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Judgment: approved by the Court for handing down | *Delivered:* **27/5/10**
*(subject to editorial corrections)**

IN HER MAJESTY'S COURT OF APPEAL IN NORTHERN IRELAND

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BETWEEN:

NORBROOK LABOATORIES LIMITED

Appellant;

-and-

THE VETERINARY MEDICINES DIRECTORATE

Respondent.

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Before: Morgan LCJ, Higgins LJ, and Coghlin LJ

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MORGAN LCJ (delivering the judgment of the court)

[1] This is an appeal from a decision of Weatherup J whereby he dismissed an application for judicial review of a decision by the Veterinary Medicines Directorate ("VMD"), an agency of the Department of the Environment Food and Rural Affairs, that a new product developed by the applicant, named NoroSeal, is a 'veterinary medicinal product by presentation' and thus requires a marketing authorisation under the Veterinary Medicines Regulations 2008. Mr Gordon QC appeared with Mr Scoffield and Ms Gray for the appellant and Mr McGleenan for the respondent. We are grateful to counsel for their helpful oral and written submissions.

Background

[2] When a dairy cow reaches the end of its milk production, it is said to be "dried off". In some cows the teat duct does not readily seal at drying off and can allow the ingress of bacteria through the external teat orifice into the teat canal, teat cistern and udder quarter. This can lead to a significant risk of developing mastitis.

[3] The applicant, Norbrook Laboratories Limited, is a pharmaceutical company. It developed a new product which it named 'Noroseal'. It is a thick paste that is introduced, by means of an internal applicator, into the distal teat canal. The label for Noroseal states, inter alia :

> "Udder Care from Norbrook Laboratories Limited.
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> …Contents: 4g paste containing bismuth subnitrate. NoroSeal provides a barrier in heifers and cows to promote and maintain healthy teats by forming a seal at the orifice of the teat. This seal is readily removed by milking the teat at the time of calving. Wear gloves while using. Wash hands after use."

[4] As stated on the label, NoroSeal contains bismuth subnitrate, an inert salt which is formulated into a highly viscous, malleable paste. Following infusion into the teat canal using the applicator, which has also been referred to as a "syringe-type device", the paste fills the fissures and folds of the teat canal, creating a physical barrier that effectively prevents the passage of microbes in the udder. Neither the bismuth sub-nitrate nor the mineral oil in which it is suspended exert conventional pharmacological actions and are totally non-toxic in nature.

[5] The Veterinary Medicines Regulations 2008, which transpose into national law Directive 2001/82/EC (as amended by Directive 2004/28/EC) ("the Directive"), provides at Regulation 4 that it is a criminal offence to place on the market a 'veterinary medicinal product' without a 'market authorisation' from the Secretary of State (administered by the VMD). Regulation 2(1) defines a 'veterinary medicinal product" in precisely the same terms as the Directive as either:

> "(a) any substance or combination of substances presented as having properties for treating or preventing disease in animals" [known as 'veterinary medicinal products by presentation'.]
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> or
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> "(b) any substance or combination of substances that may be used in, or administered to, animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis" [known as 'veterinary medicinal products by function'.]

[6] On 24 June 2008 the appellant wrote to the Irish Medicines Board with a classification enquiry as to whether the Norbrook teat seal constituted a veterinary medicinal product. By letter dated 9 July 2008 the appellant was advised by the Irish Medicines Board that the Norbrook teat seal fell within the scope of the veterinary licensing scheme under the Directive and required marketing authorisation. The appellant was advised of its appeal rights in relation to that decision but no appeal was pursued. Indeed there was further correspondence in May 2009 about the process of obtaining market authorisation.

[7] On 12 December 2008 the appellant wrote to the VMD asking for consideration of their teat seal as a non medicinal product. Proposed labelling was included which described the product as providing a film barrier in heifers and cow teats and indicated that the contents were contained in a 4g syringe. By letter dated 5 January 2009 VMD stated that it would not consider the product medicinal by function but asked for details of the syringe size and how the product would be presented. The appellant replied by letter of 12 May 2009 stating that it was not in fact administered by syringe as the applicator simply expelled the product but could not draw in. On 18 May 2009 VMD confirmed that it would not consider the product medicinal based on the description provided and the proposed labelling.

[8] On 10 July 2009 a commercial competitor complained to VMD that the appellant's unauthorised product was being marketed. That prompted a letter of 30 July 2009 from VMD to the appellant stating that the description in the letter of 12 May 2009 suggested that none of the product would enter the teat and it was not, therefore, considered an intramammary product. VMD now realised that this was not an external teat seal and regarded the product as medicinal. There was further correspondence on what was meant by intramammary but eventually on 21 September 2009 VMD indicated its view that the product was a veterinary medicinal product and required a marketing authorisation. It provided the following reasoning:

> "It is our view that Noroseal is a substance as defined in Article 1(4) of Directive 2001/82.
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> Noroseal prevents infection (mastitis) by forming a physical barrier to infection. A functional VMP prevents infection by exerting a pharmacological, immunological or metabolic action. Because Noroseal does not act by one of these routes we do not consider it to be a functional VMP.
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> We do, however, consider it to be a VMP by presentation despite the lack of specific medicinal claims in respect of the product.

> IN the van Bennekom case (C-227/88) the ECJ made it clear that the first limb of the definition of medicinal product in Directive 65/65/EEC and the concept of "presentation" must be construed broadly, and that presentation in a manner (or in a context) that gives rise to a reasonable inference on the part of a consumer that the product's purpose is to prevent disease is sufficient for it to fall within the first limb of the definition.
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> It is our view that this applies equally to veterinary medicines despite the slight differences in the wording of the definition of medicinal product in Directive 65/65 and Directive 2001/82.
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> We are also of the view that the Court would be inclined to construe the definition widely in view of the particular regulatory purpose of the legislation."

In a further letter dated 25 September VMD stated that the presentation of the product gave rise to a reasonable inference that the product's purpose was to prevent disease and that it therefore fell within the first limb of the definition of veterinary medicinal product. That letter enclosed the August newsletter for the Market Veterinary Centre which had an article on preventing early lactation mastitis and recommended the product for treating it.

[9] On 7 October 2009 the appellant applied for leave to apply for judicial review in respect of this decision. By way of interim relief the appellant sought to restrain any public authority from interfering with the marketing of the product pending the outcome of the proceedings. Although there was a detailed and substantial affidavit lodged to ground this application no reference of any kind was made to the enquiry which had been made to the authorities in the Republic of Ireland in respect of a teat seal product in June 2008 and which had been found to require an authorisation under the Directive the following month. It has long been established that there is a duty of candour on all applicants for leave to apply for judicial review to disclose all relevant matters including those adverse to the interest of the applicant (see Cocks v Thanet DC [1983] 2 AC 286). In this case where the applicant was pursuing an application for interim relief on the basis that this decision was not in accordance with European law the fact that a neighbouring member state had rejected such an argument a year earlier was plainly of significance. Treacy J granted leave and interim relief as requested on 9 October 2009 but we consider that he did so without being properly appraised of all relevant materials.

The legislative background

[10] The original Directive dealing with the regulation of medicines within the European Community was Directive 65/65/EEC. There is no need to set out its provisions except to note two of its recitals.

> Whereas the primary purpose of any rules concerning the production and distribution of proprietary medicinal products must be to safeguard public health;
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> Whereas, however, this objective must be attained by means which will not hinder the development of the pharmaceutical industry or trade in medicinal products within the Community;

The importance of these recitals is that they demonstrate that the balance between regulation in the interests of public health and the needs of a free market were already part of the legislative regime.

[11] Directive 2001/82/EC as amended is that with which we are concerned. Recitals two and three establish the primacy of the need to safeguard public health while recognising the objective of not hindering the development of trade and industry in medicinal products. Recital 6 addresses the importance of having full information on the characteristics of veterinary medicinal products. It is clear to us as it was to the learned trial judge that all such information was not available when VMD made its initial decision in May 2009.

[12] Article 1 defines veterinary medicinal product in precisely the same terms as the implementing legislation as set out in paragraph 5 above. Article 5 provides that no veterinary medicinal product may be placed on the market unless a marketing authorisation has been granted. For the purposes of these proceedings the Directive was implemented by the Veterinary Medicines Regulations 2008 which define veterinary medicinal product as set out at paragraph 5 above and make it an offence in Regulation 4 to place a veterinary medical product on the market without an authorisation.

The interpretation of the Directive

[13] The principal ground of appeal advanced by the appellant was its submission that there was a relationship between the reference to "properties" in Article 1(2)(a) of the Directive and the medicinal properties referred to in Article 1(2)(b). The appellant argued that the existing case-law was distinguishable on the grounds that it related to either the now repealed Directive 65/65/EEC governing both veterinary and human medicines or Directive 2001/83/EC on human medicines. It was submitted that the analogous provisions in these Directives were materially different to the

relevant provisions in the present Directive 2001/82/EC on veterinary medicines. The most important difference was the definition of "presentation" in Article 1(2)(a) which was amended by Directive 2004/28/EC to read "presented as having properties for treating or preventing disease". The appellant, therefore, submitted that it was essential that the presentation of the product must identify the "properties" which are said to have the result of treating or preventing disease. The appellant further argued that Article 1(2)(a) and 1(2)(b) must be read as one and, therefore, the phrase "treating or preventing disease" in 1(2)(a) must be interpreted as meaning "restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis" as mentioned in 1(2)(b).

[14] The first of the leading cases in this area is Case 227/82 Officier Van Justitie v Leendert Van Bennekom [1985] 2 CMLR 692. The defendant was a wholesaler selling vitamin tablets and was being prosecuted under domestic law relating to pharmaceutical drugs. The preparations were in tablet, pill and capsule form but contained no indication or recommendation of therapeutic of medicinal effect. The first question for the court was whether products such as the vitamin preparations at issue, which were not 'indicated or recommended' expressly as being suitable for curing, treating or preventing an infection, may none the less be substances 'presented for treating or preventing disease in human beings or animals' within the meaning of the Community definition of 'medicinal product' in Directive 65/65/EEC. The court took the view that the objective of Directive 65/65/EEC was not only to preserve customers from harmful or toxic medicinal products as such but also from a variety of products used instead of the proper remedies. Accordingly the concept of the 'presentation' of a product had to be broadly construed.

[15] The court then considered the circumstances in which a product is presented for treating or preventing disease in paragraphs 18 and 19.

> "[18] It is therefore necessary to take the view that a product is 'presented for treating or preventing disease' within the meaning of Directive 65/65 not only when it is expressly 'indicated' or 'recommended' as such, possibly by means of labels, leaflets or oral representation, but also whenever any averagely well-informed consumer gains the impression, which, provided it is definite, may even result from implication, that the product in question should, regard being had to its presentation, have an effect such as is described by the first part of the Community definition.

> [19] In particular, the external form given to the product in question— such as that of a tablet, pill or capsule— may in this connection serve as strong evidence of the seller's or manufacturer's intention to market that product as a medicinal product. Such evidence cannot, however, be the sole or conclusive evidence, since otherwise certain food products which are traditionally presented in a similar form to pharmaceutical products would also be covered."

In our view the interpretation of paragraph 19 depends upon the analysis at paragraph 18. The latter paragraph recognises that a product may be presented by the manufacturer for treating or preventing disease with that intention or may be so presented as a result of the impression gained by the averagely well informed consumer. The external form given to the product may be relevant to ascertaining the manufacturer's intention but may also, of course, be material to the impression gained by the averagely well informed consumer. This passage certainly does not support the proposition advanced by Mr Gordon that a product can only be presented as medicinal if that is the intention of the manufacturer.

[16] The next case is Case C-369/88 The Republic (France) v Jean-Marie Delattre [1993] 2 CMLR 445. Mr Delattre sold slimming and other lifestyle products in France by mail order. The products carried a statement in their packaging that they were not medicinal. The relevant regulatory authority lodged a claim for damages on the basis that the products were medicinal by presentation and that they were being marketed without an authorisation. The court confirmed that a broad construction of presentation was appropriate. At paragraph 39 of its opinion the court found that this was "to protect consumers against the marketing of products which do not have therapeutic properties or do not have the properties attributed to them." The reference to "properties" suggests that little weight should be attached to the introduction of this concept in Article 1(2)(a) by Directive 2004/28 EC. The court went on to observe that a statement in the packaging that a product is not a medicinal product is persuasive evidence which the national court may take into consideration but it is not in itself conclusive.

[17] The third relevant case is C-219/91 Johannes Stephanus Wilhelmus ter Voort [1995] 2 CMLR 591. The defendant imported and sold herbal teas. There was no representation on the packaging or otherwise to suggest that it had medicinal qualities. A third party did however send out brochures at the request of members of the public setting out the therapeutic properties of the products sold and indicating that they complemented any medicines being taken. This was a case, therefore, where apart from the representation by the third party there was no other feature identified by the court as presenting the product as medicinal. The court unsurprisingly held that if the third party

was not acting completely independently of the manufacturer there may be a presentation but equally unsurprisingly that if the third party was acting on his own initiative and completely independently there was no intention on the part of the manufacturer to present the product as medicinal. That conclusion does not, however, assist the appellant since in that case there was no other feature of the presentation of the product which would have caused the product to appear to be a medicinal product in the eyes of an averagely well informed consumer.

[18] We do not accept that the words introduced by Directive 2004/28/EC have altered the approach to interpretation of Article 1(2) of the Directive. Mr Gordon was unable to find any explanation for the amendment which suggested the effect for which he contended and the reference to "properties" in Delattre strongly suggests otherwise. It is in our view clear from the case law on Directive 65/65/EEC that no such relationship was identified by the court in the cases set out above and van Bennekom makes it plain that the presentation of a product as medicinal can arise by implication as a result of the impression formed on the averagely well informed consumer whatever the intention of the manufacturer. If it had been the intention to alter that established line of authority the amendment introduced by Directive 2004/28/EC could not on any construction have achieved that object.

[19] A second line of argument developed by Mr Gordon concerned the second and third recitals in the Directive. He submitted that the third recital was intended to secure the objective of free movement of goods within the EU. That objective argued for a restrictive interpretation of presentation. In particular when conjoined with the need for legal certainty he submitted that the proper approach to interpretation must be that presentation required an intention to present on the part of the manufacturer or seller.

[20] We do not accept that submission. Although it is clear that the third recital is intended to reflect a commitment to the free movement of goods within the EU it is relevant to note that a similar commitment was contained in the much shorter recitals to Directive 65/65/EEC. That did not prevent the court taking the view that the approach to the interpretation of presentation should be broad in order to secure the primary objective of safeguarding of public health. We also reject the submission that such an approach falls foul of the need for legal certainty. A test based on the impression formed by the averagely well informed consumer is an objective test similar to that used in many legal contexts. In this area the manufacturer also has the advantage of the opinion of the VMD as long as full information on the product is provided. We do not consider, therefore, that the appellant is correct in its submission on the interpretation of the Directive.

The first instance decision

[21] The learned judge found that Noroseal was a medicinal product by presentation. The essence of his reasoning was set out at paragraphs 31 to 33.

> "[31] VMD must make a judgment case by case in relation to the requirement for a marketing authorisation. A product may be a medicinal product by presentation based on the objective test of the average well informed consumer. The product is judged on its presentation. Does the presentation of NoroSeal give the impression that it should have the properties for treating or preventing disease? In the present case that question relates to whether the presentation gives the impression that the product should have properties that prevent mastitis. The average well informed consumer must be taken to know how NoroSeal will actually apply to the animal. That knowledge will inform the consumer that the substance will be placed through the teat orifice into the teat canal and the distal teat cistern. The average well informed consumer must also be taken to be aware of the nature of mastitis.
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> [32] The indicators of properties for disease prevention are the manner of application by the use of the applicator, the nature of the substance in the form of a paste, the use of a substance that is applied internally through the teat orifice to the teat cistern and canal, the packaging and product literature showing the use of the applicator to apply the substance to the teat, the inclusion in the ingredients of the anti infective iodine and the warnings about the need for aseptic measures. The contra-indicators are the statements that the product is concerned with udder care, that the product is non medicinal and the absence of any claims in relation medicinal properties. I am satisfied that the average well-informed consumer would gain the impression that NoroSeal should have properties for preventing mastitis.
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> [33] The presentation will be that of the applicant. However that is not limited to the terms by which or the manner in which the producer elects to package or describe or classify the product. Regard will be had

> to the warnings and express indications and recommendations but they are not conclusive of the position. Nor can the claims of third parties fix a product as being medicinal by presentation but those claims, if from a competent authority, may provide some indication of the views of an average well informed consumer."

Having regard to our conclusion on the correct legal test for the determination of the issue as to whether the product was medicinal by presentation we consider that the learned judge applied the correct test.

[22] There were a number of further maters raised on behalf of the appellant. First it was argued that the learned judge was incorrect to find that the product was a substance rather than a device. Although it was conceded the definition of "substance" in the Directive was very wide the appellant submitted that the definition must be interpreted as meaning that the product must be a substance which reacts with the animal in one of the ways set out in Article 1(2)(b). We have already rejected the argument on the relationship between that provision and Article 1(2)(a) and we consider that the same must inevitably follow here. We see no reason to interfere with the finding of the learned trial judge on this issue.

[23] The appellant pursued an argument on legitimate expectation firstly on the basis that the decision to require the authorisation made in September 2009 did not arise from any material change of circumstance. It is clear to us that this argument is unsustainable since the manner in which the product was to be administered in order to effect the necessary barrier was not disclosed initially. A second argument was advanced on the basis of a statement in VMD's guidance that products which do not contain medical ingredients and make no medicinal claims may be marketed without a marketing authorisation. That argument leaves out of account, however, the earlier advice in the same paragraph of the VMD Guidance that teat dips are considered to be medicinal by presentation since they are used as aids for the prevention of mastitis. No issue of legitimate expectation in our view arises in this case and it is therefore unnecessary to explore the argument advanced by Mr McGleenan that in any event a legitimate expectation could not prevent VMD from fulfilling its public obligation as a regulator.

[24] The appellant advanced in the court below an argument that the withdrawal of the authorisation was disproportionate having regard to the contention that the product was not likely to pose any danger to public health. In fact the papers show that a significant number of animals are adversely affected by the administration of teat seals of this type so that the regulatory regime has a real purpose. The primary need to protect human health means that the balance must be struck in favour of the authorisation

process as required by community law. We also agree with the approach taken by the learned trial judge to the submission that the appellant's rights under Article 1 Protocol 1 were breached.

[25] The last point raised by the appellant is the argument that there was unfairness in the procedure because the appellant did not see the representation made by the competitor in July 2009 before the authorisation was withdrawn. It is clear, however, that the appellant and VMD engaged in a series of meetings and correspondence dealing with all of the issues in this case prior to the decision made on 21 September 2009 so that the appellant had every opportunity to make its case and make effective representations.

[26] In light of the dearth of evidence disclosed by the appellant on its application for authorisation to the authorities in the Republic of Ireland we do not consider it appropriate to explore further the respondent's notice.

[27] Article 267 TFEU provides that where we consider it necessary to enable us to give judgment we may refer the matter to the Court of Justice. The appellant invited us to take that course on the basis that the arguments advanced had not been considered by the court. For the reasons set out above we do not consider that it is necessary to refer the issues in order to give judgment and accordingly decline the invitation to refer the matter to Europe. We are not satisfied that any of the grounds of appeal have been made out and we dismiss the appeal.