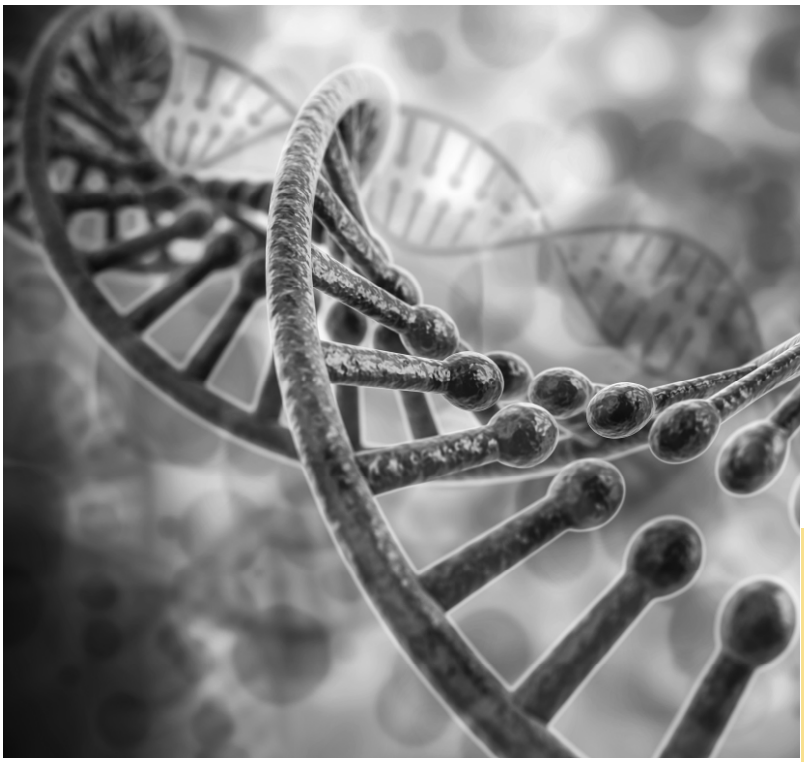

EU life sciences & regulatory newsletter

ASHURST BRUSSELS

July 2019

Content

Ashurst has a well-established practice and specialist expertise in life sciences and regulatory, and is regularly listed as one of the leading law firms in the field. Our EU life sciences and regulatory newsletter focuses on important rulings by the EU Courts as well as decisions by the ECHA Board of Appeal and the European Ombudsman affecting the life sciences sector.

1. EU Courts

GC upholds ECHA's classification of Bisphenol A as substance of very high concern

On 11 July 2009, the EU General Court ("GC") dismisses PlasticsEurope's action seeking the annulment of the European Chemicals Agency ("ECHA") decision to include Bisphenol A ("BPA") in the REACH candidate list of substances of very high concern on account of its reproductive toxicity (T-185/17, PlasticsEurope -v- ECHA).

WHAT YOU NEED TO KNOW

- In January 2017, ECHA placed BPA on the candidate list of substances of very high concern on the ground that it has been classified as toxic for reproduction. As a result, BPA may eventually be included in Annex XIV which is the list of substances subject to authorisation under REACH. The GC dismissed PlasticsEurope's action for annulment of ECHA's decision.
- The GC confirms that an intermediate substance, such as BPA, may be identified as being of very high concern allowing information on the risks and dangers associated with the substance to be shared with the supply chain and the public. The exemption laid down in Article 2(8)(b) REACH concerns only the authorisation procedure.

Background

BPA is the starting monomer for the manufacture of other substances, such as polymers, and is thus mainly used in the EU as an intermediate. In January 2017, ECHA decided to include BPA in the candidate list of substances of very high concern on the ground that it has been classified as toxic for reproduction. As a result, BPA may eventually be included in Annex XIV which is the list of substances subject to authorisation under REACH. PlasticsEurope sought to challenge ECHA's decision before the GC.

The Court's judgment

The GC rejects PlasticsEurope's argument that intermediate substances, such as BPA, would be entirely excluded from the authorisation procedure on the basis of Article 2(8)(b) REACH. Relying on earlier EU case-law on the scope of Article 2(8)(b), the GC states that intermediate substances are not automatically exempt from all the provisions governing authorisation set out in Title VII REACH. In particular, they are not exempt from the possibility of being identified as substances of very high concern. The GC recalls that such identification serves not only as a first step in the Annex XIV listing, but also serves to ensure information is shared with the supply chain and consumers on the risks and dangers of dealing with substances of very high concern.

ECHA was thus entitled to include BPA in the candidate list of substances, consistent with the objective of sharing information on substances of very high concern. Furthermore, ECHA was not required to accompany that inclusion with an express statement that intermediate uses of BPA would be exempted from any future inclusion in Annex XIV. This would, in the GC's view, only repeat what is already stated in the REACH Regulation.

The GC also upholds the ECHA decision as a proportionate measure on the basis that it aims to ensure the sharing of information on substances within the supply chain. Such information sharing objective, says the GC, should prevail over any difficulties that suppliers may experience as a result. Lastly, the GC rejects the argument alleging ECHA would have committed a manifest error of assessment by failing to consider information on the intermediate uses of BPA. ECHA can, but is not obliged, to take into account information other than that concerning the substance's intrinsic properties. In any event, any additional information would be irrelevant where the substance is included in the candidate list on account of its intrinsic properties.

This judgment may still be appealed. A separate court case brought by PlasticsEurope against ECHA on BPA is still pending (T-636/17, *PlasticsEurope -v- ECHA*). That case aims to challenge ECHA's decision to identify BPA as a substance of very high concern on the basis of its alleged endocrine disrupting properties.

Polish law on parallel import of medicines in breach of EU free movement rules

In a judgment of 3 July 2019, the European Court of Justice ("ECJ") concludes that a Polish law making the issuance of a parallel import licence conditional upon the imported medicine and the equivalent authorised product in Poland sharing the same "registration status" (i.e. as reference or generic medicine) unduly restricts the free movement of goods in the EU (C-387/18, Delfarma).

WHAT YOU NEED TO KNOW

- When deciding on applications for a parallel import licence of medicines, Member States are required to perform a bioequivalence assessment, comparing the imported product and the product authorised in their own territory based on all information submitted by the applicant. Member States may request additional information from the applicant and other national authorities where necessary.
- A national rule denying the issuance of a parallel import licence on the mere "formalistic" ground that the imported product and the equivalent product do not have the same "registration status" and have not been authorised on the basis of identical dossiers (i.e. a reference medicine versus a generic medicine) constitutes an unjustified restriction of the free movement of goods in the EU.

Background

Delfarma, a parallel importer of medicines, applied to the Polish authorities for a licence to import into Poland a medicine sold in the UK under the name Azithromycin. An identical medicine had been previously authorised in Poland and marketed under the name Sumamed.

The Polish authorities denied the application on the sole ground that Polish law precludes the grant of a parallel import licence in circumstances where the imported product and the equivalent product authorised in Poland do not have the same "registration status" and have not been authorised on the basis of identical dossiers (i.e. registration as a reference medicine versus registration as a generic medicine). Azithromycin had been authorised in the UK as a generic medicine following an abridged procedure, whereas Sumamed had been authorised in Poland as a reference medicine under the standard procedure and thus on the basis of a comprehensive product dossier.

Delfarma challenged the Polish authority's refusal arguing that the Polish law, and in particular the requirement of identity of "registration status" and dossier for the imported and equivalent domestic product, violates EU rules on free movement of goods (Article 34 and 36 TFEU). The Polish regulator invoked public health reasons to justify this requirement claiming that it would not be possible to conduct the bioequivalence assessment on the basis of different dossiers. The matter was referred to the ECJ for a ruling on the compatibility of Polish law with EU law.

The Court's judgment

By judgment of 3 July 2019, the ECJ rules that the Polish law infringes EU rules on the free movement of goods insofar as it precludes, in all cases and without any prior assessment, the issuance of a parallel import licence except where the imported product has the same "registration status" as the equivalent product authorised in Poland. The ECJ considers that the Polish law goes beyond what is necessary to achieve a high level of public health protection and is therefore contrary to Articles 34 and 36 TFEU.

The ECJ recalls that national authorities have been given the power under EU law to request from applicants or other Member States any additional information needed to assess the bioequivalence of medicines. Authorities should therefore be in a position to take a decision on the basis of all information they have in their possession or they can reasonably obtain. A parallel import licence may be refused only where the information available to the competent authority is found insufficient to verify the safety or efficacy of the imported product.

EMA disclosure of safety data on orphan medicine upheld by EU Court

By judgment of 28 June 2009, the EU General Court ("GC") upholds the decision of the European Medicines Agency ("EMA") releasing documents submitted in the context of a marketing authorisation application. Disclosure was made in response to a third party request for access to documents and concerned in particular a periodic benefit-risk evaluation report for the orphan medicinal product Ocaliva. The marketing authorisation holder unsuccessfully invoked the exception relating to the protection of court proceedings (T-377/18, Intercept Pharma and Intercept Pharmaceuticals -v- EMA).

WHAT YOU NEED TO KNOW

- The Transparency Regulation (1049/2001) grants the public as wide a right of access as possible to documents of the EU institutions, including EMA. Exceptions to the right of access are limited and must be interpreted and applied strictly.
- The exception relating to the protection of court proceedings provided for Article 4(2) of the Transparency Regulation cannot be invoked by companies to prevent disclosure of purely scientific documents submitted to EMA in an administrative procedure to monitor the safety of medicinal products.

Background

On 3 April 2018, EMA informed the marketing authorisation holder, Intercept Pharma, that it had received, from a law firm, a request for access to several documents relating to the orphan medicinal product Ocaliva. Despite Intercept Pharma's objection to disclosure of certain sections containing safety information, EMA decided on 15 May 2018 to disclose a periodic benefit-risk evaluation report.

EMA explained that the justification put forward by Intercept Pharma for the proposed redactions relating to the safety of Ocaliva did not constitute a sufficient legal basis to refuse access. In particular, it rejected the company's reliance on the exception relating to the protection of court proceedings provided for Article 4(2) of the Transparency Regulation (1049/2001).

Intercept Pharma explained in this context that its parent company was involved in a dispute in the US and that the disclosure of the evaluation report would help the opposing parties in those US proceedings to circumvent US procedural rules on discovery and would consequently seriously undermine the economic interests of its parent company by increasing defence costs.

The Court's judgment

The GC recalls that the rationale of the exception relating to the protection of court proceedings is the principle of equality of arms and of the sound administration of justice. As such, EU case-law has acknowledged that this protection applies not only to documents drawn up solely for the purposes of specific court proceedings (such as pleadings), but may exceptionally also extend to documents which were not drawn up in the context of specific court proceedings but which contain internal legal positions which subsequently became the subject of such proceedings.

Having said that, however, the GC considers that the released report is a scientific document submitted to EMA in an administrative procedure to monitor the safety of Ocaliva. It does not

qualify as a document drawn up in the context of court proceedings or as a document containing internal positions of a legal nature. The exception relating to the protection of court proceedings laid down in Article 4(2) of the Transparency Regulation can therefore not be invoked to prevent disclosure.

EMA's disclosure policy remains the subject of court challenges. In 2018, the GC delivered a series of judgments upholding EMA's approach to disclosure of data and information contained in the marketing authorisation dossier submitted by companies. An appeal against these GC judgments is still pending (C-178/18P, *MSD Animal Health Innovation and Intervet International -v- EMA* and C-175/18P, *PTC Therapeutics International -v- EMA*). The outcome of these appeals will determine EMA's future approach on disclosure.

AG advises against automatic renewal of parallel trade permits for plant protection products

In a non-binding Opinion delivered on 27 June 2019, Advocate General ("AG") Hogan invites the European Court of Justice ("ECJ") to require the renewal of a parallel trade permit for a plant protection product following the re-authorisation of the reference product. This should enable the national authorities to verify that the imported product is still identical to the re-authorised reference product (C-445/18, Vaselife International and Chrysal International).

WHAT YOU NEED TO KNOW

- Article 52 of Regulation 1107/2009 ("PPP Regulation") contains specific rules on parallel trade specifying the conditions for obtaining a parallel trade permit under a simplified regime. No provision deals expressly with the renewal of a parallel trade permit, and in particular with the impact of the renewal of the authorisation of the reference product on the validity of the permit.
- The AG opposes the automatic renewal of a parallel trade permit in case of re-registration of the reference product. The renewal of a parallel trade permit should be the subject of a decision following a simplified procedure allowing the competent authority to verify that the imported product is still identical to the reference product.

Background

In 2017, the Dutch Board for the Authorisation of Plant Protection Products and Biocides ("*CTGB*") withdrew the renewal of the parallel trade permit held by Vaselife for a growth regulator used for apples and pears. Vaselife imported this product from Italy into the Netherlands, where an identical (reference) product had been previously registered by Sumitomo. Both products were manufactured by Valent Biosciences, a division of Sumitomo.

In December 2015, the CTGB had re-authorised the reference product for sale in the Netherlands until 2025. Subsequently, the CTGB also approved a minor change to the composition of the product, and agreed to the transfer of the marketing authorisation to the company, Chrysal. In March 2016, the CTGB proceeded to automatically renew Vaselife's parallel trade permit until 2025.

The reference marketing authorisation holder, Chrysal, however opposed the CTGB's decision to renew the parallel trade permit arguing that the imported and the reference products can no longer be considered as "*identical*" in the absence of a "*common origin*" as required by Article 52(3) PPP Regulation. The CTGB upheld Chrysal's objection and withdrew the renewal of Vaselife's parallel trade permit.

Vaselife went before the Dutch courts against the CTGB decision. The Dutch courts have now seized the ECJ for a preliminary ruling, firstly, on the question whether Vaselife's parallel trade permit ought to have been automatically renewed upon

re-registration of the reference product, and, secondly, whether the two products may be considered identical in the circumstances of this case.

The Court's judgment

The PPP Regulation does not specifically deal with the renewal of a parallel trade permit. Article 52(6) merely provides that the permit shall be valid for the duration of authorisation of the reference product. Accordingly, the AG considers that the underlying objective of the PPP Regulation ought to be considered, in particular the balance which must be struck between the free movement of goods and the protection of public health and the environment.

Bearing this in mind, the AG considers that an *automatic* renewal of a parallel trade permit upon re-registration of the reference product, without any kind of regulatory control, would undermine the safety objective of the PPP Regulation. Consequently, the renewal of a parallel trade permit should be the subject of a *decision* following a simplified procedure allowing the competent authority to verify that the imported product is still identical to the reference product and thus still meets the conditions set out in Article 52 of the PPP Regulation. This decision may be taken on the initiative of the competent authority or at the request of the permit holder.

The "*common origin*" requirement of Article 52(3) PPP Regulation requires the imported and reference products to "*have been manufactured by the same company or by an associated undertaking or under licence in accordance with the same manufacturing process*". The AG considers this requirement is met where the products are manufactured using the same manufacturing process by a different entity with the consent of the right holder as part of a stable business relationship, even if this arrangement does not qualify as a formal licensing arrangement. In this context, the AG further notes that the mere changing of the location of production or a slight change in the composition of the reference product, without any appreciable impact on its effects, should not be such as to render it different from the imported product.

In any event, it is for the permit holder to produce the information required by Article 52(3) PPPR demonstrating that the products are still identical, bearing in mind that the competent authority may request information from the Member State of origin to assess the identical nature of the products. Where the marketing authorisation holder for the reference product contests the decision to issue or renew a parallel trade permit, he will have to show that the two products are not identical.

The AG Opinion is a welcome clarification of the EU rules governing parallel trade of plant protection products. A sensible and balanced approach to the "*common origin*" requirement is being advocated. A final judgment by the ECJ on the matter is however still pending.

AG endorses Hungarian law restricting cross-border supply of prescription medicines

Hungarian law prohibits pharmacies from supplying prescription medicines cross-border to doctors abroad for their own use, where the orders are placed with purchase orders that do not mention individual patient names. In a non-binding Opinion delivered on 12 June 2019, Advocate General ("AG") Bot invites the EU Court of Justice ("ECJ") to rule that this Hungarian rule is justified on public health grounds and therefore compatible with EU law (C-222/18, VIPA).

WHAT YOU NEED TO KNOW

- The cross-border supply of prescription medicines by pharmacies to doctors on the basis of purchase orders and for the doctors' own use (not for resale) is currently not regulated under EU law. Accordingly, Member States are free to introduce national rules provided that these do not unduly restrict the EU internal market.

- The AG takes the view that the Hungarian law preventing pharmacies from supplying prescription medicines cross-border to doctors abroad for their own use, where the orders are placed with purchase orders, constitutes a restriction on free movement of goods that may be justified on public health grounds, in particular the need to control the distribution chain.

Background

The case originated in Hungary where VIPA, a pharmacy operator, was sanctioned by the Hungarian Institute of Pharmacy and Nutrition for having unlawfully dispensed large quantities of prescription-only medicines to doctors practising in the UK and Austria, on the basis of purchase orders issued by those doctors.

Under Hungarian law pharmacies are allowed to supply prescription medicines on the basis of purchase orders only where these are issued by doctors authorised to practice in Hungary.

VIPA challenged the sanction before the Hungarian courts who requested the ECJ to assess the compatibility of the Hungarian law with EU law and in particular with the Patients' Rights Directive (2011/24) and EU internal market rules.

The AG Opinion

The AG considers that the Patients' Rights Directive does not apply to the supply of medicines on the basis of purchase orders. In his view, it follows from the wording and the objective of Article 11 of the Patients' Rights Directive that the notion of "prescription" only covers prescriptions issued "for a named patient". Equally, the AG holds that the Human Medicines Directive (2001/83) does not apply to the situation at hand either. The concept of "wholesale distribution" of medicines encompasses the supply by pharmacies of medicines to retailers, i.e. professionals responsible for dispensing medicines to the final consumer. By contrast, in the present case, the medicines were supplied by VIPA to doctors for their own use (and not for resale).

It should then still be verified whether the Hungarian law complies with EU fundamental freedoms and in particular the free movement of goods. In the AG's opinion, the Hungarian law restricts trade in medicines within the meaning of Article 35 TFEU. However, the AG considers that this restriction may be justified by the protection of public health and especially by the need to control the distribution chain. The AG also considers the restriction to be proportionate arguing that less stringent measures (such as a quota) would make controls more complex.

The final judgment is still awaited and will give the ECJ the opportunity to clarify the scope of EU secondary law in the sensitive area of the distribution of prescription-only drugs. It is likely to confirm the relatively wide margin of appreciation enjoyed by Member States in this specific area.

2. New Action

Human medicines – Supplementary Protection Certificates (SPCs)

The Swedish Patent and Marketing court has asked the EU Court of Justice whether Article 3(c) of Regulation 469/2009 precludes an applicant who has previously been granted a supplementary protection certificate in respect of a product protected by a basic patent, in force in respect of the product per se, from being granted a supplementary protection certificate for a new use of the product where the new use constitutes a new therapeutic indication which is specifically protected by a new basic patent (C-354/19, *Novartis AG -v- Patent-och registreringsverket*, OJ of 8 July 2019).

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