



# I-MAK FACT CHECK

## Calling out I-MAK Misinformation

A strong system of intellectual property (IP) protection provides the incentives necessary to achieve sustainable scientific advancement. The laws governing the protection of IP are essential to fostering innovation and any proposed changes based on misinformation puts into jeopardy these critical incentives. Below are some of the inaccurate statements posted by the Initiative for Medicines, Access, and Knowledge (I-MAK), regarding Lyrica® (pregabalin), with the corresponding truth.



No generic Lyrica approved or “on the market”.<sup>1</sup>

Source: I-MAK’s Lyrica website, available at <https://www.i-mak.org/lyrica/>, accessed on July 12, 2023.

**FALSE**

**FACT**

In July 2019, the FDA approved **9 generic** versions of Lyrica.<sup>2</sup>

FDA NEWS RELEASE

### FDA approves first generics of Lyrica

For Immediate Release: July 22, 2019

<https://www.fda.gov/news-events/press-announcements/fda-approves-first-generics-lyrica>



“The main compound patent [of Lyrica] expired in 2013, but secondary patents ... gave Pfizer six additional years of patent protection...”<sup>3</sup>

Source: I-MAK’s Lyrica “Fact Sheet,” available at [https://www.i-mak.org/wp-content/uploads/2020/11/LyricaFactSheet\\_85x11.pdf](https://www.i-mak.org/wp-content/uploads/2020/11/LyricaFactSheet_85x11.pdf)

**FALSE**

**FACT**

The main compound patent of Lyrica expired on **June 30, 2019** and was not extended 6 years by “secondary” patents.<sup>4</sup>



“Lyrica was set to go off-patent at the end of 2018... But Pfizer had filed and was issued patents for an additional twenty year period on a controlled-release formulation of the product (Lyrica CR). ...With these patents, Pfizer’s hold on the market will remain...”<sup>5</sup>

Source: I-MAK, *Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Prices*, pp. 9-10, available at <https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf>

**FALSE**

**FACT**

Lyrica and Lyrica CR are 2 different products. The availability of a Controlled Release option, Lyrica CR, did not change the fact that generic versions of original Lyrica were available as soon as it went off-patent in 2019.<sup>6</sup>



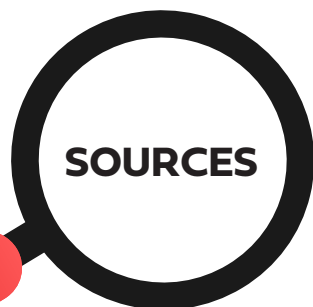
Lyrica had “**42 years** of monopoly from granted patents”.<sup>7</sup>

Source: I-MAK’s Lyrica website, available at <https://www.i-mak.org/lyrica/>, accessed on July 12, 2023.

**FALSE**

**FACT**

Lyrica had market exclusivity for **14.5 years** (2004-2019), and during that time it faced competition from several medicines that treated the same indications.<sup>8</sup>



**I-MAK**

PATENT AND MARKET DATA

**1. Lyrica**

**MARKET**

On the U.S. market since: 2004  
 Generic / biosim approved: No  
 Generic / biosim on the market: No

<https://www.i-mak.org/lyrica/>

**2. FACT**

FDA News Release: FDA Approved First Generics of Lyrica (July 2019)

**I-MAK**

FACT SHEET

**3. Lyrica**

**DRUG INFORMATION**

- **FDA Approval:** 4 total indications. Major disease indications are neuropathic pain (2004) and fibromyalgia (2007)
- **Company:** Pfizer
- **Drug Type:** Small molecule
- **On the U.S. Market since:** 2004
- **Generic/Biosimilar approved by FDA:** Yes (2019)

**DELAYED COMPETITION COST BILLIONS**

The main compound patent expired in 2013, but secondary patents filed later in the product life cycle gave Pfizer six additional years of patent protection and \$17 billion more in revenue. In July 2019, nine different generic suppliers were approved. This reduced prices by over 90%.

[https://www.i-mak.org/wp-content/uploads/2020/11/LyricaFactSheet\\_85x11.pdf](https://www.i-mak.org/wp-content/uploads/2020/11/LyricaFactSheet_85x11.pdf)

**4. FACT**

USPTO Website: Applications for patent term extension and patent terms extended under 35 U.S.C. § 156 (Lyrica Patent No. 6,197,819), last visited Aug. 1, 2023; and Pfizer Press Release: Pfizer Receives Six Months Pediatric Exclusivity for Lyrica (pregabalin), Nov. 2018, available [here](#).

**I-MAK**

**5. THE COST OF OVERPATENTING:**

**A spotlight on Lyrica**

Lyrica was set to go off-patent at the end of 2018 and the entry of generic competition would have quickly and markedly reduce Pfizer's revenue from Lyrica by 70-90% in less than two years. But Pfizer had filed and was issued patents for an additional twenty year period on a controlled-release formulation of the product (Lyrica CR), meaning that patients would take a single pill instead of two or three pills daily<sup>1</sup>. With these patents, Pfizer's hold on the market will remain and, if history is a guide, they will continue major repeated increases in the price of the drug.

<https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf>

**6. FACT**

FDA News Release: FDA Approved First Generics of Lyrica (July 2019); see also, for example, Amneal Pharmaceuticals, Inc. - Amneal Announces Launch of Generic Lyrica® (22 July 2019), Dr. Reddy's Laboratories announces the launch of Pregabalin Capsules in the U.S. Market | Business Wire (30 July 2019), Rising Pharmaceuticals Announces the U.S. Launch of a Generic Version of Pregabalin Capsules | Business Wire (19 July 2019).

**I-MAK**

PATENT AND MARKET DATA

**7. Lyrica**

**PATENTS**

Patent applications: 118  
 Patents issued: 64  
 Filed after FDA approval: 31%  
 Duration of patent protection: 42 years  
 Fold-more patents filed in U.S. vs Europe: 1.9  
 Fold-more patents filed in U.S. vs Japan: 1.9

**Key Findings**

**118** patent applications and 64 granted patents  
**42** years of monopoly from granted patents  
**83%** Price increase 2004-2019

<https://www.i-mak.org/lyrica/>

**8. FACT**

FDA News Release: FDA Approved First Generics of Lyrica (July 2019); Lyrica is indicated for Neuropathic pain associated with diabetic peripheral neuropathy (DPN); Postherpetic neuralgia (PHN); Adjunctive therapy for the treatment of partial onset seizures in patients 4 years of age and older; Fibromyalgia; Neuropathic pain associated with spinal cord injury, see [Highlights of Prescribing Information](#) (Lyrica); see also [Highlights of Prescribing Information](#) (Cymbalta), initial U.S. approval in 2004, indicated for, in part, diabetic peripheral neuropathy (DPN) and fibromyalgia; and [Highlights of Prescribing Information](#) (Qutenza), initial U.S. approval in 2009, indicated for the management of neuropathic pain associated with postherpetic neuralgia (PHN).