Case C-147/20

Request for a preliminary ruling

Date lodged:

23 March 2020

Referring court:

Landgericht Hamburg (Germany)

Date of the decision to refer:

27 February 2020

Applicant:

Novartis Pharma GmbH

Defendant:

Abacus Medicine A/S

Landgericht Hamburg (Regional Court, Hamburg)

File ref.: 312 0 177/19

Order

In the matter of

Novartis Pharma GmbH, represented by its managing director XXX, Roonstrasse 25, 90429 Nuremberg

– Applicant –

[…]

v.

Abacus Medicine A/S, represented by its Managing Director, Vesterbrogade 149, 1620 Copenhagen V, Denmark

– Defendant –

[…]

the Regional Court, Hamburg — Civil Chamber 12 — […] ordered as follows on 27 February 2020: **[Or. 2]**

I.

The proceedings are stayed.

II.

1. The following questions on the interpretation of Articles 9(2) and 15 of Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trade mark ('Regulation (EU) 2017/1001' or 'the EUTMR') in conjunction with Articles 54(o) and 47a of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use ('Directive 2001/83/EC') and on Article 5(3) of Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 ('Regulation (EU) 2016/161') are referred to the Court of Justice of the European Union for a preliminary ruling under Article 267 of the Treaty on the Functioning of the European Union (TFEU):

First question:

Can it lead to an artificial partitioning of the markets within the meaning of the case-law of the Court of Justice if the safety features of original outer wrapping/original packaging which are provided for under Article 54(o) and Article 47a of Directive 2001/83/EC can, in the event that the parallel trader retains that original packaging, be replaced in compliance with Article 47a(1)(b) of that directive only in such a way that visible traces of opening remain after the originally existing safety features have been partly or fully removed and/or covered?

Second question:

Is it of significance for answering the first question whether the traces of opening become visible only when the medicinal product has been thoroughly inspected by wholesalers and/or persons authorised or entitled to supply medicinal products to the public, such as pharmacies, in fulfilment of their obligation under Articles 10, 24 and 30 of Regulation (EU) 2016/161, or may be overlooked in a superficial inspection? **[Or. 3]**

Third question:

Is it of significance for answering the first question whether the signs of opening become visible only when the packaging of a medicinal product is opened, for example by the patient?

Fourth question:

Is Article 5(3) of Regulation (EU) 2016/161 to be interpreted as meaning that the barcode containing the unique identifier within the meaning of Article 3(2)(a) of that regulation must be printed directly on the packaging, so that Article 5(3) is not complied with if a parallel trader affixes the unique identifier to the original outer packaging using an additional external sticker?

Grounds

I.

The parties are in dispute as to whether the defendant is authorised to import the applicant's original medicinal products 'Votrient 200 mg film-coated tablets' and 'Votrient 400 mg film-coated tablets' in parallel and to distribute each of them in a new outer wrapping/packaging sent to the applicant by the defendant, or whether the defendant must instead continue to distribute the opened original packaging from the applicant's group of companies and affix a new anti-tampering device.

The applicant holds the exclusive rights of use over the word marks EM 000304857 'Novartis' for Class 5 and IR896377 'Votrient' for Class 5, which it uses for the medicinal products 'Votrient 400 mg film-coated tablets' and 'Votrient 200 mg film-coated tablets' (Annex K 1). The applicant has been authorised by agreement to represent the trade mark proprietor, Novartis AG, in legal proceedings. The applicant markets the medicinal product 'Votrient 200 mg film-coated tablets' in packets containing a bottle of 30 film-coated tablets and in packets containing a bottle of 90 film-coated tablets. It distributes the medicinal product 'Votrient 400 mg film-coated tablets' in packets containing bottles of 30 or 60 film-coated tablets.

Since 9 February 2019 at the latest, the applicant has been equipping its original packaging with an anti-tampering device as per Annex K 11. **[Or. 4]**

In Germany the defendant primarily distributes reimported and parallel-imported medicinal products of manufacturers from other EU Member States. It inter alia offers as parallel imports the medicinal product 'Votrient 200 mg film-coated tablets' in packets containing a bottle of 30 film-coated tablets or of 90 film-coated tablets and the medicinal product 'Votrient 400 mg film-coated tablets' in packets containing a bottle of 30 film-coated tablets or of 60 film-coated tablets.

Prior to further distribution, the defendant must open the applicant's original packaging, including the anti-tampering device as per Annex K 11, in order to be able to create a packet suitable for distribution pursuant to Paragraph 10 of the Arzneimittelgesetz (Law on medicinal products, 'the AMG').

The defendant sent the trade mark proprietor sample packets both for the medicinal product 'Votrient 200 mg film-coated tablets' in packets containing a bottle of 30 film-coated tablets and in packets containing 90 film-coated tablets as

per annex bundle K 3 and for the medicinal product ‘Votrient 400 mg film-coated tablets’ in packets containing a bottle of 30 film-coated tablets and in packets containing 90 film-coated tablets (Annex K 4). In sending those sample packets, the defendant announced that it would not be selling the aforementioned medicinal products in their original outer wrapping/original packaging, but would be repackaging them.

The applicant believes, however, that it has a right of prohibition under Article 9(2) of Regulation (EU) 2017/1001. It maintains that its trade mark rights are not exhausted for the purposes of Article 15(2) of Regulation (EU) 2017/1001, because the defendant is able to affix adhesive labels to the original Votrient packaging, which also shows the barcode as a unique identifier within the meaning of Article 3(2)(a) of Regulation (EU) 2016/161. In that regard, the same applies as for the other labelling elements which a parallel trader was required to affix using adhesive labels in German even before the national laws transposing Directive 2011/62/EU of the European Parliament and of the Council of 8 July 2011 (‘Directive 2011/62/EU’) were applicable. The applicant adds that it is possible for parallel importers to open the original Votrient packaging (and, in so doing, to open an anti-tampering device used by the original manufacturer), to insert their own user information in German into the original packaging and to seal the opened original packaging using their own new anti-tampering device, for example a slightly larger seal that completely covers the traces of previous opening. In order to dispel doubts as to the integrity of the medicinal products, parallel importers may also indicate that the newly affixed seal has been affixed by them, the parallel importers, as part of an authorised repackaging process. The opening of the packaging by the parallel importer is discernible in any event, since, according to the case-law of the Court of Justice, it is necessary to indicate clearly on the packaging **[Or. 5]** the fact that the medicinal product has been repackaged, the repackager of the medicinal product and the name of the manufacturer of the medicinal product.

The applicant states that is has a right of prohibition against the defendant under Article 9(2) of Regulation (EU) 2017/1001.

In its submission, only two components have been added to the previous labelling requirements: the anti-tampering device and the unique identifier (UI). Both can be implemented by means of labels. Although trade in parallel imports may serve as a gateway for counterfeit medicinal products, this does not mean that the forms of repackaging notified by the defendant are necessary. For reasons of transparency, it is safer for the patient to recognise that a product is a labelled original product and not a counterfeit. In any event, wholesalers and pharmacies are accustomed to a very wide variety of packaging. Patients, pharmacies and wholesalers as well as doctors are aware that parallel-imported products satisfy the labelling requirements in Germany by means of additionally affixed labels.

According to the applicant, the opinion poll report in Annex B 23 is not of decisive importance, because it is irrelevant whether individual economic

operators consider new packaging to be desirable. The security of each individual packet is what is essential. The European legislature laid the foundations for this with the Falsified Medicines Directive, which has been transposed by the national legislatures. Under that directive, new packaging is not necessary in principle. New packaging does not serve to increase the safety of parallel imports. Rather, the legislature's method of choice for ensuring the quality of imported goods is a consistent review of the quality assurance for parallel imports.

The applicant contests the defendant's argument that it cannot ensure the durability of a sticker due to the silicone coating of the original packaging.

The applicant requests that:

> the defendant be prohibited, on pain of a fine of up to EUR 250 000 — alternatively a term of imprisonment — or a term of imprisonment not exceeding six months, to be enforced against the managing director of the defendant,
>
> from **[Or. 6]**
>
> 1. placing on the market and/or having placed on the market and/or promoting and/or having promoted 'Votrient 200 mg film-coated tablets' imported in parallel into Germany in packs containing a bottle of 30 film-coated tablets and/or in packs containing a bottle of 90 film-coated tablets, each in repackaged configurations;
>
> and/or
>
> 2. placing on the market and/or having placed on the market and/or promoting and/or having promoted 'Votrient 400 mg film-coated tablets' imported in parallel into Germany in packs containing a bottle of 30 film-coated tablets and/or in packs containing a bottle of 60 film-coated tablets, each in repackaged configurations.

The defendant requests that:

> the action be dismissed.

The defendant maintains that the opening of the applicant's sealing label by the defendant leads to visible, irreversible damage or changes to the packaging or the label or adhesive tape. The defendant cannot affix the unique identifier to the original packaging by means of a label, because it can be removed again due to the silicone coating of Votrient's packaging. Printing pursuant to Article 5(3) of Delegated Regulation (EC) No 2016/161, which states that '*manufacturers shall print the barcode on the packaging on a smooth, uniform, low-reflecting surface*', is not possible.

It takes the view that, as a parallel importer, it is therefore forced to use its own packaging for distribution in Germany, on which it can then print the unique identifier or barcode and which it can seal with its own anti-tampering device. The applicant's original packaging can no longer be used. Due to the paradigm shift brought about by the implementation of the Falsified Medicines Directive, and due to the direct applicability of Regulation (EU) 2016/161, only completely clean medicinal product packaging showing no traces of tampering can be marketed, even in the case of parallel distribution.

The applicant therefore does not have the right of prohibition asserted by it.

The defendant also takes the view that it is not permissible for the parallel trader to open the original packaging and reseal it using its own new **[Or. 7]** anti-tampering device. The reason for this is that, in the case of Votrient, new anti-tampering devices cannot be affixed without leaving visible traces of opening, which, in turn, means that the safety features cannot be effective.

In the case of the Votrient medicinal products at issue, transparent adhesive seals are affixed to both the top and the underside of the packaging flap. The packaging surface required for the seal is not contaminated with a silicone coating, meaning that when the sealing label is torn off it leaves visible signs of tampering. If the defendant's sealing label is affixed to this damaged surface, traces of tampering remain visible, as can be seen from the photograph on page 66. Furthermore, the damage to the surface of the packaging is still noticeable despite the fact that a new seal has been affixed.

The defendant further states that affixing the new unique identifier by superimposing it on the old one is also out of the question because the new sticker might be peeled off, so that patients can see that the PC and SN number series specified in each case do not match. Such circumstances affect the integrity of the product.

II.

The success of the action pursuant to Article 9(2) and Article 15 of Regulation (EU) 2017/1001 depends on how Article 54(o) and Article 47a of Directive 2001/83/EC and Article 5(3) of Regulation (EU) 2016/161 are to be interpreted. If the repackaging by the defendant in new packaging infringes the principles laid down by the Court of Justice in, inter alia, the *Bristol-Myers-Squibb* decision (judgment of 11 July 1996, Case C-427/93), the applicant may have the right of prohibition under Article 9(2) of the EUTMR asserted in the present case. However, if the applicant's reliance on its trade mark rights is capable of resulting in an artificial partitioning of the markets, the defendant's defence may be successful. If Article 5(3) of Regulation (EU) 2016/161 imposes an obligation on the defendant to print the barcode directly on the packaging of the medicinal product, this may require the use of new outer packaging. **[Or. 8]**

Questions 1 to 3

These questions are referred on the basis of the following considerations:

The success of the defendant's defence depends on whether the trade mark proprietor cannot oppose the repackaging of the product in new outer wrapping because the defendant is obliged under Paragraph 10(1c) of the AMG, Article 54a, Article 54(o) and Article 47a of Directive 2001/83/EC and in accordance with Articles 4, 5 and 17 of Commission Regulation (EU) 2016/161 to affix equivalent safety features to the packaging, but, in the present case — the details of which are in dispute — that replacement could leave visible traces. If, due to the obligations under Article 54a of Directive 2001/83/EC and Articles 4, 5 and 17 of Regulation (EU) 2016/161, the fact that visible traces were left behind would require the original outer wrapping/original packaging to be replaced by new outer wrapping, the applicant would not have a right of prohibition under Article 9(2) of Regulation (EU) 2017/1001.

Paragraph 10(1c) of the AMG reads:

> (1c) In the case of medicinal products for human use, safety features and a device for detecting possible tampering with the outer packaging must be affixed to the outer packaging, in so far as this is required by Article 54a of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67), last amended by Directive 2011/62/EU (OJ 2011 L 174, p. 74), or is laid down on the basis of Article 54a of Directive 2001/83/EC.

According to the defendant, there is evidence that visible traces of opening are not accepted in the course of trade. Thus, three of the five leading companies in the pharmaceutical wholesale sector demand packaging without damage and do not accept medicinal product packaging on which there are traces of opening. The defendant has also submitted evidence to show that pharmacists and patients also consider new packaging to be more trustworthy than original packaging that has a seal stuck on top of it or has been sealed for the first time.

Fourth question:

The Chamber considers the fourth question to be material to the decision in the present case. **[Or. 9]**

The success of the defendant's defence depends on whether the trade mark proprietor cannot oppose the repackaging of the product in new outer wrapping because the defendant is obliged under Paragraph 10(1c) of the AMG and Article 54a of Directive 2001/83/EC and in accordance with Article 5(3) of Regulation (EU) 2016/161 to print the safety features of the barcode directly on the packaging pursuant to Article 5(3) of Regulation (EU) 2016/161.

If the defendant, as a parallel importer, is obliged to print the barcode directly on the packaging pursuant to Article 5(3) of Regulation (EU) 2016/161, the Chamber

takes the view that, for this reason, the further use of the original outer wrapping/original packaging is not possible and repackaging in completely new outer wrapping is necessary.

[Signatures]