

“Pay-for-Delay”: What Do We Disagree On?

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Antitrust concerns about “pay-for-delay” patent settlements are based on two theories of harms, one that stresses the need for courts to review the validity of patents and one that emphasizes the “probabilistic” nature of patent rights. The main weakness of the first theory of harm is that it fails to explain why some forms of patent settlements would be less desirable than others. The “probabilistic” theory of harm raises fundamental questions about the legal obligations of a patent-holder, the type of uncertainty that should be reflected in the probabilistic nature of the patents and whether the theory can be applied to anything but the simplest PFD settlements. This article also discusses the likely effect of a PFD ban on innovation and reviews both the European approach to recent and ongoing PFD cases and the recent *Actavis* decision of the US Supreme Court.

I. THEORIES OF HARM

“Pay-for-delay” or “value transfer” licensing settlements have been investigated by antitrust authorities in a number of jurisdictions, including the US, the EU and the UK. “Pay-for-delay” (PFD) refers to agreements reached between a pharmaceutical firm that produces a drug that is still protected by some patents and a (potential) generic entrant in settlement of litigation about the infringement and/or validity of the relevant patents. The key feature of a PFD agreement is that the generic agrees to enter only after a specified period and receives a positive transfer from the patent holder. The antitrust authorities’ objection to this type of settlement relies generally on two theories of harm.

According to the first theory, the fact that the patent-holder actually pays the generic challenger decreases the probability that patents will be effectively reviewed in court. As such review is an integral part of the patent system, this amounts to depriving society of the opportunity to “weed out” weak patents, thereby preserving unwarranted exclusion rights to the detriment of consumers.² The second theory of harm—commonly associated with the work of Carl Shapiro³—claims that any settlement in which the generic and the patent holder agree to allow independent generic entry prior to patent expiration but which involves a transfer from patent-holder to generic that exceeds the litigation costs expected by the patent-holder must involve a date of generic entry that is later than the “average” date that the patent-holder would—rightly or wrongly—expect to result from the continuation of litigation. This implies that the patent-holder essentially shares some of its expected monopoly rents to “delay” generic entry and that expected consumer surplus is lower than if litigation had been pursued to a final judgement. While this article tries to focus on issues that are common to both the US and the European “versions” of “pay-for-delay” cases, relatively more emphasis is given to the European approach. It is therefore important to remember that there is no equivalent to the Hatch-Waxman Act in Europe, so that keeping one generic out has no direct effect on keeping other generics out of the market.

II. THE MAIN POINTS OF DISAGREEMENT

I'll start with what I am not going to claim. I am not going to claim that any form of patent settlement should be acceptable under Antitrust Law. Clearly settlement terms that extend beyond the scope or lifetime of the patents deserve to be closely scrutinized. I would even agree that "value transfer" agreements should also be subject to some oversight as they could otherwise be used to protect extremely weak (or even sham) patents in a manner that would be hard to distinguish from a blatant market-sharing agreement. So, in my view at least, the main point of disagreement is not whether or not it is legitimate for competition authorities to be concerned about PFD agreements. Rather, the continuing disagreement between PFD "hawks" and "doves" stems from different views of the two theories of harm described above and of how these theories of harm can be applied to concrete cases. As I explain in more details below, the main question raised by the first theory of harm is why it should apply with special urgency to PFD deals. After all, *any* patent settlement effectively deprives society from the opportunity to invalidate patents that were granted in error. There are two main sources of disagreement about the second theory of harm. Firstly, as we will soon discuss, that theory is squarely based on a "probabilistic" view of patent protection. While undoubtedly appealing as a description of actual patent rights, the normative implications of the probabilistic view are far from being agreed on by all economists or legal scholars. Secondly, even if one were to subscribe to the probabilistic approach, it is not entirely clear what are the actual implications of this approach for patent settlements in general and PFD agreements in particular.

A. *First Theory of Harm: Are All Patent Settlements Objectionable?*

The review of patent applications by patent offices is necessarily imperfect, leaving a substantial portion of granted patents that are found invalid when further reviewed by the courts. This situation does not necessarily reflect poorly on the performance of patent offices. As the patents that are challenged in courts tend to be "those that matter," it is actually optimal to save the cost of a true in depth examination on the vast majority of applications. In this sense, then, ensuring an effective review of patents by the courts is important to the overall performance of our IPR systems. In spite of this, however, it is widely believed that litigation settlements have a useful role to play as they provide faster and cheaper alternatives to legal disputes. Either one believes that this principle also applies to the special case of patent litigation or one does not. If one does not, then any patent litigation settlement gets in the ways of socially useful judicial review. Our first theory of harm would then logically imply that *all* patent settlements, not just PFD settlements, should be prohibited.

If, on the other hand, one believes that settlements have a role to play in patent litigation, then the question is how one would distinguish between "good" and "bad" settlement. Following the logic of the theory of harm, bad settlements should be those that involve patents that are likely to be overturned by the court, i.e. "weaker" patents. The relevant question then is whether the presence of a transfer from the patent holder is a reliable indi-

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cator of the weakness of the patent involved in the litigation. The answer to that question is a qualified “no”. To see this, let us focus our attention on settlements that spell out a date of entry for the generic challenger as well as a possible transfer from the patent holder. Clearly the “overall package” offered to the generic must be more attractive if the patent is known to be weaker. This means that, if we compare two settlements with the same date of entry, one with a transfer and one without, one would generally believe that the settlement involving a transfer is associated with a weaker patent. On the other hand, we could not possibly draw any inference from the comparison of an agreement without payment and a given entry date and an agreement with payment that involves an earlier date of entry. So overall, when looking at a specific settlement, one simply cannot conclude that the presence of a payment implies that the patent at stake is weak. There no simple relationship between PFD and the strength of the underlying patent. Moreover, if one were to draw inferences from the combination of PFD and agreed upon entry date, one would face the following paradox: for a given size of transfer from the patent-holder to the generic entrant, a weak patent would lead to an *earlier* date of entry as the generic firm must be given a more attractive “package.” Clearly, a crackdown targeted at early entry agreements is not what competition authorities have in mind. Overall then, the first theory of harm does not seem to offer a sound basis for the singling out of PFD settlements.

B. Second Theory of Harm #1: Probabilistic Patents

It is important to clarify what economists mean when they refer to patents as “probabilistic” rights. There are essentially three “levels” of adherence to the probabilistic view.

Level 1: As a matter of positive analysis, the right to exclude granted by patents is without a doubt probabilistic as the patent-holder cannot be sure that the validity of the patent would be upheld if challenged and as, anyway, the precise coverage granted by the claims approved by the EPO remains quite uncertain until the construction of these claims has been further examined in court. Finally, even if there was no inherent uncertainty in the IP right itself, courts do make mistakes.

Level 2: As a matter of efficient design of a patent system, the probabilistic character of patent rights is actually desirable. As Ayres and Klemperer observe⁴, making patent rights “more probabilistic” is similar to reducing what economists refer to as the “breadth” of the patent. From the work of Gilbert and Shapiro⁵, we know that, under rather general conditions, a patent design that trades-off breadth against length makes it possible to ensure a given reward to the innovator at least social cost. So, at this second, normative, level, the probabilistic aspect of IPRs is useful, as long as IP owners are properly compensated by adjustments to, less distortionary, dimensions of the patent right (such as length).

Level 3: The probabilistic right is all that the patent-holder is entitled to. The patent-holder cannot therefore take any action that would eliminate the probabilistic aspects of the right if this action is to the detriment of consumers. Concretely then, a patent settlement will be seen as anticompetitive if it leads to a level of consumer surplus that is lower than the surplus that consumers would have expected as a result of continuing litigation. Assume, for example, that consumers would get a surplus of 50 if the patent-holder prevailed and did therefore continue as a monopoly supplier until the end of the litigated patent but that this surplus would increase to 100 if the generic entrant prevailed (say, if the patent was invalidated). If the ex ante probability of success of the patent-holder is p , then a settlement that leaves consumers with a surplus that is less than $50p+100(1-p)$ would be viewed as anticompetitive. This third, normative, view is what the second theory of harm relies on.⁶

While most economists have no problem with Levels 1 and 2, the same cannot be said about Level 3. Among the potential objections are:

Consistency. While they hold a valid patent, patent-owners who are not dominant are usually understood as facing no obligation to think about consumer welfare when acting within the scope of their patent. When entering a “normal” licensing agreement, for example, the terms of this agreement are properly set through bilateral negotiations without either party having to worry whether some alternative form of agreement would actually be better for consumers. Why then should such an obligation suddenly surface when an agreement—which might well involve licensing the technology—is reached as part of litigation against a potential generic entrant?

Practicality. A rule that says that a patent-holder can use and defend her patent while remaining within the scope of this patent as long as the patent is currently valid is easy for economic agents to understand and easy to enforce. A world where patent-holders would have to evaluate every substantial action regarding the use of their IPRs by assessing the fundamental uncertainty of their rights would appear to lack the clarity and predictability for which competition law should strive. If patent-holders really need to ensure that they always leave consumers with at least as much surplus as would result from actually “drawing” the “lottery ticket” that is a patent, how will patent-holders know what will or will not be deemed to be anticompetitive?

Sources of uncertainty. There are further degrees of “purity” even within the adherents to the “third level” described above regarding what should be seen as forming part of the “legitimate” probabilistic nature of patents, i.e. those probabilistic aspects that the patent holder should see as given and inalterable. Should the possibility of judicial error be included into the probabilistic nature of patents or should patent holders have the right to protect themselves against such error? What about injunction risk? In pharma, failure to obtain an injunction can be catastrophic for the patent-holder: generic entry will lead to lower prices and it is practically impossible to restore the pre-entry price level later on even if the patent-holder ultimately prevails.

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C. Second Theory of Harm # 2: What type of settlement should be prohibited under probabilistic patent approach?

Let us assume for the sake of discussion that we agree with the probabilistic patent benchmark: consumers should get at least what they would get if patent litigation was not settled. How do we know whether a given settlement satisfies such a criterion? This is where the work of Carl Shapiro becomes crucial as it is designed to provide us with a simple criterion, thereby addressing the “practicability” issue raised above. In a nutshell—and without getting into the myriad of possible variations on the model—when a settlement involves an agreed date

of independent generic entry, a transfer that exceeds the expected costs of litigation of the originator implies that the originator believes that the agreed upon date of entry is later than the expected date of entry if litigation

THE THEORIES OF HARM PRESENTED ABOVE TAKE AN EX POST VIEW: THE INNOVATION COVERED BY THE PATENT HAS ALREADY BEEN OBTAINED, SO THERE IS NO DISCUSSION OF HOW ANTITRUST ENFORCEMENT MIGHT AFFECT INCENTIVES TO INNOVATE. THIS IS AN IMPORTANT DRAWBACK. THE PATENT SYSTEM IS DESIGNED TO FOSTER INNOVATION AND ENSURES THE DIFFUSION OF KNOWLEDGE TO THE EVENTUAL BENEFIT OF CONSUMERS. AN ANALYSIS THAT IGNORES EFFECTS ON INNOVATION THEREFORE TAKES AN INCOMPLETE VIEW OF THE EFFECTS OF VALUE TRANSFER SETTLEMENTS ON WELFARE.

proceeded to the end. So, if one accepts the probabilistic patent benchmark, patent settlements involving such transfers can only be anti-competitive and should therefore be forbidden.

While useful, this criterion is not fool-proof even if one accepts the probabilistic patent benchmark. In particular it does not apply with such simplicity if the two parties have different exposure to risk or have different attitudes to risk. This later possibility should not be ruled out too easily, especially when the generic entrant is under severe financial constraints.⁷

Moreover, the Shapiro criterion simply does not apply to more complicated settlement agreements that do not simply involve an agreed date of independent generic entry with or without transfer. As just one example, there can be settlement agreements in which generic entry takes place immediately, but in which the generic must purchase from the patent holder at

an agreed transfer price or must pay an agreed royalty. Even if such agreements are accompanied by value transfers that exceed the expected future costs of litigation, it does not follow that such agreements necessarily reduce the expected welfare of the consumers of the affected drugs relative to expected consumer welfare if the parties had litigated. Since leaving consumers with at least the surplus that they could expect from continued litigation is what separates acceptable settlements from anticompetitive settlements under the probabilistic patent benchmark, the presence of a value transfer as part of such agreements simply cannot be seen as sufficient evidence that the agreement is anticompetitive.

In fact, it is easy to show that, for any date of generic entry that would be expected from the continuation of litigation, there is an immediate entry agreement with wholesale supply from the originator (or a royalty payment to the originator) that makes all parties—including consumers—better off. Moreover, in order to provide the generic with an incentive to enter this kind of welfare-enhancing agreement, a “reverse payment” from the patent holder to the generic will be required.⁸ It is therefore hard to see how the simple presence of a payment from the patent-holder to the generic could be used as evidence that any settlement involving immediate entry should be seen as anticompetitive.

D. A Policy Concern: Innovation

The theories of harm presented above take an ex post view: the innovation covered by the patent has already been obtained, so there is no discussion of how antitrust enforcement might affect incentives to innovate. This is an important drawback. The patent system is designed to foster innovation and ensures the diffusion of knowledge to the eventual benefit of consumers. An analysis that ignores effects on innovation therefore takes

an incomplete view of the effects of value transfer settlements on welfare.

There are two main issues here. Firstly, would banning value-transfer settlements actually hurt the profits of patent-holders in the pharmaceutical sector? This is not clear *a priori*. On the one hand, value transfer settlements enable the patent-holder to settle litigation at a lesser cost, so removing this possibility would hurt. On the other hand, generics also benefit from value transfers so they might be less willing to challenge the patent in the first place if the practice was removed. That effect would be beneficial to patent-holders. If the net effect is of banning value transfers is favourable to patent-holders, then we are effectively in a situation where patent-holders' own ex post rational use of value transfers militate against their ex ante interest. Is this really ground for pursuing them under antitrust law? If on the other hand, the net effect of banning value transfers is to decrease the patent holder's expected profits, then one must consider the feedback effect on innovation.

Let us first dispose of a red-herring. Authors on both sides of the debate have invoked the fact that "the patent system has been designed to balance a variety of effects optimally," so one should not unduly tinker with it through competition law. On the "anti-transfer" side, the argument is that the patent system is optimal in an environment where value-transfer settlements are not allowed, so there is no need to compensate innovators if value transfer settlements are banned. On the other side, the (implicit) view is that, since opposition to value-transfer settlements is recent, one must assume that the patent system balanced effects under the assumption that all kind of settlements within the scope of the patent would be allowed. In this view, banning value transfer settlements would therefore have potentially serious effect on the balance of the IP system in pharmaceuticals. Such debate over original intent is useless.

If one wants to study rigorously the effect of value-transfer settlements within the patent system, one must follow the usual approach used in the patent design literature evoked above: take the level of reward to innovators as given and determine whether allowing for value transfer settlements makes it more or less costly to consumers to provide this level of reward to innovators. If one conducts that analysis, one actually finds that a value transfer settlements make it possible to provide a given reward to consumers at a *lesser* cost in terms of ex post consumer welfare.⁹ In other words, even within a patent system designed on the basis of a probabilistic view of patents, there would still be room for allowing for settlements that involve payments from the patent-holder to the generic.

The second issue is whether banning value-transfer settlements would actually address the two theories of harm described at the beginning of this note. In particular, it is far from clear that a prohibition on value-transfers would actually lead to a more efficient "weeding out" of bad patents. Just as the impact of a prohibition on innovation incentives was ambiguous, one cannot conclude that it would lead to more challenges working their way to a final litigation outcome: a ban on value transfers might increase the proportion of generic challenges making it all the way through litigation but, since it decreases the expected pay-offs of the challenging generic, it could also lead to fewer challenges in the first place.¹⁰

III. THE EUROPEAN APPROACH

DG Comp has been pursuing a small number of cases. If we look across these cases, we notice that the Commission is relying on both Article 101 and Article 102, sometimes within the same case. Under Article 101, the Commission sees value-transfer settlements as "per object" infringements. The Commission's approach

under Article 102 is less clear. Still, while the Commission does present arguments relating to the therapeutic substitutability of the medicine at stake with other medicines within the same class, there appears to be a new emphasis on a definition of dominance that is arguably “tailored to the alleged abuse.” Under this approach, the very fact that the patent-holder had the power to exclude generic competition through value-transfer “bribes” and that it had the incentives to do so—since prices tend to fall abruptly when generics enter—suffices to establish dominance, irrespective of the extent of therapeutic substitutability within class, the intensity of non-price competition or the overall profit margins realized on the protected drug.

The Commission has reached a decision in the Lundbeck case, imposing rather large fines on both Lundbeck and the generic companies involved in the PFD agreements. It is worth noticing that the decision relies exclusively on Article 101, even though Citalopram’s shares in its therapeutic class were at least as high as the shares of some other medications for which Article 102 is also used. The main reason for this appears to be the urgency of closing the case to avoid running into the status of limitation.

A. Collateral Damage: Difficulties in Applying Articles 101 and 102

As mentioned above, the European Commission has at times relied on both Article 101 and Article 102 to pursue value transfer settlements. Each approach presents its own difficulties.

When using Article 101, the main difficulty comes from determining whether generic companies can be seen as “potential competitors” as long as the patent at stake is valid. Traditionally, firms that are barred from entering a market because of the presence of a valid patent have not been seen as potential competitors in this market. Since a patent is presumed valid until it is voided by a competent authority, a generic challenger which settles with the patent-owner cannot then be seen as a potential entrant since, if there is indeed infringement, at the time of the agreement entry could only occur in violation of the patent. In a sense, then, the traditional view of a patent as being either “on” or “out” is mirrored by a dichotomous assessment of potential competition as “on” if entry does not violate a “on” patent and “off” if it does. This suggests that the pursuit of PFD cases under Article 101 requires a redefinition of the notion of potential entry to fit the probabilistic theory of harm: if patents are thought to be probabilistic, then it would also make sense to consider potential entry as a probabilistic concept. In that view, a generic entrant would still be seen as a potential competitor if there is a sufficiently high probability that it would actually prevail in litigation and therefore be able to enter the market. An interesting implication of this view would be that Article 101 could only be applied if there was sufficient evidence that the patent at stake is weak. However, the European Commission has carefully avoided any reference to the strength of the patents involved in PFD deals and has certainly not presented any evidence suggesting that those patents were weak. In my opinion, this is inconsistent with the need to redefine the notion of potential entrant in a probabilistic manner that fits the probabilistic nature of the Commission’s theory of harm.

The use of Article 102 raises two main issues. The first one is the traditional unease that some observers feel when abuse of dominance is used to get at an *agreement* between willing parties. The second relates to the manner in which dominance is established. We do not need to discuss here the general issue of how one assesses market power and dominance in “high sunk cost” industries such as pharmaceuticals, since this is not specific to value transfer settlements. However, the Commission’s approach to dominance seems, as mentioned above, to be tailored to the specific abuse that it pursues. In a nutshell, the Commission considers that the fact that generic production of a given medication leads to a collapse in the price of the drug, while generic entry into

drugs that are good therapeutic substitutes does not, is evidence that, for the type of abuse considered, each drug is a market onto itself, regardless of how many close therapeutic substitutes are available. This seems to boil down to saying that any patent-holder who is the sole supplier of a drug that sells for a price that is substantially higher than its variable cost of production will be found to be dominant. In practice, that implies that, in the context of alleged abuses regarding generic entry, the vast majority of existing drugs confer dominance on the relevant patent-holder.

The Commission's approach raises two main issues. Firstly, should dominance be assessed solely in terms of price behavior? Given that, in most health systems, doctors and patients have little incentive to consider the price of the medicines that they prescribe or use, the fact that a decrease in the price of a drug has little effect on the price or sales of another drug that is a close therapeutic substitute is hardly surprising. However, under European law, dominance is defined broadly as the ability to behave to a substantial extent independently from other firms and consumers. This definition seems to imply that all forms of competition should matter. In particular there is intense rivalry between therapeutic substitutes in terms of "share of voice" (i.e. medical profession advocacy), experimental studies and research. Disregarding these dimensions of competition to narrowly focus on a price rivalry that is inhibited by the rules of the health system seems hard to justify.

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Secondly, finding a drug dominant whenever generic entry would lead to a substantial decrease in price amounts to evaluating the market power of the drug compared to a competitive benchmark where prices are equal to marginal (or at least variable) costs. This makes no sense in an industry with high sunk costs. In such industries, a much more natural competitive benchmark is the price at which the drug manufacturer breaks even over the lifetime of the product. Such a benchmark at least ensures that a firm producing a drug that does not even recover its initial R&D expenditure is not found "dominant" and hence endowed with the special responsibility that comes with dominance. Establishing dominance based on ex post marginal cost pricing makes a mockery of the whole intellectual property bargain whereby patent protection aims at rewarding inventors and hence at insuring that, on average at least, they can at a minimum recover their initial investment.

B. A Broader Policy View

It is also interesting to ask what the likely impact of banning value-transfer settlements might be. We have already discussed what the potential effect on innovation might be. We now turn to the likely effect on settlements and a potential effect on the behaviour of generics companies.

After completing its review of the pharmaceutical sector in 2008, in which it indicated that it saw value transfer settlements as potentially problematic, the Commission decided to keep track of pharmaceutical settlements, classifying them in three categories (see table). The Commission concluded, with some satisfaction,

that the proportion of settlements that imposed no restrictions on generic entry had increased. Moreover the proportion of cases that limited generic entry but without transfer payment increased compared to cases where entry was restricted and transfer payments were made.

The Commission concluded that its negative stance on value transfer settlements had not made it more difficult for firms to settle and had been effective in reducing the occurrence of the objectionable kind of settlement. The first point is of course not correct: the fact that there is still a large number of settlements tell

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us nothing, without any information on the population of actual and potential litigation cases that these numbers refer to. As for the second conclusion, there is a bit of a sleight of hand. First, cases of settlements without limit on generic entry are almost all cases where the patent-holder had already essentially lost the case because of adverse preliminary rulings. Second—and most interestingly—every single case in the category involves a settlement where the generic entry was delayed *until the end of the period of patent protection*. In other words, over four years and more than 400 settlements, there was not a single example of the type of settlement where generic entry is allowed at a date that is supposed to reflect the parties' appraisal of their respective chances at trial.

Table 1: Type of Pharmaceutical Patent Litigation Settlement Before and After the European Commission's Sectoral Inquiry

	Total settlements	Settlements, by type		
		No limit on generic entry (A type)	Generic entry restricted, but no value transfer from originator to generic (B.I type)	Generic entry restricted, value transfer from originator to generic (B.II type)
Jan 2000 to June 2008 (Inquiry)	207	104 (50%)	54 (26%)	46 (22%)
Jul 2008 to Dec 2009	93	53 (57%)	31* (33%)	9 (10%)
Jan 2010 to Dec 2010	89	54 (61%)	32* (36%)	3 (3%)
Jan 2011 to Dec 2011	120	84 (70%)	23* (19%)	13 (11%)

This raises two questions. Firstly, where are the welfare benefits from the Commission’s expressed negative view of value transfer settlements then? Have private parties just gotten cleverer without any benefit for consumers? Secondly, does this raise a question about how appropriate the counterfactual used in the “Shapiro” theory of harm? The counterfactual where parties agree on an entry date that reflects the strength of the patent is a fine theoretical benchmark, but is it a useful policy benchmark if it is never observed?

IV. THE SUPREME COURT *ACTAVIS* DECISION

One of the very few things that are clear in the recent Supreme Court Decision is that the Court could not follow an extreme “scope of the patent” approach that would have made impossible to guard against disguised “market sharing agreement. However, the Court failed to identify clear reasons why PFD might be considered to be anticompetitive. For example, while the Court recognises that patents need to be further tested in Court, it fails to explain why this might imply that some patent settlements are lawful while others are not. It seems also clear that the Supreme Court did not embrace the extreme “probabilistic patent” approach. While the Court clearly sees patents as probabilistic in our “Level 1” sense and points out that reverse payments are puzzling, there are no references to the probabilistic benchmark (our “Level 3”) according to which consumers should get at least the level of welfare that they would expect from continued litigation. Overall, then, the Court appears to have opted—not surprisingly—for a very traditional approach: the enforcement of IPRs, including settlements, is not a matter for patent law only (even if it allows for antitrust considerations) but is potentially fair game for antitrust authorities. It does not mean that enforcement will be simple however as the Court acknowledges that agreements that include reverse payments cannot be seen as “presumptively unlawful.” Interestingly, the Court seems to recognize the importance of patent strength in establishing whether or not an agreement is lawful under a rule of reason, going as far as pointing out that the relationship between the size of the payment and the implied strength of the patent would be one of several pieces of information that would make a detailed analysis of patent validity unnecessary.

THE COMMON DENOMINATOR OF THE COURT’S CONCERNS IS THAT THEY ARISE MOSTLY WHEN THERE ARE REASONS TO BELIEVE THAT THE PATENTS UNDER LITIGATION WOULD BE LIKELY TO BE OVERTURNED IF LITIGATION PROCEEDED TO THE DIRE END. IN THAT SENSE, THE *ACTAVIS* DECISION SEEMS TO BE AT ODDS WITH THE APPROACH OF REGULATORS LIKE THE EUROPEAN COMMISSION WHO HAVE GONE TO GREAT LENGTH TO KEEP THE NOTION OF “PATENT STRENGTH” OUT OF THEIR LINE OF ARGUMENT.

Clearly, then, the Court condoned neither an impervious “scope of the patent” approach nor an extreme “probabilistic” view. In this sense, the decision is compatible with our previous discussion as neither of these views is a realistic basis for effective policy. The first one ignores the real concerns that patent settlement agreements can support market-sharing deals and the second one is both too extreme in its logical implications for other aspects of licensing behaviour and would be basically impossible to implement in all but the simplest cases. One could however interpret the Court’s current position in light of the two theories of harm that we have discussed. In terms of the first theory, the Court sees the need to ensure the review of patents, especially when these are likely to be weak. In terms of the second theory of harm, the Court seems to be most concerned

by the fact that PFD settlements could be used to preserve the unjustified monopoly rents of a weak patent. The common denominator of the Court's concerns is that they arise mostly when there are reasons to believe that the patents under litigation would be likely to be overturned if litigation proceeded to the dire end. In that sense, the *Actavis* decision seems to be at odds with the approach of regulators like the European Commission who have gone to great length to keep the notion of "patent strength" out of their line of argument.

Unfortunately, the *Actavis* decision does not tell us much more than that. The decision is particularly obscure in terms of burden of proof. While most of the language suggests that the burden of proof is essentially on the FTC, the Court also seems to leave the door open to a claim that a very large reverse payment would itself be presumptive evidence that would then need to be refuted by the defendant. Furthermore, if one were to actually read the decision as establishing a "rule of reason" approach, there is very little guidance as to the type of evidence that "reason" should look at. The decision is particularly ambiguous as to the role of patent "strength." Is the demonstration that the patent could reasonably have been seen as strong at the time of the agreement always a legitimate defence or is it trumped anyway if the transfer from the patent-holder to the generic is judged to be "unreasonably" large anyway?

Overall then, even though the reasons for disagreement between value transfer "hawks" and value transfer "doves" are by now fairly clear, I fear that the *Actavis* decision has done little to bring about a quick resolution of the PFD debate.

V. CONCLUSION

Competition authorities have relied on two main theories of harm to pursue PFD settlements. The first theory states that such settlements unduly prevent the patents at stake from being properly re-evaluated by a Court. The main weakness of this theory of harm is that it fails to explain why PFD settlements should be seen as less desirable as any other type of patent settlement. The second theory of harm relies on the view of patents as probabilistic property rights. This theory of harm has two anchors. The first one is the claim that the holder of a probabilistic right should ensure that consumers enjoy a level of welfare that is at least as high as the level that they would expect from the completion of patent litigation. The second anchor is the analytical result proposed by Carl Shapiro which shows that, under some conditions, the mere presence of a transfer from licensor to licensee that exceeds the expected litigation costs of the licensor is sufficient to establish that consumers lose from the settlement. While this theory of harm is worth taking seriously, it has a number of weaknesses, including inconsistencies between the probabilistic view and traditional antitrust treatment of licensing, the fact that it cannot be applied to more complex agreements where payments are accompanied by immediate generic entry and the identification of the sources of uncertainty that are properly reflected in the "probabilistic" nature of the patent rights. The overall effect of policies banning PFD settlements on innovation is also a concern.

Turning to the ongoing investigation of PFD agreements in Europe, I briefly discuss three sources of controversy. The first issue is what the proper definition of a "potential entrant" should become when one considers the patent rights themselves to be probabilistic. I argue that the logical approach would be to adopt a probabilistic definition of potential entry itself but that this also implies that only settlement of litigation relating to patents thought to be weak should be a concern. The second issue is the approach currently taken to determine dominance in PFD cases. I argue that this approach not only relies on the wrong competitive benchmark but it simply ignores the strong competitive constraints that therapeutic substitutes exercise on each other through

non-price channels. Finally, tracking the evolution of settlements since the European Commission's review of the pharmaceutical sector—where doubts about the legality of PFD settlements were first expressed—shows that the kind of settlement where firms agree on a date of generic entry without side payments actually do not arise. Since this type of settlement is the benchmark compared to which PDF agreements are thought to be abusive, this raises questions about the very foundations of the Commission's theory of harm.

Finally we argue that the recent *Actavis* decision does not support either a pure “scope if the patent” approach or a pure “probabilistic patent” approach. Rather it seems to attempt to strike for a middle ground where the strength of the patents at stake would be an important element of the competitive approval of PFD settlements.▲

1. CRA and Imperial College. This paper reflects the opinions of the authors, not those of CRA. The authors has been representing patent-owners in European litigation.
2. Contrary to what is sometimes stated, this theory of harm is not contingent on the “quality” of the patent system: even in the best possible system, it is optimal to limit the resources devoted to the review of patent applications and let further administrative or judicial processes refine the review of patents that prove to be sufficiently controversial and/or important to be the object of post-grant challenges. Of course, the expected *level* of harm depends on how much the system relies on such ex post mechanisms and hence on the initial quality of patent review.
3. C. Shapiro, 2003, “Antitrust Limits to Patent Settlements”, *Rand Journal of Economics*, 34:2, pp. 391 – 411.
4. Ayres, I. and P. Klemperer, 1999, “Limiting Patentee's Market Power Without Reducing Innovation Incentives: The Perverse Benefits of Uncertainty and Non-Injunctive Remedies”, *Michigan Law Review*, 97:4, pp. 985 – 1033.
5. Gilbert, R.J. and C. Shapiro, 1990, “Optimal Patent Length and Breadth”, *Rand Journal of Economics*, 21:1, pp. 106 – 112.
6. One can take the view that the Level 3 interpretation of probabilistic patents is indeed a consequence of level 2. It is *because* probabilistic patents might be part of an optimal patent system that it is important to hold companies to that standard. This of course assumes that the current patent system was indeed build in accordance with what economic theory tells us about the role of such a probabilistic dimension.
7. The possibility of bankruptcy tends to make firms behave in a more “risk-loving manner”.
8. The analysis supporting this statement can be found in the working paper version of this article, P. Régibeau, “Pay for Delay: What Do We Disagree On?”, SSRN Working Paper #2368220
9. The formal analysis underlying this point can be found in the working paper version of this article. See footnote 7.
10. A formal analysis of this point is available in the working paper version of this article. See Footnote 7.