

Read : Application dt.16.12.2009 by M/s. GlaxoSmithKline Consumer Healthcare Ltd.
Heard : Shri Ashwin Acharya, Advocate

PROCEEDINGS

(under section 56(1)(e) & (2) of the Maharashtra Value Added Tax Act, 2002)

No.DDQ-11-2010/Adm-3/01/B- |

Mumbai, dt. 25/11/13

An application is received from M/s. GlaxoSmithKline Consumer Healthcare Ltd. (for short 'applicant'), holder of TIN 27220278023V/C, situated at Part A, 6th floor, Oberoi Commerz, International Business Park, Oberoi Garden City, Off Western Express Highway, Mumbai-400 063 seeking determination of the rate of tax applicable to the product 'Breathe Right Nasal Strip' sold through invoice no.9002080 dt.02.12.2009.

02. FACTS AND CONTENTION

While referring to the product as drug-free nasal strip, it is informed thus -

- " The applicant is a manufacturer and distributor of healthcare products.
- The product 'Breathe Right' is a completely drug-free product.
- It eases out problem of snoring and congested nose. It improves air flow by 31%.
- How it works : *Special adhesive of the strip holds strip comfortably in place. Two flexible 'spring-like' pieces pull nasal passage open.*
- Directions for use : *The user has to wash his nose thoroughly. Then the user has to remove the protective liner of the product and apply the product on his nose at the correct position as shown in the product literature.*
- The benefit : *The correct application of the product gently opens the nasal passage which gives instant relief from nasal congestion due to cold and flu, allergic rhinitis or deviated septum and helps in breathing better, relieve nasal congestion and reduces snoring.*
- The company is charging VAT @4% on the impugned item based on its interpretation as under :
 - The impugned item falls under entry C-29A(b).
 - Without prejudice to above and as an alternative argument, the impugned item can be held as falling under entry C-29A(a) or 107(8) of Schedule C.
- If the impugned item is held as taxable otherwise than 4% then the same may be held prospective from the date of the determination order as per the provisions of section 56(2) of the Maharashtra Value Added Tax Act, 2002. "

The applicant has submitted the following copies alongwith the application :

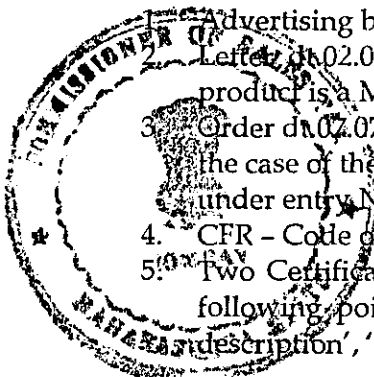
1. Advertising brochure

2. Letter dt.02.09.2008 by Joint Drug Controller (I) stating therein that the impugned product is a Medical device and not yet notified as drug.

3. Order dt.07.07.2010 under section 102 of the West Bengal Value Added Tax Act, 2003 in the case of the applicant himself holding that the impugned product is a medical device under entry No. 48 of Part I of Schedule C, exigible to tax @% u/s 16(2)(b) of the Act,03.

4. CFR - Code of Federal Regulations Title 21.

5. Two Certificates from users of the impugned product which contains matter on the following points similar to as given by the applicant in his application - 'Product description', 'How it works' and 'The Benefit'.



6. Purchase Invoice of the applicant from GlaxoSmithKline, United States.
7. Bill of Entry for Home Consumption dt.05.03.2010 showing clearance of the impugned product under Customs/Central Excise Tariff Heading 63079090.
8. Declaration of Conformity by the applicant himself of the impugned product being medical device as per norms applicable in UK.

03. HEARING

The case was fixed for hearing on different dates. However, the hearing took place on dt.03.09.2013. Sh. Ashwin Acharya (Adv.) attended the hearing and submitted thus:

1. The product 'nasal strip' is classified as bandage under entry C-29A(b).

Since the entry calls for a licence under the Drugs & Cosmetics Act,1940, it was queried whether the applicant holds such a licence. To which it was submitted that they do not hold a licence.

2. The alternative claim is made in respect of entry C-29A(a) or C-107(8).

It was brought to the notice that the first entry pertains to devices notified by the Central Government and it was agreed that the impugned product does not find a mention in the notification. As to entry C-107(8), it was agreed that the item does not fall in this entry too.

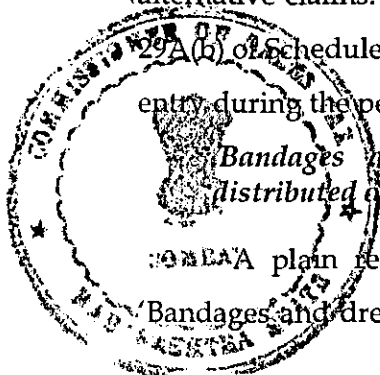
3. It is prayed that if the claim is not acceptable then prospective effect may be given to the determination order.
4. Since the applicant had made a claim under entry C-29A(b), he was asked to furnish, within a period of 15 days, a copy of the application made for applying for licence under the Drugs & Cosmetics Act,1940.

04. OBSERVATIONS

I have gone through the facts of the case. The product placed for determination of rate of tax is 'Breathe Right Nasal Strip' sold through invoice no.9002080 dt.02.12.2009. In the application for determination as well as during a hearing in the matter, I find that the applicant has, alongwith the main claim of the entry being applicable to the product, made alternate claims in respect of the entry under which the product could be said to be covered. The alternate claims pertained to entries notifying devices thereunder and the impugned product has not been notified under either of these two alternate claims. During hearing when the requirements of the alternate entries were brought to notice, the applicant has conceded to the same. Hence, I would not deal with any of the arguments in support of the alternative claims. This leaves me to deal with only the main claim, the same being entry C-29A(b) of schedule C of the Maharashtra Value Added Tax Act, 2002 (MVAT Act,2002). The entry during the period under consideration reads thus :

Bandages and dressings manufactured or imported into India, stocked, distributed or sold under licence granted under the Drugs and Cosmetics Act, 1940

The plain reading of the entry enables us to comprehend that the entry covers 'Bandages and dressings'. The entry lays down an inbuilt restriction that these 'Bandages



and dressings' should be manufactured or imported into India, stocked, distributed or sold under licence granted under the Drugs and Cosmetics Act, 1940. However, the applicant has admitted that he does not hold such a licence. Instead the applicant has come forward with a set of documents which, as per the understanding of the applicant, construe that the applicant holds such a licence. A plain perusal of these documents clearly indicates that they are not the licence documents. Nevertheless, to appreciate the applicant's perspective, I would analyse these documents thus :

1. Letter dt.30.04.2008 to the Drugs Controller General (India) on the subject of application for issue of NOC for import and sale of 'Breathe Right' Nasal strips (Drug free)

A perusal of the letter reveals that the applicant attempts to bring out the features of the product before the authorities. A part of the description of the product is worth reproducing :

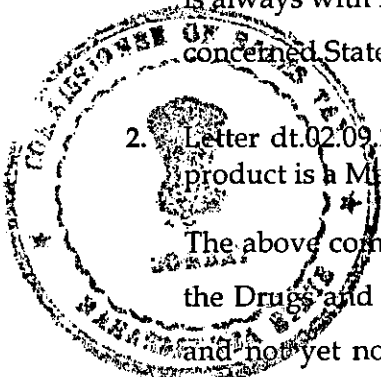
"We would like to submit that the product is Drug free and does not make disease specific drug claim on prevention, treatment, mitigation and diagnosis of a disease or disorder..... Further, we understand that the product has not been notified as a medical device as per D & C Act 1940. We wish to import and market Breathe Right as a "General" product, which is neither a "Drug" nor a "Medical Device". In view of above, we request the Directorate to kindly issue a No Objection Certificate for its import and sale in India as a general product."

What the above extract brings out is that the applicant had not made any claim of the product being falling under 'Bandages and dressings'. *As a matter of fact, the applicant has himself classified the product under the category 'General'*. Further, by self-admission of the applicant, the product is not a medical device.

Thus, reliance on orders under VAT Act of West Bengal or classification in countries other than the Union of India is not relevant to the issue at hand, more so when the entry under the West Bengal Act is not at par with the entry under which claim has been laid. The entry therein does not speak of a notification - just plain - 'Medical equipments, devices and implants'. Reliance on the position as available in countries other than India would serve little purpose in view of the fact that an interpretation is always with regard to the provisions as appearing under the concerned Act of the concerned State of the Republic of India.

2. Letter dt.02.09.2008 by Joint Drug Controller (I) stating therein that the impugned product is a Medical device and not yet notified as drug.

The above communication in simple words conveys a situation for the purposes of the Drugs and Cosmetics Act, 1940 that the impugned product is a Medical device and not yet notified as drug. There is no sort of any averment in the impugned



communication by the official in the office of the Drugs Controller General (India) as to the impugned product being falling under 'Bandages and dressings' and for which purposes a licence is being issued to the applicant. Now, when the Drugs and Cosmetics Act, 1940 has prescribed a licence to be held in respect of 'Bandages and dressings' manufactured or imported into India, stocked, distributed or sold under the Drugs and Cosmetics Act, 1940 and further if the product had satisfied the description of 'Bandages and dressings' under the aforesaid Act then on application from the applicant to the authorities under the said Act, there should not have been any reason for not granting the same. What comes out very clear from all this is that the impugned product does not fit the scope of 'Bandages and dressings'. Further, as mentioned earlier, even the applicant has also admitted to not holding such a licence and has neither produced one.

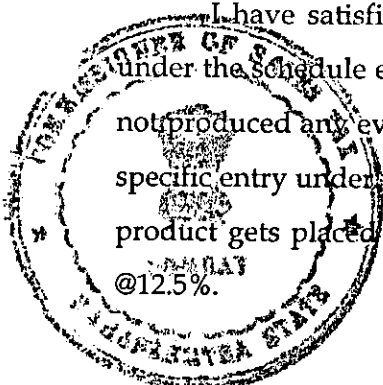
Thus, both the above communication do not help the applicant in putting across the point that the applicant holds a licence as 'Bandages and dressings' for the impugned product under the Drugs and Cosmetics Act, 1940.

Now, the entry under which claim is being laid by the applicant, when seen in the light of the impugned product, lays down the twin requirements thus :

- a. *The product should be 'Bandages and dressings'.*
- b. *The product should be manufactured or imported into India, stocked, distributed or sold under licence granted under the Drugs and Cosmetics Act, 1940.*

The impugned product has not been considered as 'Bandages and dressings' under the Drugs and Cosmetics Act, 1940 and further the applicant himself prefers to qualify the impugned product as a 'General' category item and not under 'Bandages and dressings' under the Drugs and Cosmetics Act, 1940. The applicant is, in fact, contradicting his stand when he puts a claim under the category 'Bandages and dressings' for the purposes of the MVAT Act, 2002. Further what is important is that even if the impugned product falls under 'Bandages and dressings', the requirement of licence (and which the applicant doesn't possess) would restrict any attempt at classification under the entry C-29A(b).

I have satisfied myself that the impugned product does not qualify for coverage under the schedule entry 29A(b) of the MVAT Act, 2002 and further, the applicant, too, has not produced any evidence to hold coverage under the aforesaid entry. There is no other specific entry under which the impugned product could be said to be falling. Therefore, the product gets placed in the residuary entry E-1 of the MVAT Act, 2002 and is liable to tax



@12.5%.

05. PROSPECTIVE EFFECT

The applicant has prayed for prospective effect to the determination order if his contention is not accepted. A prayer for prospective effect is to be seen in the light of the circumstances of the case and the position of law prevailing then, the interpretation of which is reflected in the determination. Any ambiguity surrounding the provisions or scope for mis-interpretation needs to be ascertained from the provisions. Any occasions of incorrect clarification or misguidance are to be weighed with regard to the facts of each case. From the facts of the case, it is seen that there has been no statutory misguidance in the case. Neither is it the case that the provisions were capable of any mis-interpretation or confusion as to its scope and meaning. We have seen above as to how the applicant has not pressed for classification under medical device. As regards classification under 'Bandages and dressings', I have to say that when the applicant preferred to classify the impugned item for the purposes of the Drugs and Cosmetics Act, 1940 under the 'General' category and not under 'Bandages and dressings', he was himself a best judge of the classification applicable to his product. What transpires from this is that the applicant has made claims in respect of such schedule entries which he was well aware as not being applicable to his product. Hence, the applicant fails to make out a case for favorable consideration of his request for prospective effect.

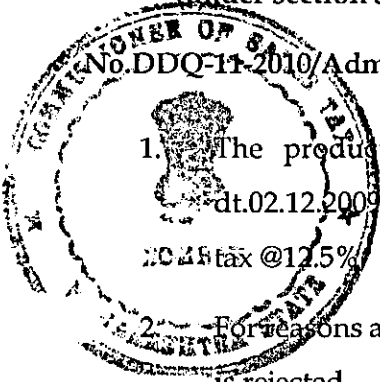
06. In view of the deliberations held hereinabove, I pass an order thus -

ORDER

(under section 56(1)(e) & (2) of the Maharashtra Value Added Tax Act, 2002)

No. DDQ-11-2010/Adm-3/01/B- I

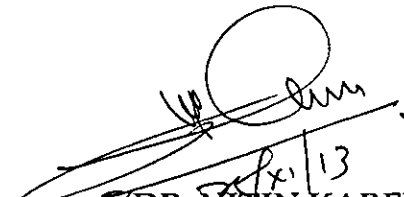
Mumbai, dt. 25/11/13



1. The product 'Breathe Right Nasal Strip' sold through invoice no.9002080 dt.02.12.2009 falls under residuary entry E-1 of the MVAT Act,2002 and is liable to

12.5% tax @12.5%

2. For reasons as discussed in the body of the order, the request for prospective effect is rejected.


(DR. NITIN KAREER)

COMMISSIONER OF SALES TAX,
MAHARASHTRA STATE, MUMBAI