THE PHARMACEUTICAL INTELLECTUAL PROPERTY AND COMPETITION LAW REVIEW

Editor
Daniel A Kracov

THE LAWREVIEWS

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PREFACE

The pharmaceutical business is truly one of the most global industries, with many companies operating in dozens of countries with differing legal regimes and healthcare systems. In certain respects, the rules governing industry activities have largely become harmonised, such as in drug manufacturing and the conduct of clinical trials. However, in other areas the legal frameworks differ, and those nuances can require significant efforts to both optimise strategies and comply with requirements in local jurisdictions. In the areas of focus of this book – pharmaceutical intellectual property, including patent linkage and exclusivities, and related competition concerns – while general concepts may be shared across jurisdictions, it can be critically important to tailor approaches to the local legal environment.

Maximising the value of intellectual property can make the difference in deciding to pursue the development of an important new treatment, and in determining its sustained success in the marketplace. Similarly, a failure to carefully manage risks in dealings with competitors, such as generic and biosimilar companies, can result in huge civil and criminal liabilities. This is an area of significant enforcement activity around the world, with large fines being imposed and transactions thwarted if applicable legal constraints are not heeded. Moreover, the links between intellectual property, such as exclusivities, and drug pricing and affordability has been a constant source of political scrutiny, as well as patient and physician concern. With the ongoing covid-19 pandemic spurring an intense focus on intellectual property and pricing issues associated with vaccines and other needed treatments, the stakes have grown even higher.

Our objective in framing this volume is to give practitioners in the field a one-volume introduction to these critical issues in an array of jurisdictions. I would like to thank the authors for their contributions to this edition of the *Pharmaceutical Intellectual Property and Competition Law Review*. They have produced what we believe is a very useful tool for managing global risks in this area.

Daniel A Kracov
Arnold & Porter
Washington, DC
August 2020

Chapter 2

BELGIUM

Philippe Campolini, Sophie Van Besien, Ignace Vernimme and Peter Wytinck[1]

I OVERVIEW

In Belgium, the pharmaceutical sector is very well developed. In fact, Belgium is even considered a world leader in research and production of medicinal products. This important sector of the Belgian economy is subject to a legal and regulatory framework of which European law forms an important part. Nevertheless, the Belgian normative and regulatory framework contains a number of peculiarities.

In addition to pharmaceutical law, other branches of law, for example, intellectual property law and competition law, are relevant to the pharmaceutical sector.

After a brief presentation of the general Belgian legislative and regulatory framework (Section II), a series of domestic peculiarities for new drugs, generics, biologics and biosimilars will be examined (Section III). Next, the interfaces between the pharmaceutical sector and patent law are analysed (Section IV). To conclude, in Sections V to VII, we will focus on the interfaces between the pharmaceutical sector and competition law. In this regard, an overview of the competition enforcers, their role in merger control and approach to anticompetitive behaviours in the pharmaceutical sector is provided.

II LEGISLATIVE AND REGULATORY FRAMEWORK

i Registration of pharmaceutical products

Prior to its use, a medicinal product must be registered and obtain a marketing authorisation (MA). Several European and national procedures coexist.

The centralised procedure is conducted by the European Medicines Agency (EMA) and organised by the legislator in EU Regulation 726/2004.[2] Approval is granted by the European Commission based on a positive opinion of the Committee for Medicinal Products for Human Use (CHMP) – an organ of the EMA. This MA is valid across the European Union (EU).

In Directive 2001/83 on the Community code relating to medicinal products for human use,[3] the legislator organises two other EU MA procedures: a decentralised procedure and a variant called the mutual recognition procedure. The various national competent

1 Philippe Campolini, Sophie Van Besien, Ignace Vernimme and Peter Wytinck are partners at Stibbe.

2 Regulation 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136/1, 30 April 2004.

3 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, OJ L 311/67, 28 November 2001.

authorities grant these authorisations. In Belgium, the Minister of Public Health grants authorisation based on a positive opinion of the Belgian Federal Agency for Medicinal and Health Products (FAMHP). Such MAs are only valid in the EU Member States where they have been approved or recognised. The difference between the decentralised procedure and the mutual recognition procedure is the existence, in the second case, of a valid MA in an EU Member State at the time of application. While the decentralised procedure takes a maximum of 210 days, the mutual recognition procedure is shorter, taking a maximum of 90 days.

Under the Belgian domestic procedure, MAs are granted that are only valid in Belgium. The rules and prosecution of the registration directly derive from the European provisions. In practice, an increasing number of innovative medicinal products marketed in Belgium have obtained European MAs. Indeed, the use of the centralised procedure is mandatory for many innovative products. If a medicinal product application for a MA is submitted in Belgium, the Belgian Committee for Medicinal Products for Human Use, which is an organ of the FAMHP, conducts the scientific assessment.

The key Belgian instruments are the Act of 25 March 1964 on medicinal products[4] and its implementing Royal Decree of 14 December 2006 on medicinal products for human and veterinary use.[5] Both instruments transpose the Directive 2001/83. For example, the decentralised procedure is set out in Articles 20 to 32 of the Royal Decree.

ii Pricing and reimbursement

National authorities are competent for pricing and reimbursement policies. However, they are bound by the principles of Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems.[6] Among others, in the Directive, the legislator provides that the time limit for obtaining a decision on a price must be within 90 days of receipt of the request.

After obtaining a MA, pharmaceutical companies are allowed to apply for pricing and reimbursement of the medicinal products.[7] Those two requests are carried out simultaneously to avoid unnecessary delays and to speed up the market entry process.[8] On the one hand, the pharmaceutical companies will have to obtain a price from the Belgian Ministry of Economic

4 Act of 25 March 1964 on medicinal products, Belgian Official Gazette, 17 April 1964: www.ejustice.just.fgov.be/eli/loi/1964/03/25/1964032508/justel.

5 Royal Decree of 14 December 2006 on medicinal products for human and veterinary use – Part 1: Medicinal products for human use (Articles 1 to 140), Belgian Official Gazette, 22 December 2006: www.ejustice.just.fgov.be/eli/arrete/2006/12/14/2006023298/justel.

6 Council Directive 89/105/ECC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems, OJ L 40/8, 11 February 1989. Two judgments of the Court of Justice of the EU concern the application of this Directive by the Belgian authority (see the judgments in cases C-245/03 (MSD) and 296/03 (GSK)).

7 Except when the centralised procedure is used. A reimbursement application can already be submitted based on a positive opinion of the CHMP.

8 Article 10 of the Royal Decree of 1 February 2018 laying down the procedures, terms and conditions relating to the reimbursement of the costs of compulsory insurance for medical care and allowances for the costs of pharmaceutical specialties, Belgian Official Gazette, 15 March 2018: www.ejustice.just.fgov.be/eli/arrete/2018/02/01/2018010896/justel.

Affairs.[9] On the other hand, reimbursement applications for prescription medicinal products must be submitted to the National Institute for Health and Disability Insurance (INAMI/RIZIV). The Belgian Minister of Social Affairs takes the final reimbursement decision.

The Belgian legislative framework on pricing of medicinal products is complex. Two procedures coexist, taking into account whether the product has also been the subject of a request for reimbursement. Yet, in practice, these different procedures have many similarities. They are described in the Code of Economic Law (CEL),[10] supplemented by a Royal Decree of 10 April 2014.[11]

With regard to the reimbursement, the rules are set out in the coordinated law of 14 July 1994 on compulsory healthcare and compensation insurance,[12] supplemented by the Royal Decree of 1 February 2018.[13] Reimbursable medicinal products are classified into reimbursement categories.[14] The therapeutic value of a medicinal product is taken into account to determine the extent of its reimbursement. There are three classes of therapeutic value (classes 1, 2 and 3), some of them having subclasses. Class 1 covers medicinal products presenting an added therapeutic value compared to other medicinal products.[15] In short, it covers new innovative medicinal products. This category also includes orphan medicinal products for which the application must, however, specify certain additional information.[16] Class 2 corresponds to medicinal products that have a similar added therapeutic value to another (or other) medicinal products.[17] Three subclasses (2A, 2B and 2C) are described in Article 5(1)(4–6) of the same Royal Decree. Class 3 (with the subclasses 3A, 3B and 3C) broadly corresponds to generic medicinal products.[18] For each of these classes and subclasses, the INAMI/RIZIV[19] has issued recommendations for pharmaceutical companies to facilitate the filing of applications to grant their reimbursement.[20] The reimbursement decision of the

9 This competence of the Ministry of Economic Affairs is derived from the Act of 22 January 1945 on economic regulation and prices, Belgian Official Gazette, 24 January 1945: www.ejustice.just.fgov.be/eli/loi/1945/01/22/1945012201/justel.

10 Articles V.9 to V.14 of the CEL. These articles are included in the section on competition and prices development. In addition to the pricing, the legislator organises procedures for lowering (Article V.10 § 6 CEL), blocking (Article V.11 CEL) or adapting (Article V.11 CEL) the fixed prices.

11 Royal Decree of 10 April 2014 establishing the conditions of admissibility, time limits and practical arrangements for requests for pricing, requests for price increases, price notifications and (price) communications for medicinal products, objects, appliances and substances assimilated to medicinal products, and raw materials, as referred to in Book V of the Code of Economic Law, Belgian official Gazette, 7 July 2014: www.ejustice.just.fgov.be/eli/arrete/2014/04/10/2014011283/justel.

12 Act of 14 July 1994 on compulsory insurance for medical care and benefits coordinated on 14 July 1994, Belgian Official Gazette, 27 Augustus 1994: www.ejustice.just.fgov.be/eli/loi/1994/07/14/1994071451/justel.

13 Royal Decree of 1 February 2018 laying down the procedures, terms and conditions relating to the reimbursement of the costs of compulsory insurance for medical care and allowances for the costs of pharmaceutical specialties, Belgian Official Gazette, 15 March 2018: www.ejustice.just.fgov.be/eli/arrete/2018/02/01/2018010896/justel.

14 Article 7 of the Royal Decree of 1 February 2018.

15 Article 5 § 1 subparagraph 2 of the Royal Decree of 1 February 2018.

16 Article 55 of the Royal Decree of 1 February 2018.

17 Article 5 § 1 subparagraph 3 of the Royal Decree of 1 February 2018.

18 Article 5 § 1 subparagraphs 5 and 6 of the Royal Decree of 1 February 2018.

19 Institut national d'assurance maladie-invalidité / Rijksinstituut voor ziekte- en invaliditeitsverzekering.

20 See these recommendations on www.inami.fgov.be/fr/professionnels/autres/industrie-pharmaceutique/Pages/default.aspx.

Minister of Social Affairs is based on a proposal from the Commission for the Reimbursement of Medicines.[21] The Commission is an advisory body made up of academics, health insurers, doctors and pharmacists, industry representatives and public health authorities. This pivotal body submits an evaluation report on the reimbursement request to the Minister. The Minister of Social Affairs, after having obtained the agreements of the Minister of Budget and Minister of Finances, decides upon this report and adopts a Ministerial Decree authorising (or not) the reimbursement of the medicinal product concerned.[22]

With regard to the time limits for obtaining a reimbursement decision, in the absence of a decision for the reimbursement of class 1 or 2B medicinal products within a 180-day period from the date of receipt of the request, the reimbursement request is considered accepted. This time frame is limited to 90 days for classes 2C, 3B and 3C medicinal products and 60 days for classes 2A and 3A medicinal products.[23]

iii Patents and supplementary protection certificates

Innovative medicinal products are generally protected by patent rights. In Belgium, the protection is granted for a 20-year period (Article XI.47 CEL) in line with the minimum requirement of the Agreement on Trade-Related Aspects of Intellectual Property Rights. The European Patent Office grants the majority of pharmaceutical patents having effect in Belgium.

To compensate for the time lost between the patent filing and the granting of a MA for the resulting medicinal product, a sui generis right has been put in place. This duration extension is obtained thanks to the supplementary protection certificates (SPCs). Unlike the US mechanism of patent term extension, SPCs are thus distinct from the patent based on which they are granted. The main SPC rules are described at EU law level by EU Regulation 469/2009 concerning the SPC,[24] recently amended by EU Regulation 2019/933 introducing the 'SPC manufacturing waiver'. In the Belgian CEL, the legislator completes the EU legal framework by adding some procedural and related rules (Article XI.92 to XI.103). Finally, certain implementation measures are set by a Royal Decree of 4 September 2014.[25]

In parallel, a system has also been put in place to promote a rapid market entry of generic copies – the Bolar exemption. This exemption is enshrined in Article 10(6) of Directive 2001/83 relating to medicinal products for human use, as amended by

21 Commission de Remboursement des Médicaments / Commissie Tegemoetkoming Geneesmiddelen.

22 The Commission for the Reimbursement of Medicines also provides opinions to the Minister regarding the reimbursement policy as well as proposals on interpretation rules related to the reimbursement of medicinal products.

23 For these three periods, see Article 15 § 1 of the Royal Decree of 1 February 2018.

24 In EU Regulation 469/2009, the legislator codifies and repeals the EU former Regulation 1768/92 concerning the SPC. Regulation 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152/1, 16 June 2009, and Council Regulation 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, OJ L 182/1, 2 July 1992.

25 Royal Decree of 4 September 2014 relating to the implementation of the provisions relating to supplementary protection certificates of the law of 19 April 2014 inserting Book XI, 'Intellectual Property' into the Code of Economic Law and inserting provisions specific to Book XI into Books I, XV and XVII of the same Code, Belgian Official Gazette, 11 September 2004: www.ejustice.just.fgov.be/eli/arrete/2014/09/04/2014011493/justel.

Directive 2004/27/EC.[26] In Belgium, this exemption is provided by Article 6 bis Section 1 last subparagraph of the Act of 25 March 1964 on medicinal products. The legislator provides that 'conducting the necessary studies, tests and trials with a view of satisfying the conditions and procedures of subparagraphs 1 to 7 and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products for human use'. The scope of the Bolar exemption covers all the studies (bio-equivalence studies and bridging studies) necessary to register a generic or a biosimilar product or even a 'hybrid product' that includes, for example, a new indication or a new delivery system.

iv Public purchasing

Regarding public purchasing of pharmaceuticals, the General Act on Public Procurement of 17 June 2016 is applicable.[27] It transposes the EU Directive 2014/24 on public procurement. There are no particular rules related to the pharmaceutical sector included in this Act.

v Innovation incentive programmes and research exemption

Several measures have been taken to encourage innovation, with obvious impacts in the pharmaceutical sector.

First, two non-cumulative measures concern R&D costs. A company can obtain an R&D tax credit for these expenses (Articles 289 quater to 289 novies of the Belgian Income Tax Code)[28] or an investment deduction for R&D expenses (for qualifying patents, environmentally friendly R&D investments, etc.). The percentage of deduction on these investments is between 13.5 per cent and 20.5 per cent depending on whether the deduction is a one-off or spread out.

Second, in the Act of 7 February 2017,[29] the legislator allows a tax deduction of 85 per cent for the benefit of Belgian companies and Belgian establishments of foreign companies of the net income they derive from qualifying IP assets from their Belgian corporate tax base. Patents, supplementary protection certificates as well as orphan drug designations income derived from data and market exclusivity for pharmaceutical products, are eligible for this tax deduction.

Finally, the Belgian legislator provides for a reduced payroll tax up to 80 per cent for qualifying researchers (not only researchers but also the research technicians and R&D project managers). This tax reduction concerns in particular companies employing researchers holding specific diplomas, 'young innovative companies', universities or approved scientific institutions and companies collaborating with them.

Another incentive for innovation is included in Article XI.34(1)(b) of the Belgian CEL, which restricts the scope of exclusive rights under a patent or an SPC. This experimental

26 Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, OJ L 136/34, 30 April 2004.

27 See also the Royal Decree of 18 April 2017 on public procurement in the classical sectors, Belgian Official Gazette, 9 May 2017: www.ejustice.just.fgov.be/eli/arrete/2017/04/18/2017020322/justel.

28 Income Tax Code of 10 April 1992, Belgian Official Gazette, 30 July 1992: www.ejustice.just.fgov.be/eli/loi/1992/04/10/1992041050/justel.

29 Act of 7 February 2017 introducing a deduction for innovation income, Belgian Official Gazette, 20 February 2017: www.ejustice.just.fgov.be/eli/loi/2017/02/09/2017029171/justel.

use exemption provides that 'the rights conferred by a patent shall not extend to acts which are performed for scientific purposes on and/or with the subject matter of the patented invention'. It does not limit its scope to research carried out 'on' the subject matter of the patented invention. It also applies to research carried out 'with' the subject matter of the patented invention, which includes the use of a patented invention as a research tool. The broad interpretation of the research exception was confirmed in the preparatory work of the Belgian patent law. On 19 December 2017, in the implementing act of the Agreement on the Unified Patent Court (UPCA),[30] the legislator changed the scope of the experimental use exemption to 'acts for experimental purposes relating to the subject matter of the patented invention'. Actions performed 'with' the patented invention are therefore no longer covered, but the legislator adds that actions 'performed for the evaluation of medicines' fall under the new exemption. However, the entry into force of this revised experimental exemption is uncertain. It depends on the date of entry into force of the UPCA, which is far from clear at this time.

vi Advertising and promoting medicinal products

Although the general rules on the advertising and promotion of medicinal products are set out at European level, the Member States have their own specific implementation rules. In Belgium, the main implementation rules are to be found in Articles 9 to 12 of the Act of 25 March 1964 on medicinal products.[31] These rules are relatively strict overall.

The advertising of medicinal products is defined as 'any form of soliciting of information, prospecting or incitement aimed at promoting the prescription, supply, sale or consumption of medicinal products'. For example, the advertising of unregistered or prescription medicinal products, as well as the direct distribution of medicinal products to the public by pharmaceutical companies for promotional purposes, are prohibited (Article 9(1)). The legislator also prohibits, subject to strict exceptions, the offering of direct or indirect advantages of any kind to wholesalers, doctors and hospitals, etc. (Article 10).

vii Competition law to ensure effective competition

To ensure access to innovative and affordable medicinal products, effective competition is warranted. Pharmaceutical companies have to compete based on quality and prices of their products and not through anticompetitive behaviour. In Belgium, anticompetitive behaviour is prohibited by Articles IV.1 Section 1 (illegal coordination) and IV.2 (abuse of dominance) of the CEL. Both provisions are almost identical to their equivalent in European Law – respectively Articles 101 and 102 of the Treaty on the Functioning of the European Union (TFEU).

In addition, to ensure innovation and affordability of medicinal products, markets will have to be shielded against excessive consolidation through concentration. The Belgian rules with regard to merger control are also enshrined in Book IV CEL (Articles IV.6–IV.11 CEL).

30 Act of 19 December 2017 amending various patent provisions in connection with the implementation of the unitary patent and the unified patent court, Belgian Official Gazette, 28 December 2017: www.ejustice.just.fgov.be/eli/loi/2017/12/19/2017031999/justel.

31 Act of 25 March 1964 on medicinal products, Belgian Official Gazette, 17 April 1964: www.ejustice.just.fgov.be/eli/loi/1964/03/25/1964032508/justel.

III NEW DRUGS AND BIOLOGICS – APPROVAL, INCENTIVES AND RIGHTS

i Drugs

The pathway for approval of new drugs contains several steps (registration, marketing authorisation, pricing, reimbursement and patent exclusivity, etc.). Some of them have already been briefly described under Section II. A few additional elements relating to new drugs may be added.

Data and market exclusivity

In addition to the exclusivity granted by a patent, the legislator specifies in the Act of 25 March 1964 that new drugs (including biologics) enjoy data exclusivity during the eight years following their MA granted in Belgium or in an EU Member State (Article 6 bis Section 1 subparagraph 1, a contrario). During this period, generic drug companies cannot apply for authorisation for copies of the original drugs.

Even when that eight-year period has passed, generic drug companies have to take into account another exclusivity (a market exclusivity) period granted to reference medicinal products they intend to copy. In Article 6 bis Section 1(2), the legislator states that generic products cannot be marketed before the end of a 10-year period following the initial MAs of the reference medicinal products (this is the '8+2 system' that combines the two exclusivities).[32] One year is added to the 10-year period when, after the initial MA has been granted for the reference product, a new therapeutic indication is obtained for this reference product (Article 6 bis, Section 1(4)).[33] In the latter case, the reference medicinal product benefits from 11 years of data and market exclusivity (8+2+1 system).

Another exclusivity is granted where an application is made for a new indication for a well-established substance: a non-cumulative period of one year of data exclusivity, provided that significant preclinical or clinical studies were carried out in relation to the new indication (Article 6 bis, Section 1(9)).

As far as orphan medicinal products are concerned, the legislator provides in EU Regulation 141/2000 for a market exclusivity in favour of the holder of a MA for these types of medicinal products.[34] This market exclusivity is even longer for orphan medicinal products for paediatric use. Under certain circumstances, the exclusivity period may also be shortened.

Medicinal products for paediatric use

Concerning medicinal products for paediatric use, two supplementary clarifications can be made.

First, the pricing procedure is simplified. This is also the case for range extensions. The specific modalities are listed in the Royal Decree of 10 April 2014 (Articles 14 and 15). The requests for pricing (or price increase) are made by registered letter sent to the Minister of Economic Affairs or via a specific digital platform.

32 Eight years of data exclusivity and two years of market exclusivity.

33 In Article 6 bis, the legislator transposes Article 10 of the Directive 2001/83.

34 Regulation 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products, OJ L 18/1, 22 January 2000.

Second, in Regulation 1901/2006 on medicinal products for paediatric use,[35] the legislator extends the duration of an SPC by six months when it concerns a medicinal product for paediatric use, and as long as it does not concern an orphan medicinal product.

In the same Regulation (Article 30), there is also contains a specific incentive (called PUMA) for off-patent medicinal products that have obtained a paediatric indication.

ii Generic and follow-on pharmaceuticals

The pathway to generic drug approval has been briefly described in Section II on the legislative and regulatory framework. Three elements relevant to generic medicinal products can be highlighted.

First, with regard to the MA procedure for generic medicinal products, the legislator provides in Article 6 bis of the Act of 25 March 1964 that the generic applicant does not need to provide the results of preclinical and clinical trials if he or she demonstrates that his or her medicinal product is indeed a generic of an authorised medicinal product (Article 6 bis, Section 1(6,7)). This abbreviated procedure allows generic companies to drastically limit the costs for obtaining a MA.

Second, the pricing procedure for generic medicinal products is simplified and identical for reimbursable and non-reimbursable medicinal products. The features of the procedure are described in Articles 14 and 15 of the Royal Decree of 10 April 2014. They are identical to those described for medicinal products for paediatric use. Since the pricing applies to a generic drug, the price is logically expected to be lower than the price of the reference medicinal product.

Third, we recall the existence of the Bolar-exemption that promotes low-cost generic copies of original medicinal products (see Section II.iii).

iii Biologics and biosimilars

Biologics are innovative medicinal products. They are governed by the general rules described in Section II. Although biosimilars are not structurally identical to the reference biological product (and therefore do not fall under the definition of a generic medicinal product), they can obtain MAs under less demanding requirements. Unlike other generic drug applications, applications for MA must be accompanied, for biosimilar medicinal products, by some additional data (often some clinical trials and studies). What is clearly required to obtain an authorisation for biosimilars is determined on a case-by-case basis (Article 6 bis Section 1 subparagraph 8). The objective of these trials or studies is to demonstrate that the safety and efficacy of the biosimilar product is indeed comparable to the reference original biological product.

The pricing procedure for biosimilar medicinal products is also simplified, as indicated in Articles 14 and 15 of the Royal Decree of 10 April 2014. Likewise, their reimbursement procedure has a number of specific features (Articles 56 to 58 of the Royal Decree of 1 February 2018) and some additional information that must be provided by the applicant.

Biosimilars also benefit from the application of the Bolar-exemption (see Section II.iii).

35 Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for pediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004, JO L 378/1, 27 December 2006.

IV PATENT LINKAGE

Patent law and pharmaceutical law (covering registration, pricing and reimbursement, and advertising) operate separately.

However, there are certain interfaces, such as circumstances where patent or SPC rules are taken into account by pharmaceutical law:

a As previously mentioned, it is allowed to conduct the studies, tests and trials necessary to obtain an MA for a generic medicinal product even though these activities would fall under the scope of protection of an existing patent in the absence of the Bolar provision.

b Content of notices: indications or pharmaceutical forms covered by a patent may not appear in the notices of generic medicinal products in order to avoid patent infringement. In Article 6 bis Section 1 subparagraph 10 of the Act of 25 March 1964, the legislator states that for the MAs for human use medicinal products, the documents accompanying these products must not mention indications or pharmaceutical forms that were still protected by patent law at the time of its marketing.

c Patent litigation in the pharmaceutical sector often focuses on preliminary measures aimed at preventing market entry by generic companies. The Brussels Business Court has an exclusive jurisdiction in patent and SPC cases regardless of the amount of the claim (Article XI.337 of the CEL). The patent or SPC holder often initiates patent litigation after the generic or biosimilar producer has applied for reimbursement of its product. Several kinds of proceedings are available in Belgium and will be briefly described below.

The procedure of '*saisie-description*' allows a patent or SPC holder to file an ex parte request to obtain descriptive measures, possibly combined with an effective seizure of the stocks encountered during the execution of the court order. The patent or SPC holder must demonstrate beforehand the prima facie validity of his or her patent or SPC and provide indications of an (imminent) infringement. The order issued by the court may be accompanied by recurring penalty payments to ensure its effectiveness. An independent court-appointed expert carries out the court order, and then files a report with the technical and commercial information that was collected on the alleged infringement. He or she is not authorised to give an opinion on whether the patent or the SPC is infringed. The plaintiff needs to initiate infringement proceedings on the merits within a month after the filing of the report, otherwise the report can no longer be used.

The alleged infringer may anticipate a procedure of *saisie-description* by filing a protective letter with the court. In this letter, he or she must convince the judge that the procedure of *saisie-description* should not be granted, notably by showing that the conditions of these procedures are not fulfilled. However, there is no legal framework organising the filing of protective letters in Belgium. This is a practice that has developed and that not all judges follow.

A patent or an SPC holder can also obtain two kinds of preliminary injunctions. First, an inter partes preliminary injunction requires the patent or SPC holder to show that the patent or SPC is prima facie valid and infringed and that the requested measures are urgent. Second, an ex parte preliminary injunction requires the holder to demonstrate extreme urgency and an imminent risk of irreparable harm.

Finally, there are two other kinds of procedure on the merits. The first one is the cease and desist procedure. This procedure is quick and effective: it follows the fast track of

summary proceedings, but the court decides on the merits of the case. Its scope is, however, limited: no damages can be obtained. Its sole purpose is to stop counterfeiting activities. The second procedure is the ordinary procedure on the merits. It allows the plaintiff to request the full range of available remedies, including damages. However, the time required for obtaining such a decision is longer.

V COMPETITION ENFORCERS

The Belgian Competition Authority (BCA) is responsible for safeguarding and promoting effective competition on the Belgian territory. The BCA, originally an administrative court, was transformed into 'an independent administrative authority' in 2013 following the entry into force of Book IV of the CEL. Within the new BCA, there is a College of Competition Prosecutors (headed by the Prosecutor-General) and a Competition College.[36] Whereas the former holds the BCA's investigative powers, the latter holds the decision-making powers.[37] Both are independent and also work independently of each other.

To accomplish its general task of safeguarding and promoting effective competition, the BCA pursues anticompetitive practices (cartels, vertical restrictions, abuse of a dominant position and by the end of the year also abuses of positions of economic dependence) and reviews concentrations that meet certain turnover thresholds. With regard to the anticompetitive practices, the BCA can start an investigation, on its own initiative or at the request of a complainant or a Minister or following a leniency declaration, adopt interim measures in case of emergency, and declare injunctions and fines.

As in most jurisdictions, the BCA has the discretionary power to decide which cases it will pursue in light of the available resources and priorities. The BCA annually announces its policy on enforcement priorities. Since 2017, the BCA has been considering the pharmaceutical sector as a priority that can count on increased attention. In particular, the BCA pays attention to all parts of the value chain: prices set by laboratories, competition between wholesalers-distributors, competitive dynamics and innovation at pharmacy level.[38]

In addition to the BCA, the national courts play an important role in the enforcement of competition law, as they are competent, for example, to assess damage claims of victims of competition law infringements, to establish infringements and order to stop them or to annul contracts in violation of competition law.

To conclude, the Minister of Economy also plays a role in competition law enforcement. In particular, the Minister has a positive injunction right; for instance, the Minister can order the Prosecutor General to investigate certain cases. The College of Competition Prosecutors and, if the case proceeds, the Competition College, remain free to dismiss the case or endorse undertakings.[39]

36 Article IV.16, Section 1 CEL.

37 Although the Competition College formally holds the BCA's decision-making power, the legislator also grants certain decision-making powers to the College of Competition Prosecutors; e.g., to authorise mergers filed under the simplified procedure. Article IV.30 Section 2, 5° CEL.

38 BCA, 'The Belgian Competition Authority's priority policy for 2020', 26 March 2020: www.bma-abc.be/nl/over-ons/publicaties/nota-prioriteitenbeleid-2020. The BCA's priority policies are only available in Dutch and French.

39 Article IV.41, Section 1, 3° CEL.

VI MERGER CONTROL

In the past 12 years, the BCA has approved three concentrations in the pharmaceutical sector.

On 8 December 2008, the BCA approved Febelco's acquisition of exclusive control of Mauroy Ets.[40] Febelco and Mauroy Ets are both full-line wholesalers of pharmaceutical products. The BCA defined the market as the market for full-line wholesale distribution of pharmaceutical products.[41] It ruled that short-line wholesalers cannot be considered as a worthy alternative as their offer of pharmaceutical products and delivery frequency is different. It also considered a further segmentation of the market for full-line wholesale distribution of pharmaceutical products based on the category of customers (pharmacists and hospitals), but decided not to focus on these potential segments since the transaction would not have an impact on competition. It further ruled that the market is national at most, but left the exact delineation of the geographic market open. The BCA concluded that the concentration would not significantly impede effective competition as the acquisition would only increase Febelco's market share to a limited extent, there was only a moderate market concentration, there was no significant overlap between the activities of Febelco and Mauroy and a sufficient number of strong competitors were to remain active in the market post transaction.

On 31 July 2009, the BCA approved Celesio AG's acquisition of exclusive control of Laboratoria Flandria NV.[42] Both parties provide wholesale distribution services for pharmaceutical products. The BCA cleared the transaction under a simplified procedure.

On 20 April 2017, the BCA conditionally approved McKesson group's acquisition of exclusive control of Belmedis, Espafarmed, Cophana and Alphar Partners and of a controlling interest in Sofadis following a second-phase procedure.[43] The acquisition concerned the full-line wholesale distribution of pharmaceutical products and other distribution services for the supply of pharmacies. The BCA considered that the transaction would significantly impede effective competition on the Belgian market for full-line wholesale distribution of pharmaceutical products due to important coordinated effects, which the efficiency gains would not counterbalance following the transaction. The BCA reasoned that the proposed transaction would result in a virtual duopoly between the parties and Febelco on the Belgian market for the full-line wholesale distribution of pharmaceutical products, as the structural characteristics of the market could result in tacit coordination on the market. The market is characterised by high market concentration, a similarity of market players, homogeneous services, stable demand and supply, lack of innovation, exchange of information via the wholesalers' trade association, transparency, repeated and frequent contact among market players, customer loyalty, and high barriers to entry and expansion. However, the main reason

40 Decision No. 2008-C/C-65 of 8 December 2008 in Case No. MEDE-C/C-08/0027. Raad voor Mededinging, 'Jaarverslag 2008': www.bma-abc.be/sites/default/files/content/download/files/2008_jaarverslag_raad.pdf.

41 Full-line wholesalers are wholesalers that can make the full range of prescription medicines available to pharmacists and that comply with the legal obligations regarding fast delivery. In contrast with the full-line wholesalers, short-line wholesalers only distribute a limited range of pharmaceutical products to pharmacists and do this on a less frequent basis.

42 Decision No. 2009-C/C-15-AUD of 27 August 2009 in Case No. MEDE-C/C-09/0013: www.bma-abc.be/nl/beslissingen/09-cc-15-aud-celesio-laboratoria-flandria.

43 Decision No. ABC-2017-CC-13 of 20 April 2017 in Case No. CONC–C/C–16/0038. Decision No. ABC-2016-C/C-39 of 21 December in Case No. CONC-C/C-16/0038. Belgische Mededingingsautoriteit, 'Jaarverslag 2017': www.bma-abc.be/sites/default/files/content/download/files/2017_jaarverslag_bma_0.pdf.

why the BCA identified a coordination risk between the two main remaining companies on the market was that there had been dawn raids in the sector during the pre-notification period, which led the BCA to presume that competition in this market was distorted.[44] To address the BCA's concerns, the parties had to divest one of their depots in the Ghent area together with all relevant related assets to allow a third player to enter the market. The parties also had to accept a number of behavioural commitments to protect smaller competitors. For example, the parties undertook not to apply any clauses in the supply contracts that prevent pharmacies from purchasing products from wholesalers other than the parties' main competitor Febelco. The BCA appointed a trustee to monitor the compliance with these commitments.

VII ANTICOMPETITIVE BEHAVIOUR

As mentioned in Section V, the BCA considers the pharmaceutical sector as a priority sector, subject to increased attention. The BCA made good on its promise. In 2019, an important share of its decisions relating to anticompetitive behaviour pertained to the pharmaceutical sector and in particular to the Belgian Order of Pharmacists. In addition, the BCA carried out several dawn raids in the pharmaceutical sector and other investigations are ongoing.

i Belgian Order of Pharmacists

In May 2019, the BCA fined the Belgian Order of Pharmacists (BOP) €1 million[45] for engaging in anticompetitive practices aimed at hindering the development of the MediCare-Market group on the market for services provided by pharmacists, or even excluding MediCare-Market from the market.[46] MediCare-Market offers pharmacy and parapharmacy services and tries to compete on prices through an innovative business model. The BOP opposed the development of the MediCare Market group in various ways. The BOP tried to exclude MediCare-Market by strategically initiating legal actions, such as referring MediCare-Market pharmacists to disciplinary boards and applying for cease-and-desist orders to stop the opening of new branches, claiming that MediCare-Market creates confusion between pharmacies and parapharmacies. Moreover, the BOP publicly disseminated threatening

44 Press Release – 20/2016, 21 November 2016, 'Het Auditoraat van de Belgische Mededingingsautoriteit bevestigt de huiszoekingen bij verschillende groothandelaars-verdelers die farmaceutische en para-farmaceutische producten leveren aan apotheken': https://www.bma-abc.be/sites/default/files/content/download/files/161121_persbericht_20_bma.pdf.

45 The BOP appealed this decision. The Brussels Market Court confirmed on 8 January 2020 that the BOP infringed the applicable competition law, but ordered the BCA to review the fine for procedural reasons (no new decision of the BCA on the fine is public yet). The Belgian legislator provided for a maximum fine of 10 per cent of an association's own turnover in the law that was applicable at the time of the facts, which in casu comes down to €250,000. Brussels, 8 January 2020, Ordre des Pharmaciens, Case 2019/MR/3: www.bma-abc.be/nl/beslissingen/2019mr3-ordre-des-pharmaciens.

46 Decision No. ABC-2019-I/O-14 of 28 May 2019 in Case No. CONC-I/O-16/0011, MediCare-Market – Ordre des Pharmaciens and Belgian Order of Pharmacists: https://www.bma-abc.be/sites/default/files/content/download/files/abc-2019-io-14_pub_0.pdf. See also Press Release – 16/2098, 5 June 2019, 'The Competition College of the Belgian Competition Authority condemns "l'Ordre des pharmaciens - Orde der apothekers" for having tried to hinder the development of the MediCare-Market group and imposes a fine of 1 million euros': https://www.belgiancompetition.be/sites/default/files/content/download/files/20190605_press_release_16_bca_0.pdf.

information to discredit MediCare-Market, such as stating that consumers are in danger at Medicare-Market. In addition, the BOP adopted a strategy of imposing a minimum resale price by limiting or prohibiting discounts, including for parapharmaceutical products. All this without an objective of general interest, but purely with an economic objective. The BCA ruled that the BOP infringed Articles IV.1 CEL and 101 TFEU between October 2015 and January 2017 by adopting a strategy to overthrow MediCare-Market's innovative business model and implementing it to defend the economic interests of the majority of its members.

In October 2019, the BCA again took formal steps against the BOP. In a settlement decision, the BCA found that several provisions of the BOP's Code of Ethics and two of its communications unduly restricted the ability of pharmacists to advertise their business and parapharmaceuticals, both online and offline.[47] Compared with its May 2019 decision, the BCA imposed a modest fine of €225,000 as the BOP accepted to settle the case and offered a number of commitments on a new deontological code and on the principle of free advertising.

ii Dawn raids

In October 2019, the BCA carried out dawn raids at the premises of different pharmaceutical companies and hospitals, including the Swiss pharmaceutical company Roche AS and the University Hospital Ghent.[48] The dawn raids relate to a possible violation of the European and Belgian cartel ban or abuse of a dominant position by restricting, delaying or preventing access to or expansion of the market for the producers of biosimilar medical products that can compete with existing patented drugs. The BCA requested, inter alia, several hospitals to provide detailed information on their suppliers, contracts and communications with pharmaceutical companies. In a first phase, the BCA focused its investigation on two of Roche's patented medical products, trastuzumab (Herceptin) and rituximab (Mabthera), and on whether Roche and the hospitals signed exclusive multiyear supply contracts just prior to the expiry date of the patent. Furthermore, the BCA's investigation also focuses on whether Roche granted certain conditional discounts to tie certain of its products.

iii Other investigations

The BCA is also investigating a complaint by Test-Aankoop, a Belgian consumer organisation, on the alleged anticompetitive practices between Novartis and Roche to block the entry of a cheap medical product for eye diseases.[49]

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47 Decision No. ABC-2019-P/K-34-AUD of 15 October 2019 in Case No. CONC-P/K-10/0024, CONC-P/K-13/0009, CONC-P/K-17/0024 and CONC-P/K-17/0030 : www.abc-bma.be/fr/decisions/19-pk-34-aud-multipharma-v-pharma-b-newpharma. See also, 'The Belgian Competition Authority imposes a fine of 225,000 euros on the Order of Pharmacists for some of its decisions limiting the ability of pharmacists to advertise, in particular via paid referencing, and the interest to apply rebates for parapharmaceuticals. The Order of Pharmacists also commits to comply with competition law by the disciplinary bodies': www.belgiancompetition.be/sites/default/files/content/download/files/20191016_press_release_34_bca.pdf.

48 Press Release – 32/2019, 8 October 2019, 'The Belgian Competition Authority is conducting inspections in the pharmaceutical sector': www.belgiancompetition.be/sites/default/files/content/download/files/20191008_press_release_32_bca_0.pdf.

49 News Test-Aankoop – 26 November 2014, 'Klacht tegen onethisch gedrag van Roche en Novartis': www.test-aankoop.be/gezond/gezondheidszorg/gezondheidsuitgaven-en-verzekeringen/nieuws/klacht-tege

VIII OUTLOOK AND CONCLUSIONS

First, it is important to remember that the legal framework applicable to medicinal products (original and generic, biologic and biosimilar), both with respect to intellectual property law (patent, SPC) and competition law (mergers, anticompetitive behaviours), is essentially designed by the EU legislator. Future important developments in these legal areas will therefore depend to a large extent on European policies. In view of the current and future state of the pharmaceutical market, it is essential to maintain a harmonised legal and regulatory framework in the EU Member States. However, this does not imply that the legal framework applicable to the pharmaceutical sector is currently totally uniform. National laws, and in particular Belgian law, provide for certain peculiarities when EU law allows. The Belgian legislative and regulatory framework has, for example, some tax incentive programmes, which have strengthened Belgium's leading position across the globe with regard to innovation.

Second, it will be interesting to analyse the possible impact of the covid-19 pandemic on the presented legal and regulatory framework. The rules adopted as a matter of emergency in the pharmaceutical sector could be maintained. Think, for example, of possible evolutions of the compulsory licensing regime, which is at the centre of important discussions relating to the research and future marketing of a vaccine. These changes could lead to a weakening of the rights of pharmaceutical companies.

Finally, the covid-19 crisis could materialise a series of measures to stimulate the production of medicinal products (currently produced outside the EU) within the EU. This could, for instance, include the development of the regulatory framework to ensure compliance with drugs legislation or the strengthening of Member States' delivery capacity to their citizens. Belgium could play an important role due to its internationally recognised expertise in the pharmaceutical sector. It is one of the world leaders in the field of clinical trials, which could make it a key player in this repatriation process.

n-onethisch-gedrag-van-roche-en-novartis and News Test-Aankoop – 5 April 2018, 'Roche en Novartis, wij eisen ons geld terug': www.test-aankoop.be/gezond/gezondheidszorg/gezondheidsuitgaven-en-verzekeringen/nieuws/roche-en-novartis-wij-eisen-ons-geld-terug.

Appendix 1

ABOUT THE AUTHORS

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Philippe Campolini is an IP law and life sciences specialist, with a particular focus on litigation work and innovations in science and technology. Philippe assists his clients in all IP areas, focusing strongly on patent law, trade secrets law and copyright. A substantive part of his practice is IP litigation. Philippe is passionate about scientific and technological innovations, and has a wealth of experience in high-end and complex patent litigations as well as innovation-driven transactional work (technology transfer, licence, R&D, etc.). He handles matters for Belgian and international clients from various sectors, notably the life sciences and medical device industries. Philippe has sat on the Belgian Patent Attorney Accreditation Commission since 2017. He serves on the executive committee of the law journal *Auteurs & Media* and on the management board of the Belgian Copyright Association. He is also a member of the International Association for the Protection of Intellectual Property, the European Patent Lawyers Association, the Licensing Executives Society and the German Association for the Protection of Intellectual Property. Philippe has authored many published works on IP topics, especially in the fields of patent law and trade secret law.

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Sophie Van Besien advises public bodies and private companies on the entire spectrum of national and EU competition law and regulatory compliance. Sophie has a wealth of knowledge and experience in EU and national competition law. She advises on complex international and multi-jurisdictional merger control proceedings, as well as investigations into cartels and abuse of dominant positions. She also focuses on state aid and damage claims. Sophie has built up extensive international experience and industry knowledge in technology, pharmaceuticals and biotechnology, postal and telecommunications, metals and mining, consumer products and retail, as well as financial services. With this valuable set of skills and know-how, she advises clients on the application of EU directives and general regulatory compliance issues. In addition, she represents clients before national competition authorities, the European Commission, national courts, and the European courts in Luxembourg. Sophie is author of several publications on competition law.

IGNACE VERNIMME

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Ignace Vernimme's expertise lies in IP law and covers the pharmaceutical, food and beverage, metallurgical, comic strip and fashion industries. Ignace specialises in patents, trademarks, copyright, designs, know-how protection, technology transfer and specific regulations that apply to pharmaceutical products. Ignace is recognised in the market as one of the very few IP experts who is highly specialised in several aspects of both soft and hard IP and thus able to assist his clients in a very broad range of legal questions or issues regarding their IP portfolio management (IP protection, IP commercialisation and IP litigation). Ignace is an arbitrator and mediator of WIPO, the founding member and chair of the editorial board of *IRDI* (one of the main Belgian IP reviews), a board member of the Dutch foundation BBMM, an organisation that provides a professional education programme for Benelux trademark and design attorneys, and a member and arbitrator of Cepani (Belgian Center for Arbitration and Mediation – Intellectual Property Litigation). He is a member of INTA, the Belgian Copyright Association, the International Literary and Artistic Association, the ethical committee of the Benelux Association for Trademark and Design Law, the Licensing Executives Society, the European Patent Lawyers Association and the Belgian National Association for the Protection of Intellectual Property).

PETER WYTINCK

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Peter Wytinck's expertise is primarily in European, Belgian and EU competition law, market practices (including product labelling and product regulations), trademark law and commercial litigation. Peter's practice of European law includes defending clients before the Court of Justice, the Court of First Instance, the European Commission, the Belgian national courts and administrative authorities (regarding among others the free movement of goods, services and capital, mergers, cartel arrangements, state aid, trademark law, EU contract litigation, and various EU directives and regulations). Peter also frequently advises on Belgian competition law matters and assists clients in the structuring of takeovers, joint ventures and contracts. He represents clients in the notification of contracts and concentrations, and in complaints and procedures before the Belgian Competition Council and Belgian courts and tribunals. Peter has extensive experience in advising on issues regarding market practices (such as labelling, (comparative) advertising, joint offers, price reduction announcements, sales and unfair competition) and regularly defends clients in these matters before the Belgian courts. His work on trademark matters mainly concerns litigation regarding the risk of confusion and parallel imports before national and international courts (Benelux Court of Justice and Court of Justice).

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