# Pharmaceutical Patent Myths

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Lowering the skyrocketing cost of prescription drugs is a top priority for Americans, many of whom struggle to afford the medicines they need. Fortunately, policymakers have signaled a willingness to take action to protect patients and ensure the sustainability of our healthcare system. But there is a broad misunderstanding of one key piece of the puzzle: **the patent system**.

This document aims to debunk common myths about patents that can stand in the way of effective, bipartisan policy solutions.

## MYTH

# On one drug, drugmakers apply for one patent

## FACT

# **Drugmakers file dozens** or even hundreds of patents on a drug

### Pharmaceutical companies regularly seek dozens or even hundreds of patents on a single drug. The bestselling drugs in America have an average of 131 patent applications.<sup>1</sup>

These patents not only cover the initial invention of the active ingredient (the primary patents), but also different features relating to the drug (termed secondary patents) -- such as the various medical conditions the drug can treat, types of formulations, and dosage forms.



### associated with it.<sup>2</sup> Over half (58%) of

the company AbbVie,

patent applications

has 165 different

the patent applications for Imbruvica cover the different diseases it can treat and formulations of the drug, all of which are already mentioned in the first patent covering the original invention of the active ingredient.

<sup>2</sup>I-MAK. Overpatented, Overpriced: Imbruvica's Patent Wall. July 2020. Available: https://i-mak.org/imbruvica.

<sup>1</sup> I-MAK. Overpatented, Overpriced: America's Bestselling Drugs of 2019. Available: https://www.i-mak.org/2019-bestselling.

<sup>2</sup>I-MAK. Overpatented, Overpriced: Imbruvica's Patent Wall. July 2020. Available: https://i-mak.org/imbruvica.





#### MAIN COMPOUND

Covers the active substance used in the marketed drug. Base patents typically have the broadest scope.

10%

13%

28



10%

#### DERIVATIVE

Structural variations of the main compound are filed as part of the main patents for the broadest protection.

#### CRYSTALLINE

Crystal structures inherent within the main compound, and can vary in their physicochemical properties (does not change biological properties).



#### METHOD OF TREATMENT

Specific indications (diseases) that can be treated with the main compound alone or with another active substance(s).



#### FORMULATION

Pharmaceutical preparations used to administer the product (e.g. tablet, transdermal patches).



#### PROCESS

Methods for preparing the main compound, derivative, crystalline form(s), or formulations for manufacture.

## MYTH

# A drug has 20 years of protection

## FACT

# Patent protection on a drug lasts much longer than 20 years



Under current law, once granted the duration of a patent is 20 years for an invention. In some circumstances, extensions of up to five years can be granted, increasing a patent owner's period of exclusivity to 25 years.

As seen in the first myth, patent owners -- many of which are corporations -- routinely file many patents in relation to an invention. For the top 10 bestselling drugs in the U.S, there are an average of 70 patents granted per drug.<sup>3</sup> In each case, no matter how big or small the change is, each patent is granted 20 years of exclusivity. Patent applications are strategically staggered throughout the drug's life cycle in order to maximize the exclusivity period; once granted the average duration of patent protection for bestselling drugs is 38 years for what is essentially one invention.<sup>4</sup>

These additional patents are considered entirely separate inventions, even if the ostensibly new features were already broadly described in the original patent. Under the current patent system, patents are granted for substantial changes to the initial invention of a drug as well as minor tweaks, such as changing the dosage amount for a drug from 20mg to 40mg.

EXAMPLE

Celgene amassed a patent wall of 109 granted patents on the multiple myeloma treatment, Revlimid.

REV 25 mg

The first patent on Revlimid was filed in 1996, expiring in 2019, while the most recent patent expires in 2036. Generic companies seeking to enter the market have had to litigate many of these patents, which resulted in settlements. These settlements only allow generic companies full access to the U.S. market in 2026, allowing Celgene to extract an additional six years of exclusivity beyond the primary patent (2020-2025). America will spend an estimated \$44 billion on Revlimid during this time. In total Revlimid will have had thirty years of patent protection.

<sup>3</sup> I-MAK. Overpatented, Overpriced: America's Bestselling Drugs of 2019. Available: https://www.i-mak.org/2019-bestselling.

<sup>4</sup> I-MAK. Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Prices. August 2018. Available: https:// www.i-mak.org/overpatented

## ΜΥΤΗ

# To get a patent, you must invent something new

# FACT

# Not all patents are inventive

In theory, to get a patent you must invent something new: that the invention has never been described in any printed publication, used, or sold. It also cannot be obvious to a person skilled in the relevant field.

But in practice, many pharmaceutical patents are modifications of existing inventions, such as additional patents for different medical conditions that can be treated using the original invention or changing the dosage form. According to an analysis of all drugs on the market between 2005 and 2015, nearly eight out of ten drugs associated with new patents are not new drugs, but existing ones.<sup>5</sup>



The original daily dosing of the drug Copaxone made by Teva Pharmaceuticals was 20mg/ml, but the company later sought and received additional patents for a 40mg/ml dose. The new patents were invalidated when challenged at the US Patent and Trademark Office and in court.



<sup>5</sup> R Feldman. May your drug prices be evergreen. Journal of Law and the Biosciences, Volume 5, Issue 3, December 2018, Pages 590–647, https://doi. org/10.1093/jib/lsy022

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## MYTH

# More patents, more innovation

## FACT

# More patents does not always mean more innovation



Two commonly used measures of innovation are (1) the number of patents filed and (2) the number of patents granted. These metrics are regularly used by organizations such as the U.S. Patent and Trademark Office, the World Intellectual Property Organization, and the U.S. Chamber of Commerce to gauge how "innovative" a country is. The implication: the more patents we file and grant, the more innovative we are.

These are not accurate measures for understanding innovation.

First, patent filings represent nothing more than a person or entity's belief they have invented something new and that it deserves a patent. Merely filing a patent tells us nothing about whether the invention claimed is new over existing technology, or if it advances knowledge in a particular field. Measuring innovation by counting how many patents have been filed is like giving a participation trophy to someone who actually has not won anything yet.

Second, even if the patent is granted, it does not mean it is a new invention. Patents are regularly granted for tweaks to existing drugs. As stated above, nearly eight out of ten drugs associated with new patents are for existing drugs. And studies have shown that more than two thirds of secondary pharmaceutical patents are invalidated when litigated.<sup>6</sup>

Third, economic theory suggests that more patents means there is more investment and, therefore, more innovation. But the reality is much more complex, and there is little clear empirical evidence that more patents results in more investment in research and development (R&D) and, therefore, more innovation. Moreover, not every patent filed or granted in relation to an invention for a product is the result of more investment and innovation. Companies filing or being granted dozens of patents are often using patenting as a defensive measure to block or delay competition than actually investing in further research. After all, it can be a lot cheaper and easier to file and litigate patents than to truly invest in genuinely new inventions that could lead to the discovery of new therapies.

<sup>&</sup>lt;sup>8</sup> HL Williams, How do patents affect research investments. National Bureau of Economic Research. NBER Working Paper 23088, 2017. https://www.nber.org/papers/w23088 <sup>9</sup> D Basulto, Patents are a terrible way to measure innovation. Washington Post. 14 July 2015. https://www.washingtonpost.com/



<sup>&</sup>lt;sup>6</sup> CS Hemphill and B Sampat. Drug patents at the Supreme Court. Science. Vol 339, Issue 6126, 1386-1387. 22 Mar 2013. Available: https://science.sciencemag.org/content/339/6126/1386.

<sup>&</sup>lt;sup>7</sup> CS Hemphill and B Sampat. Drug patents at the Supreme Court. Science. Vol 339, Issue 6126, 1386-1387. 22 Mar 2013. Available: https://science.sciencemag.org/ content/339/6126/1386.

#### EXAMPLE

## MYTH

# The private sector is the source of all innovation

## FACT

# **Public funding supports** pharmaceutical innovation

Many of the new pharmaceutical products we see on the market today originate from public funding. According to one recent study, all 210 drugs approved in the U.S between 2010 and 2016 benefited from public grants that supported early or indirect research.9 In light of the billions in taxpayer dollars given to drugmakers each year, the claim that the private sector is solely responsible for new, patentable drugs and vaccines does not hold up.

**Researchers at Northwestern** University invented Lyrica, a drug to treat nerve and muscle pain, with an initial grant of \$681,764 from the National Institutes of Health.



Northwestern then exclusively licensed the patent on the drug to the pharmaceutical company Pfizer. Between 2014-2018, Pfizer netted around \$5 billion in global sales per year for Lyrica. This licensing agreement with Pfizer gave Northwestern 18 percent of the University's endowment, with \$360 million in licensing income reported in 2014.<sup>10</sup> During this time (2014-18), Pfizer increased the price of Lyrica by 65%, from \$4,500 to \$7,500 annually.<sup>11</sup> The winners in this scenario have been Northwestern - the drug's inventor - and Pfizer - the sales and marketing machine behind the drug - but most certainly not the public that funded the initial research.

<sup>10</sup> National Academies of Sciences, Engineering, and Medicine 2020. The Role of NIH in Drug Development Innovation and Its Impact on Patient Access: Proceedings of a Workshop. Washington, DC: The National Academies Press. https://doi.org/10.17226/25591. <sup>11</sup> Based on analysis of IQVIA dataset of monthly NSP prices, Sept, 2014 to Sept, 2018. Reflects all invoice-based pricing, but not any off-invoice discounts.

All drugs

approved in the

benefited from

public grants

**U.S. between** 

2010 to 2016

2016

2015

2014

2013

2012

2011

2010

9 EG Cleary, JM Beierlein, NS Khanuja, et al. Contribution of NIH funding to new drug approvals 2010–2016. PNAS March 6, 2018 115 (10) 2329-2334; first published February 12, 2018 https://www.pnas.org/content/115/10/2329 National Academies of Sciences, Engineering, and Medicine 2020. The Role of NIH in Drug Development

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