C00114

CUSTOMS DUTY - binding tariff information - classification of Niquitin CQ nicotine patch - whether medicament under heading 3004 or chemical product under heading 3824 - held medicament - effect of World Customs Organization opinion for similar product under heading 3824 - binding tariff information quashed but decision not substituted

LONDON TRIBUNAL CENTRE

SMITHKLINE BEECHAM PLC

Appellant

- and -

THE COMMISSIONERS OF CUSTOMS AND EXCISE

Respondents

Tribunal: DR J F AVERY JONES CBE (Chairman)

MRS SHAHWAR SADEQUE M.Phil M.Sc

MR JOHN MENDELSSOHN

Sitting in public in London on 20 and 21 March 2000

Mr M P Cornwell-Kelly, solicitor, Titmuss Sainer Dechert, and Mr T S Bhalla, manager of the Appellant for the Appellant

Mr Nicholas Paines QC instructed by the Solicitor for the Customs and Excise for the Respondent

DECISION

1. This is an appeal by SmithKline Beecham against a binding tariff information (BTI) decision of the Commissioners in respect of the customs duty tariff classification of a nicotine patch known as "Niquitin CQ" (the Product) designed to assist people giving up smoking. The Commissioners, following an opinion of the World Customs Organization in November 1997 in relation to a similar product, have classified the Product in Chapter 38 under heading 3824 as "chemical products and preparations of the chemical or allied industries (including those consisting of mixtures of natural products), not elsewhere specified or excluded." The Appellant contends that it should be classified in Chapter 30 under heading

3004 as "medicaments…consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses…."

2. The Appellant was represented by Mr M C Cornwell-Kelly and Mr T S Bhalla, and the Commissioners by Mr N Paines QC. We heard evidence from Professor Godfrey Fowler, Dr David Balfour, Professor Robert West on behalf of the Appellant, and from Professor Robert Douglas and Mr Kevin Stibbards, the officer who made the BTI, on behalf of the Commissioners.

3. The Product consists of an adhesive patch designed to be affixed to the body which releases nicotine at a controlled rate into the body transdermally. The only active substance is nicotine. The remainder of the Product comprises a drug reservoir, a rate controlling membrane, an adhesive, a backing and a protective liner. The precise make up of the Product was provided to the Tribunal but is a commercial secret. The patches are imported individually packaged in foil pouches and are packed for sale in weekly packs with instructions. The Product comes in three strengths, 21 mg, 14 mg and 7 mg. It is used by affixing a patch to the skin and leaving it there for 24 hours. During this time, it provides a slow and controlled flow of nicotine into the body through the skin. A person who had been smoking more than 10 cigarettes a day will use the 21 mg patch every day for six weeks then move to the 14 mg one for two weeks and the 7 mg one for three weeks. A person who smoked less will start with the 14 mg patch for six weeks and then the 7 mg one for three weeks. The Product is authorised for sale by a pharmacist.

4. Before describing the way the Product helps a person to stop smoking, we shall start by summarising in general terms our understanding about tobacco and nicotine addiction. According to the Royal College of Physicians' report Nicotine Addiction in Britain, smoking causes serious health problems and is responsible for one in five deaths in Britain. At age 35 a man who has never smoked has a life expectancy of 45 years compared to 38 years for a smoker and 42 years for an ex-smoker, and the corresponding figures for women are 48, 42 and 46 years. In 1997-8 an estimated 364,000 hospital admissions in England (equivalent to 1,000 per day) were attributable to the diseases caused by smoking. The Report concludes (page 21):

"The burden of premature mortality and morbidity caused by smoking in Britain is massive. No other single avoidable cause of disease accounts for such a high proportion of deaths, hospital admissions or GP consultations. Cigarette smoking is the single most important public health problem in Britain.".

5. The health problems of smoking are not caused by nicotine but by carbon monoxide and other constituents of the smoke. The nicotine is an addictive substance. The Royal College of Physicians' Report says (page 100):

"On current evidence, we can conclude that cigarettes are properly categorised among the most addicting substances as this form of nicotine delivery maximises the addictive effects of the drug. The fact that nicotine is of low abuse potential in controlled dosage forms such as the transdermal nicotine patch or nicotine gum supports the conclusion that the form of delivery is an important determinant of its addiction potential….We can, however, conclude, as was concluded in the 1988 Report of the US Surgeon-General, that

The pharmacologic and behavioural processes that determine tobacco addiction are similar to those that determine addiction to drugs such as heroin and cocaine.

We can further conclude that tobacco dependence is a serious form of drug addiction which, on the whole, is second to no other."

6. The Product is a type of nicotine replacement therapy (NRT). The way it works is described in the Royal College of Physicians' report (page 143).

"The main short-term difficulties smokers experience when trying to stop smoking seem to be attributable to acute nicotine withdrawal. The basic idea behind using nicotine replacement is to break the quitting process into two phases. In the first phase, smokers learn to cope without smoking behaviour and regular rapid boli of nicotine, while protected from the worst withdrawal effects by moderate levels of nicotine provided by NRT. Later, nicotine is gradually withdrawn completely.

NRT alleviates withdrawal discomfort….Although such alleviation probably constitutes the main effect of NRT, other mechanisms may also have a role, such as the provision of a coping mechanism, or even the replacement of some of the hypothetical positive effects of nicotine.

Whatever the actual mechanism, there is ample evidence that NRT is effective in helping smokers quit…The overall odds ratio for abstinence with NRT compared to placebo was 1.73 (95% confidence interval 1.60—1.86)…In addition to enhancing early cessation, there is evidence that NRT also reduces early relapse."

7. The apparent contradiction between the effect of nicotine in smoking and nicotine in NRT is also dealt with in the Royal College of Physicians' Report in their summary and conclusions on page 184:

"The presence of nicotine is necessary, but not sufficient, for the nicotine to have a powerful psychoactive impact. To achieve the latter, nicotine must also be delivered rapidly to the brain. Tobacco smoke inhalation is the most highly optimised vehicle for nicotine administration because absorption through the lungs delivers nicotine to the brain rapidly and intensively. The potency of the nicotine effect is created by the speed of delivery, not just by the total nicotine delivered. The speed of nicotine delivery is a fundamental difference between cigarettes and nicotine replacement therapy (NRT) products which deliver nicotine at lower and slower subaddictive rates. For this reason, nicotine delivered through tobacco smoke should be regarded as a powerfully addictive drug, and smoking as the means of nicotine self-administration. The risk of addiction to NRT products is very low, but they are effective in attenuating cravings and withdrawal from tobacco-delivered nicotine dependence."

Of NRT products, the nicotine patch seems to be the type with the lowest risk of addiction. The Report says on page 144: "No cases of long-term use of the nicotine patches have been reported, suggesting that the incidence of long-term use may be related to the speed of nicotine absorption from individual products."

8. Mr Cornwell-Kelly contends for categorisation under heading 3004

Medicaments…consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses….

9. He contends that the Product is specifically designed for use as a treatment and is recognised by the Medicines Control Agency as requiring a marketing authorisation (formerly known as a product licence) under the Medicines Act

1968. It is properly described as a medicament with therapeutic or prophylactic uses.

10. Mr Paines for the Commissioners argued persuasively against the Appellant's categorisation in his skeleton as follows:

"The Appellant does not suggest that the purpose of taking nicotine through a patch is to treat or prevent any condition that is cured or prevented by nicotine, other than nicotine addiction. It is not suggested, to use everyday language, that taking nicotine through such a patch is good for health or cures any disease. The only suggested reasons for taking nicotine through a patch are that it is a less harmful way of taking nicotine than smoking and that to do so helps a person to break the smoking habit and wean his body off nicotine addiction.

Even if nicotine addiction is a 'disease' or a 'medical condition' (which is not accepted), nicotine patches do not cure nicotine addiction; i.e. they do not alter the functions of the body so as to make it no longer nicotine-addicted. Only the passage of time does that. On the contrary, nicotine patches continue to administer the addictive substance. Even if they alleviate the physical symptoms of withdrawal, they do so by continuing (albeit at a lower rate) to satisfy the addictive urge with a supply of the craved substance. It is a contradiction in terms to suggest (as the Appellant necessarily does) that an addictive substance becomes a medicament 'curing' addiction to that very substance simply because it is self-administered by a person who intends progressively to wean himself off its use."

11. Evidence was given by Professor Godfrey Fowler, emeritus professor of General Practice at the University of Oxford and vice-chairman of Action on Smoking and Health, who described the effectiveness of NRT. He categorised tobacco dependence as a medical condition recognised in the World Health Organization International Statistical Classification of Diseases and Related Health Problems, ICD-10. This was prevented or treated by a nicotine patch of which the Product is an example.

12. Dr David Balfour, reader in pharmacology and Neuroscience at the University of Dundee Medical School explained the effect of nicotine on the brain. Nicotine binds to specific receptors in the brain and affects both brain function and behaviour. The pathways in the brain which are affected are those affected by an addictive drug stimulating the release of dopamine in an area of the brain as with other addictive drugs. He described nicotine addiction as a medical condition. During smoking nicotine reaches the blood system in 10 seconds. It was the speed and quantity of nicotine inhaled by smoking which causes the addiction. By contrast, nicotine released by a patch did not. Nicotine in the patch was used as a substitution therapy in the same way as methadone for drug users. Nicotine was a recognised treatment for tobacco dependence.

13. Professor Robert West, Professor of Psychology at St George's Hospital, Medical School, and a contributor to the Royal College of Physicians' Report pointed out that tobacco dependence was recognised by ICD-10, and the American Psychiatric Association's classification of psychiatric diseases, SSM-IV, which is used across the world, recognised nicotine dependence and the nicotine withdrawal syndrome as medical conditions. He described NRT as a medication for the treatment of tobacco dependence. The critical factor was that nicotine from a patch was much less rapidly ingested than nicotine from smoking.

14. Professor Robert Douglas, professor of occupational health, called by the Commissioners, considered that smoking was a medical condition and that nicotine patches were a therapy but not a medicine.

15. The Combined Nomenclature Explanatory Notes which are not legally binding but which are an important aid to interpretation point out that classification of a product as a medicament under national legislation is not the deciding factor. It also refers to the explanation of measured doses in the Harmonised System Explanatory Notes. Those notes, which are also not legally binding, contain an explanation of measured doses. It is common ground that the Product is put up in measured doses.

16. The World Customs Organization made a classification opinion in November 1997, which was published in February 1998, as follows:

3824.90 9. Transdermal administration system, used as an alternative source of nicotine by smokers who are attempting to stop smoking, comprising (i) a transparent, external protective film of plastics to prevent leakage of the active substance (nicotine); (ii) a small reservoir from which nicotine is released by absorption through the skin into the circulatory system; (iii) a control membrane (permeable to the active ingredient) to permit a continuous and controlled release of nicotine entering the body; (iv) an adhesive contact permeable to the active ingredient, enabling absorption to start at the moment of application; and (v) a removable protective film which keeps the system closed and intact until the time of application.

It is clear that the Product is within this description and the Commissioners contend for this classification.

17. The United States Customs Service issued a ruling on 14 April 1998 classifying a nicotine transdermal device, which appears to be similar to the Product under appeal, under heading 3004. This revoked a previous ruling classifying it under heading 3005 as "wadding, gauze bandages or similar articles." There is no reference in the reasons for the classification to the previously given WCO opinion which presumably was overlooked.

18. At its meeting in May 1999 published in August 1999, which was after the BTI under appeal, the WCO gave opinions categorising two transdermal administration products under heading 3004. These were a system for treating hormone deficiency during menopause containing 17 β-estradol, and one used by angina patients for regulating the heartbeat containing nitroglycerol. The description of the device is identical to the one quoted above apart from the active ingredient. At the same meeting three changes were made to the French version of the opinion on the nicotine transdermal product. This makes it less likely that the opinion on the nicotine transdermal device was overlooked when making the two new rulings under heading 3004. It seems therefore that the WCO still support the opinion classifying the transdermal nicotine device under heading 3824, presumably on the basis that they do not consider it to be a medicament, while they do consider that the two new opinions relate to medicaments.

19. At the same meeting of the WCO the Harmonised System Explanatory Notes to heading 3004 were amended by adding a paragraph to the effect that measured doses also included doses in the form of transdermal administration systems which are generally in the form of self-adhesive patches. This does not

assist us as the point was not in doubt and does not help to resolve whether the Product is a medicament.

20. The European Court of Justice has on a number of occasions dealt with the meaning of heading 3004 usually in distinction to heading 2208 relating to tonic beverages and health foods. The decisive criterion for the classification of goods applied by the Court is to find the objective characteristics and properties as defined in the tariff. The Court has in all these cases required that products within heading 3004 should have clearly defined therapeutic or prophylactic purposes with an effect concentrated on the functions of the human organism. See Bioforce No.2 (Case C-405/95), LTM (Case C-201/96), Sarget (Case C-270/96), Glob-Sped (Case C-328/97).

21. These cases were considered by Laws J in HM Customs and Excise v Cedar Health Ltd, 21 May 1998 unreported, where he said

"If a product fell to be classified under 30.04 by reason only of the fact that it was used, even exclusively used, or intended to be used for what in ordinary language might be called therapeutic or prophylactic purposes, there would on the face of it be a likely overlap with many products properly classified under 22.06 [tonic beverages]: products under that classification may commonly be intended for no purpose other than to alleviate ills. What has happened here is that the Court of Justice has provided a tight, certain and focussed approach.

22. We understand the requirement for clearly defined therapeutic or prophylactic purposes with an effect concentrated on the functions of the human organism to mean that the item must have a specific medicinal use rather than being claimed to be generally beneficial to health.

23. We note that the Product is licensed by the Medicines Control Agency but this fact does not form any part of the reasons for our decision. The definition of medicinal product in section 130 of the Medicines Act 1968 is wider than products having the purpose of treating or preventing disease. As Moses J said in Unigreg Ltd v HM Customs and Excise 8 July 1998 unreported

"…in my judgment the fact that a medical product falls wider than directive [Directive 65/65 relating to the Medicines Control Agency] is, at the very lowest, of so little weight that it is of no assistance. That directive is dealing with control of medicines in another context and is, therefore, deliberately phrased in very wide terms. It is, however, correct, as the Tribunal said, that the facts and evidence surrounding the grant of the product licence are relevant as evidence that the product possesses the objective characteristics and properties specified in the licence."

The product characteristics in the licence application contained the following statement under the heading Therapeutic Indications: "NiQuitin CQ is indicated for the relief of nicotine withdrawal symptoms including cravings associated with smoking cessation. If possible, when stopping smoking, NiQuitin CQ should be used in conjunction with a behavioural support programme."

24. The real issue in this case is whether the Product is a medicament. The test which we must apply is to look at the objective characteristics and properties as defined in heading 3004: is the Product objectively a medicament for therapeutic or prophylactic use? One must not argue, as Laws J said in HM Customs and Excise v Cedar Health Ltd, that because it has a therapeutic use it must be a medicament. One must start by asking whether it is a medicament. It has the

precise function of treating nicotine addiction caused by smoking. The Product viewed objectively assists in curing the addiction because it provides a steady dose of nicotine instead of the immediate and high dose from smoking. Professor Fowler, Dr Balfour and Professor West all regarded the Product as a treatment for the medical condition of nicotine addiction or tobacco dependence. We do not think the distinction made by Professor Douglas that it is a therapy rather than a medicine is a valid one.

25. We note also that the Royal College of Physicians describe NRT as "the only pharmacotherapy licensed in the UK to manage nicotine addiction." (page 143). In their summary and recommendations on page 186 there is a heading Treatment of nicotine addiction in which they refer to "Treatment products such as NRT" and one of their conclusions is that "NRT is a highly effective and cost-effective smoking cessation treatment…".

26. Three of the witnesses and medical opinion generally regard NRT as a treatment, and we conclude from this, that the Product is a medicament. Its active ingredient may be the addictive substance itself but the form of delivery is all-important, as Dr Balfour and Professor West both emphasised, and the Royal College of Physicians' Report explains in the passage quoted in paragraph 0 above. Nicotine given by way of smoking is highly addictive while NRT in the form of a patch is not addictive. The Product is designed to treat nicotine addiction and it has been shown to be effective.

27. There is an attractive logic in Mr Paines' argument set out in paragraph 0 above that the Product is not a medicament, essentially because nicotine is the very thing to which the person is addicted, but we cannot accept it. Paradoxically one does treat nicotine addiction with nicotine. The reason it works is that it is the means of administering the nicotine that counts. But the question is not whether nicotine is a medicament but whether the Product is a medicament. We have concluded that it is. It seems to us that the answer to Mr Paines' point that: "It is a contradiction in terms to suggest (as the Appellant necessarily does) that an addictive substance becomes a medicament 'curing' addiction to that very substance simply because it is self-administered by a person who intends progressively to wean himself off its use", is that it does not become a medicament because it is self-administered, but because the Product is a means of administering nicotine in a way that it assists in curing nicotine addiction.

28. Accordingly we conclude that the Product is a medicament and that it has both therapeutic and prophylactic uses. Heading 3004 is therefore at least one possible categorisation.

29. It is not disputed that the Commissioners' categorisation under 3824 as "chemical products and preparations of the chemical or allied industries (including those consisting of mixtures of natural products), not elsewhere specified or excluded" is a possible categorisation, as the World Customs Organization has recognised.

30. Since there are two possible headings, General Rule of Interpretation 3(a) provides that "the heading which provides the most specific description shall be preferred to headings providing a more general description." It is common ground that heading 3004 is the more specific description. The full categorisation is 3004 40 90 90.

31. We are therefore in the unfortunate position of disagreeing with the World Customs Organization opinion. It is equally unsatisfactory that the United States

authorities have also issued a ruling contrary to the WCO opinion applying to imports to the United States from the EU. If the Commissioners had issued a BTI contrary to the WCO opinion it is clear that it would be invalid under article 12(5) of the Code, as amended by Regulation 87/92:

"Binding information shall cease to be valid—

(a) in the case of tariff information—

.(ii) where it is no longer compatible with one of the nomenclatures referred to in article 20(6):

- at international level, by reason of a classification opinion…adopted by the World Customs Organization…."

32. Although this provision assumes that the WCO ruling comes after the BTI, a BTI that is contrary to an existing WCO opinion must for the same reason be invalid from the start. The power of this Tribunal is contained in section 16(5) of the Finance Act 1994 and includes power to quash or vary any decision and power to substitute our own decision for any decision quashed on appeal. Rather than substituting a BTI categorising the Product under heading 3004 which would be immediately invalid, we merely quash the Commissioners' decision to issue a BTI categorising the Product under heading 3824 on the ground that we consider that it is correctly categorised under heading 3004. We appreciate that this leaves the Appellant with no BTI.

33. Accordingly we allow the appeal by quashing the Commissioners' decision and award the costs of and incidental to the appeal to the Appellant to be determined in default of agreement by a Tribunal chairman.

J F AVERY JONES

CHAIRMAN

RELEASED 10th April 2000

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