Pay day

A consortium of US drug companies has been ordered to pay $70m to California over pay-for-delay deals. **David J Stanoch** explores

On 29 July 2019, the California Attorney General announced four settlements with three different pharmaceutical drug manufacturers: two settlements with Teva Pharmaceutical Industries, one with Endo Pharmaceuticals, and one with Teikoku Pharma.[1]

The settlements, under which these manufacturers collectively will pay nearly $70m to the State of California for a newly-created fund for California residents, relate to so-called "pay-for-delay" agreements resulting in allegedly delayed earlier entry of competing generic drugs.[2]

The companies, it was claimed, also engaged in certain conduct in connection with patent settlements that might unlawfully delay generic entry.

These four settlements with California came on the heels of nearly identical settlements between Teva, Endo, and Teikoku and the US Federal Trade Commission ("FTC").

While the California settlements prohibited the same business conduct as the FTC settlements, and the majority of the California fund will be paid out of a pre-existing fund Teva established as part of the FTC settlements, at least one company (Endo) will be paying some money in addition to the preceding FTC settlements.[3]

Antitrust scrutiny of pay-for-delay agreements is nothing new. Such scrutiny has steadily grown over the last several years, especially in the wake of the US Supreme Court's 2013 decision in *FTC v Actavis*.[4]

Nevertheless, these four California settlements serve as good reminders that states may pursue remedies for alleged anticompetitive practices, including monetary relief, even if a company has already settled identical allegations with a federal antitrust law enforcement agency. Both the California and FTC settlements also provide a good roadmap of potential do's and don'ts to consider when companies negotiate patent infringement litigation settlements, that implicate delayed entry of generic drugs.

Pay-for-delay agreements

Pay-for-delay agreements generally refer to any agreement that settles a patent infringement action brought by a brand drug manufacturer against a generic drug manufacturer planning to launch a competing generic drug,[5] in which the brand manufacturer drops its patent lawsuit and transfers value to the generic manufacturer in exchange for the generic manufacturer's delaying launch of its generic drug until a later time.[6]

The antitrust harm implicated by such agreements is that consumers end up paying higher brand drug prices for a longer period of time, in the absence of cheaper generic versions.[7] The form of value transferred by the brand manufacturer can be both direct (eg, cash payment), or indirect. Indirect transfers of value may take different forms, some of which include 1) "side deals" in which the brand manufacturer agrees to something else concerning a different drug, such as entering into a co-promote agreement with the generic manufacturer,[8] 2) no authorised generic commitments, under which the brand manufacturer agrees not to launch its own competing generic version of the brand drug at issue, and 3) declining royalty structures in which the generic manufacturer's obligation to pay royalties to the brand manufacturer is substantially reduced or eliminated if the brand company sells an authorised generic.[9]

The preceding FTC settlements

Three of the four California settlements involved the brand drug, Lidoderm. The fourth involved the brand drug, Provigil. All four settlements largely track earlier settlements that Teva, Endo, and Teikoku entered into earlier with the FTC.

Provigil: Teva's earlier settlement with the FTC

Teva's predecessor-in-interest, Cephalon, was the brand manufacturer of Provigil, a drug used to treat excessive sleepiness caused by narcolepsy or shift work sleep disorder. Teva (prior to its acquisition of Cephalon), was one of four companies which sought to sell a generic version of Provigil. Cephalon sued Teva for patent infringement in 28 March 2003, and other generic manufacturers thereafter. While motions for summary judgment were pending, Cephalon settled all of its patent litigation. Cephalon settled with Teva in December, 2005. Cephalon agreed that Teva could sell generic Provigil in October 2012, more than six years after the date of the settlement. Cephalon settled with other generic filers on similar terms. Cephalon also agreed to pay the four generic companies, including Teva, more than $200m collectively.

The FTC filed a lawsuit against Cephalon in February 2008, alleging Cephalon's patent settlements constituted illegal reverse-payment patent settlements that unlawfully delayed generic Provigil until 2012. In the interim, Teva acquired Cephalon. As a condition of the acquisition, Teva agreed with the FTC in May 2015 that it would make a total of $1.2bn available to compensate purchasers, including drug wholesalers, pharmacies, and insurers, who overpaid for branded Provigil, because of Cephalon's challenged conduct that delayed entry of generic equivalents.[10]

This settlement also provided that Teva would not enter into any side deals at the same time as a patent settlement.[11]

Subsequently, in February 2019, the FTC and Teva entered into a global settlement of

multiple pay-for-delay lawsuits the agency had brought against Teva.[12] This new settlement was broader than the earlier one. It expressly provides that, for 10 years, Teva still will not enter into any side deals (as agreed in the prior settlement), and further would not agree, as part of a patent settlement, not to launch its own authorised generic version of the brand drug in question.[13]

Lidoderm: Teva's, Endo's and Teikoku's earlier settlements with the FTC

Lidoderm is a transdermal patch used to treat nerve pain after shingles (called post-herpetic neuralgia). Teikoku was the innovator and manufacturer of Lidoderm.[14] Endo entered into a manufacturing and licensing agreement with Teikoku to be the exclusive seller of Lidoderm in the US.[15] One or more of Teva's predecessors-in-interest had sought to sell a generic version of Lidoderm. In response, Endo sued Teva's predecessors-in-interest for patent infringement. A six-day trial in the earliest patent infringement case occurred in February 2012.[16] Shortly thereafter, in May 2012, before the trial court issued its ruling, Endo settled its patent litigation. Under the terms of the patent settlements, Endo agreed 1) not to launch an authorised generic of Lidoderm for up to 7.5 months, and 2) to provide a Teva predecessor with at least $96m of branded Lidoderm product for free.[17]

The FTC sued Teva, Endo, and Teikoku in March 2016, claiming the patent settlements were unlawful pay-for-delay agreements.[18] The FTC simultaneously settled with Teikoku at the time it filed its complaint. Teikoku is "prohibited for 20 years from engaging in certain types of reverse-payment patent settlements, including settlements containing no-AG commitments[.]"[19] Subsequently, the FTC settled with Endo (in 2017) and Teva (in 2019). Each company agreed, among other things, to refrain from promising not to launch an authorised generic in connection with patent settlements.[20]

The California settlements

Teva entered two separate settlements with the State of California, one each for conduct related to Provigil and Lidoderm. Teva agreed to pay the State of California $69m, to go into a newly-created fund for California consumers, with respect to Provigil.[21] However, this money comes from the pre-existing fund created in 2015 for the $1.2bn Teva agreed to pay per its settlement with the FTC. Teva also agreed not to engage in the same business conduct vis-à-vis patent settlements, as that set forth in Teva's February 2019 settlement with the FTC.[22]

Endo agreed to pay $760,000 to the state of California. Both Endo and Teikoku further agreed not to engage in the same conduct they each agreed to refrain from in their settlements with the FTC.[23]

Takeaways

Ultimately, the California settlements did not result in any significant incremental recovery beyond what Teva, Endo, and Teikoku had previously agreed with the FTC.

Still, the California settlements are an important reminder that state and federal agencies share coordinate jurisdiction over allegedly anticompetitive behaviour. The potential for both state and federal scrutiny of patent settlements, as well as private enforcement by consumers or other purchasers or reimbursors, should be an important consideration for brand drug and generic drug companies alike, which regularly find themselves immersed in patient infringement litigation.

Footnotes

1. See, Attorney General Becerra secures nearly $70m against several drug companies for delaying competition and increasing drug prices, at https://bit.ly/311guMb.
2. Id.
3. Id.
4. 570 US 136 (2013).
5. The Hatch-Waxman Act of 1984, 21 USC § 355(j), *et seq*, provides that a company wishing to launch a generic drug must provide notice to the brand manufacturer under Paragraph IV of the Act, § 355(j)(2)(A)(vii)(IV). This is commonly referred to as "Paragraph IV certification." The act then provides that the patent holder (eg, brand manufacturer), may file a patent infringement lawsuit against the Paragraph IV filer. This automatically triggers a 30-month stay on FDA approval of the generic company ANDA. 28 USC § 355(j)(5)(B)(iii). After expiration of the 30-month stay (unless a court has prior to this entered judgment that the patent is invalid, unenforceable, or not infringed), the FDA may approve generic manufacturer's abbreviated new drug application, at which point the generic company may commercially market its ANDA product either "at risk" (if there has not been a final resolution of the patent litigation) or without risk (by waiting until conclusion of the patent litigation). 21 USC § 355(j)(5)(B)(iii).
6. See generally, Fed'l Trade Comm'n, Pay-for-delay: when drug companies agree not to compete, at https://bit.ly/1QaTrrn.
7. Id.
8. See, eg, *In re Loestrin* 24 Fe antitrust litig., 261 F Supp 3d 307, 321 (DRI 8 Aug 2017) (alleging that brand manufacturer ag agreed to pay generic manufacturer annual fees and a percentage of net sales in connection with the co-promotion of a separate brand drug).
9. Fed'l Trade Comm'n, Then, now, and down the road: trends in pharmaceutical patent settlements after *FTC v Actavis* (28 MAY 2019), at https://bit.ly/2kpwOXD.
10. See, Fed'l Trade Comm'n, FTC settlement of Cephalon pay for delay case ensures $1.2bn in ill-gotten gains relinquished; refunds will go to purchasers affected by anticompetitive tactics (28 May 2015), at https://bit.ly/1BreNnT.
11. Id. ("The order bars Teva from entering into a business deal with a competitor within 30 days of, or expressly conditioned on, a patent litigation settlement that restricts that competitor's generic entry.")
12. See, Fed'l Trade Comm'n, FTC enters global settlement to resolve reverse-payment charges against Teva (19 Feb 2019), at https://bit.ly/2Vexpbt.
13. Id. (Teva prohibited from entering into "a no-AG commitment, in which a brand company agrees not to compete with an authorised generic version of a drug for a period of time. The prior order had not prohibited no-AG commitments.").
14. See, *FTC v Endo Pharmaceuticals, Inc, et al*, No. 2:16-cv-01440 (E D Pa 30 Mar 2016) at ¶ 1.
15. Id. at paras 2-3.
16. Id. at para 115.
17. Id. at paras 116-136.
18. See, Fed'l Trade Comm'n, FTC sues Endo Pharmaceuticals Inc *et al* for illegally blocking lower-cost generic versions of the branded drugs Opana er and Lidoderm (31 Mar 2016), at https://bit.ly/1PHztNS.
19. Id.
20. See, Fed'l Trade Comm'n, FTC enters global settlement to resolve reverse-payment charges against Teva (19 Feb 2019), at https://bit.ly/2Vexpbt; Fed'l Trade Comm'n, Endo Pharmaceuticals agrees to abandon anticompetitive pay-for-delay agreements to settle FTC charges; FTC refiles suits against generic defendants, at https://bit.ly/2jUNZOv.
21. See, Attorney General Becerra secures nearly $70m against several drug companies for delaying competition and increasing drug prices, at https://bit.ly/311guMb.
22. Id.
23. Id.

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