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Patent Portfolios and Competition Law: Some Reflections After the Recent *RPSA* Cases*

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ABSTRACT: In the pharmaceutical sector, firms often build patent portfolios in order to better protect their innovations, but also to strategically exploit the cluster to prevent entry by generic competition. In fact, once patent protection on the main invention expires, originator firms adopt a two-tiered strategy, centred on the enforcement of secondary patents composing the portfolios. At first, originators threaten generic companies of patent infringement, in a way to discourage entry by generic companies. Secondly, they push generics to enter a patent settlement (in order to compose the very same infringement proceeding), often paying them to stay out of the market: hence, prolonging their exclusivity time, to the detriment of consumers and society at large.

While EU institutions have made clear that the latter behaviour is in plain contrast with competition law provisions prohibiting agreements in restraint of trade, *RPSAs* are only the tail of a multifaceted conduct which deserves closer scrutiny.

KEYWORDS: competition, patent, patent portfolios, reverse payment settlement agreement, sham/vexatious litigation

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1. Introduction

Firms today tend to protect their innovation trail through the filing of patent portfolios, which help them fence off competitors and extend protection to the longest possible amount of time. In the pharmaceutical sector, in particular, patent portfolios have turned out to be a successful instrument to block generic competition. In fact, once patent protection on the main invention (typically a product patent) comes to an end, originator firms adopt a two-tiered strategy, centred on the enforcement of collateral patents composing the portfolios (typically process patents or second medical use patents). At first, originators threaten to sue generic companies of patent infringement, exploiting the uncertainty permeating both validity and breadth of protection of follow-on patents. Secondly, they push generics to enter a patent settlement (in order to compose the very same infringement proceeding they have commenced or menaced to commence), often paying them to stay out of the market. The effect of such agreements, hence, is the artificial prolonging the exclusivity time of the pivotal patent, to the detriment of consumers and society at large.

While EU institutions have made clear that the latter behaviour is in plain contrast with competition law provisions prohibiting agreements in restraint of trade, *RPSAs* are only the tail of a multifaceted conduct which deserves closer scrutiny.

2. Innovation and patent portfolios

While patent law textbooks seem still to tell the tale of the single inventor who conceives a break-through invention, the scenario has radically changed today,[1] gradually leading to the discard of the model one-innovation one-patent.[2] And indeed we live in a technological era where

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[1] In this sense see Kur, Dreier and Luginbuehl, *European Intellectual Property Law: Text, Cases and Materials* (2nd ed., Edward Elgar Publishing, Cheltenham (UK) – Northampton (USA), 2019): 81 ff., arguing that due to such changes in the features of technological development, especially in the information and communication technologies, the role and impact of patents in the current socio-economic environment has profoundly changed, sharing very little with the original justifications in support of the patent system.

[2] See Merges, "Intellectual property rights and the new institutional economics", *Vand. L. Rev.* 53 (2000): 1859, challenging the widespread assumption that a single patent confers monopoly over the invention, as in most industries there is no simple "one-to-one" mapping of products and property rights and products are indeed protected by a conundrum of different IP rights. By the same token, see L. Marengo, Pasquali, Valente and Dosi, "Appropriability, patents, and rates of innovation in complex products industries", *Economics of Innovation and New Technologies* 21, no. 8 (2012): 755, commenting that, notwithstanding the number of patents surrounding a single

innovation has undertaken features such that patents do not matter to the firm when taken *in isolation*, but when *together* they allow to cover (or try to cover) a certain technological trail.[3] In the information and communication technologies' sector, where products and technologies have become complex and sophisticated, inventors need to recur to several exclusive rights (mainly, but not only, patents) to protect different aspects and portions of the overall innovation.[4] On the other side, even in sectors where innovation exhibits a more linear feature, like the pharmaceutical sector, filing only one patent would seemingly not be sufficient to protect the investments in R&D, as slivers of derivative innovations may be captured by competing innovators who are pursuing the same avenues of research. Hence, an accurate protection of innovation demands several patent filings in order to gain freedom of operation.[5]

From a different angle, firms today have also come to realize that, much like it happens in the case of the company's goodwill,[6] the value accruing

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product in complex industries, patent law remains anchored "in a nineteenth century paradigm of essentially one patent, one product".

[3] See Bessen, "Patent thickets: Strategic patenting of complex technologies", *Technology & Policy Research Initiative* 1 (2004): 2, explaining that firms interact today over entire portfolios rather than over individual patents.

[4] See, in this regard, Anderman, "The Competition law/IP 'interface': An introductory note", in Anderman (ed.), *The Interface between Intellectual Property Rights and Competition Policy* (Cambridge University Press, UK, 2007): 19 and ff., arguing that when a market consists of complex systems of products, and technological progress involves the accrual of incremental improvements, "the traditional model of the patent as incentive to single product invention may not be appropriate as the sole model of innovation".

[5] According to the studies conducted by some authors, inventors' first motive to file would be to "secure freedom to operate", meaning that patent applications would be filed primarily to ensure firms' full capability to implement the invention in their own operations, with no risks of being blocked by third parties by means of a later filing. According to these scholars, therefore, obtaining actual patent protection would not be essential, as the goal of securing freedom to operate could easily be achieved by filing applications which are later withdrawn but whose content becomes a prior art: hence, impeding patentability from third parties. See Jell, *Patent Filing Strategies and Patent Management: An Empirical Study (*Gabler Verlag, Munich, 2012): 76 ff.

[6] The company's goodwill is described by Johnson and Petrone, "Commentary: Is goodwill an asset?", in *Accounting Horizons: A quarterly publication of the American Accounting Association* 12 (1998), 293. Authors identify goodwill in the company's ability to earn a greater profit from the sale of the entire business organizational complex than the simple sale of individual assets of the company. Then, they calculate the value of goodwill by the difference between the market value (consisting of the simple sum of the value of its constituent assets) and the price paid for the purchase of the business complex. *Ibidem*, 297. The concept of goodwill can also be found in Boennen and Glaum, "Goodwill accounting: A review of the literature", *SSRN Electronic Journal*, 2014, 1, where the authors define goodwill as the expected future economic benefit generated by

from holding a bundle of patent rights exceeds by far the value given by the mere sum of its individual components:[7] and, in fact, whilst the relevance of a single property right composing the portfolio may well be trivial, the power of the bundle will be enormous.[8] Differently from the business' goodwill, however, whose added value comes into play when the business is about to be transferred (i.e. typically sold) to a different entrepreneur, the value of the patent portfolio is mainly a *strategic* one, which the holder will be able to leverage against rivals.[9]

3. Strategic advantages stemming from the patent portfolio

The literature has incisively defined patent portfolio as "a *strategic* collection of *distinct-but-related* individual patents that, when combined, confer an array of important advantages upon the portfolio holder" (italics added).[10] And indeed, while patent portfolios can vary in size (i.e. extremely large number vis-à-vis more limited number of patent applications and rights) and composition (complementary technologies vis-à-vis substitute or derivative technologies), it must be pointed out that there are some

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the organisation of the company. They also develop the same calculation of the goodwill value identified by L.T. Johnson, K.R. Petrone, specifying that this value is important (i.e., it is calculated and entered in the budget) only as a result of the purchase of a company.

[7] See Parchomovsky and Wagner, "Patent portfolios", *U. Pa. L. Rev.* 154, no. 1 (2005-2006): 29, 52, explaining that firms patent heavily *not* to realize the value of individual patents, which is often negligible, but to obtain the advantages of the aggregation of these individual patents into patent portfolios. Single patents, therefore, count only as input for the creation of the portfolio. See also Phillips, "A spanner in the works – or the spanner that works? Patents and the intellectual property system", in Takenaka T. (ed), *Patent Law and Theory A Handbook of Contemporary Research*, (Edward Elgar Publishing, Cheltenham (UK) – Northampton (USA), 2009): 134 ff., explaining that the power of a patent grows exponentially when it becomes part of an expanding portfolio of patent rights.

[8] This finds confirmation in the recent increase of multimillion dollars acquisitions of high tech and pharmaceutical companies. See Girard, "Does 'strategic patenting' threatens innovation? And what could happen if it did?", in Mukhopadhyay, Akhilesh, Srinivasan, Gurtoo and Ramachandran (eds.), *Driving the Economy through Innovation and Entrepreneurship.* Springer India, 2013, 329, reporting Google's acquisition of Motorola Mobility whereby the former allegedly paid about $ 510.000 for each patent forming the mobile company's portfolio.

[9] See Guellec, van Pottelsberghe and van Zeebroeck, "Patents as a market instrument", in Guellec, Van Pottelsberghe and Van Zeebroeck (eds), *The Economics of the European Patent System: IP Policy for Innovation and Competition*, 87, noting that the strategic advantages firms can obtain and use against rivals by the mere act of patent filing will generate even more patent applications.

[10] See Parchomovsky and Wagner, "Patent portfolios", *supra* footnote n. 7, 27.

significant advantages inherent to the construction of a patent portfolio that accrue transversally to all firms, regardless of the sector they operate in.[11]

At the outset, the holding of a patent portfolio allows the holder to expand both the horizontal and vertical magnitude of its innovation trail. As far as the horizontal dimension is concerned, a first advantage consists in the firm being able to hedge the risk of innovation failure intrinsic to the patent system: the more you file, the more the chances that some of the titles will eventually be released and turn out to be profitable.[12] With regard to the "vertical" dimension, the building of a portfolio happens by filing multiple applications which are often subsequent in time: hence with subsequent priority dates.[13] Such scattered filings allows the portfolios' holder to gradually slip forward in time along the trail of the derivative innovations, as the earlier titles of protection gradually expire.[14] In this way, the portfolio holder will manage to prolong duration of rights endlessly (so called *evergreening* of patents), as long as derivative patents are still in force.[15]

From a different angle, holding large patent portfolios gives the firm a significant competitive advantage because it increases strategic informational

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[11] See Cohen, Nelson and Walsh, "Protecting their intellectual assets: appropriability conditions and why U.S. manufacturing firms patent (or not)", *National Bureau of Economic Research* 7552 (2002): 26-27, arguing that the use of patents for threatening or defending against litigation is the most important use of patents across all industries, regardless of the nature of the technology.

[12] In this sense Parchomovsky and Wagner, "Patent portfolios", *supra* footnote n. 7, 38.

[13] Only divisional patents, indeed, take the same priority date of the main patent. On the functioning of divisional patents see Arezzo, *Patent Portfolios and Pharmaceuticals: A European Perspective* (*Quaderni di AIDA*, Giappichelli Publishing, Turin, 2023), chapter IV.

[14] See Granstrand, "Are we on our way in the new economy with optimal inventive steps?", in Granstrand O. (ed.), *Economics, Law and Intellectual Property, Seeking Strategies for Research and Teaching in a Developing Field* (Kluwer Academic Publishers, UK, 2003): 247 ff., explaining that sometimes patenting in a continuous way in time – whenever there is the possibility – a sequence of "small" patents may turn out to be more profitable to the firm then to patent a single "large" patent in a specific moment. Indeed, if the firm happens to be the incumbent, or anyhow is a firm with a strong market position, engaging in continuous follow-up patenting of small (product or process) improvements serves to perpetuate its position of dominance, as an "effective patent protection is prolonged from a continuously renewed patent portfolio".

[15] On the detrimental effects of patent evergreening strategies on innovation see Bessen, "Patent thickets: Strategic patenting of complex technologies", *supra* footnote n. 3, 2. See also Gurgula, "Strategic patenting by pharmaceutical companies – Should competition law intervene?", *I.I.C.* 51 (2020): 1067; Ghidini, *Rethinking Intellectual Property, Balancing Conflicts of Interests in the Constitutional Paradigm* (Edward Elgar Publishing, Rethinking Law Series, Cheltenham (UK) – Northampton (USA), 2018): 115.

asymmetries to be used against rivals.[16] In this regard, two main advantages can be spotted. At first, the mere detention of multiple patent titles increases the uncertainty hinging on rivals, as chances to inadvertently infringe the technology enshrined in the portfolio will dramatically rise. The more the titles of protection, the greater the risk of getting caught in a lengthy and costly litigation, eventually leading to a finding of infringement and to a consequent condemnation to pay damages and royalties to the portfolio's holder (so-called *patent hold-up*).[17] The scale dimension of the portfolio, therefore, by increasing the costs of litigations and the chances of *patent hold-ups*, will raise rivals' costs,[18] strongly discouraging competing firms from pursuing the same research path of the firm holding the portfolio.[19]

Secondly, firms can well exploit the uncertainty connected to the validity of the rights contained in patent portfolios to aggressively threaten rivals of infringement suit and force them into accepting unfavourable deals or licensing arrangements.[20] This way of leveraging information *on* the patent (meaning information on their actual validity) to the detriment of their

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[16] See Patterson, "Leveraging information about patents: Settlements, portfolios, and holdups", *Houston L.Rev.* 50 (2012): 504 ff., highlighting that the informational aspects of portfolios have significant competitive advantages. Given this assumption, Patterson argues that holding a portfolio of thousands of low-quality patents could be more valuable for a firm than holding a small bunch of high-quality patents because of the cost disadvantage the bigger portfolio will impose on rivals in terms of validity assessment of the patents.

[17] On patent hold-up see Contreras, "Much ado about holdup", *University of Illinois Law Review*, 2019, 876; Chien, "Holding up and holding out", *Mich. Telecomm. and Tech. L. Rev.* 21 (2015): 1; Galetovic, Haber and Levine, "An empirical examination of patent holdup", *Journal of Competition Law and Economics*, 11-III (2015): 549; Lerner and Tirole, "Standard-essential patents", *Journal of Political Economy*, 123-III (2015): 547; Farrell, Hayes, Shapiro and Sullivan, "Standard setting, patents, and hold-up", *Antitrust L. J.* 74 (2007): 603; Lemley and Shapiro, "*Patent hold-up and royalty stacking*", *Texas L. Rev.* 85 (1990): 2007.

[18] See Rubinfeld and Maness, "The strategic use of patents: Implications for antitrust", in Leveque and Shelanski (eds.), *Antitrust, Patents and Copyright: EU and US Perspectives* (Edward Elgar Publishing, Cheltenham (UK) – Northampton (USA), 2005): 90-91, further noting that when the cost of challenging patents increases with the number of patents composing the bundle, firms might have an incentive to include weak patents in the package.

[19] Already in 1956, R. Franceschelli was warning about the effects of entry barriers created by multiple patent filings, explaining that the mere cumulation of two patent titles would multiply – rather than adding one to the other – their excluding powers ("la riunione di due brevetti non somma ma moltiplica i rispettivi effetti preclusivi"). Franceschelli, "Valore attuale del principio di concorrenza e funzione concorrenziale degli istituti di diritto industriale", *Riv. dir. ind.*, I (1956): 88.

[20] More extensively on this issue see *infra* § 6-7.

rivals gives a strong competitive advantage to the holder of the portfolio, which goes well beyond what patent law was meant to grant.[21]

As a side consideration, it is worth stressing that to benefit from the uncertainty effect generated by the portfolio, firms do not need to obtain all the patents they file for. In fact, even the mere act of patent filing successfully reaches such a goal.[22] This is because, although not yet granted, patent applications in Europe receive provisional protection immediately after the publication date, in a way to grant safeguard to the inventive concept during the time span elapsing from publication of the content of the invention to the actual release of the right.[23] Filing several applications therefore is always a profitable strategy, regardless of whether the final title of protection will be eventually granted.[24] In fact, on the one side, patent filings will immediately grant enforceable rights against alleged infringers

[21] See Patterson, "Leveraging information about patents: Settlements, portfolios, and holdups", *supra* footnote n. 16, 490, arguing that it is not clear that the advantages conferred by this type of uncertainty (i.e. uncertainty permeating the validity of the patent, nor its scope or its commercial value) should be properly viewed as rights of the patentees, and suggesting rather that the costs imposed on alleged infringers forced to enter a licensing agreement or a settlement should be viewed as the responsibility of the patentee.

[22] See, in this regard, Somaya, "Patent strategy and management: An integrative review and research agenda", *Journal of Management* 38 (2012): 1100; Ahn, *Second Generation Patents in Pharmaceutical Innovation* (Nomos, Baden-Baden, 2014): 231-232, both arguing that temporary insecurity about patent ownership created by patent filings can be exacerbated in those jurisdictions, like the German and the British ones, where examination of substantive patent requirements requires activation from the applicant. See extensively on this issue also Henkel and Jell, "Alternative Motives to File for Patents: Profiting from Pendency and Publication", *S.S.R.N. Electronic Journal* 1 (2009), available at https://ssrn.com/abstract=1271242, (last accessed on 6th March 2023).

[23] And, indeed, provided it is so established in the patent laws of the designated States, from the moment of publication patentees usually enjoy the full spectrum of enforcement instruments, including interim measures. This is confirmed by art. 67 of the European Patent Convention establishing, in its first prong, that "A European patent application shall, *from the date of its publication*, provisionally confer upon the applicant the protection provided for by Article 64, in the Contracting States designated in the application" (italics added). The *rationale* of the provision is to offer protection to the patentee immediately, given that the date of publication also represents the moment from which the twenty years term protection is calculated, pursuant to art. 63 EPC. More broadly on the theme see Arezzo, "I diritti nascenti dalla brevettazione", in Clemente, Gambino and Falce (eds.), *Proprietà intellettuale, Mercato e Concorrenza*, Trattario di Diritto Civile a cura di P. Cendon (Giuffrè, Milan, 2017): 47 ff.

[24] See Jell, *Patent Filing Strategies and Patent Management: An Empirical Study, supra* footnote n. 5, 16, arguing that in many instances, patent applicants benefit from a long period of pendency and could find it profitable to delay the patent process for years. Similarly on this point see Ullrich, "Strategic patenting by the pharmaceutical industry: Towards a concept of abusive practices of protection", in Drexl and Lee (eds.), *Pharmaceutical Innovation, Competition and Patent Law: A*

and, on the other side, they will create prior arts that will ultimately contribute to impair the novelty and inventiveness of future inventions.[25]

The recent judgements on (reverse) patent settlement agreements in the pharmaceutical sector represent the landmark example to show how the holder of a patent portfolio can successfully exploit the bundle of exclusive rights at their own disposal in a way to prevent entry from generic competition and prolong market exclusivity.

4. Reverse payment settlement agreements as landmark example of a successful exploitation of a patent portfolio

As explained by the Commission on several occasions, patent settlements are generally seen as pro-competitive agreements, as they put to an end litigation costs, reducing the uncertainty stemming from lengthy trials. The Commission has distinguished, however, between settlement agreements that are never anticompetitive, which are those that do not limit market entry of potential competitors (TYPE A *PSAs*), and agreements which prevent competitors, and in particular generic companies, to market their own products (TYPE B). This latter category is further divided into type B-I and type B-II *PSA*, according to whether or not the settlement envisages a value transfer from the originator to the genericist(s). While TYPE B-I *PSAs* may, in rare circumstances, exhibit an anticompetitive nature,[26] TYPE B-II are likely to attract the highest degree of antitrust scrutiny and can fall within the harshest category of restraints of trade.[27]

Trilateral Perspective (Edward Elgar Publishing, Cheltenham (UK) – Northampton (USA), 2013): 247 ff.

[25] See, in this regard, Guellec, Martinez and Zuniga, "Pre-emptive patenting: Securing market exclusion and freedom of operation", *Economics of Innovation and New Technology,* 21, 2012, 20, further arguing that even patenting a minor technical contribution to the art contributes to increasing uncertainty and raising patentability threshold for rivals. Hence, concluding that for these reasons (pre-emptive) patent filings largely contribute to feed the patent inflation.

[26] See European Commission, DG Competition, *8th Report on the Monitoring of Patent Settlements* (period: January-December 2016) Published on 9 March 2018, available at https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report8_en.pdf (last accessed on 6th March 2023), § 16, where the Commission explained that settlements concluded outside the exclusionary zone of the patent and/or settlement agreements on a patent for which the patent holder (or both parties) know(s) that the patent does not meet the patentability criteria may attract antitrust scrutiny.

[27] See European Commission, *Pharmaceutical Sector Inquiry*, Final Report, Jul 8, 2009, par. 467, available at: https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf (last accessed on 6th March 2023) § 741 ff.; European Commission, DG Competition, *8th Report on the Monitoring of Patent Settlements supra* footnote n. 26 § 14 ff.

As we are about to see, the European case law developed so far has centred on the assessment of TYPE B-II agreements, which the EU Institutions have punished under the specific heading of *reverse payment settlement agreements*, the term "reverse" highlighting the inner peculiarity of such agreements: namely, the circumstance that the "payment" is given from the patentee to the supposed infringer and not the other way round (as one would normally expect, assuming that the agreement should settle a controversy where the generic products *do* violate the originator's patents).[28]

4.1. The Lundbeck *case*

The *Lundbeck* saga involved the strategic construction of a patent portfolio surrounding the active pharmaceutical substance *citalopram*,[29] with a clear evergreening intent, and its strategic implementation to deter market entry when the patents on the active ingredients expired.[30] In 2002, *Lundbeck*

[28] See Kyle, "Competition law, intellectual property, and the pharmaceutical sector", *Antitrust L.J.* 81 (2016): 8; O'Donoghue and Padilla, *The Law and Economics of Article 102 TFEU* (III ed., Hart Publishing, Oxford and Portland, 2020): 783; see also Dolin, "Reverse settlements as patent invalidity signals", *Harvard J. L. & Tech*. 24 (2011): 293. The author further suggests that RPSAs should be taken as valuable proxies for patent strength, as patentees would not be prone to settle were they sure of the validity of their titles.

[29] *Citalopram* is a substance that inhibits the re-uptake of the neurotransmitter serotonin in the brain and was used as the funding ingredient for an antidepressant marketed and distributed by the originator company with the brand name *Celexa*. See European Commission, 19 June 2013, case COMP/AT.39226, *Lundbeck*, C(2013) 3803, available at https://ec.europa.eu/competition/antitrust/cases/dec_docs/39226/39226_8310_11.pdf (last accessed on 6th March 2023), (hereinafter *Lundbeck* decision) § 5, 45 ff. The decision of the Commission has been appealed before the General Court and then before the Court of Justice of the EU, both confirming the Commission's finding. See General Court, 8 September 2016, *H. Lundbeck A/S and Lundbeck Ltd. v. European Commission,* case T-472/2013, ECLI:EU:T:2016:449 (hereinafter: *Lundbeck,* judgement of the General Court); and Judgement of the Court, CJEU, *H. Lundbeck A/S and Lundbeck Ltd v. European Commission,* case C-591/16, 25 March 2021, ECLI:EU:C:2021:243 (hereinafter: *Lundbeck*, judgement of the Court). For a comprehensive review of the cases see Hull and Clancy, "The application of EU competition law in the pharmaceutical sector", *J. Eur. Compet. Law Pract.* 8 (2017): 205.

[30] *Lundbeck* obtained the first patent on *citalopram* in Denmark in 1977 and, through the subsequent filing of patent applications on processes to produce it, secured a long period of market exclusivity. Over time, *Lundbeck* successfully managed to develop and patent other processes for the making of *citalopram* by using iodo and amide (patented respectively in 2001 and 2003). In 2002, *Lundbeck* also obtained protection for a process claiming a purification method of the salts by means of crystallization. In 2002, the company obtained another patent for a process using a salt purification method by film distillation. Lastly, the company obtained several other patents to protect *escitalopram*, an active ingredient to launch a new antidepressant aimed at treating the same patients firstly treated with *citalopram*. See *Lundbeck*, judgement of the Court, *supra* footnote n. 29, §§ 16-22.

sent several letters to generic companies located in Europe threatening the beginning of infringement proceedings because, although its product patents on *citalopram* had expired, the originator company argued that production and distribution of the generic drugs would nonetheless violate its process patents. The *sham litigation* strategy[31] proved successful and even before the suits even begun, *Lundbeck* entered several settlement agreements with four generic companies, obtaining their obligation not to enter the market.[32] More specifically, genericists agreed to abstain from any production and market activities regarding drugs containing *citalopram*, in exchange of a large amount of money for the whole duration of the agreement.[33] Interestingly, while *Lundbeck* stressed that the conclusion of such agreements was necessary to put an end to the patent controversies, sparing generic firms the costs of a lengthy litigation, the latter specified in the agreements that they did not admit any violation of *Lundbeck*'s patents.[34]

4.2. The Servier *case*

In the *Servier* case, the pharmaceutical firm engaged in an even more complex and multifaceted conduct that started in 1999, precisely when the companies' patent rights (and related SPCs) were about to expire in

[31] The term *sham litigation* is generally used with regard to the vicious use of litigation against a competitor with the sole intent of damaging its position and strength on the market. With specific regard to IPRs, such conduct typically involves infringement actions merely brought to discourage market entry, even in circumstances where the right holder is not confident about the strength (read: validity) of its rights. The conduct of sham litigation will be later assessed in more detail *infra* at § 6 and 7.

[32] *Lundbeck* argued, in the *patent settlements*, that laboratory tests it had carried out on the *citalopram* produced by the generic companies indicated that, with some probability, it was obtained in violation of its crystallization process patent. It is worth noting, however, that no court had ruled on such issues. See *Lundbeck* decision, *supra* footnote n. 29, § 4. It was only in the case of the agreement with *Alpharma* that *Lundbeck* got an injunction from the UK Court, as an interim protective measure, within a patent dispute concerning the alleged infringement of *Lundbeck*'s process patent. The main proceeding never ended in a judgement, as *Lundbeck* retired its plea after signing the patent settlement. *Lundbeck* decision, *supra* footnote n. 29, § 523.

[33] *Lundbeck* decision, *supra* footnote n. 29, §§ 267-274. Similar circumstances happened in the *Fentanyl* case, where the Commission punished as restriction by object a co-promotion agreement signed by a Dutch subsidiary of Johnson & Johnson and the Swiss branch of Novartis whereby the North American company would grant monthly payment to the genericist exceeding the profit the latter assumed to make by selling the equivalent drug. See Commission Decision of 10 December 2013, case AT.39685 – *Fentanyl*, available at https://ec.europa.eu/competition/antitrust/cases/dec_docs/39685/39685_1976_7.pdf, (last accessed on 6th March 2023).

[34] *Lundbeck* decision, *supra* footnote n. 29, §§ 267, 348, 402 and 567.

some EU member States.[35] *Servier* began filing a dense net of derivative patents – some process patents and some product patents related to some specific crystalline form of the *perindopril* substance[36] – with the aim of fencing off access to the active principle to its generic competitors (once again, a patent portfolio with an evergreening purpose).[37] The strategy in itself, however, was not successful, as other firms succeeded in developing alternative methodologies to make a variation of the compound (i.e. a different crystalline form), so pure to meet the very high standard requested by the *Pharmacopeia*.[38]

In 2001, *Servier* began negotiating to acquire patent rights on such competing technologies, so as to eliminate any form of competition in the market. At the same time, as its original patents were about to expire, *Servier* itself patented a new crystalline form of *perindopril* (using arginine instead of erbumine) and introduced a new medicinal product (bio-)equivalent to *Coversyl.* At that point, *Servier* tried to shift consumers' demand towards

[35] See European Commission, 9 July 2014, case COMP/AT.39612 *Perindopril (Servier)*, C(2014) 4955 (hereinafter "*Servier* decision"); confirmed in part and reversed in part by the General Court, case T-691/14, *Servier and Others v. European Commission,* ECLI:EU:T:2018:922 (hereinafter *Servier* judgement). Extensively see Signoretta, *Reverse-Payment Settlements Under EU and US Patent Law: Convergence in Remedies,* in *G.R.U.R. Int*., 2022, 5 ff.; Piserà and D'Errico, *La valutazione concorrenziale dei patent settlement agreements nell'esperienza europea: i casi Lundbeck e Servier (perindopril),* in *Conc. e Merc.* 23 (2016): 559.

[36] *Servier* decision, *supra* footnote n. 35, §§ 113 ff.; § 2770.

[37] *Servier*'s strategic-defensive goal emerged eloquently from the internal company documentation acquired by the Commission, where reference is repeatedly made to the need to file "blocking patents" to create "a cluster of process patents around the molecule". It should be noted, however, that *Servier*'s awareness of the lack of innovative value of its secondary patents and the circumstance they had been filed for the sole purpose of composing the cluster (at other times referred to, even more incisively, as a 'maze of patents') emerges in several points of the decision. See *Servier* decision, *supra* footnote n. 35, §§ 115 ff., in particular § 117 and 122.

[38] The *European Pharmacopoeia* is an official register of medicinal substances for human use, which sets out the quality standards each molecule must meet to be granted a marketing authorization. When a molecule – *recte*: the so-called "monograph" of a compound, comprising either a description of the molecular structure or the properties of the compound – is listed in the *Pharmacopoeia*, all manufacturers are obliged to comply with the specifications contained therein. *Servier* had applied for the inclusion in the *Pharmacopoeia* of a second-generation patent (the "947" patent) covering a particularly pure crystalline form of perindopril, which could only be obtained by using the company's patented processes. The Commission considered this conduct as raising a significant barrier to entry for generic manufacturers. See *Servier* decision, *supra* footnote n. 35, § 77 ff.

the new drug,[39] although the latter did not carry any new further therapeutical advantages over the old one (so called *product-hopping* strategy).[40]

Eventually, *Servier* engaged into several patent suits, threatening generic firms with infringement were they to enter the market (the afore mentioned *sham* or *vexatious litigation*),[41] which led the latter to enter patent settlements agreements whereby the originator firm would secure more exclusive time on the market in exchange of a large transfer of money to its rivals.[42]

4.3. The Generics *case*

Similar circumstances lay at the basis of the judgement of the European Court of Justice in *Generics*, following a request for preliminary ruling submitted by the British Competition Appeal Tribunal in the so-called

[39] See *Servier* decision, *supra* footnote n. 35, §§ 223 ff.

[40] The conduct of so-called *product hopping* used to be particularly harmful in Europe for generic manufacturers wishing to enter the market for a given drug when the patent right expired. And this was, in particular, because it prevented the use of the abbreviated marketing authorization procedure, based on proof of so-called *bioequivalence* with the patented and already authorized medicinal product (see Article 10(1)(a)(iii) of Directive 2001/83/EEC of the European Parliament and of the Council of November 6, 2001, on the Community code relating to medicinal products for human use, E.U.C.E. Nov. 28, 2001, L-311, 67). Today, the replacement of the first-generation drug formulation with a new one and the subsequent withdrawal from the market of the first medicinal product, with the corresponding marketing authorization (MA), are no longer capable in Europe of raising (anti-)competitive concerns because the aforementioned Directive has been amended several times, in a way to allow the use of the abridged procedure even where the first medicinal product has been withdrawn from the market, with the consequent withdrawal of the corresponding MA (hence: with no need to perform and later provide the results of complex and costly preclinical tests and clinical trials). For an in-depth look at the topic in light of recent legislative innovations in Europe, see Domeij, "Anticompetitive marketing in the context of pharmaceutical switching in Europe, in pharmaceutical innovation, competition and patent law", in Drexl and Lee (eds.), *Pharmaceutical Innovation, Competition and Patent Law: A Trilateral Perspectiv*e (Edward Elgar Publishing, Cheltenham (UK) – Northampton (USA), 2013): 276 ff. On product hopping in general: Desogus, "Nuove frontiere tra regolazione, proprietà intellettuale e tutela della concorrenza nel settore farmaceutico: Le pratiche di brevettazione strategica", *Rivista della regolazione dei mercati* 1 (2015): 64 ff.; Shadowen, Leffler and Lukens, "Bringing market discipline to pharmaceutical product reformulations", *I.I.C.* 42 (2011): 968.

[41] And, indeed, the groundlessness of the actions seems to find broad confirmation in the evidence collected during the Commission's inspection, from which it emerges that the company was fully aware of the lack of innovative value (and, consequently, the probable invalidity) of the patents on which the warnings were based. See *Servier* decision, *supra* footnote n. 35, §§ 153-154.

[42] *Servier* decision, *supra* footnote n. 35, §§ 2793-2794 and 2927 ff.

paroxetine case.[43] The case regarded the agreements signed by the originator company *GlaxoSmithKline plc* and three generic companies from 2001 to 2004, with the purpose of delaying entry in the market of the equivalent medicine of *Seroxat*, the anti-depressant drug marketed by *GSK*, based on the active ingredient *paroxetine*. Before the expiry of patent protection on the active pharmaceutical ingredient in 1999, *GSK* filed and obtained a set of secondary patents covering four polymorphs of the active ingredient and the related processes to produce them. This, however, did not stop generic companies from taking actions to enter the market, as it results from their filing for the MA in both the UK and Ireland.[44] Of the agreements found restrictive of competition (two out of three), it is worth recalling that they were all patent settlements in its proper sense, as they came about to conclude proceedings actually started before Courts, commenced by either *GSK* or the generic company.

5. The strategic advantages stemming from the RPSA and the value transfer as crucial element within the assessment of the EU institutions

The advantages of the settlement for the patentee are manifold.[45] It will indeed avoid the risk of not getting the desired injunction or losing the proceeding in its entirety, with a likely patent invalidation, and in any case it will avoid facing significant profit losses once generic competition materializes.[46] It is worth recalling, in fact, that competition in the pharmaceutical field is characterized by the immediate fall of prices as soon as equivalent drugs enter the market.[47]

The settlement, however, may be beneficial for the genericist as well. And, indeed, in exchange for its obligation not to enter the market, the generic company will obtain a considerable transfer of value, typically but

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[43] See Judgement of the Court, CJEU, *Generics (UK) Ltd and Others v. Competition and Markets Authority,* 30 January 2020, case C-307/18, ECLI:EU:C:2020:52.

[44] See *Generics* judgement*, supra* footnote n. 43*,* §§ 8-10.

[45] For an overview of the reasons leading firms to sign such agreements, see Barazza, "Pay-for-delay agreements in the pharmaceutical sector: Towards a coherent EU approach?", *Eur. J.* 5 I (2014): 79.

[46] See, in this regard, Gschwindt, "Temporary relief of pay-for delay: the ECJ as specifically different antidepressant", *G.RU.R. Int*. 70, III (2021): 251.

[47] See, in this regard, P. Ibanez Colomo, arguing that such aspect (meaning that the settlement will keep prices of the original drug at appreciable higher level than they would be in lack of the agreement) must be taken into account when one assesses the "precise purpose" of the settlement. Ibañez Colomo, "The legal status of pay-for-delay agreements in EU competition law: Generics (paroxetine)", *Common Market L. Rev.* 57 (2020): 1938-1939.

not necessarily in the form of a direct monetary payment.[48] Therefore, the *RPSA* becomes an instrument, allowing the generic company to share part of the profits the originator will keep earning, to the detriment of consumers (and the national sanitary systems), who will continue to pay higher prices than those they would have paid had the equivalent drugs readily entered the market.[49]

In light of the above considerations, the attention of EU institutions has largely converged on the parameter of the value transfer from the originator company to the generic.[50] And, indeed, as mentioned earlier, the circumstance that a settlement agreement arising to peacefully compose a controversy on a supposed patent infringement contains an obligation on the side of the supposed damaged party to give some sort of monetary payment or other economic benefit to the supposed counterfeiter surely represents the first warning sign. The obligation upon the supposed infringer to refrain from entering the market, often coupled with a further commitment not to contest validity of the originator's patents, does the rest[51].

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[48] The generic companies may benefit from a licence to enter the market at a certain moment in time with no fear of litigation, or from favourable side-deals where the generics get to manufacture the drugs for the originator company or agrees to supply raw materials and active ingredients for such purposes or agree to share research and developments on future innovative trails. In this regard See M. Colangelo, "Reverse payment settlements in the pharmaceutical sector under EU and US competition laws: A comparative analysis", *World comp.* 40 (2017): 484-485. In this regard see also the recent judgement of the U.S. Court of Appeal for the Fifth Circuit in the *Impax* case, where the Court – confirming the finding of the FTC – established that a "payment" within *Actavis* can be also consist in the originator company pledging not to market its own generic version of the patented drug. See *Impax Laboratories, Inc. v. Federal Trade Commission, n.* 19-60394 (5th Cir. 2021), section C, 7, available at https://www.ca5.uscourts.gov/opinions/pub/19/19-60394-CV0.pdf (last accessed on 6th March 2023). See also O'Donoghue and Padilla, "The law and economics of article 102 TFEU", *supra* footnote n. 28, 783-784.

[49] In this way: Drexl, "'Pay-for-delay' and blocking patents – targeting pharmaceutical companies under European competition law", *40 I.I.C.* 40 (2009): 752; Cerulli Irelli and Bellucci, *Antitrust e proprietà intellettuale: Profili sostanziali, public e private enforcement* (Wolters Kluwer, Milan, 2019): 122; Massimino and Perinetto, "Attività del regolatore e diritto antitrust: Nuove frontiere di una interrelazione antica – il caso del settore farmaceutico", *Riv. dir. ind.* I (2020): 96-97; Maggiolino, "Antitrust law and the right to settle: The case of pay-for-delay settlements", *Conc. e Merc.*, 2021, 112, arguing that RPSAs deserve antitrust scrutiny whenever generic drug manufacturers accept to give up their independent efforts to enter the market in exchange for a guaranteed and significant share of the patentee's profit.

[50] Some scholars have observed that such an approach would have the merit of not requiring an assessment of patents' validity or strength, which is complex and beyond the competition authorities' tasks, while at the same time it provides for an easy and practical criterion of legality. See O' Pais, "The Lundbeck case through the lens of probabilistic patents", *Concurrences* 2 (2017): 37.

[51] See, in this regard, *Generics* judgement, *supra* footnote n. 43, §§ 81-82.

In the two most recent cases, the CJEU has explained that the value transfer must act as an incentive for the generic company to refrain from entering the market[52], and it has further stated that for the *RPSA* to constitute a restriction by object "it cannot have any explanation other than the commercial interest of both the holder of the patent and the party allegedly infringing the patent not to engage in competition on the merits".[53] In other words, competition authorities must inquire whether objective justifications exist to explain why the originator company agrees to a significant transfer of value towards the alleged infringing genericist.

In order to assess whether the value transfer finds its sole and only intent in the parties' common goal of substituting collusion to competition on the merit, the size of the transfer surely represents the first parameter.[54] The transfer of value must be significant, and it must be valued in the most comprehensive way: meaning comprehending all kinds of value (monetary and non-monetary) and all modes of transfer (i.e. direct or indirect).[55] The Court clarified that there is no such a requirement implying that the net gain the generic company expects to obtain through the transfer be larger than the profits it would have made by winning in the patent proceedings.[56] However, if and when such net gain exists, the former must not be justifiable by any other ancillary obligations concerning the provision of goods and services by the generic companies to the originator that have been proven legitimate.[57]

In conclusion, the European Institutions have stated the principle that while patent settlements can be – and often are – fully legitimate, *RPSAs* that purposefully aim at delaying market entry of generic companies and

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[52] *Lundbeck*, judgement of the Court, *supra* footnote n. 29, § 115.

[53] *Generics* judgement, *supra* footnote n. 43, § 87.

[54] *Lundbeck*, judgement of the Court, *supra* footnote n. 29, § 117. See, in this regard, Mungan, "Reverse payments, perverse incentives", *Harvard Journal of Law & Technology* 27 (2013): 24-25.

[55] *Generics* judgement, *supra* footnote n. 43, § 90.

[56] *Lundbeck*, judgement of the Court, *supra* footnote n. 29, § 115; *Generics* judgement, *supra* footnote n. 43, § 94.

[57] *Generics* judgement, *supra* footnote n. 43, §§ 92-93. For example, a generic company, after assessing its chances of success in the court proceeding, may well decide to abandon entry to the market and to sign an agreement to settle the proceeding. In such a case, notes the Court, the value transfer will typically correspond to compensation for the costs of or disruption caused by the litigation or to remuneration for the actual supply of goods or services to the manufacturer of the originator medicines. See *Generics* judgement, *supra* footnote n. 43, §§ 84-86. In this regard, see also Gschwindt, *Temporary Relief of Pay-for Delay: the ECJ as Specifically Different Antidepressant*, *supra* footnote n. 46, at 254.

hence purposefully substitute competition on the merits with market exclusion are extremely detrimental to competition (being tantamount to market exclusion or market sharing deals)[58]: hence, they may well amount to a violation of the most severe forms (i.e. a restriction by object, pursuant to art. 101(1) TFEU).[59] This even in cases where the patent dispute is "genuine",[60] but the sole intent of the settlement is to buy out competition.[61] In this regard, the EU bodies have made clear that the patent holder cannot legitimately use a large transfer of value to exchange the uncertainty about patent validity or strength for certainty about the extension of its monopoly and the prevention of competition.[62]

6. The missing piece of the puzzle. Sham litigation enforcing collateral patents within the portfolio

Lamentably, the aspects relating to the construction of the portfolio and *sham litigation* have barely had any weight in the analysis of the

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[58] See *Lundbeck* judgement GC, *supra* footnote n. 29, §§ 161, 355; *Generics* judgement, *supra* footnote n. 43, §§ 76-77.

[59] *Generics* judgement, *supra* footnote n. 43, §§ 84-85. *Lundbeck,* judgement of the Court, *supra* footnote n. 29, § 114. Note, however, that in both judgements the CJEU clarified that only such *RPSAs* (namely those agreements in which the reverse transfer of value cannot have any other plausible explanation than collusion) can be deemed as restriction by object, where in other circumstances they will be assessed under the milder framework of art. 101(3) TFEU, as restriction having the effects of distorting competition. *Generics* judgement, *supra* footnote n. 43, § 85. *Lundbeck,* judgement of the Court, *supra* footnote n. 29, § 113. This is a very delicate point, as several authors would be in favour of assessing *RPSAs* under the milder lenses of a restriction by effects analysis. See, in this sense, Zelger, "By object or effect restrictions – Reverse payment settlement agreements in light of Lundbeck, Servier and Generics", *Journ. of Eur. Comp. Law & Pract*., 12 (2020): 7 ff.

[60] This was precisely the case in *Generics*, where in one case the controversy had even resulted in the issuance of an interim order against the generic companies. Hence, the Court of Justice clearly stated that the agreements could not be regarded as "bringing to an end entirely fictitious disputes". Nonetheless, the Court concluded for the anticompetitive nature of such agreements. See *Generics* judgement, *supra* footnote n. 43, §§ 75-76. According to Ibañez Colomo, even a settlement following a genuine dispute may have an object analogous to that of a market-sharing or a market-exclusion cartel. See Ibañez Colomo, "The legal status of pay-for-delay agreements in the EU competition law: Generics (paroxetine)", *supra* footnote n. 47, 1938.

[61] See *Generics* judgement, *supra* footnote n. 43, § 83 and 87, *Lundbeck* (CJEU judgement), *supra* footnote n. 29, § 114, explaining that for a restriction by object to be found, the transfer of value to the generic company cannot have any explanations other than the commercial interests of both parties not to engage in competition on the merits. On the contrary, the settlement can escape a *per se* finding of anticompetitiveness if the value transfer can be plausibly justified.

[62] In this regard, see Gschwindt, *Temporary Relief of Pay-for Delay: The ECJ as Specifically Different Antidepressant*, *supra* footnote n. 46, 255.

Commission and the EU judges[63]. However, as it has been hinted earlier on, *patent settlement agreements* are often the last portion of a complex but unitary strategy that begins with the very building of the patent portfolio.

As well known, today, originator undertakings active in the pharmaceutical sector are used to accompany their main pivotal patents with a set of derivative ones, often covering minor developments or variation of the original compound or substance, manufacturing processes, forms of administration, dosage regimens, applications to a different group of patients, and so on[64]. Sometimes, the filing of a derivative patent corresponds to the production of a different drug (different than the one produced pursuant to the pivotal patent), but most of the times these collateral patents are just kept dormant (so-called sleeping patents[65]) until the time comes for them to play a role. This moment arrives precisely when the pivotal patent(s) in the portfolio come to elapse, but the holder intends to preserve exclusivity of its blockbuster drug. Here, *sham litigation* comes into play. Once the expiry date of the main patent approaches, originator companies begin an intimidating campaign suing (or threatening to sue) generic companies for infringement of collateral patents which, despite *never worked*, are still in force.[66]

Sham or *vexatious litigation* is, therefore, the first part of a two-fold strategy put into place by the originator. The second part of the strategy takes place when the originator firm, exploiting the scenario of uncertainty

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[63] In the *Servier* decision, for example, the Commission analysed the whole set of conduct within *Servier*'s foreclosing strategy, including the building of a patent cluster and the conduct involving sham litigation, in order to assess whether they could all form an abuse of dominance under the heading of art. 102 TFEU (where the Commission describes them as "*Elements of the strategy implementing the overall anticompetitive objective*"). See *Servier* Decision, *supra* footnote n. 35, § 8.1.2. These elements, however, have been considered factual circumstances, taken into account only to depict the market scenario and confirm the strategic nature of the incumbent's behaviour. *Id*., § 2772. In particular, neither the construction of the portfolio, nor the *product hopping* strategy were found to infringe competition law. *Id*. § 2770.

[64] Extensively on this issue see Arezzo, *Patent portfolios and pharmaceuticals: A European perspective*, *supra* footnote n. 13, chapt. III.

[65] The expression "sleeping patents" comes from Gilbert, "Patents, sleeping patents, and entry deterrence", in Salop (ed.), *Strategy, Predation and Antitrust Analysis* (Federal Trade Commission, Bureau of Economics and Bureau of Competition, Washington, 1981): 223 ff., discussing the anticompetitive potential of patents accumulation as an exclusionary pre-emptive strategy.

[66] See European Commission, *Pharmaceutical Sector Inquiry, supra* footnote n. 27, §§ 578-585. In this regard, the Commission explained that sham litigation can successfully be used and achieve its purpose even when it does not reach the stage of a formal proceeding and rests on a preliminary stage.

created by the *sham litigation*, takes advantage of the weaker bargaining position of the generic company and leads it to enter an agreement where it will expressly compel itself to stay off the market.[67] This will eventually favour the originator's position on the market by securing it more time of exclusivity.[68]

In what follows, we will argue that *sham litigation* should, in some circumstances, also be punishable as separate stand-alone conduct, when put into place by a dominant firm.

7. Sham litigations involving patents as a separate anticompetitive conduct

The term *sham* or *vexatious litigation* has been traditionally intended as a vicious and astute recourse to an infringement proceeding where the actor is not entirely sure of the robustness of its position and, nevertheless, commences litigation.[69] As well known, such practice has been rarely condemned as a stand-alone anticompetitive conduct,[70] given the importance

[67] As noted by some authors, a single generic company will not find it convenient to bear the high litigation costs connected with a patent dispute to obtain a judgement (declaring patent nullity) which will then benefit all other generic companies interested in entering the market. This externality intrinsic to challenging patents will negatively affect third parties, because in favouring the conclusion of the settlement, it often helps protecting weak patents from invalidation. See Frank and Kerber, "Patent settlements in the pharmaceutical industry: What can we learn from economic analysis?", in Nihoul and Van Cleynenbreuge (eds.), *The Roles of Innovation in Competition Law Analysis* (Edward Elgar Publishing, Cheltenham (UK) – Northampton (USA), 2018): 215. See also Siragusa, "The EU pharmaceutical sector inquiry. New forms of abuse and article 102 TFEU", in Caggiano, Muscolo and Tavassi (eds.), *Competition Law and Intellectual Property, A European Perspective*W(olters Kluwer, The Netherlands, 2012): 179, noting that large originator companies usually have financial resources to cover long and costly litigation that generics are not able to match.

[68] See, in this regard, Hempill, "Intellectual property and competition law", in Dreyfuss and Pila (eds), *The Oxford Handbook of Intellectual Property Law* (Oxford University Press, Oxford, 2018): 880, where the author points out that settlements of patent litigation would lead to a division of the market "by time".

[69] As clarified by the General Court (at that time Court of First Instance) in the *ITT Promedia NV v. Commission* judgement, the question does not concern "determining whether *the rights* which the undertaking concerned was asserting when it brought its action *actually existed or whether that action was well founded*, but rather of determining *whether such an action was intended to assert what that undertaking could, at that moment, reasonably consider to be its rights*" (italics added). See *ITT Promedia NV v. Commission,* Case T-111/96, 17/06/1998, E.C.R. 1998, II-02937, § 1 and 76. In other words, whether the firm was acting at the moment in good faith.

[70] The anticompetitive nature of sham litigation has been first dealt with by North American Court with the so-called *Noerr-Pennington doctrine.* The doctrine established, as a matter of principle, that no firms could be found to violate antitrust provision for enforcing its right to petition before a

to preserve each individual's right to petition before a Court.[71] In recent years, however, the cases of *vexatious litigation* based on intangible properties, and particularly patents, has sensibly grown and calls for attention.

We strongly believe that assessment of *sham litigation* should be differently tailored when the asserted right is a patent, because of the peculiar nature of such exclusive rights, which, despite being equated to property rights, bear significantly differing features.

The first important distinction regards the aura of uncertainty permeating patents' validity. As mentioned above, patents are only *presumed* valid upon granted and not only the release of the title from the patent office can be opposed immediately afterwards (and protection overturned), but in any given moment (after grant) competitors can claim patent invalidity and a Court can well revoke the patent if it finds that the title has been improperly granted[72]. Pursuant to such feature, referred to by some

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Court, not even in the case where such an action would cause a damage for competition. However, the doctrine codified an exception (so-called *sham exception*) stating that an antitrust violation could be found when i) the legal proceedings or the use of administrative proceedings were manifestly unfounded; ii) and they had been carried out solely in order to harm the competitors of the dominant undertaking. See Perrine, "Defining the 'Sham Litigation' exception to the Noerr-Pennington antitrust immunity doctrine: An analysis of the 'Professional Real Estate Investors v. Columbia Pictures Industries' Decision", *Alabama L. Rev.*, 1994, 815; Fischel, "Antitrust liability for attempts to influence government action: The basis and limits of Noerr-Pennington doctrine", *U. of Chi. L. Rev.* 45 (1977): 80; Klein, *The Economics of Sham Litigation: Theory, Cases and Policy* (Bureau of Economics Staff Record to the Federal Trade Commission, Tennessee, 1989). Following the lead of the North American jurisprudence, EU institutions also endorsed the vision that for an abuse of dominance to be found, *sham litigation* must possess the requirements set forth by the *Noerr-Pennington doctrine.* The European judges, however, have given more weight to the elimination of all forms of competition from the market rather than the likely injury caused to the competitors of the dominant firm. See *ITT Promedia NV v. Commission*, Case T-111/96, *supra* footnote n. 69, § 30. See Ricolfi, "Antitrust in Diritto Industriale", in Abriani, Cottino and Ricolfi (eds), *Trattato di Diritto Commerciale* (vol. II, Cedam, Padua, 2001): 757 ff.; Vezzoso, "Towards an EU doctrine of anticompetitive IP-related litigation", *Journ. of Europ. Comp. Law & Practice*, 3 (2012): 521.

[71] In *ITT Promedia NV v. Commission*, the (then) Court of First Instance stated that access to justice is a fundamental right and a general principle underlying the constitutional tradition of Member States, further codified also in Articles 6 and 13 of the European Convention for the Protection of Human Rights and Fundamental Freedoms. Therefore, being access to the Court the most general base principle ensuring the rule of law, it is only in very exceptional circumstances that such conduct (alone) can violate competition law (the case precisely regarded abuse of dominance). See *ITT Promedia NV v. Commission, supra* footnote n. 69, *§ 60.*

[72] On the opposition procedure before the EPO see Cornish, Llewelyn, and Aplin, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* (9th ed., Sweet & Maxwell, London, UK, 2019): 168 ff.

scholars as the "probabilistic" nature of patents,[73] the patent system naturally embeds a strong information asymmetry between the patentee and its competitors. Only the patent holder knows whether its patent covers a breakthrough innovation or a trivial one, being therefore a weak patent. Much in the same way, only the patent holder has sufficient information to guess whether a competing product is actually infringing its exclusive prerogatives.[74]

In light of this, while on the one side patent litigation is very common in the pharmaceutical sector, and this especially when the expiry of exclusivity of branded drugs allows for the entry of new generic products[75], on the other side, the above-mentioned information asymmetry surely plays in favour of the portfolio's holder.

Given all the above assumptions, we advocate that if the originator company begins an infringement action against a competitor while being rather uncertain about the strength and validity of its patent, or about the infringing nature of the competing product, which it can reasonably deem to be falling outside the scope of its patent (as in the case of a process patent: see *infra* what will be explained in the next paragraph), litigation should be deemed *vexatious*. This assumption is in line with the principles set forth in the *ITT Promedia* case, where the General Court specified that in order for the legal proceedings to be characterized as an abuse of dominance there must be no room to reasonably consider them as an attempt of the

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[73] The Anglo-American literature has addressed the issue emphasizing the "probabilistic" nature of patents, precisely noting that Courts will have the last word in assessing whether a patent is truly valid and whether the alleged infringement has taken place. See, in this regard, Lemley and Shapiro, "Probabilistic patents", *Journal of Economic Perspectives* 19 (2005): 75; Shapiro, "Antitrust limits to patent settlements", *R.A.N.D. Journal of Economics*, 34 (2003): 395 ff., Ayres and Klemperer, "Limiting patentees' market power without reducing innovation incentives: The perverse benefits of uncertainty and non-injunctive remedies", *Michigan Law Review* 97 (1999): 985.

[74] See Rubinfeld and Maness, *The Strategic Use of Patents: Implications for Antitrust*, *supra* footnote n. 18, 71-74, explaining that the uncertainty about the validity of each of the patents in the bundle (note that the author refers expressly to a situation of patent thicket) together with the potentially substantial cost of litigation creates a strong incentive for the competitor to accept a licensing arrangement.

[75] In this regard, the Commission has gone so far as to depict it as a common "a form of competition in the pharmaceutical sector […] from the side of the originator undertaking, which in this way is trying to defend its market position against generic competition". See Lundbeck decision, *supra* footnote n. 29, § 625. In the academia, this point has been embraced by M. Colangelo, *Reverse Payment Settlements in the Pharmaceutical Sector under EU and US Competition Laws: A Comparative Analysis*, *supra* footnote n. 48, 473, arguing that in the pharmaceutical sector patent litigation is to be considered a legitimate form of competition.

concerned undertaking to assert its rights[76]. Interestingly, the GC clarified in this respect that it must not be determined whether the asserted rights actually existed, or the action was indeed well founded; on the contrary, it is important to assess "whether such an action was intended to assert what the undertaking could, at that moment, reasonably consider to be the party's rights"[77]. In other words, the subjective perception and good faith of the patentee when it began litigation.

Assuming litigation has been commenced vexatiously, if competition authorities can further demonstrate that such litigation has been put in place by the patent holder to purposefully exploit the information asymmetry concerning patent validity or infringement to the detriment of competitors, using it as a lever to try to force them out of the market, such conduct should then be deemed anticompetitive . And, indeed, in the case of *sham litigation* enforcing a patent (for example a weak patent) with the purpose of preventing entry from generic companies, the purported effect is detrimental for competition, as it amounts to preservation of market foreclosure and high prices for medicinal products far longer than the twenty years term patent protection normally allows[78].

The soundness of this approach is further corroborated by the second peculiarity proper to patent rights: namely, their being "negative entitlements". This is a fundamental aspect always not fully pondered into a competition law analysis. Being a form of intangible property, non-excludable and non-rivalrous in consumption, exclusive enjoyment of patents strongly relies on active enforcement of the exclusive rights, in order to impede

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[76] Pursuant to the two-pronged test elaborated by the EU Commission in *ITT Promedia*, an abuse of dominance could be found only in very exceptional circumstances: that i) the infringing proceedings would only serve to harass the opposing party; and that ii) they were conceived in the framework of a broader plan whose goal was to eliminate competition. *ITT Promedia NV v. Commission, supra* footnote n. 69, § 55.

[77] *ITT Promedia NV v. Commission, supra* footnote n. 69, §§ 72-73. The Court concluded that the last part of this criterion implied that only when it was possible to ascertain that the legal proceedings did not have such goal, it is was possible to conclude that the action had a vexatious nature.

[78] On the perilous effects on competition stemming from the practice of strategic patenting followed by *sham litigation* see de Lima and Silva, "Sham litigation in the pharmaceutical sector", *European Competition Journal* 7 (2011): 455, at 493, defining *sham litigation* as a case of abuse of rights; Muscolo, "Abuse of litigation, abuse of patent and abuse of dominance: Where do we stand?", in Pitruzzella and Muscolo (eds), *Competition and Patent Law in the Pharmaceutical Sector, An International Perspective* (Wolters Kluwer, The Netherlands, 2016): 107.

free-riding[79]. Enforcement of (patent) rights is therefore the most important form of *exercise* of patent right, which may well fall under the lenses of competition law and be punished as an abuse, if and when put into place by a dominant firm to the precise goal of foreclosing competitors[80]. The well-known rhetoric about the perils of punishing conduct undermining the very same *existence* of IP rights is therefore misplaced[81].

Interestingly, the Courts have largely disregarded aspects related to vexatious enforcement of IP rights. On the contrary, in several instances, the CJEU has stated that the fact that uncertainty permeates the validity of the (patent) titles is quite a normal condition of competition in the pharmaceutical markets, and it is precisely what determines a condition of at least potential competition between generic companies and the originator.[82] It is worth pointing out, however, that in *Generics* the CJEU held that the complex strategy sewed by the originator company, leading to the signing of the anticompetitive *RSPAs*, could also be contested as abuse of dominance to the originator firm, being a conduct aimed at preventing the

[79] The incentive theory and the public good nature of intellectual property is brilliantly illustrated by E.C. Johnson, "Intellectual property and the incentive fallacy", *Fla. St. U. L. Rev.* 39 (2012): 624-628. M.A. Lemley, "The Economics of Improvement in Intellectual Property Law", *Texas L. Rev.* 75 (1997): 996-997; A. Devlin, "The misunderstood function of disclosure in patent law", *Harv. J. L. & Tech*. 23 (2009-2010): 412 ff.

[80] See, in this regard, Vezzoso, *Towards an EU Doctrine of Anticompetitive IP-Related Litigation*, *supra* footnote n. 70, at 525, explaining that the development of a convincing anticompetitive IP litigation doctrine, despite advocated by the Commission in its sector inquiry on the pharmaceutical field, is a very delicate task, as it regards both the fundamental right to have access to justice and the protection of the exclusive rights granted by IPRs. This probably explains why European Courts have been so hesitant to develop a clear stance on the issue.

[81] Pursuant to an old European jurisprudence, abuse of dominance could be found, in exceptional circumstances, only in case the conduct at issue involved the exercise of the exclusive rights and did not impact on their existence.

See Judgment of the Court, CJEU, *Parke Davis and Co. v. Probel, Reese, Beintema-Interpharm and Centrafarm*, case C-24/67, 29 February 1968, ECLI:EU:C:1968:11, ECR 55, 72, where the Court ruled that: "since the *existence* of patent rights is at present a *matter solely of national law*, the *use* made of them can only come within the ambit of Community law where such use contributes to a dominant position, the abuse of which may affect trade between Member States" (italics added). See on this point G. Marenco and Banks, "Intellectual property and the Community rules on free movement: Discrimination unearthed", *E.L.R.*, 1990, 226; Govaere, *The Use and Abuse of Intellectual Property in E.C. Law* (Sweet & Maxwell, USA, 1996); Bertani, *Proprietà Intellettuale, Antitrust e Rifiuto di Licenze*. (Quaderni di A.I.D.A., Giuffrè, Milan, 2004): 99 ff.; Anderman, "The competition law/IP 'interface': An introductory note", in Anderman (ed.), *The Interface between Intellectual Property Rights and Competition Policy*, *supra* footnote n. 4, 37 ff.

[82] This was indeed a crucial point within the *Lundbeck* plea. See *Lundbeck*, judgement of the Court, *supra* footnote n. 29, § 59; *Generics* judgement, *supra* footnote n. 43, §§ 46-51, 98-100.

development of competition in the market for the provision of an active principle no longer covered by patent protection[83]. Despite never mentioning *sham litigation*, the Court emphasized that the complex and multifaceted strategy was centred around the enforcement of a *process* patent related to a manufacturing process of an active principle whose protection had expired: hence, belonging to the public domain.[84]

8. Scope of the patent test vis-à-vis leveraging of (patent) information against rivals

It is noteworthy that the European courts, in both *Generics* and *Lundbeck*, made great effort to clearly discard the so-called "scope of the patent" test,[85] cherished by some US Courts, but eventually rejected also by the Supreme Court in *Actavis*.[86] In *Lundbeck*, the Court held irrelevant that the contested agreement contained restrictions potentially falling within the scope of *Lundbeck*'s new process patents because reasoning differently would have led to assume that *Lundbeck*'s patents were valid and that the equivalent drugs were infringing (both facts not ascertained by a Court at the moment the agreements were signed).[87] Quite on the contrary, as clarified by the very same Court in *Generics*, a presumption of validity upon a

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[83] *Generics* judgement, *supra* footnote n. 43, § 147, 156-157. Where the Court further observed that the anticompetitive effects of such contract-based strategy were likely to exceed the anticompetitive effects inherent to the conclusion of each of the agreements part of it.

[84] *Generics* judgement, *supra* footnote n. 43, §§ 155-157.

[85] The scope of the patent test aimed at testing the anticompetitive nature of the agreement by assessing whether the latter would impose restrictions going beyond the exclusionary rights granted by the patent. Such test was very benign towards patentees, as it would result in antitrust immunity every time 1) the exclusion did not exceed patent scope, 2) patent holder's claim was not objectively groundless, 3) the patent had not been obtained by fraud from the PTO. On the scope of the patent test see more extensively: Gürkaynak, Güner and Filson, "The global reach of FTC v. Actavis – Will Europe differ from the US approach to pay-for-delay agreements?". in *I.I.C.* 45 (2014): 134 ff.; Carrier, "Why the 'scope of the patent' test cannot solve the drug patent settlements problem", *Stanford Technology Law Review* 16 (2012): 1; H. Hovenkamp, "The rule of reason and the scope of the patent", in *Faculty Scholarship at Penn Law*, 2015, 1817. Available at https://scholarship.law.upenn.edu/faculty_scholarship/1817, (last accessed on 6th March 2023).

[86] *Federal Trade Commission v. Actavis Inc.* et al. 570/1 US. N. 12/416, 18th June 2013. For a comparison with the North American approach, generally, see Athanassiadou, *Patent Settlement in the Pharmaceutical Industry under US Antitrust and EU Competition Law* (Kluwer Law Int., The Netherlands, 2018). For a comparative analysis between American and European regulators' approach with regard to reverse-payment patent settlements, see Clancy, Geradin and Lazerow, "Reverse-payment patent settlements in the pharmaceutical industry: An analysis of US antitrust law and EU competition law", *The Antitrust Bulletin* 59, I (2014): 153-172.

[87] See *Lundbeck*, judgement of the Court, *supra* footnote n. 29, §§ 122-123.

process patent cannot trigger a presumption of illegality on the distribution of a generic drug: this even more so given the circumstance that the original product patent is in the public domain.[88]

Although not much elaborated by the CJEU, this last point is of tantamount significance: patent titles indeed may well be valid and yet not infringed by a competing product. This is often the case in the pharmaceutical sector, where secondary patents composing the portfolio are often process patents or second therapeutical use patents.

As well known, process patents grant protection on the process or methodology to achieve a certain technical result. In the case of a manufacturing process, protection extends to the so-called "products directly obtained through the claimed process"[89], but it is commonly accepted that in such cases protection of the by-products is directly dependent on the employment of the claimed manufacturing process and that, consequently, (even identical) products made through a different method or process (than the patented one) will not be infringing[90]. A presumption of counterfeiting (reversing the burden of proof on the alleged infringer) arises only in the instance the directly obtained product is a *new* product, not marketed before[91]: a circumstance which would never arise in the case of equivalent drugs.

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[88] *Generics* judgement, *supra* footnote n. 43, §§ 51, 96-98. Here the Court further explained that the circumstance that the settlement did not exceed the scope, nor the remaining duration of the patents involved did not grant any immunity against antitrust intervention, as the exercise of patent rights, such as the right to enter a settlement involving a patent, does not similarly grant the right to enter a contract in violation of art. 101 TFEU.

[89] Kur, Dreier and Luginbuehl, *European Intellectual Property Law: Text, Cases and Materials, supra* footnote n. 1, 137 ff., noting that art. 64(2) EPC contains this only rule with regard to infringement and the rest is demanded to national patent laws. This requirement has been interpreted strictly, in a way to exclude protection every time there are intermediate production steps to finalize the product and the items are not the direct and technically inevitable result of the patented production process. In this regard, see Vanzetti, Di Cataldo and Spolidoro, *Manuale di Diritto Industriale* (9th ed., Giuffrè, Milan, 2021): 453. Bently, Sherman, Gangjee, and Johnson, *Intellectual Property Law* (5th ed., Oxford University Press, Oxford, 2018): 648 ff.

[90] See Floridia, "Le creazioni intellettuali a contenuto tecnologico", in P. Auteri, G. Floridia, V. Mangini, G. Olivieri, M. Ricolfi, R. Romano and P. Spada, *Il Diritto Industriale, Proprietà Intellettuale e Concorrenza* (6th ed., Giappichelli Publishing, Turin, 2020): 251; Falce, *Profili Pro-Concorrenziali dell'Istituto Brevettuale* (Giuffrè, Milan, 2008): 246.

[91] Thanks to the harmonization following the signing of the TRIPs Agreement, many national patent laws today envisage a *prima facie* presumption of infringement applying when the directly obtained products happen to be new. In such a case, identical products released on the market by a third unauthorized party will be deemed infringing, unless the latter is capable of proving that it manufactured them through a different process. It has been rightfully pointed out, however, that

In other instances, originator companies rely on second medical use patents to prevent genericists to enter the market with an equivalent drug when patent protection on the blockbuster drug is expired. In this latter case as well, *sham litigation* leverages information not just on patent validity but rather on patent infringement, as scope of protection of second medical use patents still has very uncertain contours[92]. In the case of second medical use patents, indeed, protection is granted in light of a *new* therapeutical use of a *known* compound, often already patented.[93] Consequently, when protection on the central patent expires, generic companies prepare to enter the market, but are often stopped by the originator company claiming infringement on the basis of a second therapeutical patent still in force. And, indeed, it is often the case not only that the second medical use patent insists on an invention which is structurally identical to the one whose protection is elapsed, but also the two inventions correspond to two identical drugs which happen to be interchangeably employed for both claimed uses (the first expired one and the second one still under patent protection)[94].

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such a rule has only procedural value, reversing the burden of proof when no similar products existed in the market before the ones directly obtained through the new patented process. It seems, therefore, that novelty in this case cannot be given the same contours it has pursuant to Art. 54, 1°-3°, EPC. See Floridia, "Procedimento e prodotto nelle invenzioni farmaceutiche", *Riv. dir. ind.*, I-II (1988): 51; *contra* Giov. Guglielmetti, "Adeguamento della legislazione interna in materia di proprietà industriale alle prescrizioni obbligatorie dell'accordo relativo agli aspetti dei diritti di proprietà intettuale concernenti il commercio – Uruguay Round (d.lg. 19 marzo 1996, n. 198, sub art. 13 Legge *Invenzioni*", *N.L.C.C.*, 1998, 121.

[92] This happens precisely because patent infringement is a matter of strict liability, typically not taking into account the intention to use the protected invention for a certain purpose. This, on the contrary, is essential to prove counterfeiting in the case of second therapeutical use inventions. See Pila and Torremans, *European Intellectual Property Law* (2nd ed., Oxford University Press, Oxford, UK, 2019): 187.

[93] The first invention can be claimed as a product patent, if the chemical or biological substance was entirely new at the date of filing; as a first therapeutical patent, if the substance was known (or even patented) in a non-medical field and a first medical application has been conceived; or as a second therapeutical use patent if the invention brings about a new medical application of a known compound for which a first medical application had been previously found and patented. Broadly on the matter, Arezzo, *Patent portfolios and pharmaceuticals: A European perspective*, *supra* footnote n. 13, chapt. III, *passim*.

[94] This phenomenon is often referred to as cross-label use of drugs. Sometimes, cross-label use of drugs happens under specific suggestions of doctors and physicians, as the generic medicine entails costs savings for both the patient and the sanitary system. See Jansen, "Off-label use of medications", in Beran (ed.), *Legal and Forensic Medicine*, 1610; Vrancken, "Off-label prescription

Conclusion

Since research in the pharmaceutical sector has gradually become more and more difficult and costly, competition has turned fiercest than ever, with undertakings building clusters of patents in order to fence rivals off their innovation trails. Competition authorities often catch only the tail of a quite complex and multifaced conduct (i.e. *RPSAs*), which begins often with the very construction of the portfolio and proceeds with its strategic leveraging against rivals to preserve exclusivity on the blockbuster drug to the longest possible time.

This contribution advocates that times are ripe for competition authorities to evaluate and analyse the anticompetitive strategy in its entirety, moving backwards from the tail to the overall body of conduct. In particular, a doctrine of abusive sham litigation centred on the enforcement of patent rights should be put forward in order to distinguish cases in which firms legitimately assess the rights over their inventions from those where they leverage the information asymmetries enshrined in the patent portfolio against rivals to the sole purpose of deterring market entry, which would normally take place at the expiry date of the exclusive rights.

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