Case C-253/20

Summary of the request for a preliminary ruling pursuant to Article 98(1) of the Rules of Procedure of the Court of Justice

Date lodged:

9 June 2020

Referring court:

Hof van beroep Brussel (Belgium)

Date of the decision to refer:

25 May 2020

Appellant:

IMPEXECO NV

Respondent:

NOVARTIS AG

Subject matter of the main proceedings

Appeal brought by Impexeco before the Hof van beroep Brussel (Court of Appeal, Brussels, Belgium) against the judgment of 12 April 2018 of the President of the Nederlandstalige rechtbank van koophandel Brussel (Brussels Commercial Court (Dutch-speaking), Belgium), hearing an application for interim relief, upholding the action brought by Novartis for infringement of its trade mark rights, and ordering, on pain of a financial penalty, the cessation of the trade mark infringement which Impexeco was found to have committed under Article 9(1)(a) of Regulation No 207/2009 by rebranding the Sandoz generic medicine Letrozol with the Novartis trade mark Femara and subsequently marketing that medicine in Belgium.

Subject matter and legal basis of the request for a preliminary ruling

Interpretation, pursuant to Article 267 TFEU, of Articles 34 and 36 TFEU and of the 'BMS' conditions, as developed in the judgments of the Court of Justice of 11 July 1996, *Bristol-Myers Squibb and Others* (C-427/93, C-429/93 and

C-436/93, EU:C:1996:282), and of 12 October 1999, *Upjohn* (C-379/97, EU:C:1999:494).

Questions referred for a preliminary ruling

1) Must Articles 34 to 36 TFEU be interpreted as meaning that, where a branded medicine (reference medicine) and a generic medicine have been put on the market in the EEA by economically linked undertakings, a trade mark proprietor's opposition to the further commercialisation of the generic medicine by a parallel importer after the repackaging of that generic medicine by the affixing to it of the trade mark of the branded medicine (reference medicine) in the country of importation may lead to an artificial partitioning of the markets of the Member States?

2) If the answer to that question is in the affirmative, must the trade mark proprietor's opposition to that rebranding be assessed by reference to the BMS conditions?

3) Is it relevant to the answer to those questions that the generic medicine and the branded medicine (reference medicine) are identical or have the same therapeutic effect as referred to in Article 3(2) of the Koninklijk besluit van 19 april 2001 inzake parallelinvoer (Royal Decree of 19 April 2001 on parallel imports)?

Provisions of EU law and case-law of the Court of Justice relied on

Articles 34 and 36 TFEU

Council Regulation (EC) No 207/2009 of 26 February 2009 on the Community trade mark ('the Trade Mark Regulation') (Article 9(1)(a) and Article 13)

Judgments of the Court of Justice of 11 July 1996, *Bristol-Myers Squibb and Others* (C-427/93, C-429/93 and C-436/93, EU:C:1996:282), and of 12 October 1999, *Upjohn* (C-379/97, EU:C:1999:494)

Provisions of national law relied on

Article 3(2) of the Koninklijk besluit van 19 april 2001 inzake parallelinvoer van geneesmiddelen voor menselijk gebruik en de parallelle distributie van geneesmiddelen voor menselijk en diergeneeskundig gebruik (Royal Decree of 19 April 2001 on the parallel import of medicines for human use and parallel distribution of medicines for human and veterinary use ('the Royal Decree of 19 April 2001'): '… a person who wishes to import a medicine in parallel may obtain an authorisation to do so, provided that the medicine in question is one: (1) for which authorisation to put it on the market has been issued by the competent authorities in the Member State of origin; (2) for which a reference medicine

exists; (3) which, while not being identical in all respects, in comparison to the reference medicine at least (a) has the same qualitative and quantitative composition as regards its active ingredients; (b) has the same therapeutic indications; (c) is therapeutically equivalent; (d) has the same pharmaceutical form.'

Brief summary of the facts and procedure in the main proceedings

1 Novartis AG is the Swiss parent company of the Novartis Group, to which the Novartis Division (sale of patented branded medicines) and the Sandoz Division (sale of generic medicines) belong. In Belgium, Novartis Pharma NV puts the branded medicines on the market and Sandoz NV puts the generic medicines on the market; in the Netherlands, this is done by Novartis Pharma BV and Sandoz BV respectively.

2 Sandoz is an EU trade mark (No 003070422) of which Novartis AG is the proprietor.

3 Novartis has developed a prescription medicine containing the active ingredient letrozol for the treatment of breast cancer. That medicine is sold in Belgium (packs of 30 and 100 film-coated tablets of 2.5 mg under the marketing authorisation VHB No BE0182926) and in the Netherlands (packs of 30 film-coated tablets of 2.5 mg under marketing authorisation number RVG 20755) under the EU trade mark No 00838417 Femara, of which Novartis AG is the proprietor.

4 Since letrozol is no longer patent-protected, Sandoz BV puts the generic medicine Letrozol Sandoz 2.5 mg on the market in the Netherlands in packs of 30 film-coated tablets under marketing authorisation number RVG 106321. In Belgium, that generic medicine is sold by Sandoz NV in packs of 30 and 100 film-coated tablets under marketing authorisation VHB BE382383.

5 Femara and Letrozol Sandoz are identical medicines.

6 Impexeco is a Belgian undertaking engaged in the parallel import of medicines. It imports the generic medicine Letrozol Sandoz 2.5 mg from the Netherlands into Belgium after (1) repackaging (the packs of 100 tablets are given a new outer packaging and the packs of 30 tablets are relabelled), and (2) rebranding with the Femara trade mark. To that end, on 22 September 2014 Impexeco obtained a Belgian parallel import licence No. 1549 PI 187 F3, with Femara 2.5 mg film-coated tablets as reference medicine.

7 By letter of 28 October 2014, Impexeco notified Novartis that it had obtained authorisation to put on the market in Belgium the medicine 'Femara 2.5 mg x 100 tablets (letrozol)', imported from the Netherlands, with effect from 1 December 2014. It appears from the annexes to that letter (draft package insert and mock-up

of the packaging) that this involved the repackaging and rebranding of Letrozol Sandoz 2.5 mg, imported from the Netherlands.

8 By letter of 17 November 2014, Novartis opposed the planned parallel import on the ground that its trade mark rights had not been exhausted, so that the rebranding of the generic medicine imported from the Netherlands as Novartis's original branded medicine manifestly infringed its trade mark rights and amounted to misleading the public.

9 Impexeco proceeded with the commercialisation of the repackaged and rebranded medicine in Belgium in July 2016.

10 By letter of 10 April 2017, Impexeco notified Novartis that it also intended to sell Letrozol Sandoz 2.5 mg, imported from the Netherlands, in Belgium, as rebranded Femara 2.5 mg in relabelled packs of 30 film-coated tablets. That letter was accompanied by a finished sample of the relabelled packaging.

11 The respective Belgian and Netherlands markets for branded and generic medicines have the following characteristics:

– Prices: Due to the fact that Impexeco applied to the Rijksinstituut voor ziekte- en invaliditeitsverzekering (National Institute for Health and Disability Insurance) for reimbursements in respect of the medicines it sells, and due to the application of the reference reimbursement system (reduction of the reimbursements in respect of the branded medicine), the price of the branded medicine decreases as a result of a generic medicine (with reimbursement) coming on the market. In Belgium, the retail price for Femara 2.5 mg (Novartis) is the same as for Letrozol Sandoz 2.5 mg (Sandoz) and for Femara 2.5 mg (Impexeco). In the Netherlands, the retail price for Letrozol Sandoz 2.5 mg is significantly lower.

– Reimbursement via health insurance: in Belgium, since 1 August 2018, reimbursement in respect of medicines containing letrozol is no longer subject to prior authorisation.

– Letrozol-based medicines are 'no switch' (it is not possible to switch to another medicine during treatment).

– Market share: in Belgium, in the period 2015-2018, Femara 2.5 mg had a market share of 80% (compared with the generic Letrozol 2.5 mg), whereas in the Netherlands, Femara's market share in 2018 was 21.58%.

Main submissions of the parties to the main proceedings

Regarding the exhaustion of the trade mark rights of Novaris:

12 Novartis submits that, under Article 13(1) of the Trade Mark Regulation, trade mark rights are only exhausted in relation to goods which have been put on the market in the EEA 'under that trade mark' by the proprietor or with his consent.

13 In the present case, the medicines imported in parallel into Belgium were put on the market in the Netherlands by Sandoz BV under the International Non-proprietary Name (INN) Letrozol, followed by the Sandoz trade mark, thus not under the Femara trade mark by Novartis or an economically linked undertaking such as Sandoz BV. Article 13(1) does not apply in the case of a rebranding, that is to say, where Impexeco imports into Belgium Letrozol Sandoz, which was put on the market in the Netherlands, and for the first time applies to those medicines a sign identical to another trade mark (Femara). The rights which Novartis derives from its EU trade mark Femara are therefore not exhausted for the purposes of Article 13(1) of the Trade Mark Regulation.

14 Impexeco contends that that statement does not make any difference. The trade mark rights of Novartis in the event of the rebranding of a medicine by Impexeco as a parallel importer must be assessed on the basis of Articles 34 and 36 TFEU and on the basis of the BMS conditions concerning trade mark exhaustion in the case of repackaging of parallel imported medicines. One of those conditions, under which the trade mark proprietor cannot prohibit a parallel importer from putting a product on the market after repackaging and under the trade mark, is that it has been established that the trade mark proprietor is using its trade mark right to artificially partition markets, in particular where repackaging is necessary in order to put the product on the market in the Member State of importation. The opposition of the trade mark proprietor to rebranding by a parallel importer where rebranding is necessary in order to sell the products in the Member State of importation constitutes a barrier to trade between Member States which leads to an artificial partitioning of the markets of the Member States.

15 According to Impexeco, that case-law should also be applied to the rebranding of a generic medicine as a branded medicine when both have been placed on the market in the EEA by economically linked undertakings. Moreover, Letrozol Sandoz and Femara are identical products (the composition of the medicines is identical and the imported Letrozol Sandoz was authorised through a decentralised procedure with the Netherlands as reference Member State and without a bioequivalence study because Novartis confirmed that Letrozol Sandoz is identical to Femara, the so-called bio-waiver).

Regarding the artificial partitioning of markets

16 Novartis submits that there is no question of artificial partitioning of the markets because generic medicines and branded medicines are different products that operate in different market segments. They are distinct from a regulatory point of view (requirement of separate market authorisations and different names), from a medical point of view (substitution by the pharmacist is prohibited in Belgium and they are 'no switch' medicines), from the point of view of the pricing and

reimbursement policy, and in terms of public perception. Since branded medicines and generic medicines are sold in different markets, prohibiting a parallel importer from rebranding a generic medicine as a branded medicine cannot be said to partition the market. The principle of the free movement of goods cannot be invoked to permit rebranding; assessment against the BMS conditions is not at issue and the identical composition of the medicines and the fact that they are placed on the market by economically linked undertakings is irrelevant.

17 Impexeco argues that the question whether the markets have been artificially partitioned should not be assessed on the basis of product markets (as Novartis does) but on the basis of territorial markets (the EEA Member States). If there is no possibility of normal parallel trade between the Member States, then there is an artificial partitioning of the (territorial) markets. In fact, there is but a single pharmaceutical market, driven by the prescribing practices of doctors (using their therapeutic freedom). Once patent protection for the active ingredient has been lifted, there are fully fledged alternatives that are interchangeable, and that interchangeability is not affected by the other distinctions cited by Novartis. The only relevant criterion when examining interchangeability of medicines is therapeutic efficacy, which is assessed in practice by the prescribing doctor. Irrespective of whether the product is a branded medicine or a generic medicine, when a trade mark proprietor starts to use different brand names for the same product in the EEA, a parallel trader is entitled to rebrand if the BMS conditions are fulfilled. Furthermore, the imported medicine does not have to be 100% identical to the Belgian reference medicine (pursuant to Article 3(2) of the Royal Decree of 19 April 2001). Moreover, the medicines at issue in the present case are totally identical (Letrozol Sandoz is identical to Femara), despite the fact that Novartis presents Letrozol Sandoz 2.5 mg as a generic medicine.

Brief summary of the reasons for the reference for a preliminary ruling

18 The Brussels Court of Appeal finds that there is controversy and uncertainty as to whether the trade mark proprietor's opposition to the further commercialisation of a generic medicine by a parallel importer who has repackaged that generic medicine in the country of importation by affixing to it the trade mark of the branded medicine (the reference medicine) is liable to lead to an artificial partitioning of the markets of the Member States for the purposes of Articles 34 and 36 TFEU.

19 Various court cases are pending in Belgium in which trade mark proprietors and parallel importers disagree on this question. The question is answered in different ways by the courts.

20 Those disputes are characterised by the fact that they all concern the rebranding of a generic medicine as a branded medicine by a parallel importer, where both medicines have been put on the market in the EEA by economically linked undertakings.