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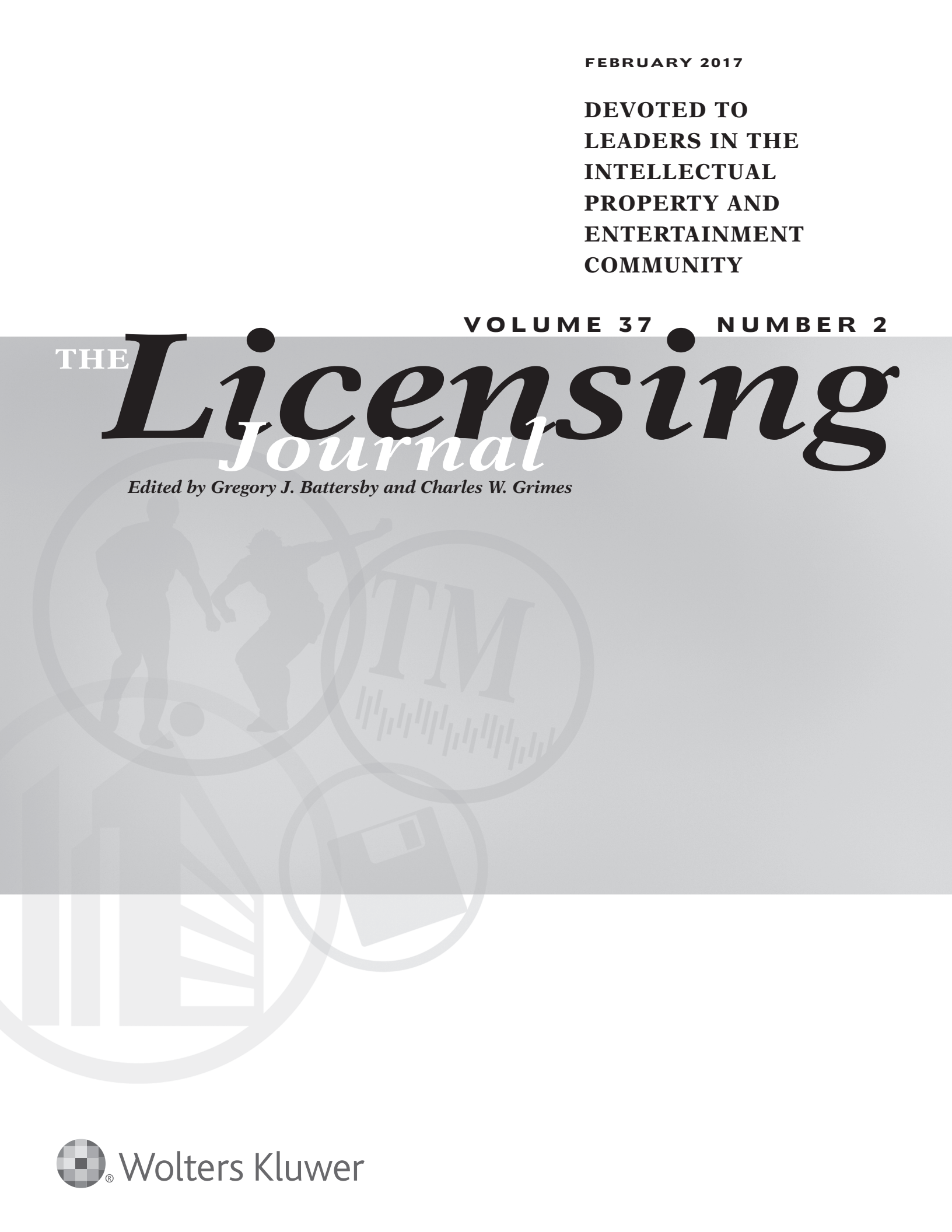

Wolters Kluwer

Praxis

Antitrust

Matthew Hall

Patent Settlements and Antitrust: An Update on the EU Position

Ever since the publication in July 2009 of the report on its antitrust inquiry into the pharmaceutical sector, the European Commission (EC) has been monitoring patent settlement agreements between originator and generic companies in the European Union plus Norway, Iceland, and Liechtenstein, thus making up the European Economic Area (EEA). This monitoring was started because the inquiry identified settlements that limit generic entry and provide at the same time for a value transfer from the originator to the generic company (pay-for-delay) as potentially raising antitrust concerns in the EU/EEA.

On December 13, 2016, the EC's latest report, its seventh, covering calendar year 2015, was published. The headline finding in the report is that, as in previous years, the vast majority of pharmaceutical settlement agreements (some 90 percent this time) are *prima facie* unproblematic in antitrust law terms. The EC says this shows the industry's increased awareness of potentially problematic practices and that companies do not feel hindered from concluding settlements in general.

What are problematic practices in the view of the EC? As set out in its latest report, the EC accepts that settlements (*i.e.*, commercial agreements to settle patent-related disputes such as over questions of patent infringement or validity) are a legitimate way of ending private disagreements. However, certain types of settlements may prove to be problematic from an antitrust law perspective. This analysis is based on two main criteria: (1) whether the agreement includes a limitation on the generic company's ability to market its own medicine; and (2) whether it includes a value transfer from the originator to the generic company.

Agreement Includes a Limitation

In relation to the first issue, a generic company's ability to enter the market can be limited in several ways. The most straightforward limitation occurs when the settlement agreement contains a clause explicitly stating that the generic company will refrain from challenging the validity of the originator company's patent(s) (non-challenge clause) and/or refrains from entering the market until the patent(s) has(ve) expired (non-compete clause). A license granted by the originator company allowing market presence of the generic company also is categorized as limiting generic entry, if the generic company cannot enter the market with its own product or it cannot set the conditions for the commercialization of its product freely (save for royalty-free licenses that allow generic companies to immediately launch their own product without any further constraints). Patent settlement agreements in which the parties agree that the generic company will be a distributor of the originator product concerned or the generic company will source its supplies of the active pharmaceutical ingredient (API) from the originator company, also are seen as limiting entry. The same is true for agreements providing for early entry of a generic medicine where entry is not immediate. This list of potential limitations on entry is, however, not exhaustive.

Agreement Includes a Value Transfer

In relation to the second issue (value transfer), this can take different forms. The most clear-cut is a direct monetary transfer (*e.g.*, payment of a lump sum) from the originator company to the generic company. This, for example, can have the purpose of purchasing an asset (*e.g.*, the generic company's stock of own products), but it also can have the purpose—explicitly or implicitly—of paying the generic company for agreeing to delay the product launch and/or for discontinuing the patent challenge, even in situations when stock is bought at market price. It is considered that originator companies are able to afford such payments, as the settlement allows the company to continue reaping the benefits of selling its product. Other types of value transfer include distribution agreements or a "side-deal" in which the originator company grants a commercial benefit to the generic company, for example by allowing it to enter the market before patent expiry in another geographical area or by allowing market entry with another product marketed by the originator

company. A value transfer also could consist in granting a license to the generic company enabling it to enter the market. Similarly, a non-assert clause, whereby, even without a license, the originator binds itself not to invoke the patent against the generic company, thereby allowing the generic medicine to come onto the market, may technically be perceived as constituting a value transfer. In these cases, the generic gained marketable value as a result of the value transfer. However, an agreement that includes no other limiting provision than determining the date of the generic entry with the originator's undertaking not to challenge such entry (a pure-early entry) is not likely to attract the highest degree of antitrust scrutiny from the EC. Again, this list of possible value transfers is not exhaustive.

Settlements

Settlements that both limit generic entry and include a value transfer from the originator to the generic company are *"likely to attract the highest degree of antitrust scrutiny"* and commonly are referred to by the EC as "Category B.II" settlements. The EC's classification for the purposes of antitrust law analysis in the EU is shown in Exhibit 1.

The EC does accept that even in Category B.II not all agreements are incompatible with EU antitrust law: *"This needs to be assessed on the basis of the circumstances of each individual case."* This is where it gets difficult (and litigious). [*e.g.*, see Competition and Markets Authority, Case No. CE/9531-11, where the CMA investigated certain agreements relating to paroxetine under Chapter I and II of the CA98 and Article 101 of the TFEU. *See https://www.gov.uk/cma-cases/investigation-into-agreements-in-the-pharmaceutical-sector*.] The EC also has investigated various cases and in a very important judgment its views were upheld by the General Court of the European Union (GC) (the European Union's second highest court) in 2016 in the Lundbeck appeal. [*Lundbeck v. Commission*, T-472/13. *See http://curia.europa.eu/jcms/upload/docs/application/pdf/2016-09/cp160090en.pdf*.] This judgment was unsurprisingly welcomed by the EC. The EC commented:

> The [GC] has today fully confirmed the [EC]'s findings. It is the first time that it has ruled on pay-for-delay agreements in the pharmaceutical sector. In particular, it found that:
>
> - The [EC] was correct in finding that, irrespective of any patent dispute, generics competitors agreed with Lundbeck to stay out of the market in return for value transfers and other inducements, which constituted "a buying-off of competition."
> - The [EC] had correctly established that the agreements eliminated the competitive pressure from the generic companies and are "a restriction of competition by object" [i.e. presumptive infringement of EU competition law]. Furthermore, Lundbeck was not able to justify why these particular agreements would have been needed to protect its intellectual property rights." [*See* European Commission Press Release, September 8, 2016 at *http://europa.eu/rapid/press-release_MEMO-16-2994_en.htm*.]

So what did the seventh report find in relation to Category B.II settlements? In the period investigated (2015), Category B.II accounted for 10 percent (13 out of 125) of all agreements (hence 90 percent were not problematic). The value transfer flowing to generic companies in these settlement agreements took different forms, and sometimes in various combinations, of early entry and a license or payment. Of the 13 B.II agreements for the 2015 period, 5 (38 percent) enabled early entry without a license or a distribution agreement, 6 (46 percent) combined early entry with a license to the generic company, 1 (8 percent) only included a license, and 1 (8 percent) included a payment to the generic company to compensate for damages. However, as noted above, the EC considers that pure early entry (although technically a value transfer) is unlikely to be very problematic. Removing the pure early entry examples, it can be seen that the EC found a very limited number of problematic settlements.

A recent speech by the EU Competition Commissioner, Margrethe Vestager, suggests that the EC is indeed largely content with the position. She commented:

> …it's important that we're clear about how you can put together a settlement

Exhibit 1

		Limitation on generic entry	
		No	**Yes**
Value transfer from the originator company to the generic company	No	Category A	Category B.I.
	Yes		**Category B.II.**

so it doesn't harm competition. That's exactly what the [EC] has been doing in recent years. First with the sector inquiry that ended in 2009…And I hope that last year's judgment from the European courts—which confirmed our decision in a case involving Lundbeck and four generics businesses—will make things even clearer.

That work certainly seems to be having the right effect. Since the sector inquiry, we've been monitoring patent settlements in Europe. And we've found that the proportion of settlements that could be problematic for competition has fallen by more than half, to a very low level. So I think this concern is now under control. [*See* European Commission Announcement "Restoring trust in our Economy," January 27, 2017, at *http://ec.europa.eu/commission/2014-2019/vestager/announcements/restoring-trust-our-economy_en*.]

The EC nevertheless stated in the latest patent settlement report that in the future it *"may decide to continue the monitoring exercise in order to examine further the development of…trends."* Despite Commissioner Vestager's comments, given the continuing focus on this area, and pharmaceutical and medical device issues generally in the European Union (under antitrust law as well as on the regulatory side), this seems likely.

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