Case C-488/20

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

Date lodged:

2 October 2020

Referring court:

Wojewódzki Sąd Administracyjny w Warszawie (Poland)

Date of the decision to refer:

9 September 2020

Applicant:

Delfarma Sp. z o.o.

Defendant:

Prezes Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych (President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products)

Subject matter of the case in the main proceedings

Action brought by a company engaged in the parallel import of medicinal products against a decision on the expiry of a parallel import licence

Subject matter and legal basis of the reference

Compatibility with Articles 34 and 36 TFEU of the automatic expiry of a parallel import licence after one year from the expiry of the marketing authorisation for the reference medicinal product.

Questions referred

1. Does Article 34 TFEU preclude national legislation under which a parallel import licence is to expire after one year from the expiry of the marketing authorisation for the reference medicinal product?

2. In the light of Articles 34 and 36 TFEU, may a national authority adopt a decision of a declaratory nature to the effect that a marketing authorisation for a medicinal product in connection with parallel import is to expire automatically, solely on the ground that the period laid down by law has expired, as from the date on which the marketing authorisation for the reference medicinal product expired, without examining the reasons for the expiry of [the marketing authorisation for] that product or other requirements referred to in Article 36 TFEU relating to the protection of the health and life of humans?

3. Is the fact that parallel importers are exempt from the obligation to submit periodic safety reports, and the authority consequently has no current data on the benefit/risk of pharmacotherapy, sufficient to adopt a decision of a declaratory nature to the effect that a marketing authorisation for a medicinal product in connection with parallel import is to expire?

Provisions of Community law relied on

Articles 34 and 36 of the Treaty on the Functioning of the European Union ('TFEU')

Provisions of national law relied on

Article 2(7b), 21a and 33a of the Ustawa z dnia 6 września 2001 r. Prawo farmaceutyczne (Law on medicinal products; 'PrFarm')

Succinct presentation of the facts and the main proceedings

1 The applicant is an undertaking engaged in an economic activity consisting of the parallel import of medicinal products on the Polish market.

2 Pursuant to a decision of the Minister Zdrowia (Minister for Health) of 27 January 2011, the applicant obtained a licence for the parallel import from the Czech Republic of the medicinal product Ribomunyl, granules for oral solution, 0.750 mg + 1.125 mg (licence No 8/11).

3 In accordance with the requirement laid down in Article 2a(7b)(a) of the PrFarm, parallel import licence No 8/11 was issued on the basis of a valid marketing

authorisation in the territory of Poland for the medicinal product Ribomunyl, granules for oral solution, 0.750 mg + 1.125 mg – licence No R/3251 – granted to Pierre Fabre Medicament Polska Sp. z o.o. The marketing authorisation for reference medicinal product R/3251 expired on 25 September 2018 by decision of the President of the Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych (Office for Registration of Medicinal Products, Medical Devices and Biocidal Products) of 25 September 2018.

4 According to the applicant company, the authorisation under which the imported parallel medicinal product is placed on the market in the country of export, that is to say the Czech Republic, remains in force.

5 By a decision of 24 September 2019, the President of the Office for Registration stated that parallel import licence No 8/11 for the medicinal product Ribomunyl, granules of oral solution, 0.750 mg + 1.125 mg, imported from the Czech Republic, the country of export, expired on 25 September 2019.

6 Following re-examination of the case at the request of the applicant company, the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products upheld the decision of 24 September 2019, by decision of 18 November 2019. The applicant brought an action before the referring court against the decision of 18 November 2019.

Essential arguments of the parties in the main proceedings

7 The applicant argued that the contested decision infringes Article 34 TFEU, in conjunction with Article 36 thereof, in that it entails a restriction on the free movement of goods which cannot be justified by reference to Article 36 TFEU. In particular, it is not justified by the need to protect the health and life of humans. Article 34 TFEU, as a provision negatively harmonising national rules relating to the conditions governing the parallel import of medicinal products, is interpreted in the settled case-law of the Court of Justice as excluding the validity and application in this regard of a provision of the national law of a Member State under which a licence for the parallel import of a medicinal product in that State is to expire following the expiry of the marketing authorisation for the reference medicinal product.

8 It further argued that Article 21a(3a) of the PrFarm is contrary to Article 34 TFEU and that fact prevents its application by the national authorities in so far as it stipulates that a licence for the parallel import of a medicinal product to Poland is to expire after one year from the expiry of the marketing authorisation for the reference medicinal product in the territory of Poland.

9 The applicant also argued that the contested decision misinterprets Article 21a(3a) of the PrFarm, in conjunction with Article 36 TFEU, in that it finds that the provision laid down in Article 21a(3a) of the PrFarm is justified on grounds of protection of the health and life of humans, whilst in actual fact that provision is

unrelated to that necessary requirement. Article 21a(3a) of the PrFarm provides that the very fact that the marketing authorisation for the medicinal reference product in the territory of Poland has expired is to be the sole and sufficient basis for the expiry of a licence for the parallel import of a medicinal product to Poland, without at the same time requiring the authority to establish the reason why the marketing authorisation in the territory of Poland for the medicinal reference product has expired.

10 The applicant further argued that the contested decision infringed Article 36 TFEU in that it failed to consider whether the expiry of the licence for the parallel import of the medicinal product to Poland after one year from the expiry of the marketing authorisation for the reference medicinal product in the territory of Poland is justified on grounds of protection of the health and life of humans, and in particular whether the further marketing of the medicinal product imported in parallel may pose a threat to the life and health of humans or animals.

11 The defendant pointed out that whilst, according to the case-law of the Court of Justice concerning the parallel import of medicinal products, the validity of a parallel import licence for a medicinal product should not expire automatically where the marketing authorisation for the reference medicinal product expires, an exception in this regard is the need, laid down in Article 36 TFEU, to withdraw a parallel import licence where the marketing authorisation for the reference medicinal product is withdrawn on grounds relating to a threat to the life or health of humans. The authority noted the absence of a medicinal product to which the medicinal product from the parallel import is to 'refer' in the event of the need to modify or update the data etc. necessary for proper pharmacovigilance and the possible updating of the leaflets which, for the patient, constitute the main source of information on the medicinal product. It pointed to similar uncertainty which forms the subject matter of the reference for a preliminary ruling in the case of [*kohlpharma*] C-602/19. It noted that parallel importers are exempt by statute from the obligation to submit periodic safety reports on medicinal products and in the absence of national marketing authorisation for the reference medicinal product the authority has no current data on benefit/risk of the pharmacotherapy. Nor is there any other medicinal product with marketing authorisation in Poland which contains active substances such as those in the medicinal product Ribomunyl.

Succinct statement of the reasons for the reference

12 The referring court notes that essence of the dispute in the main proceedings is the need, arising from the application of Article 21a(3a) of the PrFarm, to establish the correct interpretation of the provisions of EU law, and in particular of Article 34 TFEU, which determines the assessment of the compatibility with EU law of the effect arising by operation of law (ex lege) in the form of the expiry of the parallel import licence after one year from the expiry of the marketing authorisation for the reference medicinal product.

13 The referring court considers that, according to the previous case-law of the Court of Justice the national authorities must not respond automatically, but are instead required to examine on a case-by-case basis the reasons for the expiry of the marketing authorisation and take account of the justifications in support of leaving the medicinal product on the market despite the fact that the marketing authorisation for the reference medicinal product has expired (see, for example, judgments of the Court of Justice of 10 September 2002, in Case C-172/00, *Ferring Arzneimittel GmbH* and of 8 May 2003, in Case C-15/01, *Paranova Läkemedel AB and Others*).

14 The judgment of the Court of Justice of 3 July 2019 in Case C-387/18, *Delpharma*, concerning provisions of Polish law on medicinal products relating to marketing authorisations for a medicinal product, also militates in favour of a broad application of the obstacles to limitation of the movement of goods laid down in Article 34 TFEU.

15 In the view of the referring court, in the case under consideration the structure of Article 21a(3) of the PrFarm, which provides for the effect of expiry by operation of the law, does not allow the case to be resolved merely by applying an interpretation consistent with EU law. It would be necessary, in applying the law, to disregard a clearly worded provision of national law, which, in the view of the referring court, goes beyond an interpretation of the law permissible under national law, which would then take the form of an interpretation contra legem. In addition, such an approach would still not resolve the question of how the administrative authority should carry out supervision of the safety of the use of a medicinal product imported in parallel in the absence of a reference medicinal product.

16 The first question concerns the assessment of the compatibility with EU law of the rule relating to the expiry of a parallel import licence after one year from the expiry of the marketing authorisation for the reference medicinal product. The second question relates to the assessment of the lawfulness of not examining on a case-by-case basis the conditions for expiry of a market authorisation and the protection of the health and life of humans. The third question relates to the authority's argument regarding the safety of leaving the medicinal product on the market, in respect of which there is no person required to update the data on the risk associated with its use. However, it should be noted that under the law in force, a Polish authority may also request, under Article 21a(5) of the PrFarm, the authorities of the Member State to send the relevant documents which allow a comparison to be made of the products concerned. It is worth considering the possible use of this evidence-taking procedure also where a medicinal product originating from parallel import is left on the market despite the fact that the marketing authorisation for the reference medicinal product has expired.

17 At this juncture, it should be noted that the issue concerning the legal effects of the expiry of the marketing authorisation for the reference medicinal product in relation to a product originating from parallel import also arose in the case

pending before the Court of Justice as a result of a request for a preliminary ruling in [*kohlpharma*] (C-602/19), but there has not yet been a ruling which would be helpful in resolving the present case.

18 The referring court is aware of the fact that the case under consideration concerns a particular type of goods which clearly has a direct effect on the health and life of humans. In the view of the referring court it is not clear whether or not the overriding need to protect the health and life of humans justifies the restrictive effect in the form of the automatic expiry of a parallel import licence on account of the expiry of the marketing authorisation for the reference product.