



Patent Settlements that Resulted in Early Entry of Generics

Patent settlements are essential to ensure timely market entry of affordable generic and biosimilar medicines. Proponents of limiting patent settlements assert the limitations would speed patient access to lower-cost drugs. In fact, these proposals would have the opposite effect and further delay the launch of lower-cost generic and biosimilar medicines. Patent settlements provide much needed legal and commercial certainty by removing a key hurdle for generic manufacturers – unpredictable and costly litigation. Patent settlements increase access to lower-cost life-saving generic and biosimilar medicines for patients and ensure continued investment is made to bring these affordable medicines to market. Any changes to current law to limit or prevent legitimate patent settlements between pharmaceutical manufacturers would negatively impact patients in the form of reduced access and increased costs.

Allowing Brand and Generic Companies to Settle Patent Disputes is Pro-Consumer and Pro-Competitive

- In 2018, generic drugs saved the US \$293 billion.
- Biologics, medicines made from living cells through highly complex manufacturing processes, make up 40% of Medicare drug spending.
- 70% of all drug price increases from 2010-2015 came from biologics.
- Patent settlements guarantee timely generic market entry and ensure access to affordable generic medicine.
- Settlements do not delay generic market entry beyond the date of patent expiration.
- According to a survey of leading generic manufacturers,¹ the ability to settle patent litigation served as a key factor in determining investment decisions regarding bringing medicines to market.
- A study by IMS Health² found that patent settlements led to savings of more than \$11 billion.
- According to the FTC, the number of settlements involving “reverse-payments” has declined significantly since the Supreme Court’s Decision in *FTC v. Actavis* in 2013.

1 Dickey, Brett and Jonathan Orzag. “The Benefits of Patent Settlements: New Survey Evidence on Factors Affecting Generic Drug Investment.” (July 2013).

2 IMS Institute for Healthcare Informatics. (June 2013). Impact of Patent Settlements on Drug Costs: Estimation of Savings.

Settlements Prevent Patent Abuse by Brand Pharmaceutical Companies to Delay Generic Entry

- Currently, brand pharmaceutical companies deploy numerous anticompetitive tactics to game the patent system, unfairly delay generic entry and reduce patients' access to affordable medicine. This includes making non-innovative product changes to extend the life of a patent, known as evergreening.
- Patent settlements prevent brand pharmaceutical companies from using these tactics and avoid costly and protracted litigation necessary to fight these abuses of the patent system.
- Restricting the right of parties to settle litigation would have the unintended consequence of reducing the number of patent challenges brought by generic drug and biosimilar companies. This is contrary to federal law, which incentivizes generic companies to contest weak patents and bring lower-cost drugs to patients.

Examples of Patent Settlements that Resulted in Early Entry of Generics

Product	Relevant Patent/PED Expiration Date	Patent Settlement Date	Time off of patent expiry	Commentary
ivalo® (Pitavastatin)	2/2/24	8/2/23	6 months	Brand: Kowa Indication: to lower cholesterol Notes: '993 polymorph patent validity upheld by court
Seroquel XR® (Quetiapine)	11/28/17	11/1/16	13 months	Brand: AstraZeneca Indication: anti-psychotic Notes: '437 formulation patent validity upheld by court
Ofirmev® (Acetaminophen)	12/6/21	12/6/20	12 months	Brand: Mallinckrodt Indication: treatment of pain Notes: '218 formulation patent validity upheld by court
Treanda® (Bendamustine)	4/26/31	11/1/19	11.5 years	Brand: Teva/Cephalon Indication: treat chronic lymphocytic leukemia and non-Hodgkin's lymphoma Notes: '190 formulation patent validity upheld by court

Product	Relevant Patent/PED Expiration Date	Patent Settlement Date	Time off of patent expiry	Commentary
Lunesta® (Eszopiclone)	8/14/14	4/15/14	4 months	Brand: Sunovion Indication: treatment of insomnia Notes: '673 enantiomer patent found infringed
Namenda® XR (Memantine XR)	5/22/26	2/21/18	8 years	Brand: Allergan Indication: cognition enhancement/Alzheimers
Namenda® IR (Memantine IR)	10/11/15	7/11/14	6 months	Brand: Allergan Indication: cognition enhancement/Alzheimers
Orthotricyclin® (Norgestimate)	12/9/19	1/6/16	4 years	Brand: Janssen Indication: oral contraceptive
Phoslo® (Calcium Acetate)	7/7/21	10/26/15	5.5 years	Brand: Fresenius Indication: phosphate level control
Epzicom® (Abacavir)	11/14/18	3/29/17	1.5 years	Brand: Viiv Healthcare Indication: antiviral
Celebrex® (Celecoxib)	12/21/15	12/10/14	1 year	Brand: Pfizer Indication: arthritis
Diovan® (Valsartan)	12/18/17	3/22/13	4.5 years	Brand: Novartis Indication: diuretic
Seroquel® (Quetiapine)	11/28/17	8/22/17	3 months	Brand: AstraZeneca Indication: antipsychotic
Pristiq® (Desvenlafaxine)	7/5/27	3/1/17	10 years	Brand: Pfizer Indication: antidepressant
Seasonale® (EE)	6/23/17	10/25/12	4.5 years	Brand: Duramed Indication: oral contraceptive
Quartette® (EE)	3/11/29	4/1/17	12 years	Brand: Duramed Indication: oral contraceptive

Product	Relevant Patent/PED Expiration Date	Patent Settlement Date	Time off of patent expiry	Commentary
Glumetza® (Metformin)	10/25/21	2/1/16	5 years	Brand: Salix Indication: diabetes
Fortamet® (Metformin)	3/17/21	9/30/11	9.5 years	Brand: Shionogi Indication: diabetes
Niaspan® (Niacin)	5/27/17	3/20/14	3 years	Brand: Abbott Indication: cholesterol reduction
Pennsaid® (Diclofenac)	8/9/30	6/1/16	14 years	Brand: Mallinkrodt Indication: anti-inflammatory
Vigamox® (Moxifloxacin)	3/29/20	7/1/17	2.5 years	Brand: Novartis Indication: ocular antibiotic