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BRIEF BIOGRAPHY

Walid Chaiehloudj is associate professor at Grenoble-Alpes University, currently in delegation at the University of the New-Caledonia. He is also an Associate Researcher at the University Côte d'Azur. Among other things, he teaches competition law, corporate law, intellectual property law and contract law. He wrote his doctoral thesis under the supervision of Professor David Bosco at Aix-Marseille University.

His thesis, entitled « Pay-for-delay agreements », offers a new analyse of these agreements and proposes a renewed vision of the relationship between competition law and patent law. His thesis obtained the 2018 *Concurrences* Best PhD Award and the 2018 Jules and Louis Jeanbernat Prize granted by Aix-Marseille University rewarding the best doctoral schooling. His thesis was published in 2019 by *Concurrences* in the collection "Concurrences Thesis" directed by Professor Laurence Idot.

Walid is the author of several book chapters and articles published in international, European and national journals. Recently, his writings have dealt with the issue of the practices implemented by digital companies (mainly the Big Techs), the European merger control in the digital era, the interaction between competition law and intellectual property law and the impact of the coronavirus epidemic on competition law enforcement. He is currently in charge of the U.S. antitrust law chronicle in the *Concurrences* Review and directs the "European and International Law" chronicle.

LIST OF PUBLICATIONS

Book

- *Pay-for-delay agreements: Contribution to the study of the relationship between competition law and patent law*, Preface by D. Bosco, Foreword by L. Idot, *Concurrences*, 2019, 568 pages. Thesis honored with the *Concurrences* Prize for the best thesis in competition law (2018) and the Jules and Louis Jeanbernat Prize granted by Aix-Marseille University rewarding the best doctoral schooling (2018).

Book chapters

- « Non-agression pacts », in *Les pactes* (eds. J. Mestre, H. Lécuyer et J. Heinich), LGDJ, 2021 (in French, forthcoming).
- « L'ordre public économique », in *Le droit économique au XXIe siècle: notions et enjeux* (ed. J.-B. Racine), LGDJ, 2020 (in French, forthcoming).
- « Antitrust and Intellectual Property », in *Commentaire J. Mégret, Tome.1*, Les éditions de l'université de Bruxelles, 3rd ed., Autumn 2020 (in French, forthcoming).

- « Innovation and preparation of the market for the entry of competitors », in *L'articulation des droits de propriété intellectuelle et du droit de la concurrence* (ed. P. Trefigny), Dalloz, 2020, pp. 75-100 (in French).

Articles

- « L'action en responsabilité pour insuffisance d'actif en Nouvelle-Calédonie: Le droit national doit-il être source d'inspiration » (in French, forthcoming).
- « Between Relaxation and Intensification: Competition Law Tested Against the Coronavirus Headwinds », *JCP E* 2020, No 15-16, pp. 31-38 (in French).
- « The New Caledonian Competition Authority announces pursue competition law enforcement in the context of Covid-19 pandemic », *e-Competitions* 2020, April.
- « What effective tools for competition authorities in the digital economy? », *Contrats, concurrence, consommation* 2020, No 3, pp. 4-18 (in French).
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- « From contractual risk to competitive risk: the case of the preference pact included in the franchise agreement », *JCP G* 2018, No 43, pp. 1932-1938 (in French).
- « Fake news and competition law: reflections through the prism of the Facebook and Google cases », *Revue internationale de droit économique* 2018, No 1, pp. 17-40 (in French).
- « Tackling the Imbalance in Intellectual Property Contracts - Looking Ahead after the Reform of the French Contract Law », *RTD. com.* 2017, No 3, pp. 527-551 (in French).
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- « Should merger law apply to the wet-lease agreement? Cursive study based on the *Air Berlin/Lufthansa* case », *AJ Contrat* 2017, No 5, pp. 211-216 (in French).
- « Agreements injecting competition on a distinct market, a new pay-for-delay generic entry on the market », *Concurrences Review* No 1-2016, pp. 73-79 (in French).
- « The fiscal strategies of the pharmaceutical industry. A look at the attractiveness of patent boxes and the practice of corporate inversion tax deals », *Propriété industrielle* 2016, No 1, pp. 12-17 (in French).

Chronicles and notes

- « The Court of Appeals for the Seventh Circuit applies the Noerr-Pennington Doctrine in an antitrust case on the futures market », *Concurrences Review* No 2-2020, pp. 234-236 (in French).
- « Eighty-two academics file an *amicus brief* with the Fifth Circuit Court of Appeals in support of the Federal Trade Commission's position in a pay-for-delay case », *Concurrences Review* No 1-2020, p. 202 (in French).
- « The Northern District Court of Georgia receives a complaint filed by an online advertising company accusing a well-known search engine company of monopolizing the market », *Concurrences Review* No 1-2020, pp. 199-202 (in French).
- « The Antitrust Division of the Department of Justice for the first time in its history uses arbitration to challenge merger between two suppliers of aluminium car body manufacturer under the administrative dispute resolution Act of 1996 », *Concurrences Review* No 4-2019, pp. 204-206 (in French).
- « The Court of Appeal for the District of Columbia Circuit confirms that search engines, leaders in the online search market, benefit from an antitrust immunity », *Concurrences Review* No 3-2019, pp. 211-213 (in French).
- « The Federal Trade Commission rules that two pharmaceutical laboratories concluded an unlawful pay-for-delay agreement », *Concurrences Review* No 2-2019, pp. 208 (in French).
- « The U.S. Court of Appeals for the Ninth Circuit denies a challenge to the use of the *per se* rule in a criminal antitrust case », *Concurrences Review* No 2-2019, pp. 206-208 (in French).

- « The Eastern District Court of Virginia orders a company resulting from a recent merger to divest a door manufacturing plant in order to restore competition in the interior door market », *Concurrences Review* No 1-2019, pp. 217-219 (in French).
- « The US Supreme Court rules that the credit card market is a multisided market and that anti-steering clauses do not have anticompetitive effects on this market », *Concurrences Review* No 4-2018, pp. 209-212 (in French).
- « The US District Court for the Northern District of California receives a lawsuit seeking class action status against three main manufacturers active in the memory chip market for having concluded anticompetitive agreements », *Concurrences Review* No 3-2018, pp. 195-196 (in French).
- « The US District Court of Central District of California rules on fixation of FRAND rate », *Concurrences Review* No 2-2018, pp. 207-210 (in French).
- The US Court of Appeals of the Third Circuit adopts a restrictive analysis of antitrust interest in bringing proceedings », *Concurrences Review* No 1-2018, pp. 209-211 (in French).

Conferences

- « What effective tools for competition authorities in the digital economy? », Conference at University Côte d'Azur, Nice, 10 January 2020.
- « Innovation and preparation of the market for the entry of competitors », Conference at Maison de l'avocat, Grenoble, 7 December 2018.
- « Algorithms and Competition Law », Conference at Technological University of Compiègne on the subject of the neutrality of the algorithm, Compiègne, 25-26 June 2018.
- « Freedom of contract and intellectual property », Workshop at Aix-Marseille University, Aix-en-Provence, 23 September 2016.

WORK SUMMARY ON PAY-FOR-DELAY

The agreements that are the subject of this study are referred to as "pay-for-delay agreements". These agreements, referred in the U.S. as "reverse payment patent settlements"¹, may be defined as having the purpose or the effect of delaying a competitor's entry into the market. In essence, the patent holder pays compensation to a competing - or potentially competing - company in return for a time delay in the marketing of its products. Thus, the *modus operandi* used to encourage competing companies not to enter the market appears rather rudimentary. Patent holders are simply seeking to pay for the inaction of their competitors by paying considerable sums, often millions of euros. Rival companies are then encouraged to turn away from the market for a period of time, which ultimately allows companies with intellectual property rights to preserve their monopoly acquired through patents. To the extent that these agreements flourish mainly in the pharmaceutical sector, the competitors involved are often generic drug manufacturers, who are also appointed by the subject matter experts of the "generics". The companies that pay for the latter are referred to as "originator laboratories" or "innovative laboratories".

¹ They are called reverse payment settlements, since they involve payments which flow in a reverse direction: while it is normally the alleged patent infringer that pays the patent holder damages and/or litigation costs in order to settle the patent dispute. In this type of settlements value flows the other way around: from the patent holder to the alleged infringer

The originality of the subject lies in the fact that pay-for-delay agreements crystallize both patent and competition law issues. In other words, the subject is at the heart of the interaction of these two fields. This is precisely one of its interests, because it is from the convergence of these two matters that a satisfactory legal treatment of these atypical agreements can emerge. On the one hand, pay-for-delay agreements affect patent law. The emergence of these agreements results from an endogenous dysfunction of the patent system, which no longer guarantees the granting of quality patents, i.e. intellectual property titles that are certain to meet the conditions for patentability laid down by law. With these agreements, patent holders would sometimes seek to protect invalid patents. In other words, there is a significant risk that a pay-for-delay agreement may be based on a "weak patent", i.e. a patent for which there is a high probability that a legal dispute will cause it to fall into the public domain. On the other hand, pay-for-delay agreements raise questions about competition law to the extent that they may disrupt normal competition in the market. Given that there is still uncertainty about the validity of the patent, pay-for-delay agreements could be seen as a means of prolonging an unjustified monopoly and as a cause of illegal market closure. Consequently, the intervention of a set of rules external to intellectual property - competition law - is used here to verify that these agreements do not constitute an "excess of intellectual property rights" that could potentially infringe competitive public order.

The first part of the thesis explains how pay-for-delay agreements emerged. A first title, devoted to "the genesis of pay-for-delay agreements", describes the emergence of these agreements in the United States (Chapter 1). This appearance is due to the instrumentalization of the Hatch-Waxman Act, which sought to encourage generic companies to challenge weak pharmaceutical patents. This Act was to be the appropriate response to the competitive inertia that had been identified in the United States in the pharmaceutical sector in the early 1980s. This inertia was due to regulations that were too favourable to pharmaceutical patent holders. To encourage generic companies to enter the market and offer much lower prices to consumers, the Hatch-Waxman Act established a "180-day exclusivity period" to reward generic companies. Precisely, the Hatch-Waxman Act give 180 days of generic exclusivity to the first generic company to file for Federal Drug Administration (FDA) approval and succeeds in invalidating the contested patent. The idea was that by granting a market exclusivity during 180 days to generic companies that have successfully invalidated the patent in a jurisdiction, there would be increased generic competition in the market, and perhaps the beginning of a decline in patent applications for questionable or anticompetitive inventions. While it was supposed to reward the risk taken by generic manufacturers of losing their patent disputes, the most emblematic measure of the Hatch-Waxman Act was totally instrumentalized and diverted from its original function, both by patentees and generic manufacturers. The thesis shows that despite the adoption of the Hatch-Waxman Act and the reforms it has undergone, the emergence of generic

competition has not occurred. Monopolistic positions based on potentially weak patents were maintained. Also, the Hatch-Waxman Act has been a modest or at least very relative success. Not only the Act has failed to stimulate generic competition to a large extent, but worse still, its poor design has allowed pharmaceutical companies to use its provisions to frustrate the purposes it had set. To this end, patentees and generic companies have used the contractual instrument and have shaped agreements in the form of settlements ending patent litigation. By combining the manipulation of the 180-day market exclusivity with payments of several million euros to generic manufacturers, the companies have succeeded in adopting collusive behaviors that have had the effect of delaying the entry of generic competition, sometimes even beyond the life of the patent. It is this twinning that has given rise to what are known as pay-for-delay agreements. The problem with this type of agreement is that it sometimes unduly protects an undeserved intellectual property right and prevents generic competition from entering the market. It is this twinning that has given rise to what are known as pay-for-delay agreements. The problem with this type of agreement is that it sometimes unduly protects an undeserved intellectual property right and prevents generic competition from entering the market. However, if a patent is weak, it should not be granted by the patent office or, if so, it should be excluded from the legal life by private initiatives and competition by imitation may then emerge. Patent settlement prevents the emergence of such competition and leads to overprotection of potentially undeserved intellectual property rights to the detriment of competition and, ultimately, consumer welfare. Finally, Chapter I, after a lengthy historical study of US legislation, teaches that when patent settlements delay the entry of competition into the market when the patent on which the agreement is based is weak, the agreement could be equated with market sharing, conduct that is prohibited *per se* by antitrust law.

Once the reasons for the outbreak of these agreements in the United States were explained, it was necessary to ask whether this outbreak was the result of the same dysfunctions in the European Union. The research revealed that this was not the case and that the proliferation of these agreements in Europe was based on other reasons. While in the United States the agreements were born from the instrumentalization of a special law designed to boost competition in the pharmaceutical market, in the old continent, their birth is due to the instrumentalization of the patent system (Chapter 2). The imperfections of this system and the misuse of it by pharmaceutical companies have led to the conclusion of "unionist" pay-for-delay agreements. In Europe, pay-for-delay agreements are the result of a patent system that is defective in several respects. Despite the absence of patent linkage² and legislation equivalent to the Hatch-Waxman Act, pharmaceutical

² Unlike the United States, it is not mandatory in the European Union to hold a patent in order to obtain a marketing authorization (MA). Thus, an originator company cannot oppose the granting of a marketing authorisation to a generic company wishing to enter the market by opposing the fact that it holds one or more patents on the originator drug that its potential competitor is considering "genericising".

patent holders have been able to devise agreements to delay the entry of generics into the market. The strategy is to obtain patents and oppose them to generic manufacturers to discourage them from entering the market. Thanks to the dysfunctions of the patent system, it is indeed possible for originator companies to obtain a multitude of weak patents and to create artificial barriers to entry. The phenomenon is known and is covered by the terms "patent clusters" or "patent thickets". Unlike in the United States, generic companies are free to market their product once they have been granted a marketing authorization.

However, in the face of pharmaceutical patent walls, they may prefer to avoid the legal risk of an infringement or invalidity action because of the costs of the proceedings. It is in this context that pay-for-delay patent settlements are concluded. Moreover, the European patent system has neither a single patent jurisdiction nor a genuine European patent. Consequently, patentees must bring infringement proceedings in all Member States of the European Patent Convention (EPC) and are exposed to a high risk of conflicting decisions being handed down. This weakness in the system strongly encourages patentees to favor amicable resolution rather than entrusting the fate of their monopoly to judges who will not have the same appreciation of their titles. In short, the study shows that the regulatory framework in Europe encourages both patentees and generic companies to enter into pay-for-delay agreements.

A second title seeks to demonstrate that there is a "diversity of pay-for-delay agreements". It was first pointed out that these agreements mainly took the form of settlement agreements ending a patent litigation (Chapter 1). The study shows that for this category of agreements, practices have evolved. In addition to the traditional agreements containing a cash payment - which we have called "first generation" agreements - there are now much more subtle agreements where payment is made in kind. These agreements have been described as "second generation" agreements. These second-generation agreements take several forms: non-launch clauses for an authorized generic³; acceleration clauses⁴; agreements injecting competition into a distinct market (AICDM)⁵⁵. As for

³ Authorised generics are generic medicines marketed by originator laboratories. Benefiting from a marketing authorisation for the originator medicinal product, they only have to modify the packaging and the name of the product to put it on the market at a lower price. By the non-launch clause of an authorised generic, the originator undertakes not to compete with the generic drug of the generic once it is placed on the market in accordance with the date provided for in the pay-for-delay agreement.

⁴ An acceleration clause is any provision under which a generic manufacturer party to a settlement agreement agrees to postpone its entry into the market until a contractually determined date in return for which the patentee authorizes it to market its generic product in advance, while retaining the 180-day market exclusivity. In other words, by means of the acceleration clause, a generic manufacturer may no longer be bound by the market entry date stipulated in the settlement agreement.

⁵ In this case, the originator company will seek to "pay" the generic manufacturer by granting him the right to enter in a separate market that was not *a priori* coveted. To this end, it will grant a free license to launch its generic version of the patented drug immediately after the agreement is concluded. Thus, unlike first generation

agreements concluded outside patent litigations (Chapter 2), the thesis explains that they are only a subsidiary instrument of the postponement of the market entry. These agreements are certainly mobilized by companies, but only to a very small extent. For the time being, these agreements are flourishing in the form of copromotion agreements. Finally, the second title ends with the study of pre-entry agreements (Chapter 3). This passage explains that the verbal expression "pre-entry" can be misleading and that, paradoxically, this type of agreement can also lead to a delay in the entry of generic drugs into the market. At the end of this title, it is thus possible to affirm that pay-for-delay agreements have emerged in a plural way. Three lessons can be drawn. First, it was revealed that most of the pay-for-delay agreements take the form of patent settlements to settle a patent dispute, but that these agreements, while identical in appearance, did not substantially resemble each other. Thus, there would be a diversity of patent settlements in the diversity of pay-for-delay agreements, i.e. a diversity in diversity. While they all have in common that they end intellectual property litigation, their shaping has evolved, first because of the stigmatization of agreements involving a monetary reverse payment by a notable part of American doctrine, and then by different competition authorities. Indeed, these agreements, which we have called "first generation", have been the subject of numerous doctrinal studies - often initiated by economists - which have sometimes demonstrated their potential to undermine competitive public order. For this reason, competition enforcers have stepped up their efforts to contain the proliferation of such arrangements and prevent - and sometimes even eradicate - the serious market failures they could generate. In doing so, to avoid the risk of antitrust sanction, more and more patentees are now designing patent settlements that incorporate value transfers in a form other than a cash payment. The rise of these new contractual practices marks, according to the thesis, the future obsolescence of "first generation" agreements to the benefit of "second generation" agreements. According to the study, the switch to second-generation agreements is explained by the fact that they are less suspicious and above all more difficult to detect - their characteristics being to hide the reverse payment.

Secondly, we have shown that pay-for-delay agreements can be developed outside a patent context. Simple trade agreements may sometimes have the purpose of thwarting normal competition and delaying the entry of generic competitors into the market. The key figure in these trade agreements - i.e. those with the potential to have a harmful effect on competition, and thus to be assimilated to pay-for-delay agreements - is copromotion agreements. While this type of agreement has almost always been viewed favorably by the European Commission in terms of the efficiency it could

agreements, payment does not take the form of an exchange of money. Rather, the patentee will try to make the settlement attractive by highlighting the economic value of the distinct market *ab initio* not coveted by the generic manufacturer.

achieve, the *Johnson & Johnson* case has highlighted its potential perniciousness for competition. In other words, these agreements were controlled and repressed by the competitive order. Not only can they involve an unjustified reverse payment; sometimes the contracting partner does not actually promote the product. But in addition, they may aim to delay the entry of competition by imitation. However, in the absence of patent protection, this competition should be rapidly implemented - the market being free of access and free of legal barriers to entry - and thus the competition should be strengthening consumer welfare. As a result, there is no longer any risk of these agreements being reclassified as pay- for-delay agreements. Finally, using a hypothetical-deductive method, the thesis has inferred that pay-for-delay agreements could be identified even if they have for effect to advance generic entry into the market. This is the case for pre-entry agreements. Behind the term "pre-entry", there are in fact agreements that could have the effect of delaying the entry of generic companies in exchange of a value transfer in the form of an exclusivity obligation. Such agreements could be an effective tool to protect weak and questionable patents that should have been in the public domain before the contractually fixed date in the agreement. Substantially, even if the generic competitor's market entry is advanced, the patent will have been extended by a few months or even a few years, so this practice must be qualified as the evergreening.

In **a second part of the thesis**, the reflection on pay-for-delay agreements continues with the study of their control. It begins in Title 1 with a *de lege lata* review. The research concluded that there was a "partial rejection of pay-for-delay agreements" by the legal system. To demonstrate this, the study first focused on the control of pay-for-delay agreements by antitrust law (Chapter 1). It operates through a comparative approach. Indeed, American and European Union law are studied in depth. The thesis shows that the control carried out in the United States is much more balanced than that carried out in the European Union. While in the United States, the Supreme Court, in its *Actavis* judgment, imposed the application of a rule of reason, which obliges the competition enforcers to balance the pro- and anticompetitive effects of the agreements, the European Commission preferred to use the concept of restriction of competition by object, which avoids the difficult and complex task of assessing the real effects of agreements on competition. The rule of reason established to control US pay-for-delay agreements is called "structured". This is because, in *Actavis*, the Supreme Court decided to make it easier for plaintiffs. The plaintiffs can demonstrate in a shortened form the anticompetitive effects of the pay-for-delay agreement as well as the market power of the companies. To demonstrate market power, plaintiffs simply need to apply a test we have called the "payment size test". In practice, under the terms of the judgment, it is possible to infer the patentee's market power only by finding a significant reverse payment. In doing so, the structured rule of reason saves plaintiffs from a long and tedious economic demonstration. In addition, the "payment size test" prevents the plaintiff from proving the weakness of the patent. The Supreme Court considers that, if the payment is substantial, it is very likely that the agreement is intended only to delay the entry of the generic competitor. In other words, the plaintiff does not need to prove that there is a high probability that the patent will be found invalid; he only has to refer to the amount of the payment. As for anti-competitive effects, the Supreme Court has proposed four indications that lower courts may take into account when considering the presence of anticompetitive effects. For the Supreme Court, *"the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size (i), its scale in relation to the payor's anticipated future litigation costs (ii), its dependence from other services for which it might represent payment (iii), and the lack of any other convincing justification"*

(iv)". While these indications may lead to anticompetitive effects, the Supreme Court has specified that "*the existence and degree of any anticompetitive consequence may also vary as among industries*". In the European Union, to qualify pay-for-delay agreements as restrictions by object, the European Commission has developed a three-prong test. This test has been experienced both in the *Lundbeck* and *Servier* cases. In these decisions, the Commission indicates that it is necessary first to verify that the parties to the agreement were at least potential competitors (i) before examining the commitments they have entered into (ii) and the size of the reverse payment made by the patentee (iii). Thus, unlike the substantial American approach, the European Commission has favored the adoption of a formalist approach.

In short, this chapter highlights that in the United States and the European Union, the Supreme Court and the European Commission have decided to give precedence to antitrust law over patent law. Indeed, in order to verify whether pay-for-delay agreements violate competition law, the antitrust tests put in place refuse to verify the validity of the patent. In other words, a pay-for-delay agreement may be found to be contrary to Section 1 of the Sherman Act or Article 101 TFEU without even the competition enforcers having real certainty about the weakness or invalidity of the intellectual property title. To establish a violation of competitive public order, the Supreme Court and the European Commission relied on the theory of "probabilistic patent" conceptualized by Professor Carl Shapiro. Under this theory, where a pay-for-delay agreement contains a reverse payment in excess of the costs of legal proceedings or a reverse payment is equivalent to the profits expected by generic companies from the marketing of their product, the underlying patent must be considered weak. Thus, in the event that a significant reverse payment is detected, the agreement can only be justified by the patentee's intention to extend the monopoly conferred by the patents and by the desire to buy competition. This is problematic since, by refusing to take into account patent law and the possibility that the intellectual property title may be valid, the antitrust tests developed may lead to the emergence of Type I errors, namely the condemnation of perfectly legal and pro-competitive pay-for-delay agreements. This risk of a false positive appears to be higher in the European Union since, unlike in the United States, where a balancing of anticompetitive and pro-competitive effects has been imposed, the European Commission has provided a test that almost automatically condemns pay-for-delay agreements. The European position is criticized in the thesis insofar as basing control on an object-based approach and not on effects-base approach leads to an almost systematic condemnation of pay-for-delay agreements, even when they are based on solid patents and may, consequently, appear virtuous. First of all, the lack of experience of the European Commission is highlighted. Indeed, when the Brussels institution uses the "object box", the restriction in question must be an obvious restriction. This requires that the state of the art in

economic sciences act as evidence of the harmfulness of the practice. However, there is no unanimity or consensus on the issue of pay-for-delay agreements. On the one hand, there is no jurisprudential precedent, so the European Commission has only proceeded by analogy with other decisions. In particular, it referred to the Irish beef case in its decisions, whereas the factual framework of this case did not involve an intellectual property issue. On the other hand, the theory of probabilistic patent is widely debated in the United States. Secondly, the doubts of the European Commission's reasoning are perceptible when the reasoning is compared with the case law of the Court of Justice, and in particular the judgment in *the Groupement des cartes bancaires*. This judgment marks not only the intention of the Court of Justice to reduce the restriction of competition by object by returning to the status quo ante, but also the intention to call the General Court to order, which had indicated that "*the concept of restriction of competition by object must not be interpreted restrictively*". To this end, the Court of Justice wished to restore a certain orthodoxy by reaffirming that "a sufficient degree of harm to competition" was necessary to retain an anticompetitive object. In other words, according to the case law, pay-for-delay agreements should have been regarded as a new practice and, because of the patent context, not be assimilated to a market sharing practice. The same conclusions have been drawn with regard to the control of pay-for-delay agreements by the law of abuse of dominant position (Chapter 2). Due to the limited development of American law in this area, the research focused mainly on European law and revealed the weaknesses of the current control. In the United States, the Federal Trade Commission (FTC) is rather cautious about the use of the monopolization and, as a general rule, is currently refusing to file complaints for violations of Section 2 of the Sherman Act. Indeed, there are few cases where a pay-for-delay agreement has been sentenced of illegal monopolization or attempted market monopolization. Therefore, this situation led us to talk about the parsimonious use of Section 2. In the European Union, on the other hand, the Commission has acted in an uninhibited way by punishing Servier laboratories for abuse of a dominant position. For the Brussels institution, the practice of combining the acquisition of patented technologies with the conclusion of pay-for-delay agreements does not constitute competition on the merits. To reach this conclusion, it seems that the European Commission has chosen to renew its way for delimiting the relevant market. By implementing an analysis that we have described as "contextual", it has made it easier for it to retain the dominant position of the originator company almost automatically.

Indeed, instead of delimiting the relevant market by taking into account the ATC classification⁶⁶, the European Commission preferred to focus on the context surrounding the case. It did not focus on the substitutability of molecules, but delineated the relevant market by taking as a reference the point at which generics could pose a competitive threat. This contextual approach is problematic since it has the effect of defining the market in a variable way over time. In other words, the relevant market may not be identical depending on whether the molecule is at the patent protection stage or at the intellectual property title expiry stage. This method is subject to criticisms since it does not reveal the actual state or competitive functioning of the market. In the Servier case, for example, other molecules exerted competitive pressure. But by restricting the market to the perindopril molecule alone, the European Commission has ignored the real economic context to retain market dominance. For this reason, we have called for a return to orthodoxy in this area, i.e. the application of the ATC method. Moreover, given the patent context surrounding pay-for-delay cases, we believe that once the European Commission has identified a practice combining the acquisition of patented technology with a pay-for-delay agreement, the burden of proving that the patent has been used legitimately and morally should rest on the patentee. Injecting morality, or ethics into economic law, could have the effect of directing patent-holding companies towards more virtuous behavior that is in line with the aims of patent law.

In addition, the thesis proposes a broader conception of the notion of relevant market that should lead to much more nuanced results. If the current control were to be maintained, the condemnation of pay-for-delay agreements on the basis of abuse of dominant position would indeed be systematic.

The Title 2 analyses *de lege ferenda* the control of pay-for-delay agreements. It is proposed to allow these agreements, given many of which ultimately have pro-competitive effects. In other words, pay-for-delay agreements should be more widely accepted. To begin, the study details the reasons for their admission (Chapter 1). The first justification is that these agreements meet the objectives of competition law, in particular the pursuit of consumer welfare. The second justification is based on the fact that these agreements do not conflict with the conciliation of patent and competition law, since the admission of these agreements does not question the complementarity of the two

⁶⁶ Usually, in the pharmaceutical sector, the determination of the relevant market is carried out by considering demand-side substitutability. In practice, the competition authorities will delimit the market by looking mainly at the therapeutic indication of medicines. To do this, they will use the ATC (Anatomical Therapeutic Chemical Classification System) classification. According to the European Commission, "the third level (ATC-3) allows medicines to be grouped according to their therapeutic indications and can therefore be used as an operational market definition [...] [although] sometimes [it] may be appropriate to carry out analyses at other levels of the ATC classification".

matters. More precisely, to justify the admission of pay-for-delay agreements into our legal system, the thesis highlighted that the apparent disorder that the agreements seem to produce on competition is not fully justified.

First of all, the current consumer welfare standard appeared to us to be misleading. By focusing the analysis on static competition, the European Commission has so far only focused on the price drop and the date of generic entry. Specifically, it has lost interest in the effects that pay-for-delay agreements could have on a medium- to long-term horizon. However, in the medium to long term, pay-for-delay agreements could lead to the emergence of new molecules and incremental innovations, which could prove valuable for patients who currently have no treatment at all. For this reason, it has been shown that the adoption of total consumer welfare would be a more balanced standard to take into account the specificities of the pharmaceutical sector and pay-for-delay agreements.

Secondly, it was explained that pay-for-delay agreements can in certain circumstances provide an incentive to innovate and encourage pharmaceutical companies to pursue heavy and costly investments in research and development. Not only can pay-for-delay agreements be seen as a powerful incentive for innovation, but also as a tool for the early diffusion of innovation, which is beneficial to the consumer. Thus, pay-for-delay agreements could in certain circumstances contribute to the general interest and serve the purposes of patent law.

Finally, even if pay-for-delay agreements can in many cases be virtuous and do not interfere with competitive public order, competition law must nevertheless remain vigilant and dissuasive. In order not to push companies to develop deviant practices, it is necessary that this right be fully effective. However, it has been noted that the effectiveness of competition law is often sacrificed on the altar of efficiency, so much so that we have spoken of "selective effectiveness". For the time being, the competition rules are being applied vigorously to pay-for-delay agreements into the European Union since, in each case it has opened, the European Commission has sanctioned pharmaceutical companies and has completed the litigation procedure.

The reasons for the admission of pay-for-delay agreements into our legal system were now explained, all that remained was to know what resources were needed to receive and control them properly. Indeed, while the admission of pay-for-delay agreements is desirable, the fact remains that this admission remains imperfect in the current state of the law. It must therefore be accompanied by certain technical amendments, both in the field of competition law and in patent law (Chapter 2). The thesis therefore proposes to remedy certain deficiencies in the law of anti-competitive practices.

First of all, it is suggested that a safe harbor be created to exempt certain pay-for-delay agreements. In our opinion, three criteria could make it possible to separate the wheat from the chaff, i.e. agreements that are benign for competition from those that could carry the seeds of abuse. To benefit from safe harbor, laboratories would have to demonstrate that their agreement cumulatively fulfils these conditions. First, the pay-for-delay agreement must allow generic companies to enter the market at least three years before the expiry date of the patent or the expiry date of the Supplementary Protection Certificate (SPC). In this way, a balance could be struck between the objective of encouraging innovation and the development of a competitive market. On the one hand, patentees could benefit from their exclusive right over a reasonably long period of time, which would maintain the interest of obtaining patents from the competent offices. On the other hand, consumers could benefit from price competition earlier. Thus, instead of waiting until the end of the patent's life, physicians or pharmacists could prescribe substitutes for the original drug much earlier. In addition to the benefit of falling prices, the patient would have the freedom to choose between the originator product and its generics.

Secondly, an agreement could avoid an antitrust investigation if it does not alter the incentive for other generic companies, third parties to the agreement, to enter the market. In practice, any agreement incorporating acceleration clauses should automatically be excluded from the safe harbor.

Third, an agreement would be immune from antitrust proceedings if the patentee's reverse payment does not exceed a certain amount. The communication could indicate that the amount of the reverse payment made by the patentee should not exceed the costs of legal proceedings.

The thesis then proposes to impose an obligation to notify agreements that do not fall within this safe harbor. In other words, a system of "prior notification" concerning pay-for-delay agreements with significant reverse payments and based on secondary patents. Since 2010, eighty-two agreements belonging to this type of agreement have been notified to the Commission as part of its monitoring work. Therefore, the prior notification procedure should not be an extremely heavy burden for the European Commission services.

Finally, the main proposal is to introduce a so-called "bifurcation" procedure towards the patent judge to check the validity of the intellectual property title. In practice, in a pay-for-delay case, the European Commission should suspend its decision and refer the case to a specialized patent court. In practice, it would ask the specialized court whether the patent on which the agreement is based is valid or infringed by the generics' products. In the long term, it seems to us that the court best suited to manage this dispute would be the Unified Patent Court (UPC). Granting the unique competence to the UPC would have the advantage of unifying the litigation and not ending up with contradictory decisions. In the absence of the establishment of this single court, the bifurcation procedure would not be effective since, if intellectual property rights are divided into several national patents, there would be a great risk of contradictory decisions and, ultimately, of always having doubts about the validity of the patent. In pay-for-delay cases, the UPC would have two months to decide, the objective being to avoid delaying the antitrust procedure for obvious reasons of efficiency. The advantage of this procedure would be its celerity. Through the notification mechanism, agreements would be monitored at an early stage - since agreements should be notified as soon as they are concluded - and the patent law issue would be quickly resolved. The effectiveness of this bifurcation procedure would also depend on the fact that it would only cover pay-for-delay agreements based on secondary patents, which would allow UPC to focus only on the most problematic cases. Once this control has been carried out, the European Commission will trigger a different antitrust examination depending on whether the patent has been found valid or invalid by the UPC. If the patent has been found to be valid, the European Commission should terminate the proceedings provided that the patentee has not implemented the patent beyond its scope. Specifically, if the agreement respects the limits of the rights conferred by the patent, then the anti-competitive effects produced by the agreement are covered by intellectual property. In this case, the agreement would be lawful, as it would not exceed the monopoly conferred by the patent beyond its legal scope. On the other hand, if the patent is found invalid by the UPC, the European Commission should sue the patentee and the generic companies party to the pay-for-delay agreement under the conditions detailed in our thesis.

In addition, it is also proposed to remedy the deficiencies of patent law. We have suggested some changes that could perhaps eventually eradicate bad pay-for-delay agreements. The proposals are eclectic. The most original is to build a new reward for generic companies that have successfully challenged the validity of a patent. Based on the model of the US 180-day period of market exclusivity, we have devised an "European" exclusivity market period, which both takes into account the specific features of EU regulations and removes the defects of the 180-day exclusivity market period. This "European" market exclusivity has been designed in such a way that, if it were to be retained, it would have to avoid any form of regulatory gaming.

Finally, given the delays in obtaining a marketing authorization, we have proposed an extension of the SPC. As the time to obtain a marketing authorization has increased from an average of four to nine years, the additional five-year protection may no longer be sufficient in the medium term to allow patentees to recover investments in research and development. Finally, the dichotomy between primary and secondary patents should be adopted. Currently, European patent law does not recognize this distinction; it is only used by the European Commission from an antitrust law perspective. However, accepting it would allow examiners to focus on those applications which, in the end, would potentially have the most serious impact on competitive public order, and more particularly on dynamic competition. It could also help to combat the EPO's laxity in applying patentability criteria.

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In conclusion, the thesis sought to demonstrate that the current control carried out on pay-for-delay agreements into Europe is too strict. This control does not make possible to take into account the many virtuous effects that these agreements have on competition. The patent is far too marginalized in contemporary analysis. The thesis therefore calls for a more balanced examination of pay-for-delay agreements, which would allow pharmaceutical companies to continue to invest heavily in the research and development of innovative medicines. However, our research does not neglect the anti-competitive effects that some pay-for-delay agreements could have on the market. Nor does it deny that some agreements could be the support of bad intentions. In these cases, the study approves the condemnation of the agreements through the application of European competition law.

