

# DAMAGES FOR RESTRAINTS ON COMPETITION – A CASE OF PRIVATE ENFORCEMENT IN THE PHARMACEUTICAL SECTOR\*

MONIKA WAŁACHOWSKA \*\*

## 1. INTRODUCTION

The purpose of this paper is to present the most important issues arising from a specific “junction” of intellectual property rights, competition law and compensation law (conflicts of law issues are discussed separately) in the pharmaceutical sector. For several years now, the European Commission has been monitoring patent settlements<sup>1</sup> aimed at delaying the commercialization of generic medicines, which may raise questions not only from the perspective of competition law but also from other areas of law. Such settlements can be one of the forms of patent abuse, but also a dominant position, and at the same time give rise to questions about the consequences in the field of law of damages. It is discussed that such market practices not only distort competition<sup>2</sup> but

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\*\* PhD hab., Assistant Professor, Faculty of Law and Administration of Nicolaus Copernicus University in Toruń; walachowska@umk.pl

<sup>1</sup> See M. Siragusa, *The EU pharmaceutical sector inquiry. New forms of abuse and Article 102 TFEU*, [in:] G. Caggiano, G. Muscolo, M. Tavassi (eds.), *Competition law and intellectual property: A European perspective*, Alphen aan den Rijn 2012, p. 177 ff; H. Ullrich, *Strategic patenting by the pharmaceutical industry: towards a concept of abusive practices of protection*, [in:] J. Drexler, N.R. Lee (eds.), *Pharmaceutical, innovation, competition and patent law – a trilateral perspective*, Cheltenham (Elgar Publishing) 2013, p. 244 ff; D. Schnichels, S. Sule, *The pharmaceutical sector inquiry and its impact on competition law enforcement*, *Journal of European Competition Law & Practice* Vol. 1, No. 2, 2010, p. 93 ff. See also, M.K. Kolasiński, *Odpowiedzialność odszkodowawcza za uszczerbek powstały w Unii Europejskiej w wyniku zawarcia sprzecznych z prawem antymonopolowym uгод patentowych o odwróconej płatności* [Liability for damage arisen in the European Union as a result of concluding reverse payment patent settlements against the antitrust law], *Przegląd Prawa Handlowego* No. 6, 2016, p. 5 ff.

<sup>2</sup> However, if one looks at the agreements which do not contain a remuneration, the anti-competitive effect might be difficult to prove.

also affect the position of consumers<sup>3</sup> and others who are interested in the lower price of generic medicines. Moreover, the practices restraining the competition in the pharmaceutical sector may also affect the health policy of the state. Apart from the consumer, who is the “last link” in the “chain of supply” of generic drugs (substitutes for original medicines that may be marketed after the expiry of patent protection of original medicines), the economic interest of the public or private bodies co-financing patients’ access to medicines should also be considered. In Poland, introducing the generic medicines to the market undoubtedly remains in the interest of the National Health Fund (hereinafter NHF) and the state budget (entities responsible for reimbursement of medicines [in Polish *refundacja*] and financing drugs within the health system financed by the state). Moreover, it is also insurance companies which might be (economically) interested in placing the generics to the market (if, for example, the insurer participates in costs of providing medicines within the life insurance coverage). On the other hand, another generic manufacturer may be able to gain a specific “competitive advantage”, which may eventually lead to a price war<sup>4</sup> (though this effect may be actually beneficial to the consumer). It seems that, above all, the protection of the public interest requires the assessment of the legal instruments set out below in terms of competition law and its enforcement.

The reason for the use of various legal instruments to delay the commercialization of generic medicines is primarily an economic consideration related not only to the patent procedure itself, but also to the costs of introducing a new drug to the market. In addition to the hundreds of millions of euros or dollars, the drug’s release takes up to 10 to 15 years,<sup>5</sup> and therefore, before the cost of the drug is “repaid”, patent protection may expire. In the case of market success, it is in the interest of both the original and the generic manufacturer that the product is still commercially viable and profitable (which could serve as a basis for further innovative research). In the meantime, the introduction of generics naturally leads to significant price reductions (by up to several dozen percent<sup>6</sup>) and changes in the market position of the interested parties. The assessment of these types of behaviour is complicated by the fact that the consumer is not the deciding entity in choosing the product: it is the doctor who prescribes the medicine without any costs involved for himself (the costs are borne by the patient, sometimes also by the state or the national health fund or other bodies).

In 2009 the European Commission launched an inquiry on the pharmaceutical sector, monitoring the settlements concluded by manufacturers of original (patented) and generic drugs.<sup>7</sup> In the announcements published also in the subsequent years,

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<sup>3</sup> However, the quantification of damages can be difficult and will be probably only approximate – see, L. Prosperetti, *Estimating damages to competitors from exclusionary practices in Europe: a review of the main issues in the light of national courts’ experience*, [in:] G. Caggiano, G. Muscolo, M. Tavassi (eds.), *Competition law and intellectual property...*, p. 248.

<sup>4</sup> See, P.L. Parcu, M.A. Rossi, *Negotiated foreclosure and IPRs: recent developments*, [in:] G. Caggiano, G. Muscolo, M. Tavassi (eds.), *Competition law and intellectual property...*, p. 171.

<sup>5</sup> M.A. Carrier, *Competition law and enforcement in the pharmaceutical industry*, [in:] A. Ezrachi (ed.) *Research handbook on international competition law*, Cheltenham 2012, p. 522.

<sup>6</sup> *Ibid.*

<sup>7</sup> Seven reports on this matter (2008–2015) are available at: <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html> (accessed on 11.08.2017). See also,

it was clearly emphasized that such settlements could have an anticompetitive effect, thus affecting not only the functioning of the market, but also the situation of consumers (and possibly other entities, e.g. national health funds, treasury, etc.). Some of the settlements may be aimed not so much to achieve an amicable solution to the dispute but, for example, the delay of commercialization of generic medicines (for a certain remuneration).

These issues coincide simultaneously with the European Union's aspirations to provide private enforcement mechanisms, thus ensuring the injured party the right compensation.<sup>8</sup> Directive of the European Parliament and of the Council No. 2014/104/EU on certain rules governing actions for damages under national law for infringements of the competition law provisions of the Member States and of the European Union, adopted on 26 November 2014,<sup>9</sup> has just been implemented by the Polish legislator.<sup>10</sup> It is, therefore, necessary to discuss the private enforcement mechanisms possible to be applied in the pharmaceutical sector.

## 2. INTELLECTUAL PROPERTY LAW AND COMPETITION LAW – THE CASE OF GENERIC DRUGS

### 2.1. GENERAL REMARKS

Because intellectual property rights, including patent rights, are exclusive, the right-holder may exercise his rights personally or license them to third parties. The mere fact that these rights are exclusive does not mean that there is some contradiction or conflict between intellectual property law and competition law.<sup>11</sup>

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L. Kjølbj, *Article 82 EC as remedy to patent system imperfections: Fighting fire with fire?*, World Competition Law and Economics Law Review Vol. 32, issue 2, 2009 p. 163 ff.

<sup>8</sup> See, D. Ashton, D. Henry, *Competition damages actions in the EU. Law and practice*, Elgar Publishing (Cheltenham), 2013, p. 22 ff; CJEU judgment of 13 July 2006 in *Manfredi C-295/04*; see also, H.W. Micklitz, *Consumers and competition – access and compensation under EU law*, European Business Law Review 2006, p. 3 ff; U. Bernitz, *Introduction to the Directive on Competition Damages Actions*, [in:] M. Bergström, M.C. Iacovides, M. Strand (eds.), *Harmonising EU competition litigation. The new Directive and beyond*, Swedish Studies in European Law, Vol. 8, Oxford and Portland, Oregon, 2016, p. 3 ff; J.H.J. Bourgeois, S. Stievi, *EU competition remedies in consumer cases: Thinking out of the shopping bag*, World Competition No. 2, 2010, p. 242 ff.

<sup>9</sup> OJ L 349, 5 December 2014, p. 1 ff, hereinafter referred to as the Directive.

<sup>10</sup> Act on damages claims for harm caused by infringement of competition law of 6 April 2017, Journal of Laws [Dz.U.] of 2017, item 1132 (it came into force on 26 June 2017), hereinafter referred to as the Polish Act.

<sup>11</sup> See, R. Sikorski, *Wyłączność korzystania z praw własności przemysłowej* [Exclusive right to exercise intellectual property rights], [in:] E. Nowińska, K. Szczepanowska-Kozłowska (eds.), *System prawa handlowego. Tom 3 – Prawo własności przemysłowej* [Commercial Law system. Vol. 3: Intellectual property law], Warsaw 2015, p. 461 and citation of D. Miąsik, *Stosunek prawa ochrony konkurencji do prawa własności intelektualnej* [Competition protection law vs. industrial property law], Warsaw 2012; see also, K. Schöller, *Patents and standards: The antitrust objection as a defense in patent infringement proceedings*, [in:] W.P. zu Waldeck und Pyrmont, M.J. Adelman, R. Brauneis, J. Drexler, R. Nack (eds.), *Patents and technological progress in a globalized world. Liber Amicorum Joseph Straus*, Springer, Berlin Heidelberg 2009, p. 178.

Both disciplines are aimed at increasing competition through innovation.<sup>12</sup> Nevertheless, the way intellectual property rights are exercised can be evaluated in the field of national or EU competition law<sup>13</sup> (especially in the context of the abuse of a dominant position<sup>14</sup>). Therefore, if for example a biotechnological invention patent holder demands unreasonably high royalties or even refuses to grant a licence, its action may raise questions from the point of view of competition rules and consequently, lead to a claim for damages (providing a private enforcement of public competition law). Similarly, the use of other legal instruments may give rise to this anti-competitive effect. As an example, we might recall the creation of the “patent thickets”<sup>15</sup> or “overlapping patents”<sup>16</sup>. The other practices are in fact “artificial” attempts to extend protection through “ever-greening” strategy (which is related to earlier protection: for example, due to the end of patent protection for the substance itself, the patentee applies for protection for the manufacturing method), namely “extending” protection by patenting the second use or substance itself.<sup>17</sup> This type of patent strategy is referred to as “defensive patenting”<sup>18</sup>, intended to block the development of new products by competitors. The phenomenon of “continuous refreshing” of protection leads to the emergence of patent thickets around the drug (various “parts” are subject to separate protection: for example, a cluster of patents

<sup>12</sup> See, U. Petrovčič, *Competition law and standard essential patents A transatlantic perspective*, Kluwer Law International, 2014, Ch. 3, pp. 2–3 ; see also, J. Drexl, *Deceptive conduct in the patent world – A case for US Antitrust and EU competition law?*, [in:] W.P. zu Waldeck und Pymont, M.J. Adelman, R. Brauneis, J. Drexl, R. Nack (eds.), *Patents and technological...*, p. 152.

<sup>13</sup> See, *Sirena* (C-40/70); *AstraZeneca* (C-457/10); see also, I. Ottaviano, [in:] G. Caggiano, G. Muscolo, M. Tavassi (eds.), *Competition law and intellectual property...*, p. 200; G. Ghindini, *Patent ambush and reverse payments: Comments*, [in:] J. Drexl, W.S. Grimes, C.A. Jones, R.J.R. Peritz, E.T. Swaine (eds.), *More common ground for international competition law?*, Cheltenham, Elgar Publishing 2011, p. 208; J. Drexl, *Intellectual property in competition: How to promote dynamic competition as a goal*, [in:] J. Drexl et al. (eds.), *Common ground for international competition law*, Cheltenham, 2011, p. 228; M. Kort, *Intellectual property and Article 82 EC*, [in:] W.P. zu Waldeck und Pymont, M.J. Adelman, R. Brauneis, J. Drexl, R. Nack (eds.), *Patents and technological...*, p. 157.

<sup>14</sup> See, K. Szczepanowska-Kozłowska, *Naruszenie praw własności przemysłowej [Infringement of intellectual property rights]*, [in:] E. Nowińska, K. Szczepanowska-Kozłowska (eds.), *System prawa handlowego...* [Commercial Law system...], pp. 714–715. See also, CJEU case *Magill* C-242/91 (abuse of IP rights as an abuse of dominant position); see also, *Competition law as a patent ‘safety net’ in the biopharmaceutical industry*, *The Competition Law Review* Vol. 1 Issue 2, 2004, p. 75; J. Temple Lang, *European competition law and intellectual property rights – a new analysis*, ERA Forum Vol. 11, 2010, pp. 413, 436.

<sup>15</sup> See, C. Shapiro, *Navigating the patent thicket: Cross licenses, patent pools, and standard setting*, [in:] A.B. Jaffe, J. Lerner, S. Stern (eds.), *Innovation policy and the economy*, Vol. 1, Cambridge 2001, p. 120 ff.

<sup>16</sup> See, A. Fuchs, *Patent ambush strategies and Article 102 TFEU*, [in:] J. Drexl, W.S. Grimes, C.A. Jones, R.J.R. Peritz, E.T. Swaine (eds.), *More common ground...*, p. 190; M.W. Haedicke, [in:] M.W. Haedicke, H. Timmann, D. Bühler, *Patent law. A handbook on European and German patent law*, München 2014, p. 47; K. Schöller, *Patents and standards...*, p. 179.

<sup>17</sup> See H. Ullrich, *Strategic patenting...*, p. 246; C.M. Correa, *The current system of trade and intellectual property rights*, [in:] M. Bungenberg, Ch. Herrmann, M. Krajewski, J.P. Terhechte (eds.), *European yearbook of international economic law 2016*, Springer Switzerland 2016, p. 190; B. Whitehead, S. Jackson, R. Kempner, *Managing generic competition and patent strategies in the pharmaceutical industry*, *Journal of Intellectual Property Law & Practice* Vol. 3, No. 4, 2008 p. 227–229.

<sup>18</sup> See, D. Schnichels, S. Sule, *The pharmaceutical sector...*, p. 103.

on the active substance, molecules, the dosage form of the drug, concentration of preparations, second use). As an example of these activities one may indicate the patent thicket on perindopril.<sup>19</sup> The above strategies are used because the patent system in general allows medicinal products to be protected either as a single chemical compound or a mixture of compounds, etc.

Since the abovementioned practices in the pharmaceutical sector can affect the functioning of the market, the application of Article 101 (restrictive competition agreements) and Article 102 (abuse of a dominant position) of the TFEU might be necessary. The same refers to Art. 2 et seq. of the Polish Act on competition and consumer protection of 16 February 2007.<sup>20</sup>

## 2.2. LEGAL INSTRUMENTS DELAYING INTRODUCTION OF GENERIC DRUGS TO THE MARKET

It is indicated in the literature that the anti-competitive practices in the pharma sector can be primarily the reverse payment settlements concluded between the manufacturer of the reference drug (“original”), i.e. the patentee, and the manufacturer of the generic drug.<sup>21</sup> According to such agreements, the patentee is obliged to pay a certain amount of money for non-entry (or delay in introducing the product) into the market, i.e. for non-competing or delaying the competition.<sup>22</sup> Payment is called as being “in the opposite direction” (referred to as “pay-for-delay”), as pointed out by the Court of Justice of the European Union (CJEU) in *Lundbeck* case (T-472/13). The Commission, imposing fines (EUR 93 million and EUR 52 million, respectively), considered such agreements to be in breach of Article 101 section 1 TFEU.<sup>23</sup> This was confirmed by the CJEU,<sup>24</sup> considering that such settlements could constitute a breach of antitrust law.

<sup>19</sup> See, K. Roox (ed.), *Bariery związane z patentami, utrudniające wprowadzenie leków generycznych na rynek Unii Europejskiej* [Barriers related to patents hampering introduction of generic drugs onto the EU market], Centrala Europejskiego Biura Patentowego, Munich 2008, pp. 32–34.

<sup>20</sup> Journal of Laws [Dz.U.] of 2007, No. 50, item 331, as amended.

<sup>21</sup> See also, M.K. Kolański, *Ugody o odwrotnej płatności w prawie antymonopolowym USA* [Reverse payment settlements in the US antitrust law], Państwo i Prawo No. 7, 2017, p. 55 ff.

<sup>22</sup> See, P.L. Parcu, M.A. Rossi, *Negotiated foreclosure and IPRs...* [in:] G. Caggiano, G. Muscolo, M. Tavassi (eds.), *Competition law and intellectual property...*, p. 158. The Authors emphasize that often the manufacturer of generic drugs obtains higher sum as a “pay-for-delay” remuneration than the expected profits when introducing the drug into the market. The “worth” of the settlements reaches hundreds millions of Euro each year – *ibidem* p. 159–160. See also R.J.R. Peritz, *Three statutory regimes at impasse: Reverse payments in pay-for-delay settlement agreements between brand-name and generic drug companies*, [in:] J. Drexler, W.S. Grimes, C.A. Jones, R.J.R. Peritz, E.T. Swaine (eds.), *More common ground...*, p. 198; O. Zafar, *Lundbeck, Johnson&Johnson and Novartis: The European Commission's 2013 'pay-for-delay' decisions*, Journal of European Competition Law & Practice Vol. 5, No. 4, 2014, p. 208.

<sup>23</sup> Commission's press release of 19 June 2013, IP 13/563.

<sup>24</sup> See, CJEU ruling of 8 September 2016, T-472/13; see also, M.K. Kolański, *Kryteria legalności ugód patentowych o odwrotnej płatności – glosa do wyroku Sądu UE z 8.09.2016 r. w sprawie H. Lundbeck A/S i Lundbeck Ltd przeciwko Komisji Europejskiej* [Legal criteria for reverse payment

Undoubtedly, the purpose of such agreements is to maintain the market position by the reference (original) medicine manufacturer. Introducing the generic drug to the market will surely reduce the profits of the first manufacturer, and above all, it leads to a significant price drop (even 80 to 90%<sup>25</sup>). The consequences of concluding such settlements are certainly unfavourable for consumers who are forced to pay a higher price for drugs. The public (NHF) and even the private (the insurer) bodies participating in the costs of acquiring drugs may also be injured. Moreover, it can also be a health care provider who buys medicines and then treats patients. These settlements raise doubts also because neither the patients or the NHF participate in their conclusion or negotiation, although being the most interested in introducing generic as a much cheaper equivalent to the original drug.

The European Commission is also monitoring various forms of settlements in the pharmaceutical market,<sup>26</sup> emphasizing in particular the role of those intended to delay the entry generics to the market. The inquiry conducted between 2000 and 2011 only confirmed the growing number of such agreements, mostly triggered by the expiry of patent protection of many widely used drugs. The study found that the largest number of settlements in the pharma sector was discovered in Portugal, Germany, Denmark, the UK, and the least in Poland, Slovakia and Malta (this data is surely influenced by the size of pharmaceutical markets in the mentioned Member States). As the Commission found in the third report, 19% of the agreements were intended to delay entry of generic medicines to the market (and 11% involved a reverse payment).

Another instrument for delaying the commercialization of generic drugs may be the creation of “patent thickets” or applying the ever-green strategy (“refreshing” protection by, for example, applying for protection for another form of medicine when primary protection ends).<sup>27</sup> Creation of patent thickets<sup>28</sup> (or patent clusters) may take the form of “over-patenting” of different solutions, substances not necessarily essential from an economic point of view. This strategy is used only to strengthen the market position of the patentee and hamper its competitors’ market entry (e.g. patenting of a way, substance, individual components of a drug, which may be based on “weak” bases, etc.), or in general weaken the innovative research of the competitors. At times, even “finer” (smaller) solutions are patented, only in order to “artificially” strengthen one’s market position<sup>29</sup> (without the intent to commercialize these inventions). The evaluation of this type of market strategy must

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patent settlements – Gloss to the CJEU judgment of 8.09.2016 in case *H. Lundbeck A/S and Lundbeck Ltd vs. European Commission*], *Europejski Przegląd Sądowy* Vol. 6, 2017 p. 40 ff.

<sup>25</sup> See, D. Schnichels, S. Sule, *The pharmaceutical sector...*, p. 97.

<sup>26</sup> See, 3<sup>rd</sup> Report on the Monitoring of Patent Settlements (period: January–December 2011) of 25 July 2012, rec. 11 ff. See also, A. Italianer, *Innovation and competition*, [in:] B.E. Hawk (ed.), *Fordham Competition Law Institute. International antitrust law & policy*, Fordham 2013, pp. 318–319.

<sup>27</sup> See, M. Kort, *Intellectual property and Article...*, pp. 158–159.

<sup>28</sup> See, M. Blakeney, *Biotechnological patenting and innovation*, [in:] W.P. zu Waldeck und Pyrmont, M.J. Adelman, R. Brauneis, J. Drexler, R. Nack (eds.), *Patents and technological...*, p. 234.

<sup>29</sup> See, D.L. Rubinfeld, R. Maness, *The strategic use of patents: implications for antitrust*, [in:] F. Lévêque, H. Shelanski (eds.), *Antitrust, patents and copyright. EU and US perspectives*, Elgar, Northampton 2005, pp. 88–89. These actions are also called *patent flooding strategy* – *ibid.* See also, D. Schnichels, S. Sule, *The pharmaceutical sector...*, p. 97.

be performed on a case-by-case basis, since competition law is not always the right instrument of protection,<sup>30</sup> as also serving to enhance innovation.<sup>31</sup>

Another phenomenon of “over-patenting” is “swapping” the product “form” (i.e. the change of a form of drug delivery, let us say from capsule to tablet, also called “product hopping”) associated with a slight change in composition and then applying for a “new” patent protection. The reason of such action is strongly connected to the expiry of “original” patent protection.<sup>32</sup> As a result, follow-on (“improved”) products can effectively block the introduction of generic drugs into the market (especially, since the introduction of such generic products usually takes place at about 1.5 years before the primary product loses protection).<sup>33</sup>

Similar issues were investigated in *AstraZeneca* case (C-457/10). It was established that the drug manufacturer withdrew from the market in several countries a capsule drug and replaced it with a water-soluble tablet. After receiving a licence to trade of a new version of the drug, the manufacturer withdrew the original permission. In this way, it was much more difficult for generic manufacturers to market their own products (as a result, patent protection for the original drug had expired, so manufacturers could not rely on the original manufacturer’s test results and clinical trials). This also prevented the parallel import of the original drug from other Member States.<sup>34</sup> The judgment stated that such conduct was abusive.<sup>35</sup> It was also alleged that a number of misleading statements were filed at the patent offices of several Member States to extend the protection (aiming to obtain a supplementary protection certificate).

Another form of behaviour that can raise doubts from the point of view of competition law is filing multiple patent applications for the same product, which is designed to block or delay the introduction of generic patents (also called patented clusters and follow-on products).<sup>36</sup> What is essential in this respect is

<sup>30</sup> See, T. Käseberg, *Intellectual property, antitrust and cumulative innovation in the EU and the US*, Oxford 2012, pp. 112–113.

<sup>31</sup> See, H. Ullrich, *Strategic patenting...*, pp. 251–252.

<sup>32</sup> See, M.A. Carrier, *Competition law and enforcement...*, [in:] A. Ezrachi (ed.), *Research handbook...*, p. 537; B. Domeij, *Anticompetitive marketing in the context of pharmaceutical switching in Europe*, [in:] J. Drexel, N.R. Lee (eds.), *Pharmaceutical, innovation...*, p. 274.

<sup>33</sup> See, B. Domeij, *Anticompetitive marketing...*, p. 275.

<sup>34</sup> See, D.W. Hull, *The AstraZeneca judgment: Implications for IP and regulatory strategies*, *Journal of European Competition Law & Practice* Vol. 1, No. 6, 2010, p. 501. The author emphasizes that the original drugs’ producers having the dominant position when applying the IP strategies can be more often seen as infringing antitrust law – *ibid.*, p. 504.

<sup>35</sup> See also, S. Vezzoso, *Towards an EU doctrine of anticompetitive IP – Related litigation*, *Journal of European Competition Law & Practice* Vol. 3, No. 6, 2012, p. 527; R. Subiotto, D.R. Little, *The application of Article 102 TFEU by the European Commission and the European courts*, *Journal of European Competition Law & Practice* Vol. 4, No. 3, 2014, p. 263; J. Drexel, *Deceptive conduct...*, [in:] W.P. zu Waldeck und Pyrmont, M.J. Adelman, R. Brauneis, J. Drexel, R. Nack (eds.), *Patents and technological...*, p. 147–149; A. Spillman, *Transparency obligation for holders of EU IP assets in the pharmaceutical industry*, *Journal of Intellectual Property Law & Practice* Vol. 9, No. 2, 2014, p. 127 ff.

<sup>36</sup> See, the Commission’s decision of 9 July 2014 – C(2014) 4955 final [*Servier*], when many reverse payment settlements were discussed. See also, S. Priddis, S. Constantine, *The pharmaceutical sector, intellectual property rights, and competition law in Europe*, [in:] S. Anderman, A. Ezrachi (eds.), *Intellectual property rights and competition law. New frontiers*, Oxford 2011, p. 259; H. Ullrich, *Strategic patenting...*, p. 266.

undoubtedly the intention of the patentee (if it is violation of competition, both public and private enforcement rules can be applied). After all, applying for patent protection itself cannot be regarded as a violation of competition (as the essence of intellectual property rights is exclusivity). However, if the purpose of submitting a large number of patent applications is not to obtain protection for, for example, a particular molecule, but to prevent potential competitors from gaining knowledge of what is actually protected, one could come to a conclusion that this behaviour forms a restraint of competition.<sup>37</sup> Similar conclusions can be reached when trying to obtain protection for a supplementary patent. This type of patent cluster may also paradoxically lead to “fragmenting” the protection of a solution or invention (“parts” will be protected by individual patents, while the competitor would be interested to protect the invention as a whole<sup>38</sup>). Uncertainty about the period of patent protection of individual components can block a competitor’s market strategies and own actions. Although the mere filing of patent applications is legitimate, constituting an element of a market strategy, the use of the exclusive rights already granted may of course be subject to competition law (abuse of a dominant position under Article 102 TFEU<sup>39</sup>; however gaining a dominant position because of having a number of patents does not itself violate this provision). Therefore, the ownership of intellectual property rights does not mean that the patentee has a dominant position.<sup>40</sup> It is sometimes possible to conclude that the smaller the association of patents in the thicket, the more likely it is to recognize that the creation of such “clusters” has anti-competitive effects.<sup>41</sup> Thus, the misuse of patent law can in fact be regarded as infringing antitrust law.<sup>42</sup>

### 3. CLAIMS FOR DAMAGES FOR BREACH OF COMPETITION RULES IN THE PHARMACEUTICAL SECTOR

The first case and somewhat a turning point in establishing a right to compensation for damage caused by the infringement of competition law was *Courage Ltd. v. Crehan* case<sup>43</sup>. The CJEU expressly recognized the existence of a right to claim damages in favour of individuals, emphasising the direct effect of the provisions of

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<sup>37</sup> See, S. Priddis, S. Constantine, *The pharmaceutical sector...*, p. 259; H. Ullrich, *Strategic patenting...*, p. 266.

<sup>38</sup> See, H. Ullrich, *Strategic patenting...*, p. 257.

<sup>39</sup> See, P.A. van Malleghem, W. Devroe, *AstraZeneca: Court of Justice upholds first decision finding abuse of dominant position in pharmaceutical sector*, *Journal of European Competition Law & Practice* Vol. 4, No. 3, 2013 p. 232.

<sup>40</sup> See, H. Ullrich, *Strategic patenting...*, p. 262.

<sup>41</sup> *Ibid.*, p. 268.

<sup>42</sup> See, J. Drexl, *AstraZeneca and the EU sector inquiry: when do patent filings violate competition law?*, [in:] J. Drexl, N.R. Lee (eds.), *Pharmaceutical innovation...*, pp. 296–297; U. Petrovčič, *Competition law and standard...*, § 3.02; D.W. Hull, *The application of EU competition law in the pharmaceutical sector*, *Journal of European Competition law & Practice* Vol. 4, No. 5, 2013 p. 430 ff.

<sup>43</sup> C-453/99, [2001] ECR I – 6297.



the EU competition law.<sup>44</sup> The reasoning is undoubtedly connected to the doctrine of direct effect of the EU law. If an individual's rights provided for in the EU laws are infringed, that person should be allowed to claim compensation for a damage sustained by the unlawful act.<sup>45</sup> This rule was more expressly affirmed in the CJEU's ruling in *Manfredi* case<sup>46</sup>. The Court stated that "any individual can claim compensation for the harm suffered where there is a causal relationship between that harm and an agreement or practice prohibited by Article 81 EC [now Article 101 TFEU]". According to the ruling, in the absence of the EU laws on this matter, it was at that time for the Member States to designate the courts having the jurisdiction and rules to establish the liability for infringements of the EU competition law causing harm. In addition, the national laws were to provide rules for compensation of not only the actual damage, but also loss of profits<sup>47</sup> and interest. Both the Commission's Green Paper (2005) and White Paper (2008) on damages actions for breach of the EU antitrust rules, and consequently the Directive 2014/14 followed the full compensation rule.<sup>48</sup> In Poland, before implementing the Directive, these were the Civil Code rules which could have been applied in the discussed matter (Articles 361, 415).<sup>49</sup>

When it comes to the rules on compensation, the Directive itself, however, follows the concept of compensation presented in both *Courage* and *Manfredi* cases, but also leaves many issues to be decided within the framework of national laws<sup>50</sup> (especially when estimating damages<sup>51</sup>). The potential range of claimants is of course very wide and the loss suffered also must be understood broadly, followed

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<sup>44</sup> See also, F. Cengiz, *Antitrust damages actions: lessons from American indirect purchasers' litigation*, 59 *International & Comparative Law Quarterly* Vol. 45, 2010, p. 51.

<sup>45</sup> See also, I. Lianos, P. Davis, P. Nebbia, *Damages for the infringement of EU competition law*, Oxford 2015, pp. 19–21; R. Cisotta, *Some considerations on the last development on antitrust damages actions and collective redress in the European Union*, *The Competition Law Review* Vol. 10, issue 1, 2014, p. 90.

<sup>46</sup> Joined cases C-295/04 and C-298/04 *Manfredi and Others v. Lloyd Adriatico* [2006] ECR I-6619.

<sup>47</sup> For example, loss of profits by the generic drugs manufacturers who – as a result of a created patent: thicket – cannot put their products on the market. In this case, the loss can be sustained even already at the moment of the expected patent (or supplementary protection certificate) expiry. The practice will show how the notion of manifestation of damage will be understood in these cases.

<sup>48</sup> See also (on the aim pointed out in the Green Paper) Ch. Hodges, *Competition enforcement, regulation and civil justice: what is the case?*, *Common Market Law Review* Vol. 43, 2006, p. 1383.

<sup>49</sup> See also, D. Hansberry, Ch. Hummer, M. Le Berre, M. Leclerc, *Umbrella effect: damages claimed by customers on non-cartelist competitors*, *Journal of European Competition Law & Practice* Vol. 5, No. 4, 2014, pp. 202–203; P. Podrecki, *Civil law actions in the context of competition restricting practices under Polish law*, *Yearbook of Antitrust and Regulatory Studies* No. 2(2), Vol. 2009, pp. 80, 88 ff.

<sup>50</sup> See also, I. Nestoruk, *Projekt dyrektywy harmonizującej krajowe przepisy służące dochodzeniu roszczeń odszkodowawczych z tytułu naruszenia unijnego prawa konkurencji* [Draft directive harmonising national regulations serving to claim damages due to infringement of the EU competition law], *Kwartalnik Prawa Prywatnego* No. 1, 2014, pp. 215–216.

<sup>51</sup> The fact that the Directive leaves the assessment of damages to the national laws is important for *cross-border cases* (connected to at least two legal systems, by for example influencing at least two legal systems being also the relevant markets), which surely is a case in the pharmaceutical sector. The issues of jurisdiction and applicable law are discussed in another paper.

by the rebuttable presumption with regard to the existence of harm resulting from a cartel<sup>52</sup> (Article 17 of the Directive). Therefore, the presumption deals only with the cartels, and not other actions restraining the competition.<sup>53</sup> The presumption of course refers only to the existence of harm and not its size. As a consequence, the evaluation of harm and damages is left to the national laws. Therefore, the plaintiff must prove the damage (defined as encompassing both *damnum emergens* and *lucrum cessans*<sup>54</sup>), having also the right to interest from the time harm has occurred<sup>55</sup> until compensation is paid (rec. 12 of the Directive).<sup>56</sup> In other words, the Directive does not alter the national rules governing the actions for damages, not it aims at changing the standard of proof. It must be also stated that the Directive does not make any position regarding punitive damages and so it is again the Member States to decide whether in cases of private enforcement of competition law such claims will be available and on what grounds.<sup>57</sup> This could be a subject to criticism – of course, on one hand, one could argue that this is a subject of minimum harmonisation (so the Directive had to take account that in fact only a minority of national laws allows punitive damages in general), but this may lead to the whole system of private enforcement being ineffective. What I mean by that is even if a national court grants punitive damages to the plaintiff in one jurisdiction and according to applicable law (if it is a cross-border case, which in the pharmaceutical sector may be quite frequent), the recognition of that judgment and its enforcement in another Member State might be considered contrary to public order.

Detailed comments in this section should begin by saying that the infringement of the competition rules should be eligible for tort, and therefore not as an event

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<sup>52</sup> See also, E. Truli, *Will its provisions serve its goals? Directive 2014/104/EU on certain rules governing actions for damages for competition law infringements*, Journal of European Competition Law & Practice April 2016, pp. 11–12.

<sup>53</sup> This wording is – in the view of the Commission – much well founded – *The Practical Guide Quantifying Harm in Actions for Damages Based on Breaches of Article 101 or 102 TFEU*, C(2013) 3440 states that 93% of cartel cases proved to be causing harm.

<sup>54</sup> The broad meaning of damage was also underlined in *Manfredi*. See also, M. Carpagnano, *Private enforcement of competition law arises in Italy: analysis of the judgment of the European Court of Justice in joined cases C-295/289/04 Manfredi*, The Competition Law Review Vol. 3, issue 1, 2006, p. 70.

<sup>55</sup> The moment when the harm occurred must be assessed on a case-by-case basis. In the pharmaceutical sector, this could be for example a moment in which the Ministry of Health paid a price for a certain amount of drugs co-funded by the state (when for example only original [more expensive] drugs were on the market because of an existing reverse payment settlement delaying the introduction of generic drugs to the market).

<sup>56</sup> In addition Article 8 of the Polish Act states that when the basis for assessing damages is not the price from the date on which the claim is decided (usually a date of a court's ruling), but from another date, the plaintiff has the right to interest from that date to the day when the claim is eligible to be asserted.

<sup>57</sup> This follows a ruling of the CJEU in the *Manfredi* case (C-295/04 to 298/04), however in this case the CJEU did not support the view that punitive damages should be always allowed in such cases (according to the Court it should be left to the national laws, having in mind the principles of equivalence and effectiveness. The argument was connected with the assumption that the plaintiff could not be overcompensated, *de lege lata* – see Art. 3(3) of the Directive).

being the source of contractual liability.<sup>58</sup> The purpose of the parties, including for instance the reverse payment settlements, appears to be a breach of the competition rules (therefore, the element of unlawfulness is met). Responsibility will be based on the principle of fault.<sup>59</sup> This is confirmed by the wording of Article 3 of the Polish Act. This provision states that the perpetrator of the infringement is obliged to redress the damage caused to anyone by infringement of competition law, unless he is not at fault (the statute introduces the presumption of fault which is undoubtedly in favour to the plaintiffs).

As regards the situation of the indirect purchaser (e.g. a consumer, a patient), it should be noted that often, due to delay of introduction of generic medicines to the market, a direct buyer (e.g. a wholesaler) may transfer a higher price to the final buyer (this person may also be the National Health Fund, the Ministry of Health, the state, as a body participating in the costs of drug purchase, in connection with the refund of drugs). Undoubtedly, the final purchaser is also harmed and in principle should have the right to compensation (provided that the condition of an adequate causal relationship is satisfied). This rule is confirmed both by the wording of the Directive (Article 3) and the Polish Act (Article 3), granting the right to compensation to “anyone”,<sup>60</sup> thus confirming the principle of full compensation.<sup>61</sup> Demonstration of the damage amount is certainly easier for a direct buyer, but as a rule also other “supply chain” actors can bear it. Compensation will of course depend on demonstrating the condition of an adequate causal relationship (according to the Directive the interpretation of this condition is left to the national courts<sup>62</sup>). In the event of a passing-on, theoretically the latter could claim compensation only from the direct purchaser. However, since the causal relationship does not have to be direct, the consumer (and other parties) may in principle claim compensation for damages. Another issue is of course the procedural economy: often the costs<sup>63</sup> (and time)<sup>64</sup> of

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<sup>58</sup> See, D. Ashton, D. Henry, *Competition damages actions...*, p. 33. Moreover, there is no need of creating a special regime for antitrust torts – see, T. Eilmansberger, *The Green Paper on damages actions for breach of the EC antitrust rules and beyond: reflections on the utility and feasibility of stimulating private enforcement through legislative action*, Common Market Law Review Vol. 44, 2007, p. 442. See also, A. Jurkowska-Gomułka, *Private enforcement and competition law in Polish courts: The story of an (almost) lost hope for development*, YARS (Yearbook of Antitrust and Regulatory Studies) Vol. 6 (8), 2013, p. 122.

<sup>59</sup> See, D. Ashton, D. Henry, *Competition damages actions...*, p. 34.

<sup>60</sup> See, A. Andreangeli, *Private enforcement of antitrust. Regulating corporate behaviour through collective claims in the EU and US*, Cheltenham 2014, p. 257. It seems that also a so-called “umbrella effect” doctrine could be applied in the discussed cases. See, *Kone* case No. C-557/12 (the CJEU stated that also the entrepreneurs who did not take part in a cartel fixing prices but fixing prices under influence of a cartel, can be also deemed to be infringing the antitrust law. The practice will show how this doctrine will be applied in the pharmaceutical sector but it seems at a first glance that it could actually be applied).

<sup>61</sup> See, E. Truli, *Will its provisions serve...*, p. 4; this rule was also applied in the *Manfredi* (C-295/04).

<sup>62</sup> See, I. Lianos, *Uncertainty and damages claims for infringement of competition law in Europe*, Yearbook of European Law 2015, p. 4; *Manfredi* (joined cases C-295/04 to C-298/04); S. La, *The private damages action of competition law in EU and China*, Hamburg 2016, pp. 56–58.

<sup>63</sup> See, F. Cengiz, *Antitrust damages actions...*, pp. 44–45.

<sup>64</sup> See, E. Eklund, *Indirect purchasers – Is there anything new in the Directive? And introductory overview of the current and future status of indirect purchasers in the EU*, [in:] M. Bergström,

the proceedings may outweigh the sustained loss. For example, if the sole difference in price paid by the original drug consumer instead of paying for a generic, but not marketed through an agreement violating competition law, might be much smaller than the costs of legal proceedings. Perhaps the solution would be to introduce the possibility of bringing a group action (in the *op-out* model), however, so far in Poland there has been no case of a class action in the field of violation of competition law, nor is the institution of class action as such popular in Poland.<sup>65</sup>

These problems are in some ways resolved by the legislator by assuming that infringement of competition law is causing damage (understood as *damnum emergens* and *lucrum cessans*) (Article 7 of the Polish Act) and introducing the obligation to disclose evidence (Article 5 of the Directive and Article 17 of the Polish Act<sup>66</sup>). As it has been said, this might help when interpreting the notion of harm itself (primarily the difference in price,<sup>67</sup> but also the higher costs of reimbursement (*refundacja*) of medicines or even higher insurer benefits and premiums). Therefore, when establishing the size of harm and the amount of damages, we should apply the differential theory.<sup>68</sup> In this matter general rules of national law apply (so in Poland Article 361 of the Civil Code<sup>69</sup>). Certainly, when estimating the extent of compensation, Article 322 of the Code of Civil Procedure can be of great importance,<sup>70</sup> given that the presumption of harm does not prejudge its alleged weight. On the one hand, the defendant will have to prove that the breach of competition law has not caused harm, and on the other, it will be the injured party (e.g. NHF) which has to prove its amount. It seems

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M.C. Iacovides, M. Strand (eds.), *Harmonising EU competition...*, pp. 274, 278; M.C. Iacovides, *The Presumption and quantification of harm in the Directive and the practical guide*, Hart Publishing 2016, pp. 295–296.

<sup>65</sup> See, A. Piszcz, *Practical private enforcement: Perspectives from Poland*, [in:] M. Bergström, M.C. Iacovides, M. Strand (eds.), *Harmonising EU competition...*, p. 213.

<sup>66</sup> Similarly as in the Directive, the Polish Act contains rules according to which some evidence is protected fully and some has to be disclosed based on specified rules, taking into account the rule of proportionality (this also concerns the documents at the possession of the national competition authority). The general rule is that a party requesting the disclosure must present a “reasoned justification of its claim for damages”, containing “reasonably available facts and evidence sufficient to support the plausibility of its claim”. Apart from that, it seems that also Art. 248 of the Civil Procedure Code (disclosure of a document, on demand of the civil court, with exceptions provided) could be applied. We could argue that in case of generic drugs information obtained by the direct purchaser about ongoing proceedings in another Member State could be sufficient; the same applies when the Commission is conducting its proceedings on a possible antitrust violation (the principle of effectiveness should play a role here as well).

<sup>67</sup> See, M. Strand, *Beyond the Competition Damages Directive: What room for competition law restitution?*, [in:] M. Bergström, M.C. Iacovides, M. Strand (eds.), *Harmonising EU competition...*, p. 285; E. Truli, *Will its provisions serve...*, p. 11; N. Reich, *The “courage” doctrine: encouraging or discouraging compensation for antitrust injuries?*, *Common Market Law Review* Vol. 42, 2005, p. 46.

<sup>68</sup> See, F. Maier-Rigaud, U. Schwalbe, *Quantification of antitrust damages*, [in:] D. Ashton, D. Henry, *Competition damages actions...*, p. 237 ff.

<sup>69</sup> See, P. Podrecki, *Civil law actions...*, p. 88 ff.

<sup>70</sup> This provision states that if, in the case of compensation for damage, income, return of unjust enrichment or survivor’s benefit, the court finds that it is impossible or excessively difficult to prove the amount of the claim, the court may award a reasonable sum according to its assessment based on consideration of all the circumstances of the case.

impossible to establish the exact amount of harm in these cases.<sup>71</sup> It would be possible only if the legislature had introduced regulated prices of medicines (both original and generic): then the actual loss would constitute the difference between the fixed (by law) price and the actual price. *De lege lata*, the price of the final product (except for the reimbursed drugs [*leki refundowane*] where the price is sometimes fixed by the Ministry of Health,<sup>72</sup> and therefore determining the amount of compensation should be less difficult) depends on many factors. Also, the price quite often is the result of negotiations<sup>73</sup> between the drug manufacturer and the entity providing access to drugs guaranteed by the state (therefore, the hypothetical prices in the local market, original and generic, should be taken into account when establishing the probable difference in price). In this regard, the *prima facie* evidence could be of some help.<sup>74</sup> However, it seems inevitable to seek the expert's opinion. It also seems that the president of national authority might provide some information, on demand of a civil court hearing the case<sup>75</sup> (see also Article 6 of the Directive and Article 17 of the Polish Act). The rules adopted in the European Commission's Practical Guide on estimating damage in cases of violation of Article 101 or 102 TFEU of 2013,<sup>76</sup> indicating that one method to be used may be a difference method (comparison of prices, inter alia, with respect to time or geographic market), might serve as some help, however, they do not provide for a binding method and are not thorough enough to be applied in all the cases described in this Article.

Difficulties in estimating harm and corresponding damages may also be difficult when we apply the prerequisite of the causal link, which, according to Article 361 of the Polish Civil Code has to be "normal" (the Polish Civil Code follows the theory of a relevant causation). Certainly, the abuse of a dominant position by a patentee or entering the reverse payment settlements, may cause injury, but it is necessary to evaluate the consequences (the causal link does not have to be direct but must be relevant). While private enforcement rules provide for liability for "harm to anyone", it is important to consider how far the potential victim may be in the supply chain. Determining an relevant causal link will, after all, require a broad economic analysis, including a vast number of data and facts,<sup>77</sup> but of course the mere difficulty in

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<sup>71</sup> See also, A. Jones, *Private enforcement of EU competition law: A comparison with, and lessons from, the US*, [in:] M. Bergström, M.C. Iacovides, M. Strand (eds.), *Harmonising EU competition...*, p. 37.

<sup>72</sup> See, ustawa o refundacji leków, środków spożywczych specjalnego przeznaczenia żywieniowego oraz wyrobów medycznych [Act on reimbursement of drugs, special dietary and other medical products] of 12 May 2011, Journal of Laws [Dz.U.] of 2011, No. 122, item 696, as amended.

<sup>73</sup> See, D. Schnichels, S. Sule, *The pharmaceutical sector...*, p. 96.

<sup>74</sup> See, A.P. Komninos, *The relationship between public and private enforcement: quod Dei Deo, quod Caesaris Caesari*, [in:] P. Lowe, M. Marquis (eds.), *European Competition Law Annual: 2011 – Integrating public and private enforcement. Implications for courts and agencies*, Oxford and Portland, Oregon 2014.

<sup>75</sup> M.C. Iacovides, *The presumption and quantification...*, pp. 302–303.

<sup>76</sup> *Practical Guide on quantifying harm in actions for damages based on breaches of Article 101 or 102 of the Treaty on the Functioning of the European Union*, C (2013) 3440 of 11.6.2013.

<sup>77</sup> See, I. Lianos, P. Davis, P. Nebbia, *Damages for the infringement...*, p. 70; Ch.H. Bovis, Ch.M. Clarke, *Private enforcement of EU competition law*, Liverpool Law Review Vol. 36, 2015, pp. 59–60; G. Niels, R. Noble, *Quantifying antitrust damages – Economics and the law*, [in:]

establishing a causal link cannot lead to the exclusion of certain groups of entities from the circle of persons entitled to compensation. In this case, even the indirect purchaser who, because of practices restraining competition leading to delay of generic drugs in entering the market, had to pay a higher price for the product (see Article 2(20) of the Directive), might not have difficulties in proving that, e.g. a reverse payment settlement (particularly when the national competition authority issued a decision in this regard) is an event which normally causes harm (a higher market price of the drug). Nevertheless, the difficulty of demonstrating this may be due to the fact that the price of a drug depends on many factors, including the marketing strategy.<sup>78</sup> This makes the assessment done on a case-by-case basis, in line with the principle of effectiveness of the EU law and of the Directive itself. Both *Courage* and *Manfredi* cases affirmed that the question of causality remains subject to the requirements of the domestic legal system of each Member State. This could also be subject to some criticism, however, it seems that all the national laws contain rules on causation which may lead to fulfilment of the rule of full compensation and serving the corrective justice (and not just deterrence which is in general not a function of tort law and law of damages). If we apply this to the discussed pharmaceutical sector issues of private enforcement of competition law, there can be no doubts that, for example, the reverse payment settlement meets the *sine qua non* test and its normal/relevant result can be preserving higher prices of drugs. Another example is of course the abuse of patent by creating a patent thicket, which at the same time, aims at delaying the introduction of generic (less expensive) medicines to the market. We could even argue that, in fact, when looking at different strategies aiming at delaying or blocking the generics being commercialised (so unlawfully restraining the competition), not only the loss should be presumed, but also the causal link in this matter. If the payment by the patentee takes into account the price drop and moving the income from the patentee to the generic drugs producer, it is logical and obvious that the aim of reverse payment settlements is to restrain the competition but also to pay out the “lost” income by the originator after the expiry of patent protection. Therefore, surely the normal effect of such practices can be a price difference, here the estimated loss. Certainly, difficulties may arise when establishing a causal link by indirect purchasers, however, the Directive “solves” this in a way by introducing a presumption of a causal link for the benefit of indirect purchasers (see rec. 41, Article 16(2)). However, the defendant can rebut this “when he can demonstrate credibly to the satisfaction of the court that the overcharge was not, or was not entirely, passed on to the indirect purchaser” (Article 14(3)). For example, when the Ministry of Health buys a certain amount of drugs for a negotiated price and then fixes the price, the latter buyer cannot lay on a presumption of passing on (the wholesale buyer or the pharmacy cannot sell the drugs at a higher price).

Claims for compensation for damage caused by violation of competition law are subject to the limitation periods. The Directive delivers in Article 10 a detailed

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K. Hüsichelrath, H. Schweitzer (eds.), *Public and private enforcement of competition law in Europe. Legal and economic perspectives*, Springer–Berlin–Heidelberg 2014, p. 124 ff.

<sup>78</sup> See, I. Lianos, *Uncertainty and damages claims...*, p. 34.

scheme of limitation periods regarding the elements that constitute the infringement of which the party should be aware, or should reasonably be expected to be aware (the behaviour, the harm and the identity of the infringer). Moreover, the time cannot begin to run before the day on which the infringement has ceased. In addition, where a competition authority opens proceedings, the limitation period to bring the damages claims is suspended (or interrupted, depending on national law; suspension is a case in the Polish Act) until at least a year after the authority's decision is final or proceedings are otherwise terminated. The limitation period should be at least five years (see also Article 5 of the Polish Act).

The notion of the day when the infringement has "ceased" should be understood separately for each of the wrongdoers, for example, when we talk about a reverse payment settlement, it is possible to leave the cartel by one of the members (e.g. a generic drugs company), therefore, in his case the limitation period can begin, and towards the others – not yet. The same applies when a generic drug company introduces the drug to the market and the other does not. Another example of a case-by-case method to be applied in the discussed matters can be a situation when the president of Polish competition authority (UOKiK) (or any other competition authority) decides finally that certain behaviour (e.g. a reverse payment settlement, patent cluster, etc.) is, in fact, infringing competition law. If a party does not comply with the decision, the violation still continues and the limitation period cannot begin (even if another party ceased the wrongful behaviour, for example, one generic company gets another payment instalment for delaying introduction of the drug to the market, and the other does not).

According to Article 9 of the Polish Act in connection with Article 442(1) of the Civil Code, the time course of the 10-year limitation period *a tempore facti* begins on the date of termination of the infringement (and not, as in the case of CC, of the day of the incident). In these cases, it seems that, the time course of the limitation period cannot commence at a time when, for example, generics are not placed on the market, due to the conclusion of a reverse payment settlement or the existence of patent protection through the creation of patent clusters (and, for example, the indirect buyer does not know this). On the other hand, if a decision by the president of the UOKiK or the European Commission or a competition authority of another Member State, alleging an infringement of competition law, was issued, it could be considered as the date on which the injured person had knowledge (or should have had the knowledge with due diligence) of at least the debtor obliged to compensate the damage. It should be also added that the commencement of the proceedings before the UOKiK – before the implementation of the Directive – did not suspend or interrupt the run of limitation periods. *De lege lata*, however, by implementing Article 10(4) of the Directive into Article 9(2) of the Polish Act, the limitation period is suspended<sup>79</sup> from the moment of commencement of the proceedings (both mere investigation and antitrust case) by the president of the UOKiK, or by the European

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<sup>79</sup> This wording is different from a general rule contained in Articles 123–124 CC (interruption of limitation period, resulting in – after e.g. the termination of proceedings – the beginning *de novo* of the time limit).

Commission, as well as any other national competition authority. The suspension ceases after a year from the day when the decision of the abovementioned authorities is final or the proceedings are otherwise terminated.

The notion of “knowledge” about the infringement, harm and the identity of the wrongdoer should be understood in a way that if the infringement was caused by several parties, the knowledge about one should be sufficient and the limitation periods should be assessed separately for each of the defendants. For example, the injured party might have the knowledge about all the members of the reverse payment settlement or about the parties creating a patent thicket in the pharmaceutical sector. It seems to be sufficient if the national competition authority issues a decision on competition law infringement, even without naming all the participating companies, for establishing that the injured party should reasonably have known about the infringement of the antitrust law. The infringement of competition law has the objective character and the mere possibility of causing anticompetitive effect should be enough. This is in accordance with Article 17(2) of the Directive (presumption of harm in cartel cases) and Article 7 of the Polish Act (presumption of harm in (all) cases of infringement of competition).

When we talk about the *ever-greening* strategy or creating patent thickets, the case-by-case method must also be applied. For example, one can have knowledge about the attempts to restraint competition and delaying the price drop of generic medicines, without even patent being invalidated or before the decision refusing to grant patent protection is issued. Also in these circumstances, the limitation period might begin.

The Directive also refers to the issue of effect of decisions of national or the EU competition authorities, which must be read also in conformity with Article 16(1) of the Regulation 1/2003 [2003] on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty (now Articles 101 and 102 TFEU) [OJ L1/1], which provides that when national courts rule on agreements, decisions, or practice under Article 101 or 102 TFEU, which are already the subject of the Commission’s decision, they cannot take decisions running counter the decision adopted by the Commission.<sup>80</sup> However, the decision can of course be ruled out by the CJEU (see Articles 263, 267 TFEU). Having this in mind, Article 9(3) of the Directive states that<sup>81</sup> final decisions of a national competition authority issued in another Member State can be presented as *prima facie* evidence of the fact that an infringement of competition law has occurred. Of course, when it comes to the binding decisions of the Commission’s finding an infringement of the EU competition law, in fact, the national courts cannot reach different decisions from those established by the Commission.<sup>82</sup> What is

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<sup>80</sup> What is important is that the 1/2003 Regulation did not bring a change in the possibility of private enforcement, see also, T. Eilmansberger, *The Green Paper...*, p. 434.

<sup>81</sup> What is interesting, the proposal of the Directive was even more far reaching: the proposed wording aimed at providing the binding effect of the national competition authorities’ decisions in all the Member States.

<sup>82</sup> See, the 7<sup>th</sup> Amendment to the Act against restraints to competition – Gesetz gegen Wettbewerbsbeschränkungen GWB, entered into force on 1 July 2005, see Art. 33(4) – cited after I. Lianos, P. Davis, P. Nebbia, *Damages for the infringement...*, p. 287. This issue is important to



interesting is that only the German and Spanish<sup>83</sup> laws so far provide for the binding effect of final decisions of both domestic and other European authorities.<sup>84</sup> Article 30 of the Polish Act provides only for the binding effect of decisions of the president of the UOKiK for the civil courts.<sup>85</sup>

The Directive clearly states in Article 11(1) that several entities can be jointly liable for the harm caused by actions infringing the competition law. Since this behaviour can shape many kinds of actions in the pharmaceutical sector, being a source of non-contractual liability (tort), if it had not been for the Directive, Article 441 of the Polish Civil Code would apply (if of course according to private international rules Polish law were applicable<sup>86</sup>). What must be stressed, however, is that the Directive leaves – apart from one exception – the question of joint and several liability (and recourse actions) to the national laws. The general rule contained Article 11(1) is that each infringing company (so, for example, all the parties to the reverse patent settlement) is bound to compensate the claimant in full for any harm caused by the joint infringers. From the view of Polish law, the rule is the same as in Article 441 CC, meaning that there is a responsibility for one and whole loss, hence if one of the defendants pays damages, the obligation expires and the rules of recourse apply.

However, Article 11(2) of the Directive introduces a safeguard for small and medium enterprises: they shall be liable only to their own direct and indirect purchases, if the prerequisites provided for in Article 11(2) a–b are met. This solution can be criticised as introducing different rules for the parties at stake. On the other hand, the idea of such differentiation seems to aim at “protection” (but not in all the circumstances – see Article 11 of the Directive) of smaller entities to be eliminated from the market as a consequence of high remunerations paid to the plaintiffs. The special rules apply also to the parties of leniency programmes (see also Article 11(4)b of the Directive and Article 5(2) of the Polish Act). In the pharmaceutical sector, it seems that only the second limitation on joint and several liability could apply. The party of a leniency programme can be liable towards the injured other than, e.g. direct or indirect purchasers, only when the reimbursement from other responsible parties is impossible (it is, if fact, a *sui generis* subsidiary liability for damages).

What is also important is that both the Directive and the implementing national laws provide for the passing on defence taking into account the fact that the defendant could have passed on the overcharge onto its customers (economic mitigation of a loss sustained). For example, the wholesale buyer purchasing the

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follow in proceedings on claims for damages (so after the competition authority has decided on an infringement. Of course the standalone claims for damages are also possible).

<sup>83</sup> See, A. Piszcz, D. Wolski, *Poland*, [in:] A. Piszcz (ed.), *Implementation of the EU Damages Directive in Central and Eastern European countries*, Warsaw 2017, p. 217.

<sup>84</sup> See, I. Lianos, P. Davis, P. Nebbia, *Damages for the infringement...*, pp. 46, 282.

<sup>85</sup> This binding effect was already discussed by courts in Poland: in the resolution of 28 July 2008, III CZP 52/08, the Supreme Court decided that the final decision of the president of the UOKiK (Office for Protection of Competition and Consumers, so national competition authority in the wording of the Directive), declaring an infringement of competition law, is binding for civil courts.

<sup>86</sup> These issues are discussed in another paper.

original drugs from the patentee can pass on part (or the whole) overcharge in the price to the pharmacy (and of course the pharmacy can pass on its overcharge to the customers). This concept, taking into account these economically grounded actions, allows the defendant to “protect” himself from the too high claim (see Article 12 of the Directive). Moreover, according to Article 13 of the Directive, the burden of proof that the overcharge was passed on lies on the defendant. In addition, Article 4 of the Polish Act provides for a rebuttable presumption that if the infringement of competition resulted in an overcharge to the direct purchaser and the indirect purchasers acquired the products, the overcharge was passed on to the indirect purchasers. In the case of generic drugs, this situation in Poland can only touch upon the drugs non-refundable by the state (these are sold on a fixed price). For example, it is quite possible that the wholesale direct purchaser passes the overcharge on to the pharmacy and it passes it on further on the consumers.

#### 4. CONCLUSIONS

The analysis indicated that the exercise of exclusive rights and the application of various legal instruments to delay placing generic medicines on the market may be assessed in terms of breach of the competition law and the law of damages. The interpretation of Articles 101 and 102 TFEU, carried out for several years both by the European Commission and the CJEU, indicates that intellectual property and competition law do not “exclude” each other. As a consequence, an infringement by the antitrust law by a wrongful act can result in the rise of the right to compensation. The practice will show how, on the Polish market, claims for damages related to practices aimed at delaying the entry of generic products into the market will be of interest to potentially injured entities (primarily the NHF and the state) and how such concepts as harm or relevant causation will be interpreted.

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## DAMAGES FOR RESTRAINTS ON COMPETITION – A CASE OF PRIVATE ENFORCEMENT IN THE PHARMACEUTICAL SECTOR

### Summary

In this article the author analyses the most important issues arising from the interaction between intellectual property law, competition law and the damages law. For almost ten years, the European Commission has been monitoring the various market practices used by participants in this market, which may result in infringement of competition law. In particular, there are some doubts about reverse payment patent settlements aimed at delaying the introduction of generic medicines to the market, as well as other practices intended to disrupt the normal operation of the pharmaceutical market. The analysis of different practices in the pharmaceutical sector (in addition to the aforementioned settlements, they may involve various patent strategies, such as the creation of patent thickets) may bring us to the conclusion that such behaviour can be seen as a form of abuse of patent rights, but also the abuse of a dominant position (or other forms of restraints to competition), simultaneously raising questions about the consequences in the field of law of damages. As such market practices show, they can also influence the position of consumers and others interested in lowering the price of generic drugs (as substitutes for original drugs that can be marketed after the original drug's patent protection expires) but also affect the health policy of the state. Except the consumer, who is the "last link" of the generic supply chain, the economic interest of the public or private co-financiers of patients' access to medicines should also be taken into account. In Poland, commercialization of generic drugs undoubtedly remains in the interest of the National Health Fund and the state budget. The author discusses different legal instruments which aim to delay introduction of generic drugs to the market and indicates their legal consequences.

Keywords: generic medicines, pharmaceutical law, competition law, infringement of competition, damages, harm

## ROSZCZENIA ODSZKODOWAWCZE Z TYTUŁU NARUSZENIA PRAWA KONKURENCJI – ZASTOSOWANIE W INDYWIDUALNYCH PRZYPADKACH W SEKTORZE FARMACEUTYCZNYM

### Streszczenie

Celem niniejszego opracowania jest przybliżenie najistotniejszych zagadnień powstających na styku prawa własności intelektualnej, prawa konkurencji i prawa odszkodowawczego. Od niemal dziesięciu lat Komisja Europejska monitoruje rozmaite praktyki rynkowe stosowane przez uczestników tego rynku, których skutkiem może być naruszenie prawa konkurencji. W szczególności pewne wątpliwości budzą umowy patentowe o odwróconej płatności, których

celem jest opóźnienie wprowadzenia na rynek leków generycznych, a także inne praktyki, prowadzące do zakłócenia normalnego funkcjonowania rynku farmaceutycznego. Analizowane w artykule zachowania (oprócz wspomnianych ugód może chodzić o rozmaite strategie patentowe, jak tworzenie gąszczy patentów) mogą być jedną z form nadużywania patentu, ale i pozycji dominującej, rodząc jednocześnie pytania o konsekwencje natury odszkodowawczej. Jak się bowiem okazuje tego typu praktyki rynkowe mogą także wpływać na pozycję konsumentów oraz innych podmiotów, zainteresowanych niższą ceną leku generycznego (substytutu leku oryginalnego, który może być wprowadzony do obrotu po upływie ochrony patentowej leku oryginalnego), ale także wpływać na politykę zdrowotną państwa. Oprócz konsumenta, stanowiącego „ostatnie ogniwo” łańcucha nabywców generyków, na względzie należy mieć także interes ekonomiczny podmiotu publicznego czy prywatnego współfinansującego dostęp do leków przez pacjentów. W Polsce wprowadzenie na rynek generyków niewątpliwie pozostaje w interesie Narodowego Funduszu Zdrowia i budżetu państwa, jako podmiotów istotnych z punktu widzenia refundacji. Autorka analizuje różne instrumenty prawne mające na celu opóźnienie wprowadzenia na rynek leków generycznych, wskazując na ich konsekwencje prawne.

Słowa kluczowe: leki generyczne, prawo farmaceutyczne, prawo konkurencji, naruszenie konkurencji, odszkodowanie, szkoda