



CRA Insights: Life Sciences

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The economics of patent settlement agreements

The European Commission's Pharmaceutical Sector Inquiry raised significant concerns regarding patent settlement agreements, in particular those involving value transfers from the originator to the generic producers—the so-called *reverse payment* or *pay for delay* settlements.

Charles River Associates has provided economic evaluations regarding the Sector Inquiry and litigation support for reverse payment investigations, including those that were challenged by regulatory agencies and those that were not. This short article describes types of information or economic evidence that might facilitate consideration of the competitive aspects of these settlements.

Patent settlement agreements

When a patent owner and a potential generic entrant disagree regarding whether entry is legal given existing patent protection, the issue can be determined by pursuing litigation or by a settlement agreement between the parties. A settlement may allow the parties to reduce uncertainty and avoid the costs of litigation. However, this gives rise to competition concerns because a settlement agreement might allow the originator to enjoy extended marketing exclusivity, thereby preventing generic entry that would lower prices for payers and create higher short-term surplus to consumers.

Five questions might be useful in determining whether a settlement is beneficial for consumers and tax payers.

Could the agreed date of entry determine whether the settlement harms consumers and taxpayers?

In practice, the terms of patent settlement agreements are expected to reflect the parties' expectations of prevailing in patent litigation (including assessments of the strength of the patent case, the vagaries of litigation and expected litigation costs) and the consequent implications (profits for the innovator and the generic entrant).

Unfortunately, beliefs about the probable outcome of litigation are subjective and not directly observable. Incumbent patent holders are likely to have private information about the strength of their patents and the conditions in their market segment. Generic challengers may be overly optimistic about their chances to win litigation or may lack the financial resources to risk pushing for an earlier entry date. In practice, therefore, it is unlikely that an assessment of the time of entry alone could determine whether a settlement agreement is pro- or anti-competitive.

Does a value transfer in the form of cash compensation determine whether the agreement harms competition?

Agreements of this kind often raise significant concerns. However, payments have a role in facilitating agreements under circumstances that would otherwise hamper or impede a pro-competitive settlement. Cash is certain and both parties equally perceive its value. Accordingly, cash payments could facilitate settlements that would otherwise not be possible due to asymmetries between the generic and the originator. The mere existence of a payment from the originator to the generic producer does not determine whether consumers and taxpayers are harmed.

Does the magnitude of the value transfer matter?

In general, pro-competitive agreements are assumed to involve payments that the originator is willing to make in order to avoid litigation costs and uncertainty. Where payments represent a sharing of profits between a potential generic entrant and the incumbent, we might expect the payment to be higher than otherwise would be the case. However, it is unclear what an excessive payment should be, as it may be related to the unobserved cost of uncertainty for the originator. Thus, the magnitude of the payment may contain information regarding the role of the agreement but a determination of intent would need to take into account the expectations of the parties and their relevant characteristics.

What is the role of other generic entrants?

Other potential entrants affect the consideration of an agreement's competitive effects. If any were not to have an exclusionary effect, successive potential entrants may be able to identify the same business opportunity that led the settling generic producer to first challenge the validity of the patent. Therefore, evidence that other generics could equally challenge the patent may provide supporting evidence that the agreement is a means to resolve litigation costs and uncertainty rather than a payment to delay generic entry.

How should we consider the potential effects on innovation?

Patents are the cornerstone of the system to reward innovation. If the method for resolving disputes artificially favours the early entry of generic competitors or unnecessarily increases uncertainty regarding the protected period, this lowers returns to innovators and will harm innovation. Patent settlements offer the originator an alternative method of resolving uncertainty and may therefore avoid the negative impact on the incentive to innovate that would otherwise exist.

Implications for the role of agreements involving reverse payment

There are circumstances when patent-settlement agreements might be pro-competitive and there are circumstances where there might be concerns from a competition perspective. An assessment of the potential impact on competition needs to be based upon a consideration of the facts and circumstances surrounding the particular agreement.

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