C IS PAY-FOR-DELAY ACTUALLY WRONG? PHARMA HEADS TO THE SUPREME COURT

So far, we have spent this chapter describing how pay-for-delay works, the problems it can cause for generic approval, and the harm it can inflict on consumers. However, is there a sound argument that these agreements are actually unlawful? The most prevalent, and increasingly accepted, legal argument is that pay-for-delay agreements are anticompetitive given that they represent an agreement between two companies to capture the market and deny others competitive entry.

Pharmaceutical companies, however, have argued vigorously that pay-for-delay settlements are not anticompetitive, asserting that they can be understood as no more than devices by which the two parties respond to the uncertainty of patent infringement litigation – the same uncertainty we discussed in the previous section.[27] The opposing argument frames a pay-for-delay agreement as follows: Given the uncertain nature of success in the lawsuit brought on by a Paragraph IV certification, the two parties calculate what they believe their relative position is in the litigation and then settle on the basis of what they believe to be the expected value of bringing the litigation to its conclusion. Consider a very simplified example – if a generic thinks it only has a 25 percent chance of succeeding in its lawsuit, perhaps it should settle so that it does not enter until the last 25 percent of the remaining patent term. Some argue further that such settlements are even *procompetitive*, because, in many cases, the generic is allowed to enter the market before the last relevant patent expires.[28] A settlement that allows "early entry" is better than nothing, right? As a result of the settlement, the public will enjoy lower prices sooner than they would have had the Paragraph IV challenge never taken place – a result that would seemingly be consistent with the goals of Hatch-Waxman.

This argument, however, suffers from two flaws. The first is that the "procompetitive" argument about pay-for-delay lawsuits ignores the fact that Paragraph IV litigation specifically questions the validity and applicability of the patent.[29] If the patent is invalid or inapplicable to the drug, the brand-name company should have no exclusionary power.[30] In other words, there is no such thing as procompetitive "early entry" if the patent should not exist at all.

The same is true if the patent is valid but does not apply to this product. Once again, the patent should not be blocking the generic's entry at all. Thus, nothing but immediate entry would be procompetitive. Everything else is unwarranted delay.

[27] Feldman, Rethinking Patent Law, *supra* note 17, at 163.
[28] *Fed. Trade Comm'n v. Actavis, Inc.*, 133 S. Ct. 2223, 2227 (2013).
[29] *See ibid.* at 2225; Hemphill, *Aggregate Approach to Antitrust*, *supra* note 1, at 637–38.
[30] *See Actavis, Inc.*, 133 S. Ct. at 2225.