The earlier the better? Assessing early entry agreements in the pharmaceutical sector

Alexandre Carbonnel[*] and Connie Lee[†]

PRELIMINARY DRAFT

Abstract

Agreements between originator companies and generic companies regarding generic entry are common in the pharmaceutical industry. Although antitrust scrutiny has so far mainly concerned reverse payment settlements arising in the context of patent disputes, recent research shows that even agreements allowing for early generic entry may, under specific circumstances, harm consumers. We discuss relevant factors for assessing the incentives of originators and generics to reach an early entry agreement and their effects on consumers. We also highlight the antitrust risk associated with early entry agreements and the theories of harm that may be defined in this context.

1. Introduction

1. Originator companies regularly conclude agreements with generic companies allowing for generic entry in the market. The European Commission's sector enquiry ("Sector enquiry") shows that these agreements may arise outside patent disputes and before patent expiry ("Early entry agreements"). The Sector enquiry highlights the strategic incentives of originators to accommodate entry before the loss of exclusivity and in particular the originators' ability to manage the impact of generic entry on competition or to react to the presence of generics in the market.[1] Early entry agreements may take different forms, but commonly involve the supply of the drug to the generic company, the distribution of the drug or the granting of a license or a marketing authorization by the originator.[2] They mainly arise less than one year before patent expiry, but they may also start earlier.[3] Although some Early entry agreements only last for a few months, they sometimes last for years and in particular continue after patent expiry.[4]

2. A naïve view would be to consider that Early entry agreements are procompetitive because they allow generics to enter the market and compete with the branded drug, hence driving prices down. Drawing upon some recent findings from the literature, we show in this paper that the effects of Early entry agreements on consumers are a priori more ambiguous than it may seem at first sight. We identify some relevant factors for the assessment of the parties' incentives to conclude an Early entry agreement and its effect on consumers. We also discuss some theories of harm that may be relevant with respect to Early entry agreements. We show that they may have a direct negative effect on competition if they are designed in a way that weakens the

[*] Associate Director, NERA Economic Consulting.

[†] Economic Analyst, NERA Economic Consulting.

[1] Sector enquiry, para. 809.

[2] *Ibid*. para. 840.

[3] *Ibid*. para. 816.

[4] *Ibid*. paras. 824 and 825.

In the context of licensing agreements, the CJEU confirmed, in response to the question posed by the Paris Court of Appeal in *Genentech Inc. v Hoechst and Sanofi-Aventis*, that a licensee could be obliged to pay royalties even after the patent expires or is declared invalid or non-infringed as long as the licensee may terminate the agreement upon reasonable notice. See: CJUE, 7 July 2016, *Genentech Inc. v Hoechst and Sanofi-Aventis*, Case C-567/14, ECLI:EU:C:2016:526.

competitive constraint exercised by generics. They may also have an indirect negative effect on competition if they prevent further entry or facilitate anticompetitive strategies from the originator. These results point up the antitrust risks that might arise with Early entry agreements and provide a framework for assessing them.

3. Early entry agreements have received much less scrutiny from competition authorities in Europe than agreements arising in the context of patent disputes, in particular when they involve substantial value transfers from the originator to the generic and lead to delayed generic entry ("reverse payment settlements"). Contrary to Early entry agreements, reverse payment settlements have given rise to an extensive literature on the topic, aiming to determine whether and under what conditions reverse payment settlements harm consumers.[5] Their evaluation is complex because they generally do not consist of a naked cash payment but have different components, sometimes including a supply or licensing agreement as a side deal.[6] In this case, competition authorities have assessed the potential restrictions of competition associated with the agreement to determine their effects on consumers.

4. The agreements that we consider in this paper differ from reverse payment settlements for several reasons. First, we do not focus exclusively on agreements arising as part of patent disputes. Early entry agreements as defined in this paper may be concluded under the threat of potential litigation before patent expiry, but this is not a necessary condition. Second, whereas reverse payment settlements may delay generic entry beyond the expected entry date had litigation taken place, we define Early entry agreements as agreements implying entry before the patent expiry date or, if litigation is a credible threat, before the expected entry date. Third, reverse payment settlements typically include a lump sum transfer from the originator to the generic, for instance in the form of cash, stock purchases or marketing deals, which may incentivize the generic to delay its entry.[7] In this paper, we only consider agreements that are limited to the supply, distribution or licensing of the drug.

5. The differences between the characteristics of Early entry agreements and reverse payment settlements have repercussions on the incentives of originator companies and generic companies to reach an agreement. Therefore, Early entry agreements give rise to specific theories of harm that we discuss in this paper.

2. The incentives of originators and generics to conclude Early entry agreements

6. Both originators and generics may have an incentive to conclude Early entry agreements. For the originator, it is an attractive option when there is a significant risk of independent generic entry, either upon patent expiry or following litigation, because it may allow the originator to control the impact of generic entry on its profit through the agreement. Although the originator may sacrifice profit by accepting generic entry, it may still be better off than under independent generic entry. Moreover, the Sector enquiry shows that originators use Early entry agreements in particular when they are not the market leader, which suggests that they may rely on these agreements to reinforce their market power.[8] An originator may also increase its presence on a

[5] See for instance Shapiro (2003), Willig and Bigelow (2004), Dickey *et al.* (2010), Elhauge and Kruger (2012) and Meunier and Padilla (2016).

[6] See Athanasiadou (2020).

[7] In a recent litigation case before the U.S. District Court for the Northern District of Illinois involving Abbvie, the manufacturer of Humira (adalimumab), Early entry agreements were considered as different from reverse payment settlements because they *"allow for early entry without a payment"* instead of *"paying a competitor to stay out of the market"*. See: US District Court for the Northern District of Illinois, 8 June 2020, *Humira*, No. 19 CV 1873.

This approach was confirmed in appeal by the Seventh Circuit. See: http://media.ca7.uscourts.gov/cgi-bin/rssExec.pl?Submit=Display&Path=Y2022/D08-01/C:20-2402:J:Easterbrook:aut:T:fnOp:N:2911279:S:0.

[8] Sector enquiry, para. 813.

geographical level by reaching agreements with generic companies that have a better knowledge of specific local markets.[9] For a generic, the incentive to accept an Early entry agreement may be particularly strong when it is the first one to enter the market because it allows it to capture a substantial market share before facing competition from other generic entrants. Furthermore, originators and generics may prefer an Early entry agreement to litigation because of the uncertainty associated with litigation.

7. There are, however, trade-offs for both the originator and the generics. The originator balances the profit sacrifice in the short term due to early entry with the additional profit generated by the agreement in the long term in comparison with independent generic entry. Symmetrically, for the generics, the additional profit generated by early entry must be put in perspective with the potentially lower profit than under independent entry in the long term, for instance if the agreement implies higher production or distribution costs.

8. This shows that the incentive of originators and generics to accept an Early entry agreement must be assessed on a case-by-case basis. When the originator and the generic believe that litigation may arise prior to patent expiry in the absence of the Early entry agreement, parameters such as the patent strength[10], the magnitude of litigation costs or risk aversion[11] are relevant to evaluate the incentives of the parties to conclude an Early entry agreement. The literature on reverse payment settlements provides insights on the effects of these parameters on the incentives of the firms to reach an agreement when litigation is the counterfactual outcome.[12]

9. In a more general setting, several other parameters must be considered to assess the incentives of originators and generics to accept an Early entry agreement:

    a. The length of the agreement: for an originator, a long-term agreement may be attractive to the extent that it maintains control over the competitive constraint exercised by generics, for instance because it imposes minimum amounts to be purchased by the generic from the originator or non-challenge clauses regarding patent validity. For a generic, the longer the agreement, the higher the risk that independent generic entry occurs. Unless the terms of the Early entry agreement are revised upon entry by a competitor[13], this harms the competitiveness of the generic.

    b. The existence of an exclusivity clause: exclusivity may either apply to the originator, for instance if it agrees not to license to other generics (exclusive licensing), or to generics (exclusive distribution or exclusive sourcing). Exclusivity makes the Early entry agreement less attractive for the firm bound to it. For instance, exclusive sourcing is likely to be preferred by the originator than by a generic because exclusivity prevents the generics from dealing with cheaper suppliers, which would increase the competitive constraint on the originator.

[9] Sector enquiry, para.839.

[10] Patent strength may be measured according to the probability that a patent is held valid or infringed. The number of patents related to a drug is also relevant. For instance, biologics are often complex and protected by several patents, which makes litigation more uncertain for potential entrants.

[11] In theory, risk aversion is a relevant factor, but it is difficult to measure and therefore economists are still undecided on its importance. With respect to the originator, shareholders may be able to diversify their activities and therefore be risk neutral. However, one may consider the potential risk aversion of individual decision-makers within the firm. Dickey *et al.* (2010) and Willig and Bigelow (2004) argue that the originator's employees may be risk averse, which justifies considering risk aversion from the originator. Elhauge and Krueger (2012) argue otherwise and assert that, even in case of risk aversion from the firm's managers, this does not make settlements with reverse payments potentially procompetitive. With respect to the generic, risk aversion may arise in the case of small firms that do not have a broad portfolio of drugs.

[12] See sources in para. 3.

[13] See Sector enquiry, para. 822.

c. The expected generics penetration rate: for the originator, a high expected penetration rate of generics may increase the attractiveness of Early entry agreements to limit the competitive constraint exercised by generics. For a generic, a high expected penetration rate increases its profit under independent entry, and therefore its bargaining power when negotiating the Early entry agreement with the originator.

d. The number of potential entrants: if the originator expects entry by several generics, it may increase its incentive to conclude Early entry agreements to mitigate the impact on competition, in particular under of threat of patent invalidation because litigation may pave the way for entry by several generics. As a result, the originator may be willing to make concessions when negotiating an Early entry agreement. For a generic, the prospect of entry by other generics lowers its expected profit under independent entry, and therefore its bargaining power. Furthermore, the perspective of intense competition also affects the generics' incentive to litigate in the context of patent invalidation because each generic internalizes potential free riding by other generics firms following a successful patent challenge. In this context, the literature emphasizes the incentive that each entrant may have to play a waiting game and let other firms litigate with the incumbent to invalidate a patent.[14]

3. The effects of Early entry agreements on consumers

10. Assessing the effects of an Early entry agreement on consumers is a complex task requiring a detailed review of the characteristics of the agreement and its implications on competition between the originator and generics. We discuss below several factors that must be considered as well as the potential theories of harm that may arise. We highlight the consequences of Early entry agreements beyond the competitive interactions between the parties, in particular when they affect the originator's strategies with respect to other generics.

3.1. Relevant factors for assessing Early entry agreements

11. Early entry agreements must be evaluated by considering both the time dimension (entry date) and the value dimension (agreement terms). With respect to the time dimension, the entry date under the agreement must be compared to the counterfactual entry date, which depends on whether litigation would arise in the absence of the Early entry agreement. The value dimension is also relevant because, depending on the type of agreement, it impacts generics prices and sales volumes. For instance, an Early entry agreement allowing a generic to enter much earlier than in the counterfactual scenario may not benefit consumers if it maintains limited competition between the originator and generics.

12. Different factors may affect the negotiated entry date and agreement terms and, hence, the likelihood that it is procompetitive. Some of them, which we listed in Section 2, are not specific to Early entry agreements and already discussed in the literature on reverse payment settlements. This is the case of litigation costs, patent strength and risk aversion, which matter when firms would litigate in the absence of an agreement.[15] An agreement is more likely to be procompetitive if the originator faces high litigation costs or has a weak patent[16] because it lowers the originators' counterfactual profit and hence its bargaining power when negotiating

[14] For instance, Choi (1998) shows that, depending on the patent strength, an originator facing potential entry by two generics may decide to litigate with the first entrant. In this case, each generic prefers to free ride by waiting and letting the other generic incur the litigation costs.

[15] See sources in para. 3.

[16] In the context of private information on patent strength, the characteristics of the agreement that a firm is willing to accept may act as a signal regarding patent strength for the other firm. For instance, if the originator is willing to accept an unfavourable agreement, this may suggest to the generic that the patent is weak and that its probability to win litigation is high.

with a generic. Similarly, risk aversion from the originator increases its preference for an agreement and makes it more likely to be procompetitive.

13. The number of potential generic entrants has an a priori ambiguous effect on consumers, in particular when firms negotiate in the shadow of litigation. On the one hand, we explained in Section 2 that the originator may be more willing to accept an Early entry agreement when facing entry by several generics. On the other hand, the coordination issue between generics makes litigation uncertain. Even a weak patent may be sufficient to deter a challenge by a generic firm, thereby making entry a non-credible threat. As a result, it is unclear whether, when this is anticipated by both the originator and the litigating generic, multiple entry increases the likelihood of a procompetitive agreement.

14. The length of the Early entry agreement and potential exclusivity clauses also matter from the perspective of consumers. An agreement lasting long beyond the counterfactual entry date[17] or requiring exclusivity from the generic may harm consumers by restricting competition.

15. Finally, in the case of licensing agreements, the literature highlights the impact of the scheme on consumers. More specifically, a well-known result is that fixed fees are preferable to royalties from the perspective of consumers when licensees sell homogenous products, which is the case of generics, and firms compete in quantities. This is because production is higher with a fixed fee than with a royalty. This result holds whether the patentholder is an outsider in the industry (Kamien and Tauman (1986)) or an insider (Wang (1998)).[18] Fixed fees are also superior to per-unit royalties when licensees sell differentiated products and compete in prices (Muto 1993)). Although the literature focuses on the licensing of cost-reducing innovations, these results may also be relevant in the context of generic entry since this corresponds to the launch of a cheaper version of the originator's drug, which means that the implications for consumers are similar.

3.2. Potential theories of harm

16. Although Early entry agreements may benefit consumers, they may also harm them if they restrict competition by limiting the generics' competitiveness. To understand why this may be the case, it is useful to recall that the originator does not seek to maximize the profit generated by the agreement but rather the sum of the profit generated by both the agreement and the sales of the branded drug. Therefore, the originator cares not only about the sales of generics in the context of the agreement but also about the degree of competition exercised by generics on the originator's drug and the extent to which generic sales cannibalize the originator's drug sales.

17. There are two sources of concerns associated with Early entry agreements: they may weaken the competitive constraint from generics despite allowing for entry and they may prevent more competitive outcomes, such as litigation if the entry threat is credible, or facilitate the exclusion of certain potential entrants.

18. In this section, we discuss reasons why Early entry agreements might harm consumers:

    a. They may soften competition from generics if they allow the originator to raise generics cost.

    b. In markets of intermediate size, the originator may use Early entry agreements to strategically limit generic entry in the market.

[17] According to the Sector enquiry (para. 817), some agreements are concluded for an undetermined period of time.

[18] A similar conclusion holds in the case of differentiated products (Wang (2002)) but may not hold in a more general context. For instance, Lin (2022) shows that royalties may prevent the risk of exclusion of downstream firms through exclusive dealing in the context of vertical relationships.

c. The originator may propose Early entry agreements to a subset of generics in order to decrease the cost of reverse payment settlements with other potential entrants.

3.2.1. Softening generic competition

19. By concluding an Early entry agreement with a generic, an originator faces the risk of intense competition from a close competitor. Therefore, its incentive from a profit-maximizing perspective is to design the Early entry agreement to minimize the impact of generic entry on competition. The originator may achieve this objective in different ways, such as raising the price of the active substance sold to generics to increase their production cost or restricting the volume sold to generics.

20. The potential competition softening effect induced by an agreement between a patentholder and licensees has been extensively studied in the literature. In a licensing context, Amir et al. (2014) show that the patentholder may, under mild conditions, increase the royalty level to relax competition with licensees. The incentive of patentholders to soften competition by increasing the marginal cost of licensees means that patentholders prefer contracts based on royalties or, more generally, two-part tariffs to fixed fees.[19] Hernandez-Murillo and Llobet (2006) show that the effect of the contract type on competition is more significant when licensees produce homogenous goods, which is the case of generics. Furthermore, Fauli-Oller and Sandonis (2002) explain that, when firms compete in prices, the patentholder strategically commits to be less aggressive and raise its own prices when increasing the licensees' marginal cost.

21. If an Early entry agreement softens competition for the reasons exposed above, its duration is relevant to assess the implications for consumers. This is because, as explained in Section 3.1, both the time dimension and the value dimension matter from the perspective of consumers. The benefits associated with early entry must be balanced with the potentially weak competitive constraint exercised by generics throughout the duration of the agreement. This trade-off is in particular relevant if the agreement lasts beyond the patent expiry date. Therefore, if an agreement softens competition because it increases the cost for generics, the longer its duration, the more likely it harms consumers.

3.2.2. Limiting generic entry

22. A recent paper by Montez and Marxen (2020) focuses on Early entry agreements in the pharmaceutical sector arising slightly before patent expiry when there are no generics in the market, which is a common feature of many Early entry agreements. They consider the effects of Early entry agreements on consumers in markets of intermediate size in which only one generic can profitably enter. In a market with one originator and two potential generic entrants, each generic concludes an Early entry agreement with the originator at the patent cliff or enters following patent expiry.[20] Since the market is assumed to be too small to accommodate two generics because of the entry cost faced by each generic, an Early entry agreement deters entry by the second generic.

23. From the perspective of the originator, there is a trade-off between sacrificing profit by accepting early entry and risking more intense competition in case of simultaneous entry by both generics after patent expiry. Montez and Marxen (2020) show that Early entry agreements arise when the entry cost is low or if the entry process is short since entry would in this case most likely occur quickly after patent expiry. However, this is precisely when Early entry agreements hurt consumers. Therefore, they conclude that these agreements harm consumers.

[19] See for instance Filippini (2005), Wang (1998) and Wang (2002).

[20] The reason why agreements do not arise in Montez and Marxen before the patent is about to expire is because they ignore the threat of litigation.

3.2.3. Decreasing the cost of reverse payment settlements

24. Reverse payment settlements have been extensively discussed in the literature, in particular from the perspective of the relevant factors to consider when assessing whether a settlement delays generic entry and harms consumers. Although there are debates on the appropriate framework for evaluating reverse payment settlements, most authors consider that, in the absence of a reverse payment settlement, litigation would take place. This means that, in the counterfactual scenario, independent entry occurs with a certain probability corresponding to the probability that the patent is invalid or non-infringed.

25. This ignores the possibility offered to originators and generics to conclude an Early entry agreement, such as a standard licensing or supply agreement. Broadening the range of counterfactual strategies beyond litigation not only provides a more realistic picture of the interactions between originators and generics but also sheds a new light on the implications of Early entry agreements for consumers. Palikot and Pietola (2022) show that, in a setting with an originator facing potential simultaneous entry by several generics, the originator may strategically use licensing agreements[21] to exclude some entrants from the market. In their paper, each generic may either litigate, agree to stay out of the market in exchange for reverse payment, conclude a licensing agreement or wait for the patent to be potentially invalidated if another generic litigates. They show that, for a certain type of reverse payment settlement[22], the outcome of the negotiation between the originator and generics depends on the patent strength and the litigation costs:

    a. When the patent is strong, the originator either litigates if litigation costs are low or concludes reverse payment settlements if litigation costs are high. Reverse payment settlements are less costly than licensing agreements, and hence preferred, because generics accept small transfers reflecting their small probability of winning in court.

    b. When the patent strength is uncertain or weak, the originator either litigates if litigation costs are low or grants licenses if litigation costs are high. Reverse payment settlements are too costly for the originator because generics are likely to win if the dispute goes to court. Therefore, this is when the originator prefers licensing. Although it accommodates entry, it saves litigation costs and allows the originator to manage competition from generics through the licensing agreement.

    c. Finally, for intermediate patents, the strategy implemented by the originator varies depending on the generic firm. In this case, proposing reverse payment settlements to all generics is too costly and granting licenses to all generics is also not optimal for the originator because generics do not have a high probability of winning in court. The originator instead prefers to either litigate with a generic if litigation costs are low, or license to a subset of generics and conclude reverse payment settlements with others. This type of strategy, known as "divide-and-conquer" in the literature, minimizes the consequences of potential entry for the originator. Contrary to the case of weak patents, licensing has here an anticompetitive motive because it is used to lower the cost of excluding other entrants through reverse payment settlements.[23]

[21] In their static baseline model, licensing cannot be categorized as an Early entry agreement in the absence of a time dimension. Palikot and Pietola (2022) also consider a dynamic model as an extension, in which case licensing occurs at the date when litigation would end, which is strictly earlier than the expected entry date under litigation unless the generic is certain to win in court.

[22] More specifically, this applies to simple reverse payment settlements, which do not allow generics to enter after the patent is invalidated, as opposed to conditional reverse payment settlements.

[23] The idea that an originator may facilitate entry by a generic through licensing to deter further entry is also central in Bokhari *et al.* (2020), in the context of the Hatch-Waxman Act in the US. They explain that an originator may choose to grant a licence to the first potential entrant or launch its own generic to take away the first mover advantage and reduce the incentives of other generics to enter the market. The originator faces a trade-off by facilitating entry, as it gets the profit made by the

26. These results from Palikot and Pietola (2022) provide some interesting policy implications. In particular, the originator may use licensing in combination with reverse payment settlements to mitigate the competitive constraint from generics. Therefore, these results suggest that enforcement efforts targeting reverse payment settlements should in particular focus on patents that are sufficiently strong to make potentially anticompetitive strategies involving Early entry agreements credible.

27. Their paper does not, however, take into consideration the potential coordination problem between generics regarding litigation, which arises when there are several potential entrants (see Section 2). [24] If litigation is a weakly credible threat because each generic believes that other generics will free ride, the originator may be able to exclude generics through reverse payment settlements, which would restrict the scope for licensing agreements.

28. Furthermore, the originator's strategy may be different if generics enter sequentially as opposed to simultaneously because this affects the cost of excluding each generic. In a scenario where the litigation threat is credible, the originator may prefer licensing agreements for early entrants when reverse payment settlements are too costly, that is when the degree of competition is low. However, it becomes less costly for the originator to offer reverse payment settlements when there are already generics in the market because the expected litigation profit for the generics is lower. The originator may also strategically prefer to grant licenses to early entrants as part of the same divide-and-conquer strategy observed under simultaneous entry if the originator takes into account the cost of excluding late entrants. Regardless of the reason, this would mean that licensing agreements are more common for early entrants and reverse payment settlements are more common for late entrants.[25]

4. Conclusion

29. Early entry agreements are common in the pharmaceutical sector. They allow the originator to manage the impact of generic entry on competition through the agreement and generics to be among the first entrants, which provides a competitive advantage. Contrary to reverse payment settlements, Early entry agreements have so far received little attention from competition authorities, although recent developments in the economic literature show that they have an a priori ambiguous effect on consumers.

30. We highlighted the relevant factors to consider for assessing the incentives of originators and generics to conclude an Early entry agreement as well as the effects on consumers. The factors relate in particular to the market environment (number of potential entrants, expected generics penetration rate), contract terms (contract length, existence of an exclusivity clause, pricing scheme in the case of licensing agreements) and characteristics of the counterfactual outcome when firms negotiate in the shadow of litigation (litigation costs, risk aversion, patent strength).

31. Although Early entry agreements may be procompetitive, we also described some theories of harm that may apply to Early entry agreements. They may have a direct negative effect on consumers by softening competition from generics. They may also have an indirect effect by deterring entry by other generics or by decreasing the costs of reverse payment settlements with some generics. In this case, Early entry agreements must be evaluated in a broader context to

first generic entrant (either partly through the license fee or entirely if it is an authorised generic) but faces the risk of more intense competition if other generics are not deterred. When the first mover advantage is significant, the originator prefers to accommodate the first entrant to prevent further entry.

[24] Although they mention free riding between generics in their paper, its nature is different. Palikot and Pietola define a free rider as a firm deciding to wait when one generic litigates. Therefore, free riding does not affect the likelihood of litigation by creating a coordination problem between generics as discussed here. It only means that, as long as one entrant litigates, other entrants have an incentive to wait for the court decision.

[25] Since entry is more profitable for early entrants than for late entrants, generics have a clear incentive to be among the first entrants.

account for their effects over the strategy implemented by the originator with respect to generic entry.

Bibliography

Amir, R., Encaoua, D., & Lefouili, Y. (2014). Optimal licensing of uncertain patents in the shadow of litigation. *Games and Economic Behavior, 88*, 320-338.

Athanasiadou, A. (2020). Side-deals as part of pharma patent settlements: a new landscape after Servier and Paroxetine? *European Competition Law Review, 41*(12), 620-630.

Bokhari, F., Mariuzzo, F., & Polanski, A. (2020). Entry limiting agreements: First-mover advantage, authorized generics, and pay-for-delay deals. *Journal of Economics and Management Strategy, 29*, 516-542.

Choi, J. (1998). Patent Litigation as an Information-Transmission Mechanism. *American Economic Review, 88*(5), 1249-1263.

Dickey, B., Orszag, J., & Tyson, L. (2010). An Economic Assessment of Patent Settlements in the Pharmaceutical Industry. *Annals of Health Law, 19*(2), 367-400.

Elhauge, E., & Krueger, A. (2012). Solving the Patent Settlement Puzzle. *Texas Law Review, 91*, 283-330.

European Commission. (2009). *Pharmaceutical Sector Enquiry Final Report.* Retrieved from https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf

Fauli-Oller, R., & Sandonis, J. (2002). Welfare reducing licensing. *Games and Economic Behavior, 41*, 192-205.

Filippini, L. (2005). Licensing Contract in a Stackelberg Model. *The Manchester School, 73*(5), 582-598.

Hernandez-Murillo, R., & Llobet, G. (2006). Patent licensing revisited: Heterogeneous firms and product differentiation. *International Journal of Industrial Organization, 24*, 149-175.

Kamien, M. I., & Tauman, Y. (1986). Fees Versus Royalties and the Private Value of a Patent. *The Quarterly Journal of Economics, 101*(3), 471-492.

Lin, Y.-J. (2022). Consumer welfare, licensing, and exclusive dealing with vertically- and horizontally-differentiated products. *International Review of Economics and Finance, 80*, 147-158.

Marxen, A., & Montez, J. (2020). Licensing at the Patent Cliff and Market Entry. *CEPR Discussion Paper No. DP14276*. Retrieved from https://ssrn.com/abstract=3518617

Meunier, V., & Padilla, J. (2016). Should Reverse Payment Patent Settlements Be Prohibited per se ? *Concurrences, 3*.

Muto, S. (1993). On Licensing Policies in Bertrand Competition. *Games and Economic Behavior, 5*(2), 257-267.

Palikot, E., & Pietola, M. (2022). Pay-for-Delay with Settlement Externalities. *Working paper*. Retrieved from https://www.pietola.com/research/documents/patent2016.pdf

Shapiro, C. (2003). Antitrust limits to patent settlements. *RAND Journal of Economics, 34*(2), 391-411.

Wang, H. (2002). Fee versus royalty licensing in a differentiated Cournot duopoly. *Journal of Economics and Business, 54*, 253-266.

Wang, X. (1998). Fee versus royalty licensing in a Cournot duopoly model. *Economics Letters, 60*, 55-62.

Willig, R. D., & Bigelow, J. P. (2004). Antitrust policy toward agreements that settle patent litigation. *The Antritrust Bulletin, 49*(3), 655-698.