictions contemplated by one statute should not be
lightly and mechanically imported and applied to fiscal
statue for non levy of excise duty, thereby causing a loss
D of revenue. Therefore, the prohibition on the sale of
Physician Samples intended for distribution to medical
practitioners as free samples by Rule 65 (18) of the Drugs
Rules shall have no bearing or effect upon the levy of
excise duty under the Act, since excise is a duty on
E manufacture, duty is payable whether or not goods are
sold. Excise duty is payable even in case of free supply,
since sale is not a necessary condition for charging duty
under the Act. The Revenue is only concerned with the
manufacture of the goods and the possibility of
marketability of the goods. When the product is
F manufactured by a Pharmaceutical Company, it is for the
purpose of sale i.e., every such product including
Physician Sample is capable of being sold in the open
market, but the pharmaceutical company makes the
choice to distribute the same as a free sample. In other
G words, it is not mandatory for the pharmaceutical
company to distribute free physician samples of every
drug they manufacture. This choice made by the
pharmaceutical companies in terms of Rule 96 (1) (ix) of
the Drugs Rules by overprinting words '*Physician's*
H *sample-Not to be sold*' on the label of the drugs will not

come in the way of the Revenue from levying excise duty on the drugs so manufactured. [Paras 23-27] [760-E-F; 761-A-D-G-H; 762-A-C]

Union of India v. Delhi Cloth and General Mills AIR 1968 SC 922; *Union Carbide India Ltd. v. Union of India* (1986) 2 SCC 547; *Bhor Industries Ltd. v. Collector of Central Excise, Bombay* (1989) 1 SCC 602; *Hindustan Polymers v. CCE* (1989) 4 SCC 323; *A.P. State Electricity Board v. CCE, Hyderabad*, (1994) 2 SCC 428; *Indian Cable Company Ltd., Calcutta v. Collector of Central Excise and Others* (1994) 6 SCC 610; *Triveni Engineering & Industries Ltd. v. CCE*, (2000) 7 SCC 29; *Union of India v. Sonic Electrochem (P) Ltd.*, (2002) 7 SCC 435; *ITC Ltd. v. Collector of Central Excise, Patna*, (2003) 1 SCC 678; *Cadila Laboratories (P) Ltd v. CCE, Vadodara*, (2003) 4 SCC 12; *Hindustan Zinc Ltd. v. CCE*, (2005) 2 SCC 662; *Dharampal Satyapal v. CCE*, (2005) 4 SCC 337; *Gujarat Narmada Valley Fertilizer Co. Ltd. v. Collector of Excise and Customs* (2005) 7 SCC 94; *Moriroku UT India (P) Ltd. v. State of Uttar Pradesh and Ors.* (2008) 4 SCC 548; *State of Bihar v. Shree Baidyanath Ayurved Bhawan (P) Ltd.* (2005) 2 SCC 762; *Kedia Agglomerated Marbles Ltd. v. CCE*, (2003) 2 SCC 494; *CCE v. Shree Baidyanath Ayurved Bhawan Ltd.*, (2009) 12 SCC 419 – relied on.

2.2. Although it is correct to say that the manufacture of patent and proprietary drugs is complete only after the labelling is completed, for the purpose of levy of excise duty, however, a perusal of the labelling provisions in the Drug Rules shows that they deal with the name of drug, contents of the drug, name and address of manufacturer, a distinctive batch number (details of manufacture of drug is recorded and available for inspection as a particular batch), preparation of drug, date of manufacture and date of expiry of drug, its storage conditions, etc., which are in aid of the object of the Act, viz. promoting the use of good quality drugs, and ensuring that drugs that do not

- A live upto quality do not find their way into the market. Rule 96(1)(ix) of the Drug Rules states that while complying with the labelling provisions under clauses (i) to (viii) of Rule 96 (1), the manufacturer must further *overprint* on the label '*Physician's Sample-Not to be Sold*',
- B in case they are to be distributed free of cost as physicians samples. Further, the bare perusal of Rule 96 shows that its heading bears 'Manner of Labelling' and clause 1 of this Rule contemplates or govern the manner of labelling in a way that the particulars on the label of
- C the container of a drug shall be either printed or written in indelible ink and shall appear in conspicuous manner. This gives ample clarification that the process of labelling is distinct or different from the *overprinting* on the label of a physician's sample, and, therefore, it is incorrect to
- D state that the manufacture for the purpose of the Central Excise Tariff Act is not completed until '*Physicians Sample – Not to be Sold*' is printed on the label. [Para 28] [762-E-H; 763-A-C]

- 2.3. The primary reason of distributing free physician
- E samples by the manufacturer of pharmaceutical drugs appears to be only for the purpose of advertising of the product and thereby enhancing the sale of the product in the open market. It was shown by research that the
- F market of a pharmaceutical company is enhanced substantially by the distribution of free physician samples. In other words, the distribution of such physician samples serves as a marketing tool in the hands of the pharmaceutical companies [Para 29] [763-D-E]

- G *Characteristics of Recipients of Free Prescription Drug Samples: A Nationally Representative Analysis*, 98 Am. J. Pub. Health 284 (2008) – referred to.

- H 3. This Court has consistently held that the medical supplies supplied to the Doctors are liable to excise duty.

A	(1942) FCR 90	referred to	Para 7
	1994(74) ELT 22(SC)	relied on	Para 8
	AIR 1968 SC 922	relied on	Para 9
B	(1986) 2 SCC 547	relied on	Para 10
	(1989) 1 SCC 602	relied on	Para 11
	(1989) 4 SCC 323	relied on	Para 12
	(1994) 2 SCC 428	relied on	Para 13
C	(1994) 6 SCC 610	relied on	Para 14
	(2000) 7 SCC 29	relied on	Para 15
	(2002) 7 SCC 435	relied on	Para 16
D	(2003) 1 SCC 678	relied on	Para 17
	(2003) 4 SCC 12	relied on	Para 18
	(2005) 2 SCC 662	relied on	Para 19
E	(2005) 4 SCC 337	relied on	Para 20
	(2005) 7 SCC 94	relied on	Para 21
	(2008) 4 SCC 548	relied on	Para 22
	(2005) 2 SCC 762	relied on	Para 23
F	(2003) 2 SCC 494	relied on	Para 25
	(2009) 12 SCC 419	relied on	Para 25
	(2003) 9 SCC 199	relied on	Para 30
G	(2003) 9 SCC 185	relied on	Para 31
	(2000) 5 SCC 373	relied on	Para 32
	(2000) 6 SCC 359	relied on	Para 33
H	(1981) 2 SCC 362	relied on	Para 34

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2005 (188) ELT 48	relied on	Para 41	A
1978(2) ELT (J121)	held inapplicable	Para 35	
(2004) 172 ELT 466	held inapplicable	Para 36	
2002 (146) ELT 477	held inapplicable	Para 37	B
(2007) 210 ELT 407	held inapplicable	Para 38	
(2005) 187 ELT 427	held inapplicable	Para 39	

**CIVIL APPELLATE JURISDICTION : Civil Appeal No.3626
of 2005.** **C**

**From the Judgment & Order dated 03.12.2004 of the
Customs, Excise and Service Tax Appellate Tribunal, West
Zonal Bench, Mumbai in Appeal Nos. E/549/03.**

WITH **D**

C.A. No. 1354-1355 of 2010.

**S. Ganesh, Pratap Venugopal, Manoj Sanklecha, Surekha
Raman, Ramdas Gadiyar, Ananjay Singh, Namrata Sood (for
K.J. John & Co.) for the Appellant.** **E**

**R.P. Bhatt, Sunita Rani Singh, Rekha Pandey, B. Krishna
Prasad for the Respondent.**

The Judgment of the Court was delivered by **F**

**H.L. DATTU, J. 1. A group of three appeals is filed by the
appellant – Medley Pharmaceuticals Ltd., under Section 35 L
(b) of the Central Excise Act, 1944 (hereinafter referred to as
'the Act'). In Civil Appeal No.3626 of 2005, the appellant calls
in question the correctness or otherwise of the order passed
by Customs Excise and Service Tax Appellate Tribunal
(CESTAT) (in short, "The Tribunal") in Appeal No. E/549 to E
551/2003-Mum, dated 3.12.2004. By the impugned order, the
Tribunal has confirmed the order passed by Commissioner of** **G**
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A Customs and Central Excise, Valsad dated 30.12.2002. In this appeal, the appellant has raised the following question of law for our consideration and decision:-

B "Whether Physician samples manufactured and distributed as free samples have to be assessed on the basis of cost of manufacture plus normal profits, if any, earned on the sale under Rule 6(b)(ii) of the Central Excise Valuation Rules, 1975 (for short, "Rules 1975") upto 1st July, 2000 and thereafter, on application of Rule 8 of Central Excise Valuation Rules, 2000 (for short, "Rules 2000") i.e. on cost of manufacture plus 15% profit basis and not on pro-rata basis as has been done by the Revenue?"

2. The Commissioner, while passing the order in Original No. 01/MP/Valsad/2002 dated 30.12.2002, has held that the value should be determined under Rule 4 of Rules 1975. In the appeal filed by the appellant, the Tribunal, following the judgment in the case of *Mayo India Ltd. and Cheryl Laboratories (P) Ltd.*, held that the value of Physician samples should be determined in accordance with the principle laid down in Rule 6(b)(i) read with Rule 7 of the Rules 2000. After coming to the aforesaid conclusion, the Tribunal has accepted the method of assessable value adopted by the Commissioner, though it was under Rule 4 of the Rules 1975.

F 3. In Civil Appeal Nos. 1354-1355 of 2010, the appellant is aggrieved by the final order passed by the Tribunal, bearing No.A/490/WZB/AHD/2009 dated 27th February, 2009 and the order No.H/853/WZB/AHD/2009 dated 4th August, 2009 passed on the rectification application in Appeal No. E/384/2005. By the impugned order, the Tribunal dismissed the appellant's appeal and upheld the order passed by the Commissioner of Central Excise (Appeals) dated 24th November, 2004 holding that for the purpose of payment of Excise duty, Physician samples have to be valued for the period post 1st July, 2000 upto December, 2001 on pro-rata basis on the value of trade packs under Rule 4 read with Rule

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11 of the Central Excise Valuation (Determination of Price of Excisable Goods) Rules 2000. The Tribunal, while rejecting the application filed for rectification of the order dated 27th February, 2009, held that merely because a product is statutorily prohibited from being sold, would not mean that the product is not capable of being sold. In this appeal, the appellant has raised the following questions of law for our consideration and decision. They are:-

- (A) Whether "Physician Samples" are excisable goods in view of the fact that they are statutorily prohibited from being sold under the Drugs and Cosmetics Act, 1940 (in short, "Drugs Act") and the Rules made thereunder?
- (B) If physician's samples are held to be excisable, then what is the appropriate method of valuing physician samples for the purpose of excise duty?

4. Shri S. Ganesh, learned senior counsel for the appellant, submitted that the Physician Samples of Patent and proprietary medicines come into existence as a manufactured product only when the same are labeled and packed for the purpose of sale and distribution. Our attention is invited to Note 5 of Chapter 30 of Central Excise Tariff Act, 1985, wherein it is provided that packing and labeling would amount to manufacture. Therefore, it is contended that the Physician Samples of Patent and proprietary Medicines become manufactured goods only when the same are packed and labeled. It is further contended that the physician samples of patent and proprietary medicines, at the time they are manufactured, are statutorily prohibited from being sold by virtue of Section 18 of the Drugs Act read with Rule 65(18) of the Drug Rules and the breach of the Drug Rules invites prosecution under Section 27(d) of the Drugs Act, and also invites penalty under Section 27(c) of the Drugs Act. It is further submitted that the two conditions that require to be satisfied for levy of excise duty are existence of manufacturing process and as a result of such process, goods are produced

A which are capable, in the ordinary course, of being taken to the market for being bought and sold. It is further submitted that the word 'excisable goods' has been construed to mean not only goods specified in the Schedule to the Central Excise Tariff Act, 1985, but also goods which are capable of being sold i.e. marketable. In the present case, the 'Physician Samples' are statutorily prohibited from being sold and therefore, do not satisfy the twin test required to make physician samples excisable goods.

C 5. Shri R. P. Bhatt, learned senior counsel for the Revenue, justifies the reasoning and conclusion reached by the Tribunal.

D 6. In pith and substance, the submission of learned senior counsel Shri Ganesh is that the physician samples of patent and proprietary medicines are statutorily prohibited from being sold by virtue of Rule 65(18) and Rule 95 and Rule 96 (1) (ix) of the Drugs Rules. It is contended that every drug intended for distribution as physicians sample while complying with the labeling provisions under Drugs and Cosmetic Rules further bear on the label of the container the words "*Physician's Sample- Not to be Sold*" requires to be over printed and further, the sale of such Physician samples is expressly prohibited under Rule 65 (18) of the Drug Rules. He contends that patent and proprietary drugs are excisable only after the labeling is complete. Since these physician samples cannot be sold in the market after the completion of the labeling in view of the statutory prohibition, the physician samples are not marketable and hence, no excise duty is leviable on their manufacture.

G 7. The Central Excise Act, apart from others, provides for charging of duty, valuation etc. Section 3 of the Act is the charging provision. It states, there shall be levied and collected in such a manner as may be prescribed duties on excisable goods which are produced or manufactured in India. Basic excise duty and special excise duty are levied under the charging provision at the rates specified in First and Second H Schedule to Central Excise Tariff Act, 1985. The duty is on

excisable goods which are manufactured or produced in India. A
This Court in *Shinde Brothers vs. Deputy Commissioner*, AIR
1967 SC 1512 has held that excise duty is imposed on goods,
and the taxable event for the levy is manufacture or production
of the goods. A duty of excise is a tax upon the goods and not
upon sales or proceeds of sale of goods. In terms of Entry 84, B
List I of Seventh Schedule to the Constitution, taxable event in
respect of excise is manufacture or production (See *CCE vs.
Acer India Ltd.*, 2004 AIR SCW 5496). The levy is on the
manufacture or production of goods. The collection is shifted
to stage of removal. Since excise is a duty on manufacture, duty C
is payable whether or not goods are sold. Therefore, sale is
not necessary condition for charging excise duty. This Court in
the case of *Ram Krishna Ramanath Agarwal Vs. Secretary,
Municipal Commissioner, Kamptee* 1950 SCR 15, has
referred to the distinction made by the Federal Court between D
the duty of excise and a tax on sale in *Province of Madras vs.
Boddu Paidanna and Sons* (1942) FCR 90, wherein it is
observed:

*" Plainly, a tax levied on the first sale must, in the nature
of things, be a tax on the sale by the manufacturer or
producer, but it is levied upon him qua seller and not qua
manufacturer or producer. It may well be that a
manufacturer or producer is sometimes doubly hit... If the
taxpayer who pays sales tax is also a manufacturer or
producer of commodities subject to a central duty of
excise, there may no doubt be overlapping in one sense, F
but there is no overlapping in law. The two taxes which
he is called on to pay are economically two separate and
distinct imposts. There is, in theory, nothing to prevent
the Central Legislature from imposing a duty of excise
on a commodity as soon as it comes into existence no
matter what happens to it afterwards, whether it be sold
consumed, destroyed, or given away... It is the fact of
manufacture which attracts the duty even though it may*

A *be collected later. In the case of a sales tax, the liability to tax arises on the occasion of a sale and a sale has no necessary connection with manufacture or production.” ...” [emphasis supplied]*

B 8. The consistent view of this Court is that for the purpose of levy of excise duty, an article must satisfy two requirements to be ‘Goods’ i.e. (a) it must be movable and (b) it must be marketable. In these appeals, we are primarily concerned whether the ‘Goods’ namely Physician samples of patent and proprietary medicines intended for distribution to the medical practitioner as free samples, satisfies the test of ‘Marketability’.

C Marketability is an essential criteria for charging duty. The test of marketability is that the product which is made liable to duty must be marketable in the condition in which it emerges. The word ‘Marketable’ means saleable or suitable for sale. It need not in fact be marketed. The article should be capable of being sold to consumers, as it is without anything more. The essence of marketability of goods is neither in the form nor in the shape or condition in which the manufactured article is found. It is the commercial identity of the article known to the market for being bought and sold. The fact that the product in question is generally not being bought or sold or has no demand in the market, would be irrelevant. [See *Indian Cable Co. Ltd. vs. CCE, 1994(74) ELT 22(SC)*]. We will now refer to some of the decisions of this Court, which have explained the concept of

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F ‘Marketability’ for the purpose of the Act.

9. The Constitution Bench of this Court, in the case of *Union of India vs. Delhi Cloth and General Mills*, AIR 1968 SC 922, after referring to definition of ‘excisable goods’, stated:

G *“These definitions makes it clear that to become goods an article must be something which can ordinarily come to the market to be bought or sold”.*

H 10. A three Judge Bench of this Court in the case of *Union Carbide India Ltd. v. Union of India*, (1986) 2 SCC 547 has

discussed the concept of 'marketability' in order for the Revenue to impose excise duty as under: A

"6. It does seem to us that in order to attract excise duty the article manufactured must be capable of sale to a consumer. Entry 84 of List I of Schedule VII to the Constitution specifically speaks of "duties of excise on tobacco and other goods manufactured or produced in India....", and it is now well accepted that excise duty is an indirect tax, in which the burden of the imposition is passed on to the ultimate consumer. In that context, the expression "goods manufactured or produced" must refer to articles which are capable of being sold to a consumer. In Union of India v. Delhi Cloth & General Mills, AIR 1963 SC 791, this Court considered the meaning of the expression "goods" for the purposes of the Central Excises and Salt Act, 1944 and observed that "to become 'goods' an article must be something which can ordinarily come to the market to be brought and sold", a definition which was reiterated by this Court in South Bihar Sugar Mills Ltd. v. Union of India, AIR 1968 SC 922". B
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11. In *Bhor Industries Ltd. vs. Collector of Central Excise, Bombay*, (1989) 1 SCC 602, it was held: E

"Excise is a duty on goods as specified in the Schedule. The taxable event in the case of excise duties is the manufacture of goods. Under the Central Excise Act, as it stood at the relevant time, in order to be goods as specified in the entry, it was essential that as a result manufacture goods must come into existence. For articles to be goods these must be known in the market as such or these must be capable of being sold in the market as goods. Actual sale in the market is not necessary, user in the captive consumption is not determinative but the articles must be capable of being sold in the market or known in the market as goods. It is, therefore, necessary to find out whether there are goods, that is to say, articles F
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A as known in the market as separate distinct identifiable
commodities and whether the tariff duty levied would be
as specified in the Schedule. Simply because a certain
B article falls within the Schedule it would not be dutiable
under excise law if the said article is not 'goods' known
to the market. Marketability, therefore, is an essential
ingredient in order to be dutiable under the Schedule to
Central Excise Tariff Act, 1985."

C 12. In *Hindustan Polymers v. CCE* (1989) 4 SCC 323,
this Court observed:

D "11. *Excise duty is a duty on the act of manufacture. Manufacture under the excise law, is the process or activity which brings into being articles which are known in the market as goods and to be goods these must be different, identifiable and distinct articles known to the market as such. It is then and then only that manufacture takes place attracting duty. In order to be goods, it was essential that as a result of the activity, goods must come into existence. For articles to be goods, these must be known in the market as such and these must be capable of being sold or are being sold in the market as such. In order, therefore, to be manufacture, there must be activity which brings transformation to the article in such a manner that different and distinct article comes into being which is known as such in the market.*"

F 13. In *A.P. State Electricity Board vs. CCE, Hyderabad*, (1994) 2 SCC 428, this Court stated:

G "Marketability is an essential ingredient in order to be
dutiable under the Schedule to the Act.....The
'marketability' is thus essentially a question of fact to be
decided in the facts of each case. There can be no
generalization. The fact that the goods are not in fact
marketed is of no relevance. So long as the goods were
H marketable, they are goods for the purposes of Section

3. It is not also necessary that the goods in question should be generally available in the market. Even if the goods are available from only one source or from a specified market, it makes no difference so long as they are available for purchasers..... The marketability of articles does not depend upon the number of purchasers nor is the market confined to the territorial limits of this country.”

14. In *Indian Cable Company Ltd., Calcutta vs. Collector of Central Excise and Others*, (1994) 6 SCC 610, this Court has stated:

“Marketability is a decisive test for dutiability. It only means ‘saleable’ or “suitable for sale”. It need not be in fact ‘marketed’. The article should be capable of being sold or being sold, to consumers in the market, as it is — without anything more.”

15. In *Triveni Engineering & Industries Ltd. v. CCE*, (2000) 7 SCC 29, this Court, while demonstrating the attributes of excisable goods under the excise law, has observed that:

“13. ... The article in question should be capable of being brought and sold in the market — a test which is too well established by a series of decisions of this Court to be elaborated here.”

16. In *Union of India v. Sonic Electrochem (P) Ltd.*, (2002) 7 SCC 435, this court has held:

“9. ... It is difficult to lay down a precise test to determine marketability of articles. Marketability of goods has certain attributes. The essence of marketability is neither in the form nor in the shape or condition in which the manufactured articles are to be found, it is the commercial identity of the articles known to the market for being bought and sold. The fact that the product in question is generally not being bought and sold or has no demand in the market would be irrelevant.”

A 17. In the case of *ITC Ltd. v. Collector of Central Excise, Patna*, (2003) 1 SCC 678, this Court while applying the test of marketability for the purpose of levy of excise duty on the manufacture of the cigarette, has observed:

B "17. From a conspectus of the aforesaid decisions, it
C would be clear that for the purposes of levy of excise duty,
D the test to be applied is whether the goods manufactured
E are marketable or not. In the present case, the cigarette,
F which is the end product of tobacco, is fit for consumption
G before the same is removed for test. Packing of the
H cigarettes cannot be said to be incidental or ancillary to
the manufacturing process, but the same may be incidental
or ancillary to its sale only. In case it is laid down that
packing of cigarettes is incidental or ancillary to the
completion of manufactured products, the same may result
in evasion of excise duty as before packing the cigarettes
the same may be regularly supplied to each and every
employee for his consumption without payment of excise
duty thereon. The definition of "manufacture" under Section
2(f) very clearly includes process which is incidental or
ancillary to the completion of manufactured product.
Manufacture of cigarette is completed when the same
emerges in the form of sticks of cigarettes which are sent
to the laboratory for quality control test. Sticks of cigarettes
can be consumed and manufacture of the end product i.e.
cigarette, which is commercially known in the market as
such, is completed before its removal for test and after
testing only packing of the same, which is the requirement
of Rule 93 of the Rules, is done. Thus, we hold that sticks
of cigarettes which are removed for the purpose of test in
the quality control laboratory located within the factory
premises of the appellant Company are liable to excise
duty."

H 18. In the case of *Cadila Laboratories (P) Ltd v. CCE, Vadodara*, (2003) 4 SCC 12, this Court has held:

"9. Thus the law is that in order to be excisable, not only goods must be manufactured i.e. some new product brought into existence, but the goods must be marketable. By marketable it does not mean that the goods must be actually bought and sold in the market. But the goods must be capable of being bought or sold in the market. The law also is that goods which are in the crude or unstable form and which require a further processing before they can be marketed, cannot be considered to be marketable goods merely because they fall within the Schedule to the Excise Act".

19. In *Hindustan Zinc Ltd. v. CCE*, (2005) 2 SCC 662, this Court observed:

"5. Excise duty is levied under Section 3 on goods manufactured or produced in India. Thus, before excise duty is levied on an item, even if it is mentioned in the tariff, two conditions have to be cumulatively satisfied, namely, that the process by which an item is obtained is a process of manufacture and that the item so obtained is commercially marketable and bought and sold in the market or known to be so in the market."

20. In *Dharampal Satyapal v. CCE*, (2005) 4 SCC 337, it was held by this Court:

"18. ... Marketability is an attribute of manufacture. It is an essential criteria for charging duty. Identity of the product and marketability are the twin aspects to decide chargeability. Dutiability of the product depends on whether the product is known to the market. The test of marketability is that the product which is made liable to duty must be marketable in the condition in which it emerges. Marketable means saleable. The test of classification is, how are the goods known in the market. These tests have been laid down by this Court in a number of judgments including *Moti Laminates (P) Ltd. v. CCE* (1995) 3 SCC

A 23, *Union of India v. Delhi Cloth & General Mills Co. Ltd.* (1997) 5 SCC 767 and *Cadila Laboratories (P) Ltd. v. CCE-(2003) 4 SCC 12*”

B 21. In *Gujarat Narmada Valley Fertilizer Co. Ltd. vs. Collector of Excise and Customs*, (2005) 7 SCC 94, it was held that unless the product is capable of being marketed and is known to those who are in the market, as having an identity as a distinct and identifiable commodity, that the article is subject to excise duty. Simply because certain articles fall within the Schedule does not make them marketable. Actual sale in market is not necessary, but the articles must be capable of being sold in the market or known in the market as goods.

C 22. In *Moriroku UT India (P) Ltd. vs. State of Uttar Pradesh and Ors.*, (2008) 4 SCC 548, it was observed that D excise duty is a levy on a taxable event of ‘manufacture’. Liability under excise law is event based on manufacture and irrespective of whether the goods are sold or captively consumed. Excise duty is not concerned with ownership or sale.

E 23. Having said so in so far as exciseability of Goods for the purpose of duty under the Act, we may notice the purpose and object of Drugs Act. In our opinion, the main object or real purpose of the Drugs Act, 1940 and Rules made thereunder, is to regulate the manufacture of drugs in order to maintain the standard or quality of drugs for sale and distribution as a drug. F This Court in *State of Bihar v. Shree Baidyanath Ayurved Bhawan (P) Ltd.*, (2005) 2 SCC 762, has held:

G “14. ... The object of the Drugs Act is to maintain the quality of drugs as drugs. Its use as any other commodity in the hands of the consumer is not regulated. Hence, the Drugs Act is relatable to Entry 19 of List III, which deals with drugs and poisons, subject to Entry 59 of List I regarding opium. Lastly, the said Act regulates the manufacture of drug for sale and distribution as a drug.”

H

24. Therefore, any requirement or condition imposed by the Drugs Act and Rules made thereunder, is in furtherance of its above stated object of regulating and maintaining the quality of Drugs.

25. The primary object of the Act is to raise revenue by imposing duty on goods that are manufactured as mentioned above (see *Kedia Agglomerated Marbles Ltd. v. CCE*, (2003) 2 SCC 494). In other words, the scope of the Act extends to the event of manufacture of goods, for the levy of excise duty. These two Statutes and the Rules made thereunder, operate in entirely two different fields having different objects, purposes and schemes. The conditions or restrictions contemplated by one statute should not be lightly and mechanically imported and applied to fiscal statute for non levy of excise duty, thereby causing a loss of revenue. This Court in *CCE v. Shree Baidyanath Ayurved Bhavan Ltd.*, (2009) 12 SCC 419 has held:

“55. True it is that Section 3(a) of the Drugs and Cosmetics Act, 1940 defines “Ayurvedic, siddha or unani drug” but that definition is not necessary to be imported in the new Tariff Act. The definition of one statute having different object, purpose and scheme cannot be applied mechanically to another statute. As stated above, the object of the Excise Act is to raise revenue for which various products are differently classified in the new Tariff Act.”

26. Therefore, the prohibition on the sale of Physician Samples intended for distribution to medical practitioners as free samples by Rule 65 (18) of the Drugs Rules shall have no bearing or effect upon the levy of excise duty under the Act, since excise is a duty on manufacture, duty is payable whether or not goods are sold. Excise duty is payable even in case of free supply, since sale is not a necessary condition for charging duty under the Act.

A 27. Even assuming that Shri. Ganesh is correct, when he
contends that physician samples are not allowed to be sold in
the open market in view of the statutory prohibition on their sale,
and hence are not marketable; the Revenue is only concerned
with the manufacture of the goods and the possibility of
marketability of the goods. When the product is manufactured
by a Pharmaceutical Company, it is for the purpose of sale i.e.,
every such product including Physician Sample is capable of
being sold in the open market, but the pharmaceutical company
makes the choice to distribute the same as a free sample. In
other words, it is not mandatory for the pharmaceutical
company to distribute free physician samples of every drug they
manufacture. This choice made by the pharmaceutical
companies in terms of Rule 96 (1) (ix) of the Drugs Rules by
overprinting words '*Physician's sample-Not to be sold*' on the
label of the drugs will not come in the way of the Revenue from
levying excise duty on the drugs so manufactured.

28. We agree with Shri Ganesh, learned senior counsel
for the appellant, that the manufacture of patent and proprietary
drugs is completed only after the labelling is completed, for the
purpose of levy of excise duty. However, on a perusal of the
labelling provisions in the Drug Rules, we find that they deal
with the name of drug, contents of the drug, name and address
of manufacturer, a distinctive batch number (details of
manufacture of drug is recorded and available for inspection
as a particular batch), preparation of drug, date of manufacture
and date of expiry of drug, its storage conditions, etc., which
are in aid of the object of the Act, viz. promoting the use of good
quality drugs, and ensuring that drugs that do not live upto
quality do not find their way into the market. Rule 96 (1) (ix)
of the Drug Rules on which Shri Ganesh heavily relies in support
of his submission, states that while complying with the labelling
provisions under clauses (i) to (viii) of Rule 96 (1), the
manufacturer must further *overprint* on the label '*Physician's
Sample – Not to be Sold*', in case they are to be distributed
free of cost as physicians samples. Further, the bare perusal

of Rule 96 shows that its heading bears 'Manner of Labelling' and clause 1 of this Rule contemplates or govern the manner of labelling in a way that the particulars on the label of the container of a drug shall be either printed or written in indelible ink and shall appear in conspicuous manner. This gives ample clarification that the process of labelling is distinct or different from the *overprinting* on the label of a physician's sample, and hence we are unable to agree with him that the manufacture for the purpose of the Central Excise Tariff Act is not completed until '*Physicians Sample – Not to be Sold*' is printed on the label.

29. The primary reason of distributing free physician samples by the manufacturer of pharmaceutical drugs to us appears to be only for the purpose of advertising of the product and thereby enhancing the sale of the product in the open market. It has been shown by research that the market of a pharmaceutical company is enhanced substantially by the distribution of free physician samples. In other words, the distribution of such physician samples serves as a marketing tool in the hands of the pharmaceutical companies [See Sarah L. Cutrona et al., *Characteristics of Recipients of Free Prescription Drug Samples: A Nationally Representative Analysis*, 98 Am. J. Pub. Health 284 (2008)].

30. Before we conclude, in our view, the issue raised in these appeals is no more res-integra. This issue came up for consideration before this Court in the case of *Ranbaxy Laboratories Ltd. Vs. Commissioner of Central Excise, Pune*, (2003) 9 SCC 199, wherein it was held:

"1. In these appeals, the question is whether free medical samples supplied to the doctors are liable to excise duty. In our view, this question is answered by a decision of this Court rendered today in Civil Appeal No. 3643-44 of 1999.

2. However, in these matters one further question arises i.e. how are the samples to be valued. The question arises

A as to whether the price of physician samples are to be
worked out on pro-rata basis for the samples as per
Section 4(1)(b) of the Central Excise Act read with Rules
7 and 6(b) of the Central Excise (Valuation) Rules, 1975
or on some other basis. The Tribunal has not decided this
B question even after holding that the goods were excisable.
We, therefore, remit these matters back to the Tribunal for
a decision on this point. The appeals stand disposed of
accordingly. No order as to costs."

C 31. This Court, while passing the aforementioned order,
has relied on the judgment and order passed in the case of
*Bharat Heavy Electricals Ltd. v. Commissioner of Customs
& Central Excise*, (2003) 9 SCC 185 [referred to as Civil
Appeal No. 3643-44 of 1999], in which this Court held:

D "4. It is next submitted that the value of an assessable
goods can be zero. It is submitted that when a part is
replaced under a warranty to the assessee the value is
zero. It is submitted that as the value is zero, no excise duty
should be payable on that part. We are unable to accept
E this submission also. In order to promote sales
manufacturers and dealers very often offer incentives e.g.
supply of free TV or some other equipment or goods. One
of the incentives offered, is a warranty to replace a part
within a particular period. *Merely because manufacturers
and dealers choose to offer such incentives does not
F mean that goods which are otherwise excisable, should
be exempted from paying excise duty. When offering the
incentive, the manufacturer or dealer is choosing to take
upon himself the cost of those goods. So far as the
Revenue is concerned, those goods remain excisable."*

G 32. This Court has consistently held that the medical
supplies supplied to the Doctors are liable to excise duty.
Elaborate consideration may not be forthcoming in these
judgments, but, in our view, the issue stands concluded. We say
H so for the reason that this Court, in catena of cases, has opined

that in case, the appeal has been dismissed in the absence of detailed reasons or without reasons, such order will entail the application of the doctrine of merger, wherein the superior court upholds the decision of the lower court from which the appeal has arisen. In the case of *V.M. Salgaocar & Bros.(P) Ltd. Vs. C.I.T.*, (2000) 5 SCC 373, this Court held:

"8. Different considerations apply when a special leave petition under Article 136 of the Constitution is simply dismissed by saying "dismissed" and an appeal provided under Article 133 is dismissed also with the words "the appeal is dismissed". In the former case it has been laid by this Court that when a special leave petition is dismissed this Court does not comment on the correctness or otherwise of the order from which leave to appeal is sought. But what the Court means is that it does not consider it to be a fit case for exercise of its jurisdiction under Article 136 of the Constitution. That certainly could not be so when an appeal is dismissed though by a non-speaking order. Here the doctrine of merger applies. In that case, the Supreme Court upholds the decision of the High Court or of the Tribunal from which the appeal is provided under clause (3) of Article 133. This doctrine of merger does not apply in the case of dismissal of a special leave petition under Article 136."

33. In the case of *Kunhayammed v. State of Kerala*, (2000) 6 SCC 359, it was held:

"41. Once a special leave petition has been granted, the doors for the exercise of appellate jurisdiction of this Court have been let open. The order impugned before the Supreme Court becomes an order appealed against. Any order passed thereafter would be an appellate order and would attract the applicability of doctrine of merger. It would not make a difference whether the order is one of reversal or of modification or of dismissal affirming the order appealed against. It would also not make any difference if

A the order is a speaking or non-speaking one. Whenever
this Court has felt inclined to apply its mind to the merits
of the order put in issue before it though it may be inclined
to affirm the same, it is customary with this Court to grant
leave to appeal and thereafter dismiss the appeal itself
B (and not merely the petition for special leave) though at
times the orders granting leave to appeal and dismissing
the appeal are contained in the same order and at times
the orders are quite brief. Nevertheless, the order shows
the exercise of appellate jurisdiction and therein the merits
C of the order impugned having been subjected to judicial
scrutiny of this Court.

42. "To merge" means to sink or disappear in something
else; to become absorbed or extinguished; to be
combined or be swallowed up. Merger in law is defined
D as the absorption of a thing of lesser importance by a
greater, whereby the lesser ceases to exist, but the greater
is not increased; an absorption or swallowing up so as to
involve a loss of identity and individuality. (See *Corpus
Juris Secundum*, Vol. LVII, pp. 1067-68.)"

E 34. It is settled law that this Court should follow an earlier
decision that has withstood the changes in time, irrespective
of the rationale of the view taken. It was held by a Constitution
Bench in the case of *Waman Rao v. Union of India*, (1981) 2
F SCC 362:

"40. It is also true to say that for the application of the rule
of stare decisis, it is not necessary that the earlier decision
or decisions of longstanding should have considered and
either accepted or rejected the particular argument which
is advanced in the case on hand. Were it so, the previous
G decisions could more easily be treated as binding by
applying the law of precedent and it will be unnecessary
to take resort to the principle of stare decisis. It is,
therefore, sufficient for invoking the rule of stare decisis that
H a certain decision was arrived at on a question which arose

or was argued, no matter on what reason the decision rests or what is the basis of the decision. In other words, for the purpose of applying the rule of stare decisis, it is unnecessary to enquire or determine as to what was the rationale of the earlier decision which is said to operate as stare decisis. ...”

35. Now we may notice the decisions on which reliance placed by learned senior counsel Shri Ganesh. In *Delhi Cloth and General Mills Vs. Joint Secretary*, 1978(2) ELT (J121) (Delhi High Court), the question before the court was whether calcium carbide, which does not comply with regard to purity and packaging with statutory rules answers the test of 'Marketability'. The Court on facts has found that the calcium carbide manufactured by the company was for further utilization in the production of acetylene gas was not of purity that rendered it marketable nor was it packed in such a way as to make it marketable that is to say, in air tight containers. The Court has further noticed that the commodity in question would require further processing to make it marketable and therefore, the commodity in question is not marketable and hence, not excisable.

36. Reliance is placed on the decision of CESTAT in *Amar Lal Vs. CCE*, (2004) 172 ELT 466. That was a case where assessee manufactured a new drug for trial which were supplied for clinical trials. In view of the Drugs Control Act and the Rules framed thereunder, any drug could be marketed only after successful clinical trials and after approval and licence from Drugs Controller. Hence, the Tribunal held that the drug supplied free for clinical trials is not excisable Goods as it cannot be bought and sold at that stage.

37. In *Pfizer vs. Commissioner of Central Excise 2002* (146) ELT 477, the question before the Tribunal was, whether excise duty is leviable on 'Sugar syrup' manufactured by the assessee for use in the manufacture by it for cough syrup. The Tribunal, while answering the issue, has stated that since the

A sale of Sugar Syrup containing artificial sweetener sodium saccharin would contravene the provisions of Prevention of Food Adulteration Rules, the Goods cannot be considered as marketable.

B 38. In *Hindustan Petroleum Corporation Ltd. vs. CCE*,
(2007) 210 ELT 407 (CESTAT), it was a case where assessee
C manufactured 'diesel stem' by refining the sour crude for
D captive-consumption and sale in the market. The sale of 'diesel
stem' containing high sulphur content was prohibited by Ministry
of Petroleum and Natural Gas in the light of the notification
issued by Ministry of Environment and Forest for preventing
environmental pollution caused by emission due to burning of
sulphur along with fuel. In the light of the notification issued by
Ministry of Environment & Forest, the 'diesel stem' in its high
content of sulphur is incapacitated from being sold in the
market. In other words, this inherent incapability in the
ingredients of the Goods, from being sold in the market makes
it non-marketable and hence not excisable.

E 39. In *Himalaya Drug Company vs. C.C.E.*, (2005) 187
ELT 427, the question before the Tribunal was, whether the
excise duty is leviable on 'vegetable extracts' manufactured by
the assessee for use in the manufacture of Ayurvedic, Unani
or Siddha Medicines. The Tribunal, while answering the issue,
concluded that such vegetable extracts, unless subjected to
F preservative process, are not liable to be considered as Goods
attracting excise duty and such Goods should be considered
as only intermediary Goods. Further, in view of the fact that the
licence issued by the Drug Controller prohibits assessee from
selling such semi finished products. Therefore, the Tribunal
G concluded that such intermediary or semi finished Goods
manufactured by assessee cannot be compared with the
products manufactured by others for sale, for the purpose of
'marketability'.

H 40. In our considered view, the reliance placed by the
learned senior counsel for the appellant on some of the

decisions of the Tribunal would not assist him in support of his submission for the reason that the goods therein were not marketable and hence, excise duty was not leviable, not because of any statutory prohibition for the sale of the goods, but because they had not reached the stage of satisfying the test of marketability of the goods.

B

41. Now coming to the valuation of the physician samples for the purpose of levy of excise duty, in our view, this issue need not detain us long in view of the decision of this Court in the case of Commissioner of Central Excise vs. M/s. Bal Pharma [Civil Appeal No. 1697 of 2006]. This Court has upheld the conclusion of the Tribunal that the physician's samples have to be valued on pro-rata basis. The Tribunal, while arriving at the aforesaid conclusion, had relied upon its earlier decision in the case of *Commissioner of Central Excise, Calicut vs. Trinity Pharmaceuticals Pvt. Ltd.*, reported as 2005 (188) ELT 48, which has been accepted by the department. Therefore, we hold that physician samples have to be valued on pro-rata basis for the relevant period.

C

D

42. In view of the above discussion, we pass the following order:-

E

- (a) Civil Appeal No. 3626 of 2005 is allowed and the matter is remitted to the Adjudicating Authority with a direction to value the goods in question on pro-rata basis for the relevant period.
- (b) We dismiss Civil Appeal Nos. 1354-1355 of 2010. Parties to bear their own costs.

F

D.G.

Appeals disposed of.