August 2024

VBB on Belgian Business Law

Issue Highlights

"Van Bael & Bellis' Belgian competition law practice [...] is a well-established force in high-stakes, reputationally-sensitive antitrust investigations."

Legal 500, 2019

Topics covered in this issue

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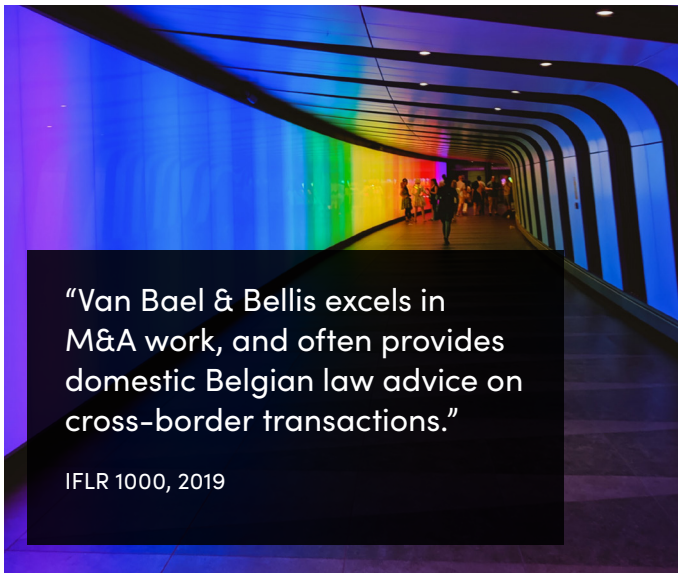

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COMPETITION LAW

Belgian Competition Authority Concludes Cooperation Agreement with Ombudsman to Handle Whistleblower Reports of Competition Law Infringements

On 21 August 2024, the Belgian Competition Authority (*Belgische Mededingingsautoriteit / Autorité belge de la Concurrence* – the ***BCA***) made public a cooperation agreement with the federal Ombudsman to facilitate and handle whistleblower reports of competition law infringements. Like many other competition authorities, the BCA has for some time encouraged individuals with knowledge of possible violations of competition law to step forward and detail these violations. That system, dating back to October 2022, has now been expanded to implement EU Directive 2019/1937 on the protection of persons who report breaches of Union law and the Law of 28 November 2022 on the protection of persons reporting breaches of Union law or national law in the private sector (*See*, VBB on Belgian Business Law, Volume 2022, No. 10).

The cooperation agreement seeks to delineate the jurisdiction of the BCA and the Ombudsman, determine the practical terms of the cooperation between those bodies, regulate the assessment of the reporting procedures, and ensure compliance with the personal data protection rules.

From the BCA's perspective, the cooperation agreement complements existing tools that allow the BCA to be advised of competition law infringements. These include leniency applications by both private firms and natural persons and may give rise to immunity from fines, reduced fines, or immunity from prosecution.

DATA PROTECTION

Belgian Data Protection Authority Publishes 2023 Annual Report

On 20 June 2024, the Belgian Data Protection Authority (*Gegevensbeschermingsautoriteit / Autorité de protection des données* - the ***DPA***) published its annual report for 2023 (the ***Report***). 2023 marked a year of transformation for the DPA, characterised by the restructuring of its Executive Committee with the addition of two new directors in June and an updated regulatory framework governing its operations. The Report provides a comprehensive overview of the DPA's major initiatives and accomplishments throughout the year.

DPA's Key Initiatives in 2023

At the close of 2022, the DPA set forth its primary objectives for 2023, focusing on the regulation of cookies and the pivotal role of Data Protection Officers (***DPOs)***. These efforts continued in 2023.

Enhanced Guidance on Cookies

In response to growing public concern over privacy, the DPA provided detailed guidance on cookies and other tracking technologies. It developed educational resources and participated in the Cookie Banner Taskforce of the European Data Protection Board (***EDPB***), contributing to a European consensus on the issue (report available here). The DPA summarised the findings of this report for wider distribution to the Belgian public (available here). Additionally, in October 2023, the DPA released the "Cookie Checklist", a step-by-step guide to best practices and common pitfalls in cookie and tracker management.

Closer Relationship with Data Protection Officers

The DPA highlighted the essential role of DPOs as key advisors and protectors of privacy within organisations. Recognising the necessity for a standardised skill set of DPOs, the DPA supported the creation of a certification mechanism for DPO training in 2024 following French standards. The DPA also took part in a coordinated European action on the DPO.

At the national level, the Inspection Service and the Litigation Chamber of the DPA verified whether DPOs had adequate independence and resources for effective data protection management. Two decisions of the Litigation Chamber specifically dealt with the role of the DPO:

- In decision 110/2023, the DPA noted the legal requirement for public authorities to appoint a DPO as stipulated in Article 37(1)(a) of the GDPR. It inquired whether the DPO had adequate resources to counsel the data controller on implementing necessary data protection safeguards, support data subjects in exercising their rights, and prevent data protection breaches. The DPA found that the annual hours allocated were insufficient for the effective collaboration between the data controller and the DPO.

- In decision 116/2023, the DPA clarified that there is no closed list of roles incompatible with the DPO position, observing that such conflicts must be assessed on a case-by-case basis.

New Challenges Posed by Artificial Intelligence

The DPA reports that it closely monitored advancements in artificial intelligence (***AI***), advocating for adherence to GDPR principles amid rising concerns about machine learning and data processing risks. The authority has been proactive, offering opinions on draft legislation and advising on the ethical and societal impact of AI, including the use of chatbots.

Awareness Efforts

Throughout 2023, the DPA continued its public education efforts, particularly through its flagship initiative "ik beslis" / "Je décide" ("I decide"), designed to teach children and youth about privacy. Additionally, the First Line Service of the DPA provided valuable legal and technical information to both data subjects and controllers.

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Year in Practice

The DPA reported a significant uptick in activities in 2023, with complaints rising from 604 to 694, largely concerning direct marketing and the use of photographic and video surveillance. Requests for opinions surged by 90%, primarily from Flemish public authorities. Data breach notifications slightly decreased by 9%, with human error remaining the primary cause for breaches, although incidents related to hacking and malware saw an increase. Enforcement actions included 86 investigations by the Inspection Service and 171 decisions by the Litigation Chamber, with fines totaling EUR 80,000 across three cases.

The Report is available here (in Dutch) and here (in French).

According to European Data Protection Board, Data Protection Authorities Should Become Artificial Intelligence Market Surveillance Authorities

On 16 July 2024, the European Data Protection Board (***EDPB***) adopted a statement on the role which it proposes Data Protection Authorities (***DPAs***) should play under the Artificial Intelligence Act (***AI Act***), which entered into force on 1 August 2024. The AI Act contains harmonised rules governing the placement on the market, putting into service and the use of AI (*See,* VBB on Belgian Business Law, Volume 2024, No. 5). The AI Act will be implemented gradually and requires Member States to designate one or more competent authorities to assume the role of market surveillance authority (***MSA***) by 2 August 2025.

The EDPB now advocates for DPAs to take up this role, given their profound understanding and experience in managing AI's impact on fundamental rights — especially data protection. This recommendation is predicated on several considerations:

- The integration of personal data processing within the AI lifecycle, particularly for high-risk AI systems, is central to the technologies defined under the AI Act. National DPAs have been proactive in addressing these technological evolutions and their complex relationship with EU data protection laws.
- DPAs possess specialised skills in areas critical under the AI Act, including data computing, data security, and risk assessment concerning new technologies.
- Due to their independence, DPAs are well-positioned to offer impartial oversight of AI systems, aligning with the mandates of the AI Act.

In view of these considerations, key recommendations of the EDPB include:

- Designating DPAs as MSAs for high-risk AI systems used for law enforcement, border management, administration of justice and democratic processes but also for other high-risk AI systems likely to impact natural persons' rights and freedoms with regard to the processing of personal data
- Designating these DPAs as a single contact point for public and other stakeholders at both national and EU levels.
- Establishing clear protocols for collaboration among MSAs and other regulatory bodies overseeing AI, grounded in the principle of "sincere cooperation" provided for by the Treaty of the EU. This approach aims to prevent decision-making discrepancies and promote synergistic, coherent enforcement actions.

It is unclear whether Member States will follow the recommendations of the EDPB in practice.

FOREIGN DIRECT INVESTMENT

Belgian Interfederal Screening Committee Publishes New Belgian Foreign Direct Investment Notification Forms

On 2 September 2024, the Interfederal Screening Committee (*Interfederale Screeningscommissie / Comité de Filtrage Interfédéral* - the ***ISC***), responsible for coordinating the application of the Belgian mechanism (the ***Mechanism***) for the screening of foreign direct investment (***FDI***), published an updated version of its Belgian FDI notification form and summary form, dated 29 August 2024.

Since the entry into force of the Mechanism on 1 July 2023, the ISC has regularly published updates of its notification forms, expanding the information that should be submitted when notifying FDI under the Mechanism (*See*, this Newsletter, Volume 2023, No. 11).

In a welcome move, the ISC has removed specific previous formalistic document and information requests from its new forms. However, the disclosure requirements under the new forms remain elaborate when compared to the requirements of many other jurisdictions.

The updated Belgian FDI notification forms can be found here (Dutch) and here (French).

INTELLECTUAL PROPERTY

Brussels Court of Appeal Delivers Judgments on Parallel Imports of Medicinal Products and Sides with Innovative Pharmaceutical Industry in Thwarting Attempt to Repackage and Rebrand Generic Products as Originator Products

On 10 June 2024, the Brussels Court of Appeal held in two judgments in disputes pitting parallel importers (PI Pharma and Impexeco, respectively) against Novartis that parallel importers cannot validly import a generic medicinal product and repackage and rebrand it with the brand name of the pioneering substance (Brussels Court of Appeal, 10 June 2024, 2018/AR/858, *PI Pharma NV v. Novartis AG and Novartis Pharma NV*; Brussels Court of Appeal, 10 June 2024, 2018/AR/1027, *Impexeco NV v. Novartis AG*). A few days earlier, on 23 May 2024, the President of the Dutch-language Brussels Enterprise Court had delivered a similar judgment in cease-and-desist proceedings initiated by Novartis against PI Pharma (President of Dutch-language Brussels Enterprise Court, 23 May 2024, A/23/03788, *Novartis AG v. PI Pharma NV*). The Brussels Court of Appeal and the President of the Dutch-language Brussels Enterprise Court are hereinafter together referred to as the ***Courts***.

All three judgments apply the judgment which the Court of Justice of the European Union (***CJEU***) delivered on 17 November 2022 in response to requests for a preliminary ruling from the Brussels Court of Appeal in the present proceedings (CJEU, 17 November 2022, Joined Cases C-253/20 and C-254/20, *Impexeco*, ECLI:EU:C:2022:894, available here; the ***CJEU Judgment***). In the CJEU Judgment, the CJEU held that the trade mark owner of an originator medicinal product can oppose the repackaging and rebranding of a parallel imported generic medicinal product as its original medicinal product unless (i) the two medicinal products are "*identical in all respects*"; and (ii) the repackaging/rebranding satisfies the BMS criteria, including the condition of necessity (*i.e.*, the first BMS criterion) (*See,* Van Bael & Bellis Life Sciences News & Insights of 8 December 2022).

Facts and Background

The proceedings before the Brussels Court of Appeal concerned the importation of generic Sandoz medicinal products, respectively "Letrozol Sandoz" and "Methylphenidate HCl Sandoz", from the Netherlands into Belgium and their repackaging and rebranding as, respectively, "Femara®" and "Rilatine®" (*i.e.*, the brand names of Novartis' originator medicinal products in Belgium), with a view to marketing the reconditioned medicines in Belgium. In their applications for parallel import licences, the parallel importers had submitted "Femara®" and "Rilatine®" as the Belgian reference products. At the time of the applications for parallel import licences, "Letrozol Sandoz" was also marketed in Belgium by Sandoz, contrary to "Methylphenidate HCl Sandoz", which Sandoz had not placed on the market in Belgium.

The proceedings before the President of the Dutch-language Brussels Enterprise Court, in turn, revolved around the importation in Belgium of "Amlodipine/Valsartan Sandoz" from Croatia and its repackaging as "Exforge®", which is the brand name of Novartis' originator medicinal product in Belgium. The parallel importer, PI Pharma, used "Exforge®" as the Belgian reference product in its application for a parallel import licence, even though Sandoz had been commercialising "Amlodipine/Valsartan Sandoz" in Belgium since 2019.

Importantly, in all three cases the generic products and the originator products were completely identical in composition. Furthermore, the generic products and the originator products had a "*common origin*" in that the manufacturer of the generic medicines, Sandoz, was at the relevant time still a part of the Novartis group (it was only spun off from Novartis as an independent company on 4 October 2023). As follows from the CJEU's case law, a "*common origin*" is considered to

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exist if the imported product and the reference product have been manufactured by (i) the same manufacturer; (ii) a manufacturer which operates as an associated company (*i.e.*, which is part of the same group of companies); or (iii) a manufacturer which operates under licence on behalf of the manufacturer of the reference product (*see*, for instance, CJEU, 27 October 2016, Case C-114/15, *Audace and Others*, ECLI:EU:C:2016:813, available here, para. 47). Finally, all products concerned were prescription-only medicines.

Findings of Courts and Assessment

Identical Medicinal Products

First, as regards the requirement that the parallel imported generic medicinal product and the original reference medicinal product should be "*identical in all respects*", the Courts logically concluded that this requirement was satisfied.

The Brussels Court of Appeal noted that the products had an identical composition and that they were all manufactured by the Novartis group. Unhelpfully, however, it went on to note that "[a] *generic medicinal product and a*[n originator] *reference medicinal product can be regarded as identical, for the purposes of the exhaustion of the trade mark rights, if they are completely identical as regards their intrinsic characteristics*" and that "[i]*t does not suffice that they have the same therapeutic effect*". To the extent that this language were to imply that "*common origin*" is not an essential requirement for a generic and an originator product to be regarded as "*identical in all respects*" for the purposes of the exhaustion of trade mark rights, the Brussels Court of Appeal would seem to have erred in law. If so, this error presumably stems from the ambiguous language in paragraph 65 of the CJEU Judgment (*See*, Van Bael & Bellis Life Sciences News & Insights of 8 December 2022).

Objective Necessity of Rebranding Generic Medicines as Originator Medicines to Market them in Belgium (First BMS Criterion)

Second, once it was established that the generic medicines and originator medicines qualified as "identical medicinal products", the Courts turned to the question of whether it was objectively necessary for Impexeco and PI Pharma to market the generic medicines in Belgium as originator medicines.

Mimicking the language of paragraph 72 of the CJEU judgment, the Brussels Court of Appeal held that "[w]*here the generic medicinal product corresponds in every respect to the reference medicinal product which has a marketing authorisation* [in the Member State of importation], *there is no reason why the authority of the Member State of importation would refuse to grant a licence for the identical generic medicinal product that is being imported in parallel and the parallel importer will, therefore, obtain a licence to market the generic medicinal product*". The Brussels Court of Appeal continued that "[t]*his implies that the condition of necessity is not satisfied, given that, in such a situation, the parallel importer must be regarded as being able to market the generic medicinal product under its mark of origin*".

Further noting that "*the medicine imported in parallel and the reference medicine must not have a common origin, in the sense that the manufacturers of both medicines are part of the same group of companies or manufacture the medicines on the basis of agreements concluded with the same licensor*", the Brussels Court of Appeal concluded that "[a]*n obligation to rebrand to the name of the reference medicine would, therefore, always amount to a trade mark infringement for medicines which do not have a common origin*" which "[…] *obviously cannot be the objective*".

In view of these findings, the Brussels Court of Appeal concluded that it was not objectively necessary for Impexeco and PI Pharma to market the generic medicines in Belgium as originator medicines.

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Whilst this conclusion should be welcomed as it is favourable to Novartis and the innovative pharmaceutical industry more generally, it is legally flawed in that it equates a parallel import licence with a marketing authorisation, thereby creating an arguably unjustified regulatory shortcut for parallel imports of generic medicines. Notwithstanding the 2019 *Delfarma* judgment of the CJEU (CJEU, 3 July 2019, Case C-387/18, *Delfarma,* ECLI:EU:C:2019:556, available here; discussed in Van Bael & Bellis Life Sciences News and Insights of 5 August 2019), for parallel trade to occur, the parallel traded product and the reference product in the Member State of import must necessarily have a "*common origin*". Parallel trade indeed refers to the importation by a third party of validly authorised goods from a specific manufacturer into a country where the same goods are already validly marketed by the same manufacturer. Parallel trade takes place outside (*i.e.*, in parallel to) the manufacturer's distribution system and is typically driven by price differences between countries. This implies that:

- Impexeco should have used the generic Letrozol Sandoz as the reference product in its application for a parallel import licence (and not the originator Femara®) considering that Letrozol Sandoz was being marketed in Belgium by its marketing authorisation holder, Sandoz;

- PI Pharma should have used the generic Amlodipine/Valsartan Sandoz as the reference product in its application for a parallel import licence (and not the originator Exforge®) considering that Amlodipine/Valsartan Sandoz was being marketed in Belgium by its marketing authorisation holder, Sandoz; and

- PI Pharma should have applied for a generic marketing authorisation for Methylphenidate HCl Sandoz, and not for a parallel import licence with Rilatine® as the originator reference product, considering that Methylphenidate HCl Sandoz was not yet marketed in Belgium.

Further, the Courts dismissed the arguments of Impexeco and PI Pharma that it was objectively necessary to rebrand the generic medicines as originator medicines in view of (i) the prohibition on parallel importers to advertise the imported medicines otherwise than through advertising reminding the name of the medicine or economic advertising; and (ii) the prescription practices which favour the originator reference product. In this regard, the Courts noted that:

- Physicians and pharmacists are familiar with the names of generic medicines and the fact that these take the form of an International Nonproprietary Name (***INN***) substance name followed by the name of the marketing authorisation holder;

- Since physicians and pharmacists are familiar with the names of generic medicines, the advertising restrictions applicable to parallel importers cannot hinder market access for parallel importers, which is all the more true in view of the fact that the products at hand are prescription medicines;

- Even if prescription practices were to make it more difficult for generic medicines to enter the market, "more difficult" is not "impossible" and, therefore, cannot justify the rebranding from generic to originator medicine; and

- It cannot be concluded from the fact that the market share of the generic medicine is small compared to that of the originator medicine that it is objectively necessary to rebrand the generic medicine as an originator medicine. The decision of the parallel importer to rebrand to the brand with the highest market share rather shows that the decision of the parallel importer to rebrand is exclusively motivated by the pursuit of an economic advantage.

Whilst the above findings are favourable to Novartis, they again start from the highly questionable premise that Impexeco and PI Pharma could validly use Novartis' originator medicines as the reference products for the purpose of obtaining a parallel import licence for the generic Sandoz medicines.

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One of the *BMS* criteria not being satisfied, the Courts concluded that Novartis could legitimately seek to block the further commercialisation of the repackaged/rebranded medicines. As a result, the requested cease-and-desist order was granted (President of Brussels Enterprise Court) and maintained (Brussels Court of Appeal).

LITIGATION

Court of Justice of European Union Rules on Territorial Jurisdiction Over Consumer Contracts

On 29 July 2024, the Court of Justice of the European Union (***CJEU***) confirmed that Regulation (EU) No 1215/2012 on jurisdiction, recognition and enforcement of judgments in civil and commercial matters, known as Brussels Ia Regulation (the ***Regulation***), applies when the consumer and the tour operator are domiciled in the same Member State and the trip is abroad. According to the CJEU, this international element is sufficient for the Regulation to apply.

Background

This case arose out of a dispute between JX, a consumer domiciled in Nuremberg (Germany), and FTI Touristik GmbH, a tour operator based in Munich (Germany). On 15 December 2021, JX concluded a package travel contract with FTI Touristik. Claiming that he had not been sufficiently informed by FTI Touristik of the entry conditions and visas required for his trip to a foreign country, JX brought an action for damages in the amount of EUR 1,499.86 before the court of his place of domicile, the Amtsgericht Nürnberg, in Nuremberg (Germany) (the ***Local Court***).

According to JX, the Local Court had territorial jurisdiction, in accordance with the rules applicable to consumer contracts laid down in Articles 17 and 18 of the Regulation, as the trip abroad constituted an international element that enabled the Regulation to apply. By contrast, FTI Touristik challenged the territorial jurisdiction of the Local Court and claimed that the Regulation did not apply to a domestic dispute in which both parties reside in the same Member State. The Local Court stayed the proceedings and referred the case to the CJEU for a preliminary ruling on the interpretation of the Regulation.

In essence, the Local Court asked whether Article 18 of the Regulation determines both the international and territorial jurisdiction of the national court of the district in which the consumer is domiciled in the event of a dispute between a consumer and a tour operator domiciled in the same Member State in relation to a trip whose destination is abroad.

Judgment

First, the CJEU ruled that even in situations in which both the consumer and the tour operator are domiciled in the same Member State, the fact that the trip is abroad is a sufficient international element for the Regulation to apply.

Second, the CJEU reiterated that the Regulation also directly grants jurisdiction to the local court in which the consumer has its domicile. As a result, it guarantees that the consumer, who is the weaker party, can easily bring an action against the stronger party before an easily accessible court.

Accordingly, the CJEU interpreted the Regulation as determining both the international jurisdiction and territorial jurisdiction of the local court of the district in which the consumer is domiciled, in the event of a dispute relating to a travel destination abroad between a consumer and a tour operator domiciled in the same Member State.

The full judgment is available here.

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