Case C-254/20

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:

PI PHARMA NV

Respondents:

NOVARTIS AG

NOVARTIS PHARMA NV

Subject matter of the main proceedings

Appeal brought by PI Pharma 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 PI Pharma was found to have committed within the meaning of Article 2.2[0].1.(a) of the Benelux Convention on Intellectual Property (BCIP) by importing Sandoz's generic methylphenidate from the Netherlands into Belgium and affixing to it the Novartis Rilatine trade mark and then marketing it under that trade mark through wholesalers, pharmacists or other distribution channels.

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 legislation and Benelux legislation and case-law of the Court of Justice relied on

Articles 34 and 36 TFEU

Benelux-Verdrag inzake de intellectuele eigendom (BVIE) (Benelux Convention on Intellectual Property (BCIP)), Article 2.20.1.(a); Article 2.20.2; and Article 2.23.3, equivalent to Article 13 of Council Regulation (EC) No 207/2009 of 26 February 2009 on the Community trade mark

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, its subsidiary, Novartis Pharma NV (together: 'Novartis'), puts the original branded medicines on the market.

2 Novartis has developed a prescription medicine containing the active ingredient methylphenidate for the treatment of attention deficit disorder combined with hyperactivity (ADHD) and for the treatment of narcolepsy. That medicine is commercialised under the trade mark Ritalin, Ritaline, Ritalina or Rilatine. The Rilatine at issue in the present case is a Benelux word mark (No 0054047) of which Novartis Pharma NV has been the proprietor since 1973. The branded medicine Rilatine is put on the market in Belgium (inter alia in packs of 20 tablets of 10 mg under the authorisation VHB — No BE051597) by Novartis Pharma NV and in the Netherlands (inter alia in packs of 30 tablets of 10 mg under marketing authorisation number RVG 03957) by Novartis Pharma BV.

3 Since methylphenidate is no longer patent-protected, Sandoz BV puts the generic medicine Methylphenidate HCI Sandoz 10 mg on the market in the Netherlands in packs of 30 tablets. Sandoz BV does so by virtue of marketing authorisation number RVG 27033= 09357, with the equal sign indicating that the medicine Methylphenidate HCI Sandoz 10 mg tablet is identical to the medicine Ritalin 10 mg tablet. Sandoz BV does not market the medicine Methylphenidate HCI Sandoz in Belgium.

4 PI Pharma is a Belgian undertaking engaged in the parallel import of medicines. It imports the medicine Methylphenidate HCI Sandoz 10 mg from the Netherlands into Belgium after (1) repackaging (new outer packaging of 20 tablets) and (2) rebranding (with the Rilatine trade mark). For Rilatine 10 mg tablets, PI Pharma

obtained a Belgian authorisation for parallel import No 1637 PI 0322 F003 on 10 September 2014, with Rilatine 10 mg tablets as reference medicine.

5 By letter of 30 June 2015, PI Pharma notified Novartis Pharma NV that it had obtained authorisation to put on the market in Belgium the medicine Rilatine 10 mg x 20 tablets, imported from the Netherlands (Methylphenidate Sandoz 10 mg), and that it would enter the Belgian market with the medicine.

6 By letter of 22 July 2015, Novartis opposed the planned parallel import on the ground that its trade mark rights in respect of Rilatine had not been exhausted, so that the rebranding of the imported generic medicine as Novartis's original medicine manifestly infringed its trade mark rights and amounted to misleading the public.

7 PI Pharma proceeded with the commercialisation of the repackaged and rebranded medicine in Belgium in October 2016.

8 The respective Belgian and Netherlands markets for medicines with the active ingredient Methylphenidate have the following characteristics:

– Prices: Due to the fact that PI Pharma applied to the Rijksinstituut voor ziekte- en invaliditeitsverzekering (National Institute for Health and Disability Insurance) for reimbursements in respect of the medicines it sells, where reimbursement is subject to prior authorisation, the retail price for Rilatine 10 mg x 20 tablets Novartis is EUR 8.10 (or EUR 0.405 per tablet), whereas the retail price for Rilatine 10 mg x 20 tablets PI Pharma is EUR 7.95 (or EUR 0.398 [per tablet]). The retail price of Methylphenidate HCI Sandoz 10 mg in the Netherlands is EUR 0.055 per tablet.

– Market share: In Belgium, in the period 2015-2018, Rilatine's market share for Novartis decreased from 94% to 71%, whereas PI Pharma's market share rose from 0% to 18% over the same period. In the Netherlands, in the period 2015-2018, the market share for Ritalin (Novartis) decreased from 6% to 4%, while the market share for Methylphenidate HCI Sandoz (Sandoz) decreased from 30% to 26% over the same period.

Main submissions of the parties to the main proceedings

– Regarding the exhaustion of the trade mark rights of Novartis:

9 Novartis submits that, under Article 2.23.3 BCIP, 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 the proprietor's consent.

10 In the present case, the medicines imported in parallel in Belgium were put on the market in the Netherlands by Sandoz BV under the International Non-proprietary Name (INN) 'Methylphenidate HCI', followed by the Sandoz trade mark. Those

individual products were not put on the market under the trade mark 'Rilatine' (or 'Ritalin') by Novartis or an economically linked undertaking such as Sandoz BV. Article 2.23.3 BCIP does not apply in the case of a rebranding, that is to say, where PI Pharma imports medicines into Belgium which were put on the market in the Netherlands as 'Methylphenidate HCI Sandoz', and for the first time affixes to those medicines a sign identical to another trade mark (Rilatine). The rights which Novartis derives from its Benelux trade mark Rilatine are not exhausted for the purposes of Article 2.23.[3] BCIP.

11 PI Pharma contends that that statement does not make any difference. The trade mark rights of Novartis in the event of the rebranding of a medicine 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.

12 According to PI Pharma, that case-law should also be applied to the rebranding of a generic medicine as a branded medicine where both have been placed on the market in the EEA by economically linked undertakings. Moreover, the medicine Methylphenidate HCI Sandoz 10 mg is not a genuine generic medicine but rather, according to PI Pharma, 'an authentic medicine with a generic name', which is identical to the branded medicine Rilatine or Ritalin. [That is apparent from a comparison of the composition and the fact that the imported Methylphenidate HCI Sandoz 10 mg was authorised under the derived registration procedure (and not by an appropriate authorisation procedure for generic medicines)].

– Regarding the artificial partitioning of markets:

13 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), 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.

14 PI Pharma 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 the territorial markets of 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. There is, in fact, 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 identical (Methylphenidate HCI Sandoz is identical to Rilatine), despite the fact that Novartis presents Methylphenidate HCI Sandoz as a generic medicine.

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

15 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.

16 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.

17 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.