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E-ALERT | Food & Drug

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EU COURT OF JUSTICE STRENGTHENS RIGHTS OF ORIGINATORS TOWARDS GENERIC APPROVALS

In a ruling of 23 October 2014,[1] the EU Court of Justice concluded that the Medicines Directive 2001/83/EC,[2] in combination with the EU Charter of Fundamental Rights, guarantees the right for the marketing authorisation holder of a "reference product" to challenge the decision authorising a generic medicinal product.

This ruling will significantly strengthen the rights of originator companies in jurisdictions that currently provide no, or only limited, legal standing to challenge generic authorisations. This is for instance the case in Germany where the originator could traditionally only legally challenge a generic authorisation when it infringes data exclusivity rights.

1. FACTS AND QUESTION REFERRED TO THE COURT OF JUSTICE

In 2008, Olainfarm obtained a marketing authorisation for Neiromidin (ipidacrine) in Latvia based on a "bibliographical" application, as the medicine was in well-established medicinal use for ten years.[3] In 2011, Grindeks obtained a generic marketing authorisation in Latvia for "Ipidakrine-Grindeks", with Neiromidin as reference medicinal product.[4]

Olainfarm challenged the generic marketing authorisation before the Ministry of Health, which rejected the complaint on the ground that the holder of a reference medicinal product does not enjoy an individual right to challenge a generic authorisation.

Olainfarm started proceedings before the national court, which asked the EU Court of Justice whether the Medicines Directive 2001/83/EC guarantees a right to judicial remedy for the holder of the reference product to challenge the generic marketing authorisation under Article 10 of the Directive.[5] This article provides for a period of data exclusivity and marketing protection for innovative medicines, and sets the conditions under which generic authorisations can be granted.[6]

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[1] Case C-104/13, *Olainfarm AS v. Latvijas Republikas Veselības ministrija, Zāļu valsts aģentūra*, 23 October 2014, available at http://curia.europa.eu.

[2] 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, as amended ('Medicines Directive 2001/83/EC').

[3] Article 10a of the Medicines Directive 2001/83/EC.

[4] As per Article 10 of the Medicines Directive 2001/83/EC.

[5] The Latvian Court also asked whether a product approved on the basis of a bibliographical application can be employed as a reference product for the purpose of a generic application. The EU Court of Justice answered affirmatively.

[6] The decision does not touch upon the question whether the data exclusivity rights were respected. Grindeks' product was approved about three years after the bibliographical approval of Neiromidin, but there was an older pre-accession approval based on only partially EU-compliant national rules.

2. COURT CONFIRMS LEGAL STANDING AGAINST GENERIC APPROVALS

The Court of Justice concluded that EU law guarantees a right to judicial remedy for the holder of the reference product to protect the rights conferred on him by Article 10 of the Medicines Directive 2001/83/EC, and thus to challenge a decision granting a generic authorisation.

While a generic marketing authorisation procedure does not involve the holder of the reference product and the Medicines Directive 2001/83/EC does not include any express judicial remedy for him, the Court noted that Article 47 of the EU Charter of Fundamental Rights provides for a right to an effective remedy before a tribunal in case rights guaranteed by EU law are violated.

Article 10 of the Medicines Directive 2001/83/EC contains a right for the holder of the reference product to challenge the approval or marketing of a generic product (i) because it infringes the data exclusivity and marketing protection periods (under Article 10(1)), as well as (ii) because the conditions regarding the notion of "reference medicinal product" or a "generic medicinal product" (at least with regard to the required similarity with the reference product) are not met (under Article 10(2)). EU law therefore guarantees judicial protection for the reference product's holder to challenge any generic authorisation infringing these principles.

3. ANALYSIS - BROADENING OF THE CONCEPT OF "*SUBJEKTIVES ÖFFENTLICHES RECHT*"

As highlighted by the Advocate General, while the Court already tackled cases where the marketing authorisation holder of the reference product challenged the legality of a generic authorisation in national procedures, it is the first time that the Court expressly rules on the question whether such legal standing right for originator companies can be directly derived from EU law.[7]

The Court confirms that EU law ensures legal standing for the holder of a reference product against a generic authorisation, on the basis of its data exclusivity rights or the regulatory requirements for a medicine to act as "reference product" or to be approved as a "generic" (at least with regard to the required similarity with the reference product). Interestingly, the Court does not accept the suggestion of the Advocate General that such standing right should be limited to the period of data exclusivity and marketing protection of the reference product.[8]

This ruling provides better legal protection in jurisdictions where a limited legal standing prevented originator companies from challenging generic marketing authorisations until now. This is for instance the case in Germany. Until now, the originator could only challenge the generic authorisation to the extent it infringes data exclusivity (and marketing protection) rights, but not, for instance, because of lack of bioequivalence. This was based on the concept of "*subjektives öffentliches Recht*", which must be linked to rules that directly protect the originator and cannot be derived from rules that protect public health. The ruling of the Court of Justice now expressly broadens the concept of *subjektives öffentliches Recht* to include lack of compliance with the standards of similarity laid down in Article 10(2) of the Directive.

4. TIMING AND SCOPE OF THE RULING

The ruling of the Court of Justice is an interpretation of the EU law principles. It has immediate effect and also applies retroactively. It can thus be invoked in litigation involving generic authorisations that predate the decision.

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[7] Opinion of AG Wahl, Case C-104/13, *Olainfarm*, para. 45, available at http://curia.europa.eu.
[8] Opinion of AG Wahl, Case C-104/13, *Olainfarm*, para. 50, available at http://curia.europa.eu.

The ruling does not clearly define what requirements under Article 10(2)(b) provide an enforceable right to the originator company. The Court refers to the requirement that the generic must be "similar to the reference product in terms of its composition in active substances and pharmaceutical form" as a right that can be enforced. Logically speaking, this should also apply to an assessment of the relevance of a different salt, ester, metabolite, derivative, etc. Similarly, the ruling should also apply to other approval routes laid down in Article 10 of the Medicines Directive 2001/83/EC, such as hybrid and biosimilar applications; and possibly also to bibliographical and fixed combination applications.

Challenging other aspects such as the quality of a generic (when it does not affect bioequivalence), may for the moment remain subject to the national rules on standing, but such disputes are less frequent.

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