UNCERTAINTY IN PHARMACEUTICALS MARKETS

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I. INTRODUCTION

In a number of industries, competitive constraints come mostly from outside the market. Think of markets where access is dependent on the grant of an exclusive right via a concession, or some digital platform markets where network effects create exclusive ecosystems. That is also the case in most pharmaceutical markets, where patents protect the position of an operator. I say "most," because the intensity of competition between molecules depends on the regulatory design. The common feature of all these markets is the presence of an incumbent that earns some rents and that has to internalize the constraints coming from outside of the market. How incumbents deal with outside constraints is currently the subject of intense scrutiny: Big tech is accused of nipping emerging platforms in the bud; big pharma of proceeding with killer acquisitions against emerging competitors or pay for delay deals with possible generic entrants; etc. All these markets share a common feature which is the uncertainty of where, or when, the threat to the market position may come. This begs the question of how such uncertainty should be addressed in a competition law assessment. This article seeks to answer that question by focusing on the pharma markets and pay for delay, but many of the developments could be equally applicable to other markets.

II. THE CONTEXT: PAY-FOR-DELAY CASES ARE ABOUT UNCERTAINTY

In most pharma markets there are barriers to entry in the form of IP. It is a legitimate effort from incumbents to protect their past investments and use existing laws and regulations to make rivals' efforts to enter more uncertain and therefore costly. Candidate entrants may try to work around IP barriers or challenge them. Either way, the success of the efforts is uncertain and will depend on findings by courts. The outcome of court cases cannot be safely predicted, not because they are random, but because the court relies on mechanisms that enables it to combine information from both parties, and possibly experts. Each party on its own does not have access to complete information. The courts aggregate and interpret information, and adjudicate under the applicable law. Before a court reaches its decision, each party can only make its best estimates of the outcome of disputes based on assumptions, private and public information, and internal decision processes. It follows that in pharma markets successful, or even profitable, entry by generic companies is, by definition, uncertain and companies' actions, whether they are contemplating entry or monitoring possible efforts to enter, are based on incomplete information and best estimates of the outcome of future events.

Intuitively, it does not sound good for competition that an incumbent pharma company would either buy a candidate entrant, purchase assets that had been developed to prepare an entry (killer acquisition), or agree, against compensation, with a candidate entrant that the latter will not enter (a pay-for-delay agreement). However, all these decisions are shrouded in present and future uncertainty, whereas competition law's role

is to deliver legal certainty and objective, *in concreto*, assessment. This article argues that the EU competition law concept of potential competition seems to be the right prism through which to address these possible theories of harm. It examines how potential competition has been applied and reconciled with the prevalent uncertainty to pay for delay transactions in the pharmaceutical industry; it also looks at how this translates for showing restrictive object or effect in a context of uncertainty.

There have been four pay-for-delay cases decided on the basis of Article 101 since 2012: *Lundbeck*,[2] *Fentanyl*,[3] and *Servier*[4] by the European Commission, and *Paroxetine*[5] by the UK authorities. All but *Fentanyl* are under appeal. A fifth one, *Cephalon*, is currently in an administrative phase.[6]

A typical strategy of originator companies when facing the end of the patent protection on a molecule is to raise IP barriers against generic entry by applying for patents to block several alternative routes for producing a bioequivalent medicine, for example by protecting a number of processes of manufacturing the molecule or by patenting certain salts, crystalline forms, etc. Despite this, given that the compound itself is no longer protected, generic companies may retain various possible routes to market: They can try to avoid the IP protection by inventing around the incumbent's patent, get into the market "at risk" (i.e. be ready to face a court action by the incumbent), clear the IP barrier in advance through interaction or judicial process, etc. For instance, reflecting these parameters, the *Lundbeck* decision (para. 635) lists eight routes to market.

The same *Lundbeck* decision quotes internal documents that use language that reflects vividly the context of decisions under uncertainty that originator and generic companies face when they have to make choices between entering, litigating or negotiating. "It is like a poker game We have been dealt a mediocre hand – no aces, a couple of queens and some small uneven cards But we have a large pile of $$$ at our side We call it – "the art of playing a l[o]sing hand slowly" Our strategy Our objective: To create a window of opportunity for the Cipralex switch Focus on EU and particularly the northern European markets – the generic markets Three main tactics: – Influencing the authorities – Patent defence, mainly process patents – Deal making." (*Lundbeck* decision, para. 804)

In those cases, prior to entering into the agreement, the generic company had developed a process to produce the molecule. The generic company was technically able to enter the market but there were uncertainties on the outcome of entry because of legal and commercial risks. To make its decision on whether, and how, to enter, the generic company would rely on both private and public information in order to reduce and model uncertainty. Typically, the generic company future profits will depend on its own performance, general uncertainty surrounding competitive conditions, actions of originator and outcomes of possible court procedures.

On the other side, the originator knows that its patent protecting the molecule will lapse on a given date. Beyond that, the originator may be aware of efforts by some generic companies (based on public or private information) to enter the market. There is uncertainty as to whether these efforts to enter will translate into actual entry or not; and related to this, there is uncertainty on the outcome of a possible IP dispute.

The uncertainty of the outcome of patent court cases is perhaps best described by this quote in the UK litigation concerning a Servier patent:

> [The '947 patent] is the sort of patent which can give the patent system a bad name. I am not sure that much could have been done about this at the examination stage. There are other sorts of case where the Patent Office examination is seen to be too lenient. But this is not one of them. … The only solution to this type of undesirable patent is a rapid and efficient method for obtaining its revocation. Then it can be got rid of before it does too much harm to the public interest. It is right to observe that nothing Servier did was unlawful. It is the court's job to see that try-ons such as the present patent get nowhere. The only sanction (apart, perhaps, from competition law which thus far has had nothing or virtually nothing to say about unmeritorious patents) lie in an award of costs on the higher (indemnity) scale if the patent is defended unreasonably (*Servier* Decision, para. 1132)

2 Commission decision of 19.06.2013 relating to a proceeding under Article 101 of the Treaty on the Functioning of the European Union and Article 53 of the EEA Agreement (AT.39226 – *Lundbeck*). Judgment of the General Court of September 8, 2016, Case T-472/13, under appeal.

3 Commission decision of 10.12.2013 relating to a proceeding under Article 101 of the Treaty on the Functioning of the European Union (AT.39685 – *Fentanyl*).

4 Commission decision of July 9, 2014 relating to a proceeding under Article 101 and Article 102 of the Treaty on the Functioning of the European Union (Case COMP/ AT.39612 – *Perindopril* (*Servier*)); Judgment of the General Court of December 12, 2018, *Servier SAS and Others v. European Commission*, Case T-691/14, under appeal.

5 Decision of the UK Competition and Market Authority of 12.02.2016 (*Paroxetine* – Case CE-9531/11).

6 Case COMP / AT.39686 where the Commission sent a Statement of Objections on 17.07.2017.

This Court decision came a year after the European Patent Office OD had confirmed on first instance the validity of the same patent.

If any generic would enter the market, profits would drop significantly. This means that the originator company has a very strong incentive to challenge the generic efforts by arguing that they infringe some of its patents even though they are perceived as possibly invalid. In that regard, the pharma sector enquiry found that whilst the originator companies initiated the majority of the cases, generic companies won 62 percent of the patent litigation cases and in 46 percent of the cases in which injunctions were granted the subsequent court proceedings in the main case ended either with final judgments favorable to the generic company, or settlements which appear to be favorable to the generic company.[7]

Once the originator perceives the threat of entry, it adapts its behavior to potential entry. For it to be able to make a self-assessment of the legality of its behavior, it should be able to base its decision on information that is known to it: Knowns, as well as known-unknowns. There is no reason to make a separation between the two categories. Any business decision is based on both. Typically, there are objective processes in place within the organization to deal with the information available and a best judgment is applied on the outcome of these processes. In other words, it is inevitable that in situations of uncertainty, companies' decisions are a mix of subjective and objective determinations. One cannot ask the originator company to second-guess information that it does not know but the generic knows.

It follows that prior to any agreement, there are knowns (end of patent protection, generic's ability to produce), known-unknowns (who will prevail in case of dispute before a court, commercial success, evolution of general factors such as overall demand, evolution of economy, etc.), and unknowns. In order to make the best possible decisions, each party will try to gather as much and as complete information as possible. There are always some elements that will be random (i.e. unpredictable). The gathered information can be private or public (say at least shared with the other party). The judicial process makes the information, as much as possible, complete and shared, and on that basis courts interpret and apply the law.

III. EVIDENCE IN TIMES OF UNCERTAINTY: SUBJECTIVITY RATHER THAN WAIT-AND-SEE

A common thread in pay-for-delay cases is how to objectively prove a restriction of competition based on evidence that reflects the uncertainty at the time of the agreement. It would be easy, but wrong, to use later evidence when the fog of uncertainty has dissipated, as it would be equally wrong to reject evidence based on perception of the parties. I will illustrate this by looking at how the concept of potential competition has been applied to pay-for-delay, then at the value of the transfer that changes the incentive to compete for the generic company, and finally at a proper test for a restriction by effect analysis.

A. Potential Competition

How should a competition agency acknowledge these uncertainties and the incompleteness of information? When, and on the basis of what evidence, is the competitive constraint exercised by a generic company that is making efforts to enter strong enough to be considered as "potential competition"? There are three possible options. First, the agency could rely on each party's expectations in order to determine competition constraints from operators not in the market. Second, the agency could refuse to consider any internalization of uncertainties by the parties and rely only on knowns. Third, the agency could consider that the existence of uncertainties does not allow to conclude that the generic is a potential competitor, in other words that the knowns are not enough. I now discuss these three options.

Option two appears overly extensive or restrictive, depending on whether the ability to produce the molecule is enough. In fact, the only know that would remain in that option would be that the active pharmaceutical ingredient (i.e. the molecule) is no longer protected, but with no view allowed on whether that could translate into market entry. That would lead to numerous type one and type two errors.

Option three amounts to excluding potential competition as soon as there is a dispute (and in effect any other uncertainty such as commercial risk). There are two major weaknesses to this approach. First, is that it provides an incentive for the originator to challenge before the courts. It puts in the hands of the originator the power to decide whether a generic is not a potential competitor. Second, there is no limiting principle. Unless there would be a convincing way to separate various types of uncertainties, any type of uncertainty should be excluded. Intuitively, that cannot be right, given that the very nature of competition is to deal with uncertainty. In that case, the only possible potential competitor that could be considered under competition law would be the one about to enter, a split second before entry. This is underlined by the Technology

7 Pharmaceutical Sector Inquiry Report of 08.07.2009.

Transfer Guidelines that state that it is in the interest of the parties to deny the quality of potential competitor.[8]

Let us turn now to option one. The fact that the information about the originator and generic companies' perceptions is observable and verifiable makes the criteria operant. It remains to be seen if they correspond to the competition reality, or, in situations where these criteria would be met but the generic company would not be a potential entrant, if it would be bluffing the originator. That does not seem likely. The judicial process is organized to identify bluffers, so the originator could proceed with the litigation in order to call the bluff, and if it appears not to be a bluff, then still has the option to offer a settlement. From the generic perspective, this appears a high-risk strategy, given that preparations for market entry entail costs and investment in reputation. Bluffing is also incentivized by the possibility of pay for delay.

The two recent General Court decisions in *Lundbeck* and *Servier* make a distinction between possibilities and intentions. Possibilities are assessed on the basis of a "*faisceau d'indices*" that aims at establishing that the candidate potential entrant has the ability to enter the market. This is the essential factor according to the *Lundbeck* judgment, a purely theoretical possibility of market entry is not sufficient (para. 101). An undertaking cannot be a potential competitor if its entry into a market is not an economically viable strategy (*Lundbeck*, para. 100). The intention to enter is an optional and complementary factor. According to the *Servier* judgment (para. 382), the intention to enter in a market is neither necessary to establish the existence of potential competition on the market nor liable to challenge it; it remains that, when established, it is likely to confirm the ability to enter. What matters is a pressure represented by the likelihood that a new competitor will enter the market if the market becomes more attractive (*Lundbeck*, 102).

The *faisceau d'indices* to establish the possibility to enter included the following findings in both the *Lundbeck* and *Servier* cases: Significant investments and efforts already made by the generic undertakings in order to prepare their entry to the market which resulted in (access to) capacity of production and stocks; obtention of a marketing authorization, or having taken the necessary steps to obtain one within a reasonable period; existence of non-infringing routes to the market; no conclusion by a Court of infringement; a non-negligible possibility that some of the secondary patents (for production process, formulation etc.) might be declared invalid; occurrence of entry at risk; evidence of expected profits; and the significant transfers of value through the agreement.

In fact, the joint reading of these two Court decisions leads to the following test for potential competition:

1. Considering its production capacities, commercial arrangements, and regulatory approvals, does the entity have the capacity to enter the market within a reasonable time period?

2. Are there any exogenous objective reasons that would lead to insurmountable barriers to entry, such as final court decisions that would take a stance on infringement or validity? (*Servier*, para. 321).

3. Would the entry be economically viable? (However, it does not need to be the most profitable return on investment, see for instance *Servier*, para. 340).

These first three steps provide real, concrete possibilities. They concentrate on showing the ability to enter. There is no need to show incentive to enter which would require more than economic viability. They can be complemented by an examination of the intentions of the parties for instance in terms of entry or conflict over infringement or validity. But, they must not.

Then comes the question of the type of evidence that can prove that these three steps are met. First, from a temporal perspective, it is the evidence available at the time of signing the agreement. This can be illustrated or clarified by recourse to posterior evidence, but such *ex post* evidence cannot disprove the test. Second, the issue arises of the nature of the evidence. Since the questions asked in the test are concrete, their answers call for objective evidence to support them. Judging the profitability of future entry requires to make some assessment of risk factors linked to litigation or commercialization. In *Lundbeck* (para. 141), the Court tries to square the necessary subjective nature of such prediction with a level of objectivity of the evidence:

> The Commission therefore did not err in relying on objective documents reflecting the perception that the parties to the agreements at issue had of the strength of Lundbeck's process patents at the time those agreements were concluded (see inter alia

8 Section 2.4 of the Communication from the Commission — Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements, OJ C 89, 28.3.2014, pp. 3–50.

recital 669 of the contested decision) in order to evaluate the competitive situation between those parties, it being noted that subsequent evidence may also be taken into account provided that it is capable of clarifying those parties' positions at the time, confirming or challenging their arguments in that respect as well as allowing a better understanding of the market concerned. In any event, that subsequent evidence cannot be decisive in the examination of the potential competition between the parties to the agreements at issue.

This approach makes sense because it corresponds to the reality of human organizations. On the other hand, the *Servier* judgment (para. 384) categorizes such evidence as showing the intention of the parties and therefore not necessary to prove potential competition.

I think there is an argument to be made that such anticipations, when made by experts, do not amount to subjective intentions, but rather form objectively informed predictions. This is similar to predictions that the Commission may make of the effects of a proposed merger on the markets. However, in pay-for-delay cases, the very fact that the parties signed an agreement is likely to be sufficient evidence that given a capacity to enter, it would likely be profitable. That was acknowledged in both the *Servier* and *Lundbeck* cases.

B. Value Transfer and Incentive

Turning now to the restriction of competition analysis, I will first recall the test applied in the *Servier* and *Lundbeck* cases to focus on the third condition, which deals with a change in incentives for the generic company against a payment by the originator, and conclude that it is appropriate to treat these as restrictions by object. Finally, given the reasoning followed by the General Court in *Servier*, it is useful to review the test and type of evidence to rely on to assess effects.

To state the obvious, any elimination of a credible threat of entry is likely to release a competitive constraint on the originator company. If an agreement leads to absence of possible entry, the competitive situation with the agreement is always worse than that without an agreement. In that instance, the evidence of intentions of the parties is irrelevant as the object is clear from the agreement itself: For a potential competitor to withdraw from competition. This was the case of both the *Servier* and the *Lundbeck* agreements. Since the competitive situation is always worse with such an agreement, it seems appropriate to label this as a restriction by object.

The test applied by the Commission in both *Servier* and *Lundbeck* beyond showing, first, that the generic company is a potential competitor, and, second, that the agreement leads to the abandonment of its efforts to enter, calls for a third condition to be met: That a transfer of value would change the incentives of the generic company to enter. This raises two questions: First, since the test addresses incentives, does that involve examining the parties' intentions? And, second, is that test superfluous if in any event the agreement bars entry?

From the generic company perspective, assuming it meets the potential competitor test, if the value transfer would exceed any level of profit it could have expected to make (even if none of the risks would materialize), it would be profit maximizing to stop its efforts and sign the agreement. If the value transfer exceeds the expected profits discounted by the risks incurred (commercial, litigation, etc.) at the time of the agreement, there is again no incentive to earn this money by continuing the efforts to enter the market and confronting risks inherent to competition, and it is profit maximizing to sign the agreement. Such an assessment does not require an examination of the intentions of the generic company prior to the agreement, but, based on its assessment of risks, does confirm that the payment cancels any possible profit out of entering. In that sense there is no subjective element, but for the part of putting a value on the risks. The third scenario is when the value transfer is greater than zero but below the expected profits linked to entry. In that case, there is a need to explain why there are no incentives to enter any more. It could be that investing the same efforts in an adjacent market would bring more profits when including the value transfer for instance. This is again an assessment based on the generic company's expectations and not its intentions.

It is not superfluous to examine the link between payment and incentives. The payment shows that there is a distance between the agreement and a settlement based on the merits of the parties claims on infringement and validity. It shows that the generic company expected to make a profit out of its efforts, most likely out of entry in the market. If there was no transfer of value, it would not make economic sense to consider the generic company as a potential entrant since it did not need any financial prompting to undertake not to enter.

It follows that when the three *Servier/Lundbeck* conditions are met, it is highly likely that the competitive conditions are worse than without the agreement. In other words, a qualification as a restriction by object is justified.

The legal determination of the value transfer is of a high importance. It must be a transfer that would not take place if there was no agreement, otherwise there would not be a change in the incentives of the generic company. So, for instance, if the value transfer takes the form of a side agreement, the Commission would have to prove that it would not have been signed absent the main agreement. If that is proven, then the overall value attached to the side agreement may have an effect on the incentives of the generic company. The fact that the side agreement was signed at arm's length or not is irrelevant, the whole economic benefit brought to the generic company, even if made at arm's length, is a value transfer. However, the General Court judgment in *Servier* contains statements which could suggest a narrower interpretation such that the value transfer is only established when its terms do not reflect normal market conditions. In my opinion, that appears inconsistent with a proper analysis of the impact on the generic company incentives. Let me add that under EU competition rules, there is no way under Article 101 to balance the possible beneficial effects of the side agreement on another market with the negative effects of the pay-for-delay.

If there is a value transfer and one relaxes the second condition of the test, so that the generic company undertakes not to enter only for an initial period (and not anymore for the length of patent protection) but the originator keeps the freedom to challenge entry of the generic company past this initial period of time, the conclusions remain the same. The agreement does not solve anything and just postpones the problem. The two parties are likely to face the same choice at the end of the initial period but the originator is relieved of competitive pressure meanwhile. Competition conditions are worse with the agreement.

If, on top, the originator undertakes not to challenge entry of the generic company past this initial period of time, the assessment becomes more complex. This is a so-called "early entry" settlement: The generic company receives a payment for not competing, but only for a while, and it may enter before the end of the patent protection under dispute. The existence of a value transfer would suggest that the generic company would derive a profit from not signing and therefore competing on the market during some time in the initial period. Similarly, if the originator company is ready to share part of its profit, that points towards elimination of competition. The same arguments that point towards a restriction by object apply here. However, the context in which the early entry agreement has been signed must be understood. There could be anticipated changes, such as regulatory changes, product hopping that could enhance or decrease the merits of the scenarios, etc.

C. Restriction by Effect

Turning now to the analysis of effects of a pay-for-delay agreement, there are a number of issues to examine: The nature of the effects, the type of evidence that can be used, definition of the counterfactual scenarios, whether effects should have occurred *ex post facto*, etc.

First of all, likely effects should be found at the time of signing the agreement. This is not specific to pay-for-delay agreements but the uncertainty relating to infringement/validity of a patent at time of signing should not be left aside in favor of a later decision by a court on the subject under dispute. The main argument for that is one of legal certainty. A company must be able to self-assess the legality of its actions at the time of the behavior in question. Having to wait for future events to determine the legality of an agreement increases the legal uncertainty: Both the scenario under implementation of the agreement, and that under the but-for, include many more unknowns than a determination based on *ex ante* facts. In addition, if the legality depends on future events, not only would the company be unable to determine with certitude whether its planned behavior is legal, but it would increase the attractiveness of potentially anticompetitive practices. The amount of the fine would be the same whether the determination is made on facts *ex ante or ex post*. Since it is less likely that the behavior be found illegal based on unknown future facts, a company will be more likely to adopt an anticompetitive behavior.

The scenario under the pay-for-delay agreement then should include likely events. For instance, if an agreement which, hypothetically, does not amount to a restriction by object excludes a potential competitor, it is important to assess the likely other entrants at the time, even if they face uncertain prospects. Similarly, if an existing dispute over IP rights has non-negligible probabilities of ending with validity or invalidity, both scenarios should be considered.

Counterfactual scenarios, absent the pay-for-delay agreement, must also include likely events. Most of them are equivalent to those that may happen in the presence of the agreement, because they do not depend on whether the potential competitor is in or not. However, some events are agreement dependent. The most obvious one is the possible entry of the potential competitor. As discussed above, a potential competitor must have the (future) ability to enter, but it may not have the incentive to do so. For instance, there might be alternative investments with higher returns. However, for the potential competitor to have an influence on the competitive behavior of the incumbent, its entry must be likely, at least from the perspective of the incumbent. That means that the Commission should prove, not only ability to enter, but also that the potential competitor has the incentive to do so. If contemporary documents would show intent to enter, then that should confirm the existence of the incentive.

The question remains whether the Commission should prove that actual (but future and unsure) entry would have effects on competition or should prove that the threat of entry has effects as well. The latter corresponds to the recent US FTC opinion in the Impax case: "The Commission explained that the U.S. Supreme Court's Actavis decision held that eliminating the risk of competition through a reverse payment settlement itself constitutes an anticompetitive harm. The Commission found there was ample evidence of a risk that Impax could have launched a generic product before the agreed-upon date, had it not entered into the reverse payment settlement with Endo. The Commission therefore concluded that Complaint Counsel established a prima facie case."[9] First of all, if the threat of entry has an effect, it should be enough, since the only reason why it would have an effect is because the incumbent would deem it credible. If the Commission cannot prove that the threat of entry likely alters the competitive behavior of the incumbent, it is probable that the only arguments available would then be one of common sense: If the potential competitor enters, there is one more competitor for a product that before its entry commended high margins, it is therefore likely that entry would lead to a drop-in prices. The argument would remain the same if entry by one or two other players were also possible. That is economics 101.

To summarize,

- By effect restriction should be assessed at the time of the agreement
- Both the scenarios with and without the agreement must account for likely events
- The potential entrant must not only have the ability to enter, but also the incentive (intention to enter proves an incentive)
- Threat of entry or actual entry must have effects on competition outcomes, unless there are many entrants that should be obvious most of the time

The *Servier* decision applied a similar framework of analysis. It argued that each of the generic companies that signed a pay-for-delay agreement with Servier, intended to enter and there were only very few alternative entrants so that their withdrawal from the competitive process had an effect on competition.

If one turns now to the *Servier* court ruling on restriction by effect,[10] the General Court stated that it is not enough to find that the elimination of a potential competitor is likely to have anticompetitive effects, but that the Commission should prove actual effects (*Servier* GC, paras. 1092, 1128). The General Court considers that while Servier's market power and the absence or scarcity of sources of competition may confirm the existence of restrictive effects, this is not sufficient to make likely and concrete the effects of an agreement hindering a competitive threat (*Servier* GC, para. 1180). In particular, in the counterfactual scenario, the Commission should: (i) prove that the potential entrant would likely have entered the market in the absence of the agreement (*Servier* GC, para. 1169) in view notably of events that took place after the conclusion of the agreement and the evolution of its perception of the validity of the patent (*Servier* GC, para. 1170), notably that it would have entered before generic entry actually occurred (*Servier* GC, para. 1203); and (ii) explain what likely effects the potential entrant competitive threat would have had on *Servier*, notably on prices, quantities, quality, diversity of products or innovation, in the absence of the agreement (*Servier* GC, para. 1179).

The test applied by the General Court in *Servier* resembles the one discussed above, but has two important points of tension. First, the GC considers that factual developments that took place after signing the pay-for-delay agreement should be considered. As discussed, this flies in the face of legal certainty and may increase the incentives to behave illegally. Second, the GC calls for proof of likely entry. Likely entry is not the same thing as likely effects. That goes beyond the incentive to enter. It would mean that the Commission would have to prove that generic company is likely to win the patent litigation. This leads to a confusion of powers, asking the Commission to second-guess what a specialized patent court would have said in cases where no court decision would have taken place, because of the pay for delay agreement. Alternatively, when there would have been a court decision, we are back to the first point of tension and the issue of legal certainty.

9 https://www.ftc.gov/news-events/press-releases/2019/03/ftc-concludes-impax-entered-illegal-pay-delay-agreement; emphasis added.

10 The General Court decision is in French, the translation in English is mine.

IV. CONCLUSION

Pay for delay cases raise interesting issues on what consists of a potential competitor and how to assess effects. As in many markets, uncertainty is the hallmark of competition in these cases and what makes the assessment challenging. Both competition authorities and the courts should acknowledge uncertainty, not ignore it nor use *ex post facto* developments to solve it. Specifically, there are lessons to be learned and applied to the digital economy, where one of the main concerns is how to preserve the ability of potential competitors to develop into rivals to the incumbent platforms, while there is very high uncertainty on how they will develop.

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