Case C-204/20

Request for a preliminary ruling

Date lodged:

13 May 2020

Referring court:

Landgericht Hamburg (Germany)

Date of the decision to refer:

2 April 2020

Applicant:

Bayer Intellectual Property GmbH

Defendant:

kohlpharma GmbH

Landgericht Hamburg (Regional Court of Hamburg, Germany)

[…]

Order

In the matter of

Bayer Intellectual Property GmbH, […] Monheim

– Applicant –

[…]

v

kohlpharma GmbH, […] Merzig

– Defendant –

[…]

the Landgericht Hamburg (Regional Court, Hamburg) […] ordered as follows on 2 April 2020:

I. The proceedings are stayed.

II. The following questions on the interpretation of Article 47a of Directive 2001/83/EC ('Community Code relating to medicinal products for human use') and Article 15 of Directive 2015/2436 ('Trade Mark Directive') 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:

Question 1:

Is Article 47a of Directive 2001/83/EC to be interpreted as meaning that, in the case of parallel imported products, the measures for the removal and reaffixing of the safety features pursuant to point (o) of Article 54 of Directive 2001/83/EC, which are carried out by the **[Or. 2]** parallel importer either by means of relabelling (use of adhesive labels on the original secondary packaging) or by means of reboxing (production of new secondary packaging for the medicinal product), can be considered equivalent if both measures otherwise comply with all the requirements set out in Directive 2011/62/EU ('Falsified Medicines Directive') and Delegated Regulation (EU) 2016/161 ('Delegated Regulation') and are equally effective in enabling the verification of authenticity and identification of medicinal products and in providing evidence of tampering with medicinal products?

Question 2:

If the first question is to be answered in the affirmative: In the light of the new anti-falsification rules, can a trade mark owner oppose the repackaging of the product in new external packaging ('reboxing') by a parallel importer where the parallel importer is also able to achieve packaging which may be marketed in the Member State of importation by merely affixing new adhesive labels to the original secondary packaging ('relabelling')?

Question 3:

If the second question is to be answered in the affirmative, is it the case that no harm is done if, in the case of relabelling, it is apparent to the relevant public that a safety feature of the original supplier has been damaged, as long as it is ensured that the parallel importer is responsible for this and has affixed a new safety feature to the original secondary packaging? Does it make any difference whether the signs of opening become visible only when the secondary packaging of a medicinal product is opened?

Question 4:

If Question 2 and/or 3 is to be answered in the affirmative, must repackaging by means of 'reboxing' nevertheless be deemed to be objectively necessary within the meaning of the five conditions for exhaustion in respect of the repackaging (see […] judgments of 11 July 1996, *Bristol-Myers Squibb and Others*, C-427/93, C-429/93 and C-436/93, EU:C:1996:282, paragraph 79, and of 26 April 2007, *Boehringer Ingelheim and Others*, C-348/04, EU:C:2007:249, paragraph 21) if the national authorities state, in their current guidelines for implementing the requirements of the Falsified Medicines Directive or other such announcements of the authorities, that the resealing of opened packaging is not normally accepted or, at least, is accepted only on an exceptional basis and under strict conditions? **[Or. 3]**

Grounds:

I.

The applicant opposes the parallel import of a medicinal product for which new packaging ('reboxing') is to be produced even though — according to the applicant — the affixing of a new label ('relabelling') is less of an encroachment on its trade mark rights. The parties to the present proceedings are ultimately in dispute as to the extent to which the new provisions of Directive 2011/62/EU ('Falsified Medicines Directive') and Delegated Regulation (EU) 2016/161 ('Delegated Regulation') affect the requirements imposed on parallel imports.

1. The relevant facts:

The applicant is the owner of the German trade mark ANDROCUR and is part of the Bayer Group. ANDROCUR (active ingredient: cyproterone acetate) is a hormone preparation that is sold, inter alia, in Germany. The trade mark ANDROCUR is protected in respect of '*medicines, chemical preparations for healing purposes and health care, pharmaceutical drugs*'. The trade mark was originally registered in the name of Schering Aktiengesellschaft on 2 November 1956. After several changes to the company name, the trade mark was assigned to the applicant in 2012 […].

The defendant is the largest German importer of medicinal products. By letter of 28 January 2019, it announced to the applicant that it would be importing the medicinal product ANDROCUR 50 mg from the Netherlands in packs of 50 film-coated tablets and distributing it in Germany in packs of 50 and 100 tablets. In subsequent correspondence, the defendant stated that the imported outer packaging of the medicinal product was sealed in accordance with the requirements of the Falsified Medicines Directive and that the seal would have to be broken for the purposes of parallel importation, meaning that relabelling was not possible and reboxing was necessary.

The applicant expressly objected to the planned reboxing, referring to the possibility of less invasive repackaging methods in the form of relabelling, and requested that the defendant give a legally binding assurance that it would refrain from carrying out the reboxing that had been announced. The defendant refused to do so.

[…]

2. Applicant's arguments

The applicant submits that it is possible and legally sufficient for the side flaps (or one of the side flaps) of the packaging for the medicinal product to be sealed with a type of adhesive seal after being opened by the parallel importer. This would generally be a round or rectangular transparent or coloured adhesive label. Even when **[Or. 4]** removed, it leaves clear traces on the packaging, meaning that any tampering by an unauthorised party would be immediately visible. Legally, both variants of the 'anti-tampering device' ('ATD') are regarded by the legislature as being equally effective (see DIN EN 16679). The applicant takes the view that there is no principle, of any kind, according to which repackaged medicinal products must always be marketed with (unopened) perforated packaging. The assessment as to whether reboxing is actually necessary is subject to strict requirements. In particular, one condition is that relabelling would prove to be a barrier that would hinder the parallel importer's access to the market to a not insignificant extent. The prevailing view is that purely economic considerations do not justify such reboxing […]. Nor would a possible consumer preference — which does not actually exist — for newly manufactured outer packaging by way of reboxing be legally sufficient to justify an infringement of the applicant's trade mark rights.

The applicant takes the view that, in the context of parallel imports, sufficient protection against falsification can be fundamentally ensured by means of relabelling using the ATD and 'unique identifier' ('UI') features. The Community legislature had therefore made further provision for the possibility of relabelling specifically in the case of parallel imports. Article 47a of Directive 2001/83/EC expressly regulates the circumstances as to when existing safety features may be covered. Points (a) to (d) of paragraph 1 list the conditions that have to be fulfilled in order for such covering to be permitted. There is nothing in any part of the legislation to indicate that completely new packaging must necessarily be manufactured and that the new safety features cannot simply be affixed to the original packaging even though they provide equivalent protection against tampering. The Community legislature has therefore proceeded on the basis that relabelling is possible in the case of parallel imports, even in the light of the Falsified Medicines Directive. Nor are there such restrictions in any part of the Delegated Regulation. Rather, the reference to Article 47a of Directive 2001/83/EC in Article 33(1) of the Delegated Regulation once again makes clear that the legislature also had in mind the possibility of safety features being

covered. The reference also makes clear that Article 47a of Directive 2001/83/EC relates specifically to the case of parallel imports and also provides for the possibility of relabelling in that context. It is, moreover, assumed in point 4 of Article 34 and point 4 of Article 35 of the Delegated Regulation that relabelling is possible. Those articles contain the words '*before and after the repackaging or re-labelling operations*' and '*repackaged or relabelled packs of a medicinal product*', respectively. From the perspective of protection against falsification, reboxing and relabelling have therefore been established, in principle, as alternatives. The recitals regarding Article 12 of the Falsified Medicines Directive also suggest that the European legislature continued to consider relabelling to be permissible and possible. This understanding is also confirmed by the Q&A documents of the 'Co-ordination Group for Mutual Recognition and Decentralised Procedures — Human' ('CMDh'). **[Or. 5]**

Finally, the applicant argues that the two variants, relabelling and reboxing, are at least equivalent in terms of safety in the case of parallel imports. In the case of perforated packaging also, adequate protection against tampering is ensured by the affixing to that point of breakage of a new ATD that complies with the requirements of the Falsified Medicines Directive. Each time packaging is opened, the parallel importer has to cover the signs of opening by affixing a new, intact adhesive seal, thus ensuring complete protection against falsification, which is also visible to the public.

3. Forms of order sought by the parties

The applicant requests that:

I. the defendant be ordered to desist, immediately, on pain of incurring statutory penalties, from

repackaging, in the course of trade, the pharmaceutical product ANDROCUR 50 mg, 50 film-coated tablets, originating in the Netherlands for marketing in the Federal Republic of Germany, in new external packaging and affixing the trade mark ANDROCUR to that packaging and/or displaying for sale, marketing and/or advertising new packaging bearing that indication, where the medicinal product was marketed in the country of origin in packets of 50 film-coated tablets;

II. the defendant be ordered to inform the applicant in writing of the nature, scope, dates and duration of the act referred to in point I;

III. it be declared that the defendant be obliged to compensate the applicant for all the damage which it has already suffered and will suffer in the future as a result of the act described in point I above.

The defendant requests that

the action be dismissed.

4. Defendant's arguments:

The defendant takes the view that it can rely on the trade-mark-law principle of exhaustion pursuant to Paragraph 24 of the Markengesetz (Law on trade marks, 'MarkenG') (corresponding to Article 15 of Directive (EU) 2015/2436, 'Trade Marks Directive'; Article 15 of Regulation (EU) 2017/1001, 'EUTMR'), since the previous repackaging **[Or. 6]** practice is obsolete due to the higher level of protection against falsification that has to be guaranteed. The rule/exception relationship between relabelling and reboxing has now, it contends, been reversed.

The defendant submits that, when opening the ANDROCUR 50 mg packaging, the perforated parts of the front side panel are opened, leaving visible signs of damage in the previously directly connected areas on the sides. It is also not possible for the packaging to be opened from the side and glued back together without any traces being left, as the paper/cardboard would be torn or worn down and an additional layer of adhesive would have to be applied when gluing it back together. Wholesalers are obliged to check packaging for tampering, meaning that ultimately only a new foldable carton could prevent rejection by wholesalers and pharmacists. Noticeable damage is also a warning sign for patients/consumers, however. Resealing is therefore not sufficient, especially since counterfeiters could also use such seals.

In addition, a survey carried out by the Institut Pflüger Rechtsforschung GmbH […] showed that 73.5% of the pharmacists/pharmaceutical assistants questioned were of the opinion that it would be better for the acceptance of parallel imported medicinal products if they were repackaged by the importer in a new foldable carton. Large stickers also raised suspicions. On the whole, therefore, it has to be assumed that the use of original adhesive packaging significantly inhibits market entry in the pharmacy/wholesale sector. The claim that relabelling is just as safe and cheaper is also incorrect. Reboxing is 25% [more] expensive.

In the current 16th version of the Q&As (September 2019 […]), points 1.20 and 1.21 clarify that the marketing of repackaged products with visible signs of opening is permitted only under very strict conditions. According to point 1.20, relabelling is generally subject to the approval of the authorities, which is not the case with reboxing. The pharmaceutical authorities of various EU Member States also affirm the objective necessity of a new folding carton, and refer to reboxing, if it is not possible for the original packaging to be sealed […].

The defendant contends that, as a result of the changed legal situation, relabelling is no longer a less severe method; on the contrary, it is now completely unsuitable.

II.

The success of the action depends on how Article 47a of Directive 2001/83/EC, introduced by Directive 2011/62/EU ('Falsified Medicines Directive'), is to be interpreted against the background of the trade-mark-law defence of exhaustion under Article 15 of Directive (EU) 2015/2436 (with effect from 15 January 2019), in the light of Articles 34 and 36 TFEU (formerly Articles 28 and 30 of the EC Treaty). **[Or. 7]**

1. Background in the context of trade mark law

In the context of parallel imports of medicinal products, it is generally necessary, for regulatory reasons, to make physical alterations to the original outer packaging, for example in order to insert an information leaflet in the national language or to replace inscriptions in the national language. According to the case-law of the Court of Justice, it is the repackaging in itself which is prejudicial to the specific subject matter of the medicinal product's trade mark as applied to the packaging (see, for example, […] judgment of 26 April 2007, *Boehringer Ingelheim and Others*, C-348/04, EU:C:2007:249). In this case, however, the parallel importer must meet five conditions for exhaustion in respect of repackaging for pharmaceutical/medical products (see […] judgments of 11 July1996, *Bristol-Myers Squibb and Others*, C-427/93, C-429/93 and C-436/93, EU:C:1996:282, paragraph 79, and of 26 April 2007, *Boehringer Ingelheim and Others*, C-348/04, EU:C:2007:249, paragraph 21):

[…] a) the repackaging is necessary in order to enable the medicinal product to be marketed in the Member State of importation;

[…] b) the repackaging cannot affect the original condition of the product inside the packaging;

[…] c) the new packaging clearly states who repackaged the product and the name of the manufacturer;

[…] d) the presentation of the repackaged product is not such as to be liable to damage the reputation of the trade mark and of its owner; thus, the packaging must not be defective, of poor quality, or untidy;

[…] e) the importer gives notice to the trade mark owner before the repackaged product is put on sale, and, on demand, supplies him with a specimen of the repackaged product.

The first of these conditions is affected in the present case.

2. The new regulatory background: Directive 2011/62/EU ('Falsified Medicines Directive') and Delegated Regulation (EU) 2016/161 ('Delegated Regulation')

First of all, the Directive on the Community code relating to medicinal products for human use was adopted in 2001. It served primarily to harmonise the general legislation of the individual Member […] States of the EU in the field of

medicinal products. The Community code relating to medicinal products for human use was transposed accordingly by the German legislature in the Arzneimittelgesetz (Law on medicinal products, 'AMG').

Ten years later, there was an '*alarming*' increase of medicinal products detected in the EU which were falsified in relation to their identity, history or source (see recital 2 of Directive 2011/6[2]/EU). This increase was connected, in particular, to the purchase **[Or. 8]** of medicinal products via the internet. For this reason, Directive 2001/83/EC was amended and supplemented. Directive 2011/62/EU and Delegated Regulation (EU) 2016/161 supplementing Directive 2001/83/EC on the Community code relating to medicinal products for human use have been in force since 9 February 2019. According to recital 33 of Directive 2011/62/EU, the objective of the directive is '*to safeguard the functioning of the internal market for medicinal products, whilst ensuring a high level of protection of public health against falsified medicinal products*'. It is emphasised in recital 12 that the safety features should be replaced in the case of repackaging '*by equivalent safety features*'. Through the provisions of the Falsified Medicines Directive and the Delegated Regulation, the European legislature has implemented further regulations that are intended to improve the prevention of falsification of medicines. It provides for two main means of doing so, which are to be affixed to the outer packaging of (prescription) medicines: a 'unique identifier' ('UI') and an 'anti-tampering device' ('ATD'). A UI is a two-dimensional barcode or QR code that conceals a unique number allowing each medicine to be uniquely identified. The code is created by the manufacturer himself and notified by him to the system. Falsified medicines bearing a QR code can therefore be immediately identified as such by those involved in the supply chain. Via a simple system query, they can immediately determine whether a corresponding medicine with the correct QR code has actually been manufactured and marketed by the original supplier. This can be done in every pharmacy within a few seconds by means of a simple system verification.

In addition to this IT-supported protection against falsification, it is also possible to carry out a physical check by inspecting the ATD. The purpose of the ATD is to make it possible to see whether unauthorised persons have opened or tampered with the packaging. The ATD can be designed in various ways. It is possible for packaging to be firmly glued at both side flaps and/or have a perforation at the point where the outer packaging is opened, as is the case with the original packaging at issue here, that of the medicinal product ANDROCUR 50 mg, 50 film-coated tablets. Third parties are able to see if the packaging has been opened via the perforated area or the glued side flap.

The German legislature transposed these requirements, inter alia, in Paragraph 10(1)(c) AMG: '*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, where 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 L 311, 28.11.2001, p. 67), last amended by Directive 2011/62/EU (OJ L 174, 1.7.2011, p. 74), or laid down by virtue of Article 54a of Directive 2001/83/EC.' **[Or. 9]**

Therefore, the question is how the parallel importer can implement these new requirements if repackaging is necessary in order to be able to market the product in the Member State of importation.

The *Oberlandesgericht Köln* (Higher Regional Court of Cologne) takes the view that the Falsified Medicines Directive (Directive 2011/62/EU), which introduced Article 54a of Directive 2001/83/EC, does not mean that a re-importer who has to open the packaging of a medicinal product in order to insert a German-language information leaflet cannot continue to use that packaging, even if it remains apparent to the patient that it has been opened […].

The *SVEA HOVRÄTT* (Svea Court of Appeal, Sweden) takes the view that the conditions on the national market play a decisive role when it comes to answering the question whether it is objectively necessary for medicinal products to be repackaged. As the Swedish Medical Products Agency took the view that repackaging in a new carton appeared to be necessary, the court, setting aside the judgment under appeal in that case, refused the trade mark proprietor's application for interim measures […].

The success of the action therefore crucially depends on how Article 47a of Directive 2001/83/EC is to be interpreted against the background of the trade-mark-law defence of exhaustion under Article 15 of Directive (EU) 2015/2436, in the light of Articles 34 and 36 TFEU (formerly Articles 28 and 30 of the EC Treaty).

In that context, the first question addresses the defendant's argument that, as a result of the new rules, reboxing and relabelling are now subject to a rule/exception principle in the sense that, as a general rule, reboxing is preferable.

The second question addresses a new direction developing in the German case-law, according to which, where repackaging is necessary, it is ultimately for the parallel importer to decide how to implement the national requirements in order to be able to market the medicinal product in the Member State of importation, provided that he complies with the other requirements established by the Court of Justice (see above). Accordingly, the Oberlandesgericht Frankfurt a. M. (Higher Regional Court of Frankfurt am Main) […] and the Hanseatisches Oberlandesgericht Hamburg (Hanseatic Higher Regional Court, Hamburg) […] have recently ruled that the requirement of necessity relates only to the repackaging as such and not to the manner in which the repackaging has been carried out. However, this involved the affixing of the '*Pharmazentralnummer*' (central pharmaceutical product number) and a new barcode, and the reaffixing of the batch number, expiry date and manufacturer's trade mark. The referring court also takes the view that, given the large number of inscriptions and safety features

that the parallel importer has to affix to pharmaceutical containers nowadays, which, in practice, often leads to extensive overstickering, it is not entirely understandable why the production of new packaging to which there can be no objection and which cannot be falsified constitutes an unacceptable and greater encroachment on trade mark rights. **[Or. 10]**

The third question addresses the objection raised by the defendant that professionals and end users may be deterred or unsettled by signs of opening.

The fourth question takes account of the arguments of the *SVEA HOVRÄTT* (Svea Court of Appeal), which considered statements made by the national authorities on the interpretation of provisions of EU law for the question of the necessity of reboxing. According to the defendant, the national medicines authorities in other Member [[…]] States also appear to interpret the new anti-falsification rules as meaning that, as a general rule, a new foldable carton must be produced after the anti-tampering device has been broken […].

[…]