[2019] UKFTT 93 (TC)

TC06976

Customs duty – tariff classification of ThermaCare therapeutic heat products – whether Commission Implementing Regulation (EU) 2016/1140 arguably gives incorrect classification – whether referral to CJEU should be made to determine validity of Regulation – test to be applied in deciding whether to make referral – order for referral made

FIRST-TIER TRIBUNAL **Appeal number: TC/2017/08925**

TAX CHAMBER

BETWEEN

PFIZER CONSUMER HEALTHCARE LIMITED **Appellant**

-and-

THE COMMISSIONERS FOR HER MAJESTY'S REVENUE AND CUSTOMS **Respondents**

TRIBUNAL: JUDGE KEVIN POOLE
MOHAMMED FAROOQ

Sitting in public at Taylor House, Rosebery Avenue, London on 17 January 2019

Valentina Sloane, counsel, instructed by Hogan Lovells International LLP for the Appellant

Howard Watkinson, counsel, instructed by the General Counsel and Solicitor to HM Revenue and Customs for the Respondents

DECISION

Introduction

1. This appeal is concerned with the correct tariff classification of the appellant's "ThermaCare®" range of therapeutic heat products ("the Products").

2. It is common ground that a particular EU Regulation (Regulation (EU) 2016/1140 of 8 July 2016 ("the Contested Regulation")) applies to afford a particular tariff classification to the Products.

3. The appellant however maintains that the Contested Regulation is inconsistent with the Combined Nomenclature and Common Customs Code and accordingly ought to be disapplied in classifying the Products for customs purposes. It is agreed that this Tribunal has no power to override or annul the Contested Regulation, that power resides in the Court of Justice of the European Union ("the CJEU") (see *Foto-Frost v Hauptzollamt Lübeck-Ost* [1987] C-314/85). The essence of this appeal, therefore, is whether the Tribunal should make a reference to the CJEU with a view to the Contested Regulation being annulled, though the form of the appeal is against the issue of a Binding Tariff Information by HMRC, which categorises the Products in accordance with the Contested Regulation.

4. The parties have helpfully agreed the terms of a draft Order of the Tribunal making the reference to the CJEU, which is to be made if the Tribunal considers it appropriate to make one. The terms of that agreed draft ("the Proposed Order") are set out in the Appendix to this decision. The issue before the Tribunal was whether it is appropriate for it to make a reference to the CJEU and, if so, whether the terms of the Proposed Order are appropriate.

The facts

5. We received uncontested written witness statements from:

   (1) Dr Thomas Schettler, the Country/Cluster Medical Affairs Lead for Global Clinical and Medical Affairs for Central Europe at the appellant's associated company in Germany;

   (2) Andrew Walker, Europe, Middle East and Africa lead for Global Trade Controls in the appellant's group of companies, overseeing compliance with customs regulations across the EMEA region for the appellant and its associated Pfizer legal entities; and

   (3) Dee Rigling, the HMRC officer who had dealt with the appellant's latest application for a Binding Tariff Information and rejected it, applying the Contested Regulation.

6. The relevant facts emerging from the evidence before us are fairly summarised in the Schedule to the Proposed Order. There is no need to set them out again in this decision.

The issue

7. The preliminary issue to be decided by the Tribunal is therefore whether it is appropriate to make the Proposed Order.

8. The approach to such an issue in the Tribunal is largely well-established and was agreed between the parties.

9. The starting point is the decision of the CJEU in *The Queen (on the application of International Air Transport Association and European Low Fares Airline Association) v Department for Transport* [2006] C-344/04. In that case, the CJEU said this:

> "27. It is settled case-law that national courts do not have the power to declare acts of the Community institutions invalid. The main purpose of the jurisdiction conferred on the Court by Article 234 EC is to ensure that Community law is applied uniformly by national courts. That requirement of uniformity is particularly vital where the validity of a Community act is in question. Differences between courts of the Member States as to the validity of Community acts would be liable to jeopardise the very unity of the Community legal order and undermine the fundamental requirement of legal certainty (Case 314/85 *Foto-Frost* [1987] ECR 4199, paragraph 15; Case C-27/95 *Bakers of Nailsea* [1997] ECR I-1847, paragraph 20; and Case C-461/03 *Gaston Schul Douane-expediteur* [2005] ECR I-10513, paragraph 21). The Court of Justice alone therefore has jurisdiction to declare a Community act invalid (joined cases C-143/88 and C-92/89 *Zuckerfabrik Suderdithmarschen and Zuckerfabrik Soest* [1991] ECR I-415 paragraph 17; and Case C-6/99 *Greenpeace France and others* [2000] ECR I-1651, paragraph 54).
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> 28. Article 234 EC does not constitute a means of redress available to the parties to a case pending before a national court and therefore the mere fact that a party contends that the dispute gives rise to a question concerning the validity of Community law does not mean that the court concerned is compelled to consider that a question has been raised within the meaning of Article 234 EC (see, to this effect, Case 283/81 *Cilfit* [1982] ECR 3415, paragraph 9). Accordingly, the fact that the validity of a Community act is contested before a national court is not in itself sufficient to warrant referral of a question to the Court for a preliminary ruling.
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> 29. The Court has held that courts against whose decisions there is a judicial remedy under national law may examine the validity of a Community act and, if they consider that the arguments put forward before them by the parties in support of invalidity are unfounded, they may reject them, concluding that the act is completely valid. In so doing, they are not calling into question the existence of the Community act (*Foto-Frost*, paragraph 14).
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> 30. On the other hand, where such a court considers that one or more arguments for invalidity, put forward by the parties or, as the case may be, raised by it of its own motion (see, to this effect, Case 126/80 *Salonia* [1981] ECR 1563, paragraph 7), are well founded, it is incumbent upon it to stay the proceedings and to make a reference to the Court for a preliminary ruling on the act's validity.
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> 31. In addition, the spirit of cooperation which must prevail in the operation of the preliminary reference procedure means that the national court is to set out in its order for reference the reasons why it considers such a reference to be necessary."

10. The High Court considered the application of this principle in the UK courts in *The Queen (on the application of Telefonica O2 Europe plc and others v Secretary of State for Business Enterprise and Regulatory Reform* [2007] EWHC 3018 (Admin), where the validity of an EU Regulation ("the Roaming Regulation") was in issue. Mitting J said this:

> "3. Both of the substantive claims are a legitimate procedural device by which the underlying question of the lawfulness of the Roaming Regulation can be determined. If I am satisfied that the challenge to the validity of the Roaming Regulation is unfounded, I can and should so declare and would give effect to my conclusion by refusing permission *[to bring judicial review proceedings to challenge the validity of the UK regulations based on the Roaming*

> *Regulations]*. If I consider the issue to be arguable, I cannot determine it myself but may refer it for decision to the European Court of Justice, case C-344/04 IATA [2006] ECR I-403, paragraphs 29 and 30. The European Court alone is competent to make such a decision. If this course is not adopted, the issue cannot be got before the European court by the claimants. It could only be litigated by one of the parties named in Article 230 of the Treaty. The European Court encourages national courts in a proper case to permit natural and legal persons to have the validity of a Community act which affects them to be determined by that court on a reference by the national court: case C-50/00P Unión de Pequeños Agricultores v Council of the European Union [2002] ECR 1_6677 paragraphs 40-42.
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> 4. The underlying question therefore is the validity or otherwise of the Roaming Regulation. There is no doubt that it has a significant direct and indirect affect *[sic]* on the business activities of the claimants. If satisfied that the challenge to its validity is reasonably arguable or, put negatively, not unfounded, I should refer the issue to the European Court and grant permission for the domestic challenge to the UK regulations."

11. Thus far, the parties were agreed.

12. On the above basis, after reciting various grounds upon which she submitted the Contested Regulation was invalid, Ms Sloane submitted simply that it was "strongly arguable that the Contested Regulation was invalid" and that accordingly a reference to the CJEU must be made.

13. Mr Watkinson, on the other hand, effectively argued that the enquiry of the Tribunal should go a little further. He submitted that in reaching a view as to whether a referral should be made, it was necessary to consider the test that would be applied by the CJEU in deciding whether the Contested Regulation was invalid; only if it was reasonably arguable that that test was satisfied should the Tribunal make an order for reference. Given the nature of that test, he submitted that this was not an appropriate case for a reference.

14. In his submission, the nature of the test to be applied by the CJEU should be derived from *Cabletron Systems Limited v The Revenue Commissioners* [2001] C-463/98, in which the CJEU said this:

> "22. The Commission ought to have realised, in the light of the wording of headings No 8471 and No 8517, read in conjunction with the explanatory notes… that it was wrong to classify under heading No 8517 the types of network equipment mentioned in items 1 to 3 of the annex to Regulation No 1638/94 and in item 4 of the annex to Regulation 1638/94. That error is manifest and consequently renders those regulations invalid."

15. In his submission, this made it clear that the CJEU would only invalidate the Contested Regulation if it contained a "manifest error". The High Court in *Vtech Electronics (UK) plc v HMRC* [2003] EWHC 59 (Ch) (Lawrence Collins J) had expanded on the point as follows:

> "24. A classification by a Commission Regulation is invalid, if the error made by the Commission is "manifest," for example if it is based on an interpretation which is inconsistent with the Community's international obligations, or does not take account of the Explanatory Notes or the GIRs: see e.g. Case C-463/98 *Cabletron Systems Ltd* [2001] ECR I-3495, para 22 the Court annulled part of a regulation, holding that the Commission had committed a manifest error of classification in determining that network cards and cable used in conjunction with computers to transfer information through

> a network should be classified as telecommunications equipment under CN 8517 rather than under CN 8471 which applies to automatic data processing machines.
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> 25. In his opinion in Case C-463/98 *Cabletron Systems Ltd* [2001] ECR I-3495 Advocate General Jacobs explained that intensive scrutiny by the Court is justified where a Commission Regulation is alleged to bring the Community into conflict with its international obligations under the Harmonised System. This will be the case where, as in the present case, the dispute centres on whether a product should be classified under one chapter heading rather than another. He said (para 84):
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> > 'Closer scrutiny is I consider justified in such cases, where the dispute is between headings or sub-headings whose contents is established at that higher level and which fall only to be interpreted for Community purposes, than where the Commission enjoys a fuller discretionary power, for example as regards the determination of the correct eight-digit sub-heading, which is a matter of Community law alone. In the former case… a regulation may be invalid by reason of its failure to comply with the Community's international obligations; in the latter it will not be invalid unless the classification was manifestly at odds with the CN.'"

16. Further light was cast on the meaning of the phrase "manifest error" in this context by the CJEU in *Goldstar Europe GmbH v Hauptzollamt Ludwigshafen* [1994] C-401/93 where the Court said this:

> "28. In view of the distinction drawn in the combined nomenclature between apparatus and parts of apparatus, and in view of the obvious importance of the electronic components, the Commission could not reasonably consider that the mechanical assembly of a mecadeck on its own had the essential character of a video recorder, enabling it to be classified under the same tariff heading as complete video recorders.
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> 29. It follows that the Commission committed a manifest error of assessment in classifying mecadecks under subheading 8521 10 39."

17. Mr Watkinson also referred to *Targetti (UK) Limited v HMRC* [2014] UKUT 0274 (TCC), in which Newey J had repeatedly referred to the need for a "manifest error" to be shown in the relevant regulation if an application for a referral to the CJEU of an anti-dumping duty regulation were to be granted.

18. In Mr Watkinson's submission, therefore, the test to be applied by the Tribunal in deciding whether or not to order a reference to the CJEU was "whether it is reasonably arguable that the Commission made a manifest error, or acted unreasonably, in coming to the classification decision as recorded in the [Contested Regulation] for the reasons alleged by the Appellant."

19. Ms Sloane pointed to the fact that the CJEU had on more than one occasion declared regulations akin to the Contested Regulation invalid (in whole or in part) without reference to the question of whether the Commission had made a "manifest error", in particular:

> (1) *Kawasaki Motors Europe NV* [2006] C-15/05 at [50], where the reason given was that by making the offending regulation the Commission had "restricted the scope of heading 8701 and hence exceeded the bounds of its discretion",

(2) *Kawasaki Motors Europe NV* [2016] C-91/15 at [62], where it held the Commission had "altered, by reducing it, the scope of those subheadings and therefore exceeded the powers conferred on it…",

(3) *GROFA GmbH and GoPro Coöperatief UA* [2017] C-435/15 and C-666/15 at [51] – [52], where it held a regulation invalid on the basis that its effect was to "[alter], by extending it, the scope of" the relevant subheading, on the basis that it was "incompatible with the scope of that subheading", and

(4) *Vision Research Europe BV* [2018] C-372/17 at [51], where it held a regulation invalid on the basis that, by adopting it, the Commission had "altered the scope of CN Subheading 8525 80 30 by restricting it. The Commission consequently exceeded the authority conferred on it…"

Discussion and decision

20. From the history set out in Section F of the Schedule to the Proposed Order, it is clear that until the Contested Regulation came into force, HMRC agreed with the appellant's view of the correct classification of the Products.

21. It is therefore difficult to see how they could seriously argue that the appellant's challenge to the validity of the Contested Regulation is "unfounded". Their main defence to this point appears to be that now the Contested Regulation is in force, the only basis upon which the Tribunal could refer the question of its validity to the CJEU is if the Commission had, arguably, made a "manifest error" (rather than an error of some lesser degree of seriousness) in adopting the Contested Regulation.

22. This seems to us to be a somewhat artificial distinction, and one which in any event appears to be based on a misapplication of the test set out in *Cabletron*, when that case is considered in detail.

23. Paragraph [21] of the judgment in Cabletron read as follows:

> "21. Second, for the reasons set out in points 82 to 95 of the Advocate General's Opinion, the argument submitted by the Commission and the Revenue Commissioners, to the effect that Regulations No 1638/94 and No 1165/95 are none the less invalid inasmuch as the Commission's classification error cannot be described as 'manifest', must be rejected."

24. It is clear from this paragraph that:

(1) The Court specifically adopted the reasoning set out in paragraphs 82 to 95 of the Advocate General's opinion, and

(2) On the basis of that reasoning, it rejected the Commission's argument that the relevant regulations "are none the less valid inasmuch as the Commission's classification error cannot be described as 'manifest'".

25. The key parts of the Advocate General's opinion were as follows:

> "78. In *GoldStar Europe*, the Court approached that question *[i.e. whether the Commission had exceeded its powers in making the relevant regulation]* by examining whether the Commission had committed a 'manifest error of assessment' in the classification made.
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> 79. At the hearing in the present case, there was discussion as to what is necessary, where it is agreed that a classification was made in error, to render that error 'manifest' and thus vitiate the regulation.

> 80. The consensus appeared to be that it was not enough for the error to have been made manifest as a result of a subsequent decision of the Court or the HS Committee but that it must have been manifest – to an 'informed observer', in the Commission's words – at the time of adoption of the regulation in issue.
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> 81. However, that does not address the question of the requisite degree of 'manifestness'.
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> 82. I would suggest that the Court should not be reluctant to review the Commission's assessment in a case such as the present.
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> 83. Where there is real doubt, it is important that the Commission should be able to resolve that doubt within the Community in the interests of legal certainty but it is also important that Community law should not find itself at odds with the intended tenor of the HS. The concern not to limit unduly the Commission's power to settle genuinely doubtful cases by way of regulation must be qualified by the need to control the exercise of that power where it brings the Community into conflict with the uniform international practice which the HS seeks to achieve.
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> 84. What is at issue here is the correct classification of the goods in accordance with the Community's obligation to comply with the HS Convention. Closer scrutiny is I consider justified in such cases, where the dispute is between headings or subheadings whose content is established at that higher level and which fall only to be interpreted for Community purposes, than where the Commission enjoys a fuller discretionary power, for example as regards the determination of the correct eight-digit sub-subheading, which is a matter of Community law alone. In the former case (as here), a regulation may be invalid by reason of its failure to comply with the Community's international obligations; in the latter, it will not be invalid unless the classification was manifestly at odds with the CN.
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> …
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> 95. I am satisfied that it should have been clear to the Commission from the wording of the headings, in particular when read in conjunction with the explanatory notes as they stood at the time, that it was in error in classifying the items… In the light of the opinion I have expressed above in paragraphs 82 to 84, that error is in my opinion such as to vitiate the regulations."

26. In other words, the Advocate General was specifically stating that when classification is in dispute between CN headings and subheadings which are laid down by the HS, the CJEU should give "closer scrutiny" to regulations made by the Commission by way of purported resolution of that dispute, and it is only where disputes in classification between sub-subheadings arise that the CJEU should apply the "manifestly at odds with the CN" criterion in deciding the validity of any classification regulation made by the Commission.

27. The present case (as was *Cabletron*) is clearly concerned with a dispute between headings laid down by the HS, and accordingly the "manifestly at odds" formulation referred to by the Advocate General in the above passage (adopted, as it was, by the Court as a whole) would not appear to apply. The fact that the Court in its decision in *Cabletron* said "the error is manifest and consequently renders those regulations invalid", if taken to mean that a "manifest error" (in the sense of an error of some extra degree of egregiousness) was essential to its decision, would conflict not only with the reasoning of the Advocate General which the Court had specifically adopted, it would also ignore the context in which the phrase appeared, namely the prior statement in [22] of the judgment that "[t]he Commission ought to have realised… that it

was wrong" to classify the goods as it had done in the regulation. We note also that, from the more recent decisions of the CJEU about the validity of implementing regulations to which Ms Sloane referred us (see [19] above), the question of "manifestness" no longer appears to feature as an explicit consideration in its deliberations. To the extent this represents a shift of emphasis in the CJEU's view of the relevant law, it is a shift which ought to be taken into account when considering the UK courts' and tribunals' previous decisions on the requirements to be met before ordering a reference to the CJEU.

28. We did not find *Targetti* to be of much assistance, as it was concerned with an anti-dumping duty regulation, in relation to which it was stated that a "wide discretion" existed for the European institutions, and case law specific to such duties laid down, in a very different context, that judicial review of the appraisal of "complex economic matters" must be limited to whether there had been "manifest errors in the assessment of those facts or a misuse of powers" – see [14], citing *The Dow Chemical Company v Council* [2012] ECR II-0000.

29. Furthermore, if Mr Watkinson's submissions are correct, then effectively an importer such as the appellant could easily be deprived of any legal remedy in precisely the situation in which one is most needed. If he is right, it would mean that there is a class of "error" made by the Commission in passing classification regulations (i.e. an error which is somehow less than "manifest", but still an error) which is entirely non-justiciable. This would appear to us to conflict with the statement of principle set out by the CJEU in *Unión de Pequeños Agricultores* [2002] C-50/00P:

> "38. The European Community is, however, a community based on the rule of law in which its institutions are subject to judicial review of the compatibility of their acts with the Treaty and with the general principles of law which include fundamental rights.
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> 39. Individuals are therefore entitled to effective judicial protection of the rights they derive from the Community legal order, and the right to such protection is one of the general principles of law stemming from the constitutional traditions common to the Member States. That right has also been enshrined in Articles 6 and 13 of the European Convention for the Protection of Human Rights and Fundamental Freedoms…
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> 40. By Article 173 and Article 184 (now Article 241 EC), on the one hand, and by Article 177, on the other, the Treaty has established a complete system of legal remedies and procedures designed to ensure judicial review of the legality of acts of the institutions, and has entrusted such review to the Community Courts… Under that system, where natural or legal persons cannot, by reason of the conditions for admissibility laid down in the fourth paragraph of Article 173 of the Treaty, directly challenge Community measures of general application, they are able, depending on the case, either indirectly to plead the invalidity of such acts before the Community Courts under Article 184 of the Treaty or to do so before the national courts and ask them, since they have no jurisdiction themselves to declare those measures invalid… to make a reference to the Court of Justice for a preliminary ruling on validity.
>
> 41. Thus it is for the Member States to establish a system of legal remedies and procedures which ensure respect for the right to effective judicial protection."

30. Accordingly we consider the better view is that the threshold that the appellant must pass in order to be entitled to an order for reference is that contended for by Ms Sloane.

31. We should add, however, that even if we are wrong in this and Mr Watkinson is correct, it would not affect our final decision.

32. Given that HMRC themselves took the view, until the Contested Regulation was passed, that the Products were properly classified under heading 3005 10 00 00 and 3005 90 50 00, and in the light of the submissions of both parties summarised in paragraphs [32] to [35] in Section G of the Schedule to the Proposed Order, we consider it to be reasonably arguable that the Contested Regulation is invalid; if it were relevant, we would consider it to be reasonably arguable that it is manifestly so.

33. The Proposed Order appears to us to be satisfactory in form. Accordingly we hereby make the Order set out in the Appendix.

Right to apply for permission to appeal

34. This document contains full findings of fact and reasons for the decision. Any party dissatisfied with this decision has a right to apply for permission to appeal against it pursuant to Rule 39 of the Tribunal Procedure (First-tier Tribunal) (Tax Chamber) Rules 2009. The application must be received by this Tribunal not later than 56 days after this decision is sent to that party. The parties are referred to "Guidance to accompany a Decision from the First-tier Tribunal (Tax Chamber)" which accompanies and forms part of this decision notice.

KEVIN POOLE
TRIBUNAL JUDGE

RELEASE DATE: 14 FEBRUARY 2019

APPENDIX

The Proposed Order

ORDER

Before the First-tier Tribunal (Tax Chamber)

UPON reading the witness statements, other evidence, and skeleton arguments for the Appellant and the Respondents;

AND UPON hearing the submissions of both parties at a hearing on 17 January 2019;

AND UPON finding that, in order to enable the First-tier Tribunal to give judgment in this case, it is necessary to resolve a question concerning the validity of an instrument of European Union legislation and the interpretation of other European Union law, it is appropriate to request the Court of Justice of the European Union ("CJEU") to give a preliminary ruling thereon;

IT IS ORDERED that:

1. The question set out in the Schedule on the validity of Commission Implementing Regulation (EU) 2016/1140 of 8 July 2016 concerning the classification of certain goods in the Combined Nomenclature and on the interpretation of the Combined Nomenclature of the Common Customs Tariff, set out in Annex I to Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff, as amended, be referred to the CJEU for a preliminary ruling under Article 267 of the Treaty on the Functioning of the European Union.

2. All further proceedings in this appeal be stayed until after the CJEU shall have given its ruling on the said question or until further Order.

3. This Order be communicated to the CJEU forthwith.

4. There be liberty to apply on all aspects of this Order to all parties.

……
JUDGE OF THE FIRST-TIER TAX TRIBUNAL

[ ] 2019

SCHEDULE

REQUEST FOR A PRELIMINARY RULING UNDER ARTICLE 267 OF THE TREATY ON THE FUNCTIONING OF THE EUROPEAN UNION BY THE FIRST-TIER TRIBUNAL (TAX CHAMBER) OF THE UNITED KINGDOM

A. INTRODUCTION

1. This reference for a preliminary ruling concerns the validity of Commission Implementing Regulation (EU) 2016/1140 of 8 July 2016[1] concerning the classification of certain goods in the Combined Nomenclature ("the contested Regulation"). A copy of the contested Regulation is at **Annex 1** to this Order for Reference.

2. The issue of the validity of the contested Regulation in turn depends upon the interpretation of the Combined Nomenclature contained in Annex I to Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ 1987 L 256, p. 1), as amended relevantly by Commission Implementing Regulation (EU) 2016/1821 of 6 October 2016 amending Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff[2].

3. This reference has been made in the context of an appeal by Pfizer Consumer Healthcare Limited before the First-tier Tribunal (Tax Chamber) of the United Kingdom against decisions of the Commissioners for Her Majesty's Revenue and Customs concerning the tariff classification of products falling under the registered trademark ThermaCare® ("Thermacare products"). Decisions such as those appealed against are known as Binding Tariff Informations, or BTIs.

B. THE APPELLANT

4. The Appellant is Pfizer Consumer Healthcare Limited ("Pfizer") and is established in the United Kingdom, with its registered office in Sandwich, Kent. It has UK company registration number 00132018. Pfizer imports Thermacare products into the UK.

C. THE RESPONDENTS

5. The Respondents are the Commissioners for Her Majesty's Revenue and Customs ("HMRC"). They are responsible for the administration and collection of customs duties in the United Kingdom, including the issue of BTIs.

D. SUMMARY OF THE FACTS IN THE CASE

6. None of the relevant facts are in dispute. The evidence before the national court has established the following facts in relation to the objective characteristics and properties of the Thermacare product:

[1] OJ [2016] L No 189, 14.7.2016, p. 1.
[2] OJ [2016] L No 294, 28.10.2016, p. 1.

a. Thermacare is the brand name of a family of single use, disposable medical products which provide therapeutic heat therapy. The physiological effects of therapeutic heat provide the following medical benefits:

i. Analgesia: it stimulates nerves to relieve pain by blocking the transmission of pain signals;

ii. Reduced stiffness: it relaxes tight and sore muscles to improve flexibility and decrease stiffness; and

iii. Promotion of tissue healing: it increases circulation to provide more nutrients to damaged tissue and increases the rate of the cells' metabolic reactions to speed up the healing process in damaged tissue.

b. The products in the family are as follows: "Lower Back & Hip Heat Wraps", "Neck, Wrist & Shoulder Heat Wraps", "Flexible Use Heat Wraps", "Menstrual Heat Wraps", and "Knee & Elbow Heat Wraps". Some but not all are available in more than one size. Some but not all are available in two variants – one providing heat for 8 hours, and one providing heat for 12 hours.

c. The products share the following relevant features.

d. All of the products (except the "Flexible Use Heat Wraps" variation) are designed for use on a specific area of the body, for example, the lower back, hip, neck, shoulder or wrist. They are each flexible (and, except the "Flexible Use Heat Wraps", shaped) to conform securely to the relevant part of the body and to stay in place over the affected area by use of either adhesive strips or velcro fastening, depending on the product variation.

e. All the products are broadly composed of a fabric wrap with “heat cells” inside. The wrap is comprised of a synthetic cloth-like layered material which holds the heat cells in place and protects the user if the contents of the heat cells were to escape. The heat cells consist of a permeable (i.e., allowing air to pass through) synthetic material which forms the walls of the heat cell, and a mix of materials held within the cell (including iron powder, carbon, salt, and water).

f. The products are sold in a sealed pouch. When removed and exposed to air, they heat up. Specifically, when the mix of materials is exposed to air via the permeable heat cell wall, an exothermic reaction takes place which releases heat.

g. In order to provide a therapeutic effect the tissue temperature of the user must be elevated to at least 40°C. The heat cell wall has limited permeability, and this controls the rate of the reaction. This in turn results in safe and long-lasting therapeutic heat i.e. a constant temperature of 40°C which is maintained for between 8 to 12 hours, depending on the product variation.

h. Numerous published and peer-reviewed clinical studies show that therapeutic heat therapy, and specifically that provided by Thermacare products, has the

physiological effects with medical benefits identified above, being: (i) analgesia, (ii) reduced stiffness and (iii) promotion of tissue healing.

i. The therapeutic benefit of heat is confirmed in the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), which is based on the World Health Organisation's Ninth Revision of the International Classification of Diseases (ICD-9).

j. Heat therapy is also recognised and advised as treatment for e.g. back pain by various clinical guidelines published by recognised national bodies, including by the UK's National Institute for Health and Care Excellence ("NICE"), by the German Association for Quality Assurance in Medicine (Ärztliches Zentrum für Qualität in der Medizin), and by the American College of Physicians and the American Pain Society.

k. The products are presented and marketed specifically and exclusively for the purposes of heat therapy, to deliver benefits such as analgesia, reduced stiffness and acceleration of healing to damaged tissue.

l. The products are classified as “active medical devices” under Council Directive 93/42/EEC and have been approved and certified to carry a CE mark (European Conformity mark) by a notified body.

m. The products operate - as regards pain relief - in a similar way to a poultice (which uses a counterirritant to block the body's pain signals, and also to create surface heat), albeit the products operate in a more convenient and effective way and offer the additional medical benefits identified above.

n. The products are put up in forms or packings for retail sale.

7. Representative copies of the packaging of the products are at **Annex 2** to this Order for Reference.

8. Examples of the marketing material for the products are at **Annex 3** to this Order for Reference.

E. THE LEGAL FRAMEWORK

9. The Combined Nomenclature (“CN”) is based on the International Harmonised Commodity Description and Coding System (‘the HS’). The HS was drawn up by the Customs Cooperation Council, now the World Customs Organisation (“WCO”), and established by the International Convention on the Harmonised Commodity Description and Coding System (‘the HS Convention’) concluded in Brussels on 14 June 1983 and approved, with its amending protocol of 24 June 1986, on behalf of the European Economic Community by Council Decision 87/369/EEC of 7 April 1987 (OJ 1987 L 198, p. 1).

10. Under Article 3(1) of the HS Convention, each Contracting Party undertakes to ensure that its customs tariff and statistical nomenclatures are in conformity with the HS, to use all the headings and subheadings of the HS without addition or modification together with their related codes, and to follow the numerical sequence of that system. Each Contracting Party also

undertakes to apply the general rules for the interpretation of the HS and all the section, chapter and subheading notes of the HS, and not to modify their scope. The general rules for the interpretation of the CN ("the GIRs") are identical in their terms to the general rules for the interpretation of the HS.

11. The WCO is to approve, under the conditions laid down in Article 8 of the HS Convention, the Explanatory Notes and Classification Opinions adopted by the HS Committee.

12. The GIRs, which appear in Part One, Section I A, of the CN, provide inter alia:

"*Classification of goods in the [CN] shall be governed by the following principles:*

1. The titles of sections, chapters and sub-chapters are provided for ease of reference only; for legal purposes, classification shall be determined according to the terms of the headings and any relative section or chapter notes and, provided such headings or notes do not otherwise require, according to the following provisions.

2.

(a) Any reference in a heading to an article shall be taken to include a reference to that article incomplete or unfinished, provided that, as presented, the incomplete or unfinished article has the essential character of the complete or finished article. It shall also be taken to include a reference to that article complete or finished (or falling to be classified as complete or finished by virtue of this rule), presented unassembled or disassembled.

(b) Any reference in a heading to a material or substance shall be taken to include a reference to mixtures or combinations of that material or substance with other materials or substances. Any reference to goods of a given material or substance shall be taken to include a reference to goods consisting wholly or partly of such material or substance. The classification of goods consisting of more than one material or substance shall be according to the principles of rule 3.

3. When by application of rule 2(b) or for any other reason, goods are prima facie classifiable under two or more headings, classification shall be effected as follows:

(a) the heading which provides the most specific description shall be preferred to headings providing a more general description. However, when two or more headings each refer to part only of the materials or substances contained in mixed or composite goods or to part only of the items in a set put up for retail sale, those headings are to be regarded as equally specific in relation to those goods, even if one of them gives a more complete or precise description of the goods;

(b) mixtures, composite goods consisting of different materials or made up of different components, and goods put in sets for retail sale, which cannot be classified by reference to 3(a), shall be classified as if they consisted of the material or component which gives them their essential character, in so far as this criterion is applicable.

(c) when goods cannot be classified by reference to 3(a) or (b), they shall be classified under the heading which occurs last in numerical order among those which equally merit consideration

4. Goods which cannot be classified in accordance with the above rules shall be classified under the heading appropriate to
the goods to which they are most akin.

5. In addition to the foregoing provisions, the following rules shall apply in respect of the goods referred to therein:

(a) camera cases, musical instrument cases, gun cases, drawing-instrument cases, necklace cases and similar containers, specially shaped or fitted to contain a specific article or set of articles, suitable for long-term use and presented with the articles for which they are intended, shall be classified with such articles when of a kind normally sold therewith. This rule does not, however, apply to containers which give the whole its essential character;

(b) subject to the provisions of rule 5(a), packing materials and packing containers (1) presented with the goods therein shall be classified with the goods if they are of a kind normally used for packing such goods. However, this provision is not binding when such packing materials or packing containers are clearly suitable for repetitive use.

6. For legal purposes, the classification of goods in the subheadings of a heading shall be determined according to the terms of those subheadings and any related subheading notes and, mutatis mutandis, to the above rules, on the understanding that only subheadings at the same level are comparable. For the purposes of this rule, the relative section and chapter notes also apply, unless the context requires otherwise".

13. As regards the goods at issue in the main proceedings, the CN includes Section VI entitled "*Products of the chemical or allied industries*".

14. The section notes for Section VI include note 2, which provides as follows:

"*2. Subject to note 1 above, goods classifiable in heading 3004, 3005, 3006, 3212, 3303, 3304, 3305, 3306, 3307, 3506, 3707 or 3808 by reason of being put up in measured doses or for retail sale are to be classified in those headings and in no other heading of the nomenclature*".

15. Within Section VI, Chapter 30 contains heading 3005:

Description	CN code
Wadding, gauze, bandages and similar articles (for example, dressings, adhesive plasters, poultices), impregnated or covered with pharmaceutical substances or put up in forms or packings for retail sale for medical, surgical, dental or veterinary purposes	**3005**
- Adhesive dressings and other articles having an adhesive layer	3005 10 00 00
- Other	3005 90 00

- - Wadding and articles of wadding	3005 90 10 00
- - Other	3005 90 31
- - - Of textile materials:	3005 90 31
- - - - Gauze and articles of gauze	3005 90 31 00
- - - - Other	3005 90 50 00
- - - Other	3005 90 99 00

16. The Explanatory Notes to the HS ("HSEN") for heading 3005 sets out the following:

"***30.05 - Wadding, gauze, bandages and similar articles (for example, dressings, adhesive plasters, poultices), impregnated or coated with pharmaceutical substances or put up in forms or packings for retail sale for medical, surgical, dental or veterinary purposes***.

3005.10 - Adhesive dressings and other articles having an adhesive layer

3005.90 - Other

This heading covers articles such as wadding, gauze, bandages and the like, of textile, paper, plastic, etc., impregnated or coated with pharmaceutical substances (counter-irritant, antiseptic, etc.) for medical, surgical, dental or veterinary purposes.

These articles include wadding impregnated with iodine or methyl salicylate, etc., various prepared dressings, prepared poultices (e.g., linseed or mustard poultices), medicated adhesive plasters, etc. They may be in the piece, in discs or in any other form.

Wadding and gauze for dressings (usually of absorbent cotton) and bandages, etc., not impregnated or coated with pharmaceutical substances, are also classified in this heading, provided they are put up in forms or packings for retail sale directly to private persons, clinics, hospitals, etc., without repacking, and they are recognizable by their characteristics (presented in rolls or folded, protective packaging, labelling, etc.) as exclusively intended for medical, surgical, dental or veterinary uses.

This heading also covers the following types of dressings :

> *(1)* ***Cutaneous dressings*** *consisting of prepared frozen or lyophilised (dried) strips of animal skin tissue, usually porcine, used as temporary biological dressings for direct application to areas of skin loss, open tissue wounds, surgical infections, etc. They are available in various sizes and are packed in sterile containers (retail packings) labelled with information concerning their use.*

(2) ***Liquid dressings*** *put up in a spray can (retail packing) and used to cover wounds with a protective transparent film. They may consist of a sterile solution of a plastic (e.g., a modified vinyl copolymer or a methacrylic plastic) in a volatile organic solvent (e.g., ethyl acetate) and a propellant, whether or not with added pharmaceutical substances (antiseptics in particular).*

The heading ***excludes*** *bandages, adhesive plasters, etc., containing zinc oxide, and plaster-coated fracture bandages, not put up in forms or packings for retail sale for medical, surgical, dental or veterinary purposes.*

The heading also ***excludes*** *:*

*(a) Plasters specially calcined or finely ground for use in dentistry and preparations with a basis of plaster for use in dentistry (****headings 25.20*** *and* ***34.07*** *respectively).*

*(b) Medicaments put up in the form of transdermal administration systems (****heading 30.04****).*

*(c) Goods specified in Note 4 to this Chapter (****heading 30.06****).*

(d) Sanitary towels (pads) and tampons, napkins (diapers) and napkin liners for babies and similar articles ***of heading 96.19***".

17. The Explanatory Notes to the CN ("CNEN") for heading 3005 provide simply as follows:

"***3005 Wadding, gauze, bandages and similar articles (for example, dressings, adhesive plasters, poultices), impregnated or coated with pharmaceutical substances or put up in forms or packings for retail sale for medical, surgical, dental or veterinary purposes***
3005 10 00 *Adhesive dressings and other articles having an adhesive layer*
*This subheading does not cover liquid dressings (****subheading 3005 90 99****)*".

18. Also within Section VI, Chapter 38 contains heading 3824. The main sub-headings, and other relevant sub-headings under 3824 are below. See **Annex 4** for an extract of heading 3824 from the relevant published CN.

Description	CN code
Prepared binders for foundry moulds or cores; chemical products and preparations of the chemical or allied industries (including those consisting of mixtures of natural products), not elsewhere specified or included:	**3824**
- Prepared binders for foundry moulds or cores	3824 10 00
- Non-agglomerated metal carbides mixed together or with metallic binders	3824 30 00

- Prepared additives for cements, mortars or concretes	3824 40 00 00
- Non-refractory mortars and concretes	3824 50 00
- Sorbitol other than that of subheading 2905 44	3824 60 00
- Mixtures containing halogenated derivatives of methane, ethane or propane	3824 71 00 to 3824 79 00
- Goods specified in subheading note 3 to this chapter	3824 81 00 to 3824 88 00
- Other	3824 91 00
- - Other	3824 99 00
- - - Other	3824 99 45
- - - - Other	3824 99 75
- - - - - Other	3824 99 96
- - - - - - Other	3824 99 96 99

19. The HSEN and CNEN for heading 3824 are very lengthy and are not replicated here.

F. BACKGROUND TO THE CONTESTED REGULATION

20. In 2002, the German customs authorities issued BTIs classifying certain Thermacare products ("ThermaCare® Lower Back & Hip Heat Wraps", "ThermaCare® Neck, Wrist & Shoulder Heat Wraps" and "ThermaCare® Menstrual Heat Wraps") to CN heading 3005, applying GIR 1 and the HSEN.

21. A number of other BTIs were issued by the German and Slovakian customs authorities in respect of products similar to Thermacare in 2009, 2010 and 2012, each classifying those products to CN heading 3005, and each applying GIR 1, GIR 6, Note 2 to Section VI, and the HSEN.

22. In 2012, HMRC similarly issued two BTIs classifying certain Thermacare products to CN heading 3005, applying GIR 1 and the HSENs. Specifically, one of the BTIs classified "Menstrual Heat Wraps", "Neck, Wrist & Shoulder Heat Wraps", and "Knee & Elbow Heat Wraps" under sub-heading 3005 10 00 00 of the CN, and the other BTI classified "Lower Back & Hip Heat Wraps" under sub-heading 3005 90 50 00 of the CN on the basis it does not use medical adhesive to attach to the body.

23. The French customs authorities took a different view and in 2015, they requested that the classification of Thermacare products be considered by the European Commission, which referred the matter to the Customs Code Committee (Tariff and Statistical Nomenclature) (the "Nomenclature Committee").

24. The minutes of the Project Group concerning the Food Chapters of HS/CN meeting on 26 and 27 November 2015 state relevantly as follows:

> *11. Tariff classification of self-heating patches and belts to relieve pain, TAXUD/3263302/2015.*
>
> *The Chair presented the file related to the tariff classification of self-heating patches and belts to relieve pain and proposed a classification in CN code 3005 10 00, taking into consideration that these products:*
>
> - *are corresponding to the wording of this subheading because they are in the form of adhesive patches or belts which adhere with 'Velcro' type strips;*
> - *are for a medical purpose as heat therapy is an acknowledged method of treating pain listed in the 'International Statistical Classification of Diseases and Related Health Problems (IDC-9 -M)' under code 93.35;*
> - *are presented in packings for retail sale for medical purposes.*
>
> *One participant (NL) considered that more arguments needed to be found to enable a classification of these products in Chapter 30.*
>
> *Another participant (PL) informed that its administration has issued a BTI for a similar self-heating product with an adhesive in CN code 3824 90 97 and a BTI for a self-cooling product also in CN code 3824 90 97.*
>
> *A round of the table showed that there was a majority of 7 participants (BE, DK, ES, ET, PI, LV and PL) in favour of a classification under heading 3824. No participant was in favour of a classification under heading 3005 and 4 participants (BG, HU, NL and PT) abstained.*
>
> *Taking into account the results of this round of the table, a draft classification regulation related to these self-heating patches and belts to relieve pain was drafted during the meeting (working document TAXUD/5435320/2015).*
>
> *Action points: The Commission services will present the item together with a draft proposal for discussion at a forthcoming Committee meeting.*

25. The minutes of the Nomenclature Committee meeting on 10 October 2015 state relevantly as follows:

> *4.14 Tariff classification of self-heating patches and belts to relieve pain, TAXUD/3263302/2015 and TAXUD/5435320/2015.*
>
> *The Committee examined the tariff classification of self-heating patches and belts to relieve pain.*
>
> *The main question concerning these products is whether or not they have a therapeutic or prophylactic effect within the meaning of Chapter 30. If this is not the case, these products have the essential character of a preparation of heading 3824.*

After some editorial revision of the proposed classification Regulation, a round of the table indicated that the majority of the represented Member States was in favour of a classification under heading 3824.

Two Member States suggested using the term used in classification Regulation (EC) No 323/2008 related to different products and in particular concerning the heating belt filled with grains of cereals.

Two other Member States suggested using the term used in the classification Regulation (EU) No 1303/2011 related to a gel put up for the release of pain.

The Chair concluded by saying that an inter-service consultation will be launched with the revised draft classification Regulation with a view to presenting it for vote at a forthcoming Committee meeting or by written procedure.

26. Following a non-unanimous decision by that Committee, the contested Regulation was published in the Official Journal on 14 July 2016 and entered into force on the 20th day following its publication. The Annex to the contested Regulation provides as follows:[3]

Description of the goods	Classification (CN-code)	Reasons
(1)	(2)	(3)
1. A product in the form of a self-heating patch to relieve pain. The patch is made of adhesive material intended for attaching to the skin (neck, wrist or shoulder). The product is made of a soft synthetic material conforming to the body's shape and contains a number of discs which, on exposure to the air, generate heat. The discs contain iron powder, charcoal, salt and water. When the individual packets containing the patch are opened and exposed to air, an exothermic reaction takes place.	3824 90 96	Classification is determined by general rules 1, 3 (b) and 6 for the interpretation of the Combined Nomenclature and the wording of CN codes 3824, 3824 90 and 3824 90 96. The discs contained in the product are used as a heat source due to the exothermic reaction. This gives the product the essential character of a preparation of heading 3824. Therefore, the product cannot be considered as bandages and similar articles of heading 3005. Therefore, the product should be classified in CN code 3824 90 96.
2. A product in the form of a self-heating belt to relieve pain.	3824 90 96	Classification is determined by general rules 1, 3 (b) and 6 for the

[3] There was a change in the CN as regards heading 3824 between 2016 and 2017. The CN applicable in 2016, as set out in Regulation 2015/1754, classified under subheading 3824 90 96 (Prepared binders for foundry moulds or cores; chemical products and preparations of the chemical or allied industries (including those consisting of mixtures of natural products), not elsewhere specified or included: Other; Other; Other; Other) chemical products not classified under a more specific subheading. The equivalent classification under the CN version applicable in 2017, as set out in Regulation 2016/1821, changed to subheading 3824 99 96. For that reason, the contested Regulation adopted in 2016 and the BTI issued by HMRC in 2017 bear different subheadings, 3824 90 96 and 3824 99 96 respectively, which are nevertheless equivalent in terms of scope.

The belt is made of non-adhesive material, which is attached by means of a self-adhesive strip. The product is made of a soft synthetic material conforming to the body's shape and contains a number of discs which, upon exposure to air, generate heat. The discs contain iron powder, charcoal, salt and water. When the individual packets containing the belt are opened and exposed to air, an exothermic reaction takes place.		interpretation of the Combined Nomenclature and the wording of CN codes 3824, 3824 90 and 3824 90 96. The discs contained in the product are used as a heat source due to the exothermic reaction. This gives the product the essential character of a preparation of heading 3824. Therefore, the product should be classified in CN code 3824 90 96.

27. As a consequence of the contested Regulation, by letter dated 3 August 2016 HMRC revoked the BTIs they had issued to Pfizer in 2012, which classified the Thermacare products under heading 3005.

28. By an application on 12 September 2017, Pfizer applied for a new BTI for the Thermacare products under heading 3005, specifically sub-heading 3005 10. On 10 November 2017, HMRC issued a BTI classifying the Thermacare products under heading 3824. The justification set out in the issued BTI included reference to the contested Regulation.

29. By appeals lodged before the First-tier Tribunal (Tax Chamber) on 8 December 2017, the Appellant appealed against HMRC's decision set out in their letter of 10 November 2017. The grounds of the appeal set out legal arguments that the products are correctly classifiable to heading 3005 and that the contested Regulation was incorrect.

30. Following a hearing on 17 January 2019, the First-tier Tribunal found that Pfizer has arguable grounds on which to challenge the validity of the contested Regulation and that a reference should be made to the CJEU pursuant to Article 267 of the Treaty on the Functioning of the European Union.

G. THE DISPUTE IN THE MAIN PROCEEDINGS

31. The dispute between the parties turns on the validity of the contested Regulation and the proper CN classification of the Thermacare products.

(1) Submissions of Pfizer

32. Pfizer submits that the contested Regulation is invalid insofar as it classifies the Thermacare products under CN heading 3824. It submits that the Thermacare products must be classified under CN heading 3005 for the following reasons.

32.1. The decisive criterion for the classification of goods for customs purposes is in general to be sought in their objective characteristics and properties as defined in the wording of the relevant heading of the CN and in the section or chapter notes.

32.2. The products fall within the wording of heading 3005, being "*Wadding, gauze, bandages and similar articles (for example, dressings, adhesive plasters, poultices)…put up in forms or packings for retail sale for medical…purposes*":

> 32.2.1. They are similar to wadding, bandages, plasters and poultices, in that they are designed to be applied to the skin for medical purposes.
>
> 32.2.2. They perform a function similar to poultices particularly in relation to pain relief (also doing so by physiologically similar means), albeit in a more effective way and with additional medical benefits.
>
> 32.2.3. They are put up in forms or packings for retail sale for medical purposes, (see paragraphs 6(k), 7 and 8 above).

32.3. The products meet the requirements of "active medical devices" under EU legislation. Although that is not determinative by itself (see the CNEN to Chapter 30), it is nevertheless a relevant confirmatory factor.

32.4. The HSEN set out a broad approach to the scope of heading 3005, specifically refer to wadding and poultices "*in any form*" and contain no applicable exclusion.

32.5. Unlike (for instance) heading 3004, there is no requirement in heading 3005 that the products must be for "*therapeutic or prophylactic uses*" but in any event, as stated above the Thermacare products are designed and marketed specifically for medical and therapeutic purposes and uses (and have medical and therapeutic effects).

32.6. As the Thermacare products are classifiable under heading 3005 by reason of being "*put up in forms or packings for retail sale for medical … purposes*", they cannot be classified under any other heading of the CN, pursuant to Note 2 to Section VI.

32.7. Further, as heading 3824 is applicable only to products "*not elsewhere specified or included*", being classifiable under heading 3005 they cannot be classified under heading 3824.

32.8. Thus, applying GIR 1, the Thermacare products are classified under heading 3005.

32.9. Even if Note 2 to Section VI, and also the wording in heading 3824 noted above, were inapplicable, where goods are prima facie classifiable under two or more headings, it is necessary to apply GIR 3(a), according to which "*the heading which provides the most specific description shall be preferred to headings providing a more general description*". It is only where the application of that rule does not allow an appropriate classification of certain goods that it is necessary or permissible to apply GIR 3(b) and to classify such goods "*as if they consisted of the material or component which gives them their essential character*": Case C-288/15 MIS, at paragraph 29. In this case, applying GIR 3(a), there is a heading for the goods (i.e., 3005) that is more specific than heading 3824. As already stated, heading 3824 is a residual heading for products "*not elsewhere specified or included*" and so is inapplicable also for the purposes of GIR 3(a): see Case C-144/15 *Customs Support Holland BV*, at paragraphs 30 and 48. Heading 3005 also refers to a more limited range of goods and more clearly identifies the Thermacare products.

33. For all these reasons, the contested Regulation has wrongly reduced the scope of heading 3005 and accordingly the Commission has exceeded the powers conferred on it in Article 9(1)(a) of Regulation No 2658/87: see Case C-15/05 *Kawasaki*, at paragraph 35, and Case C-91/15 *Kawasaki*, at paragraph 62.

34. The contested Regulation states that classification to heading 3824 has been made according to the application of GIRs 1, 3(b) and 6. Pfizer submits that its reasoning is inadequate and incorrect:

> 34.1. GIR 3(b) applies to cases in which '*goods are prima facie classifiable under two or more headings*'. In this case, as the goods are classifiable under 3005, they cannot also be classifiable under 3824 because classification is determined conclusively at the GIR 1 stage by Note 2 to Section VI (and in this case by the wording of heading 3824 specifically stating it to be a residual heading).
>
> 34.2. Further, GIR 3(b) only applies to products which cannot be classified by reference to GIR 3(a). However, if for some reason the Thermacare products were not definitively classified to heading 3005 at the GIR 1 stage, they would be so classified by GIR 3(a), for the reasons stated above.

(2) The submissions of HMRC

35. The proper customs classification of the Thermacare products has been determined by the Commission Implementing Regulation (EU) 2016/1140 of 8 July 2016. There is nothing disclosed in the order for reference which calls into question the validity of the contested Regulation. The area of CN classification is a matter for the expert and discretionary judgment of the Commission and the Customs Code Committee. No manifest error of assessment has been disclosed. The classification adopted is correct for the reasons given and is consistent with the CNENs and the HSENs referred to above.

H. THE QUESTION REFERRED

36. The First-tier Tribunal accordingly refers the following question to the CJEU:

> 1. Is Commission Implementing Regulation (EU) 2016/1140 of 8 July 2016 concerning the classification of certain goods in the Combined Nomenclature invalid in so far as it classifies under CN code 3824, specifically 3824 90 96, products which:
>
> i. are composed of a bandage-like material, containing "heat cells" including chemicals,
>
> ii. operate in similar fashion to a poultice, though providing additional benefits,
>
> iii. through an exothermic chemical reaction relieve pain, decrease stiffness and promote tissue healing (as verified in multiple clinical trials),
>
> iv. are put up in forms or packings for retail sale, and

v. are explicitly presented and marketed as being for medical purposes and as producing the effects identified in (iii) above,

on the basis of the chemicals being the material or component which gives them their essential character and not under heading 3005 (on the basis of the wording of the relevant headings, section or chapter notes, and explanatory notes under General Rule of Interpretation 1, the operation of General Rule of Interpretation 3(a) requiring classification in accordance with the most specific description, or otherwise)?