THE BURDEN OF PATENT THICKETS

Extending patent protection nets drugmakers $158 billion on just four drugs

BACKGROUND

To help determine the cost of patent thickets, we examined four of the leading biologic drugs that have had biosimilar competition introduced since 2019 – Humira, Avastin, Rituxan, and Lantus. For each drug we identified the remaining duration of primary patent protection once the product was commercially launched[1] and the duration of extended[2] patent protection. The amount of U.S. revenue generated for each drug during these periods of time was assessed.

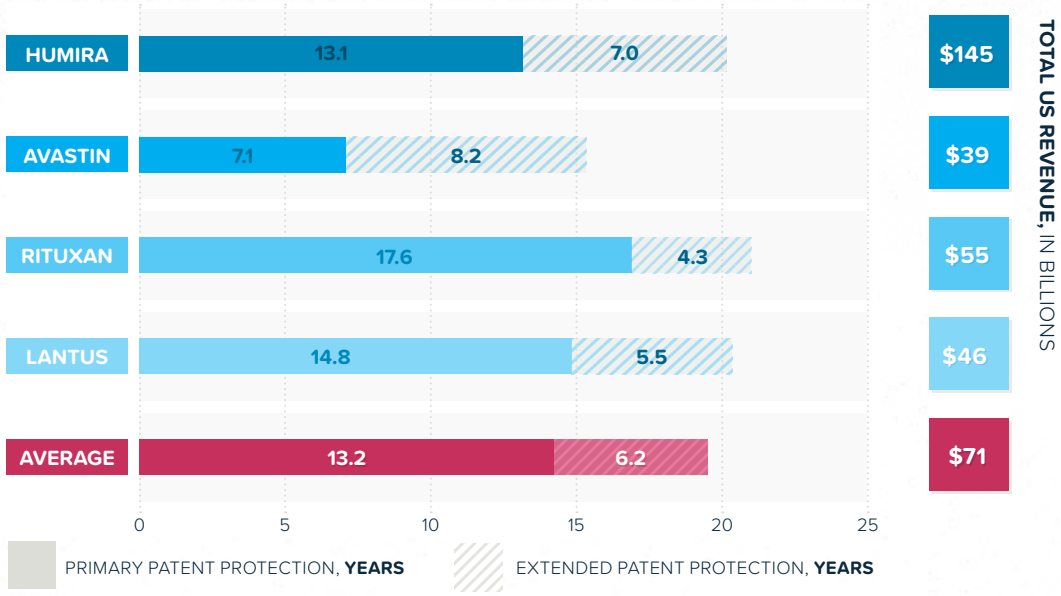
KEY FINDINGS

1

Market Monopolies Averaged 19 Years *After* Launch

These four drugs had an average of 19.4 years of market monopoly *following* commercial launch before they faced their first biosimilar competition. This included 13.2 years of remaining primary patent protection, plus an added 6.2 years of extended patent protection. Over this period, these drugs averaged over $70 billion dollars in U.S. sales.

TOTAL YEARS AND TYPE OF PATENT PROTECTION
FOLLOWING COMMERCIAL LAUNCH



[1] Patents are typically granted for a period of twenty years from the date of filing for an invention. We define primary patents as those disclosing the composition of the biologic drug, in other words the actual invention covering the substance that forms the basis of the medicine in question. Thus, the expiration date of the primary patent would mark the earliest date for biosimilar entry, presuming that FDA exclusivity would also have expired. We identified primary patents by a combination of means: 1) examination of the claims and specification; 2) using the company's own public statements, including SEC filings, about the anticipated earliest date for competitive product launch; 3) publicly available information from patent litigation.

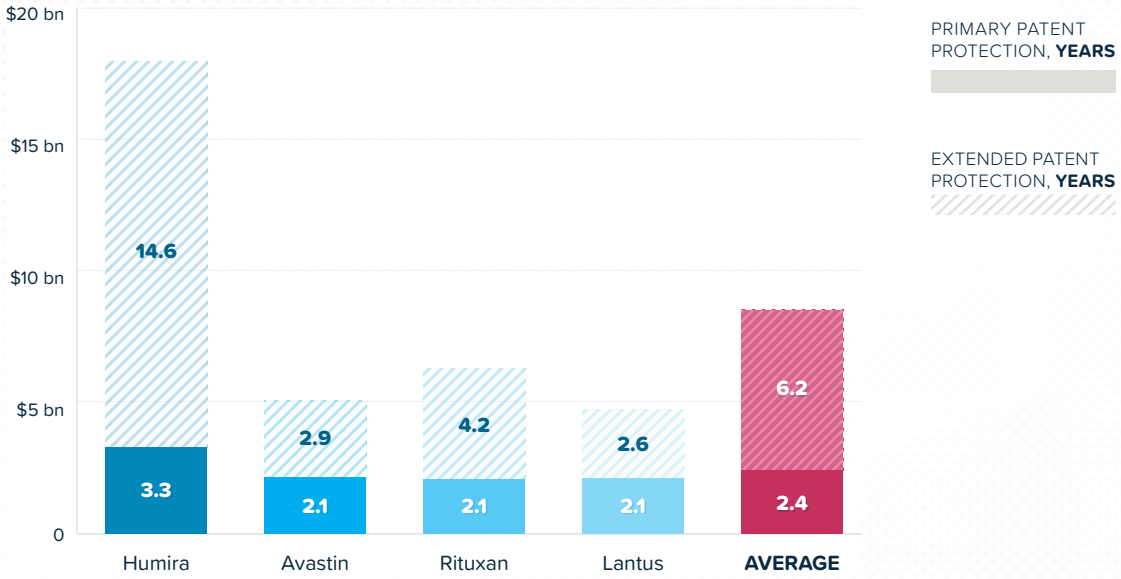
[2] Extended patents include all non-primary patents that protect the drug from losing exclusivity until the launch of a first biosimilar product.

2

Annual Revenues are Higher During Extended Patent Protection

Just how lucrative are patent thickets to drugmakers? All four biologic drugs earned significantly more per year after the primary patent protection expired. The drugs averaged $6.2 billion per year in the extended period versus $2.4 billion in the primary period – demonstrating the outsize cost to the system for each year of extended patent protection.[3]

AVERAGE U.S. REVENUE PER YEAR (BILLIONS)
EARNED IN PRIMARY AND EXTENDED PATENT PROTECTION

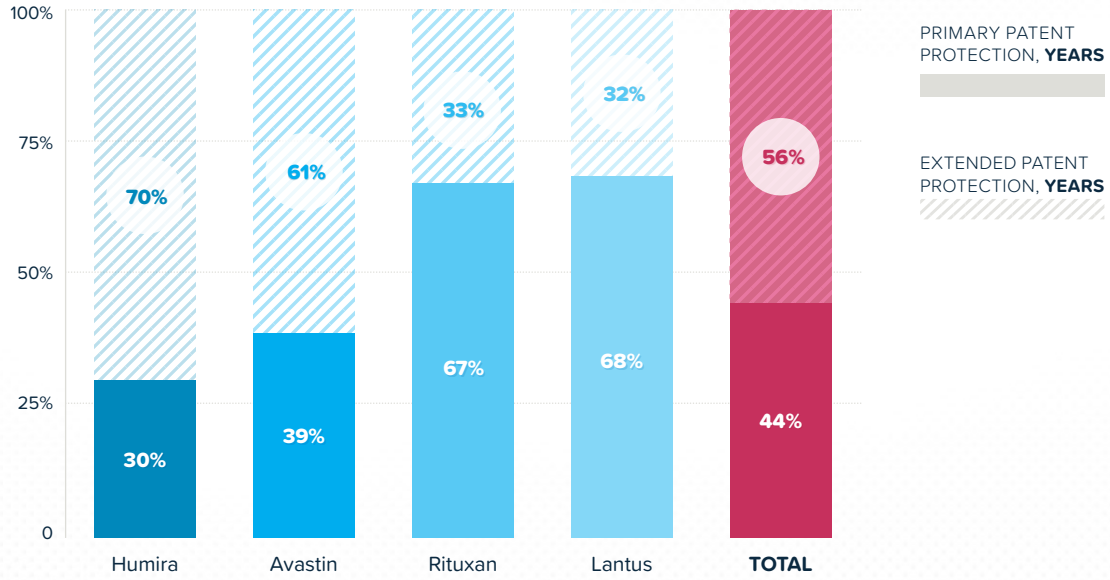


3

Extended Patent Protection Accounts for Majority of Total Sales

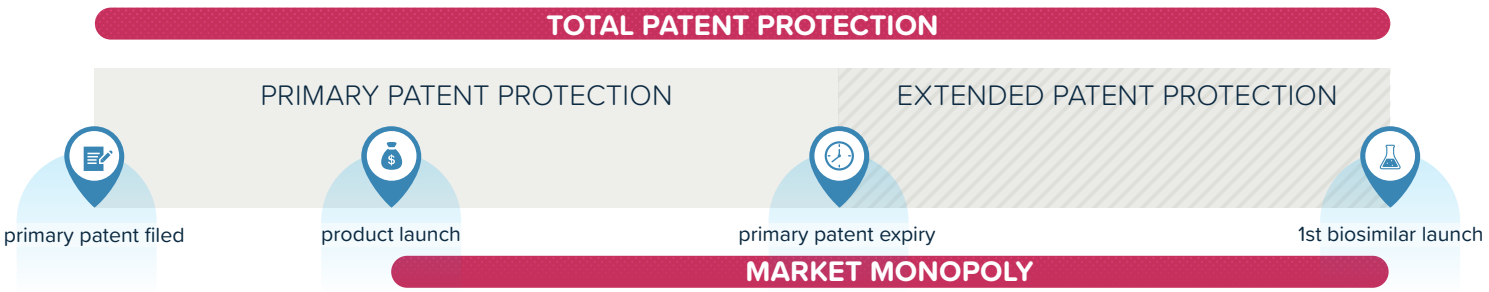
During the period of extended patent protection for these four drugs, total U.S. sales more than doubled — in less than half the time — as compared to revenues generated during primary patent protection. Combined, they had 25 years of extended patent protection that reaped $158 billion dollars, accounting for 56% of total U.S. revenues.

PERCENTAGE OF TOTAL REVENUE GENERATED
IN THE PRIMARY AND EXTENDED PATENT PROTECTION



[3] While the average annual revenue earned for each of the drugs was greater in the extended patent protection, it is worth noting just how magnified the difference was for Humira relative to the others.

DATA TABLE	 HUMIRA	 AVASTIN	 RITUXAN	 LANTUS	AVE	TOTAL
Primary patent #	US6090382	US6582959	US5736137	US5656722		
Primary patent filing date	Feb, 1996	Oct, 1997	Nov, 1993	Sep, 1994		
Primary patent expiry	Feb, 2016	Mar, 2011	Jul, 2015	Feb, 2015		
Product launch / first FDA approval	Dec, 2002	Feb, 2004	Nov, 1997	Apr, 2000		
Date of first biosimilar launch	Jan, 2023	Jun, 2019	Oct, 2019	Aug, 2020		
Total patent protection (yrs)	27.0	21.7	26.0	25.9	**25.1**	**100.6**
Market monopoly (yrs)	20.1	15.3	21.9	20.3	**19.4**	**77.6**
Primary patent protection, post-launch (yrs)	13.1	7.1	17.6	14.8	**13.2**	**52.7**
Extended patent protection (yrs)	7.0	8.2	4.3	5.5	**6.2**	**25**
US revenue in primary patent protection ($bn)	$43.1	$15.1	$36.6	$31.3	**$31.5**	**$126.1**
US revenue in extended patent protection ($bn)	$101.7	$24.0	$18.0	$14.4	**$39.5**	**$158.0**
Total U.S. revenue in market monopoly	$144.8	$39.1	$54.6	$45.7	**$71.0**	**$284.1**
Average revenue per year in primary patent protection ($bn)	$3.3	$2.1	$2.1	$2.1	**$2.4**	
Average revenue per year in extended patent protection ($bn)	$14.6	$2.9	$4.2	$2.6	**$6.1**	



HUMIRA

27 YEARS OF TOTAL PATENT PROTECTION

20 YEARS OF MARKET MONOPOLY

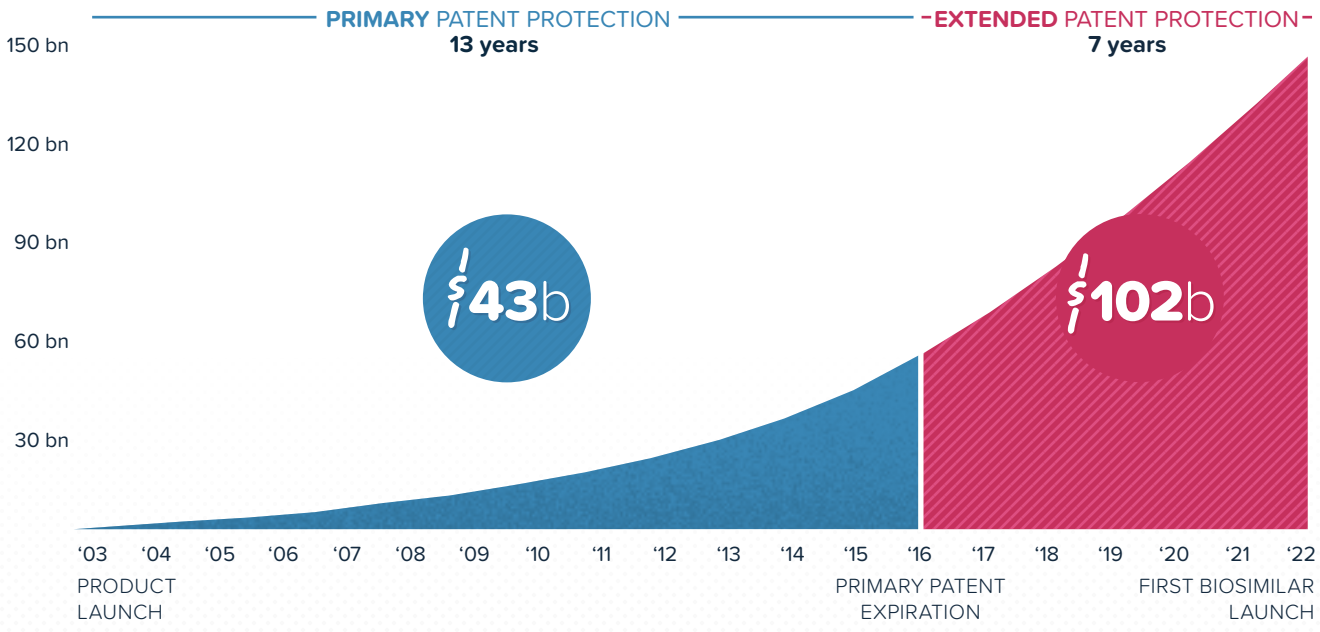
$145 BILLION IN U.S. REVENUE

1996
primary patent filed

2003
product launch

2016
primary patent expiry

2023
1st biosimilar launch



AVASTIN

22 YEARS OF TOTAL PATENT PROTECTION

15 YEARS OF MARKET MONOPOLY

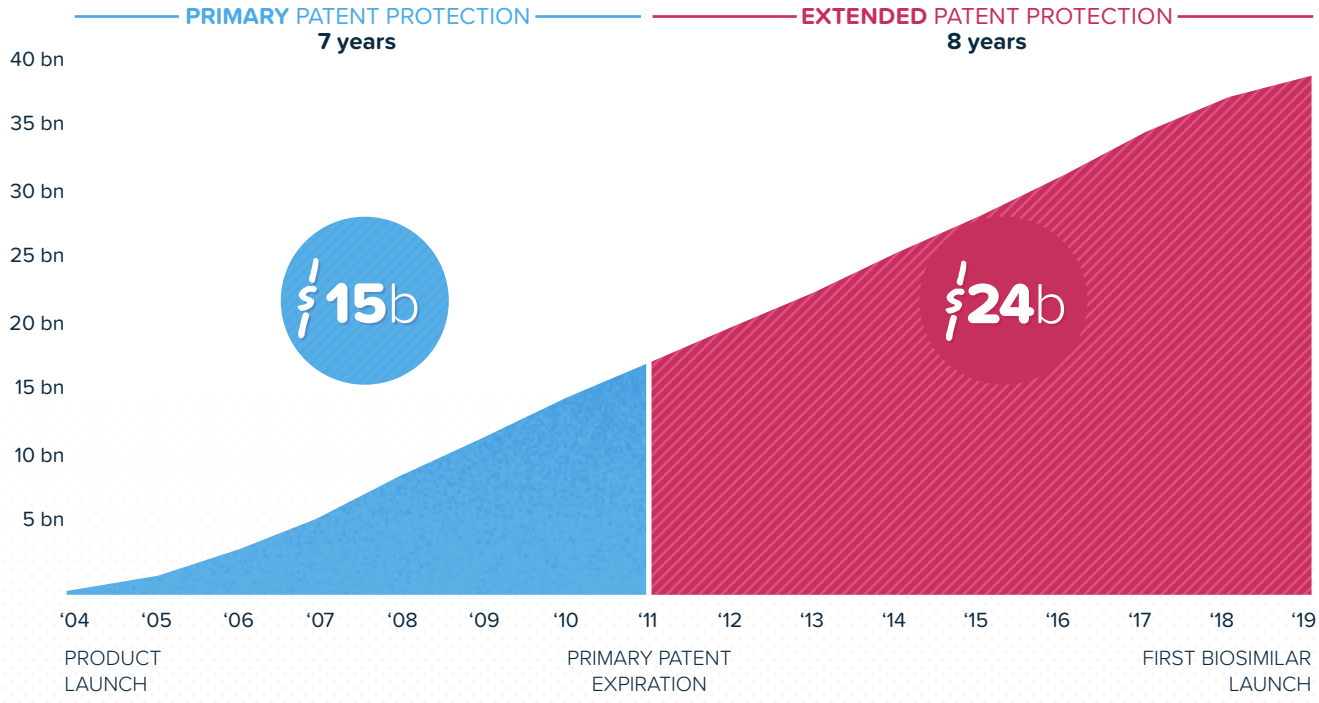
$39 BILLION IN U.S. REVENUE

1997
primary patent filed

2004
product launch

2011
primary patent expiry

2019
1st biosimilar launch



RITUXAN

26 **YEARS** OF TOTAL PATENT PROTECTION

22 **YEARS** OF MARKET MONOPOLY

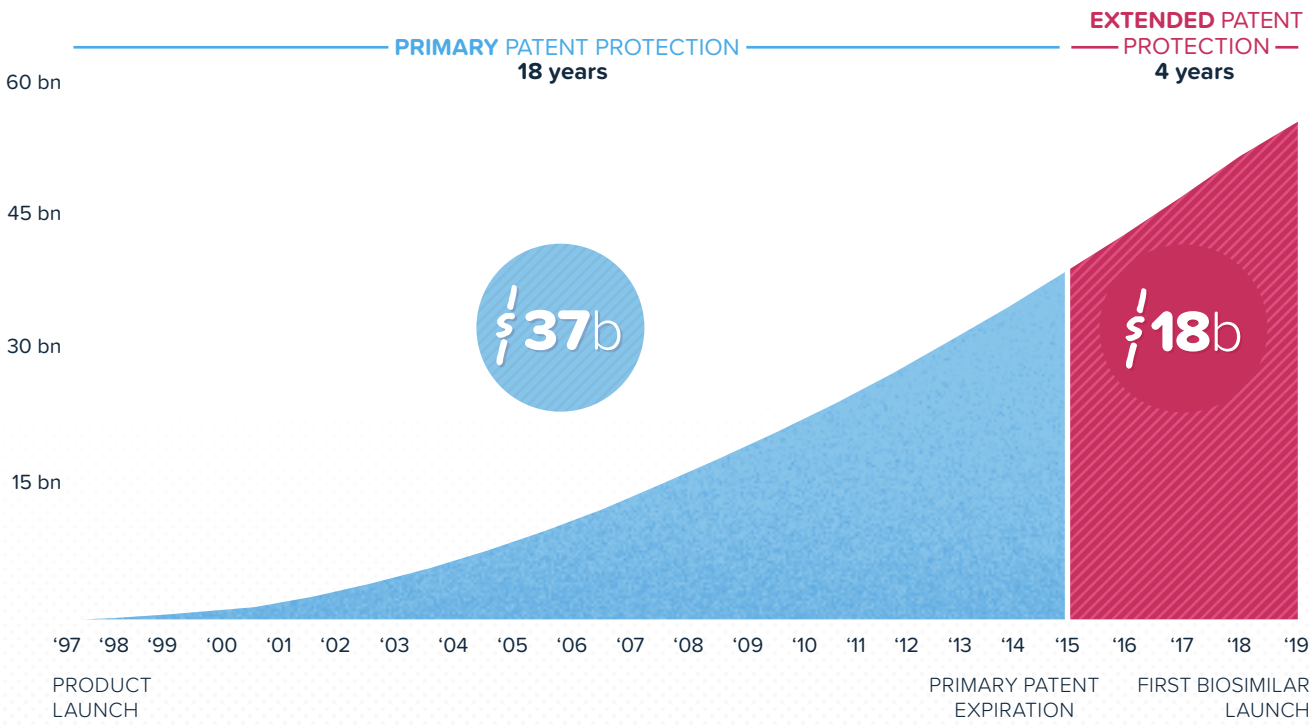
$55 **BILLION** IN U.S. REVENUE

1993
primary patent filed

1997
product launch

2015
primary patent expiry

2019
1st biosimilar launch

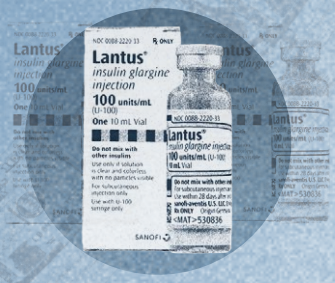


LANTUS

26 YEARS OF TOTAL PATENT PROTECTION

20 YEARS OF MARKET MONOPOLY

$45 BILLION IN U.S. REVENUE

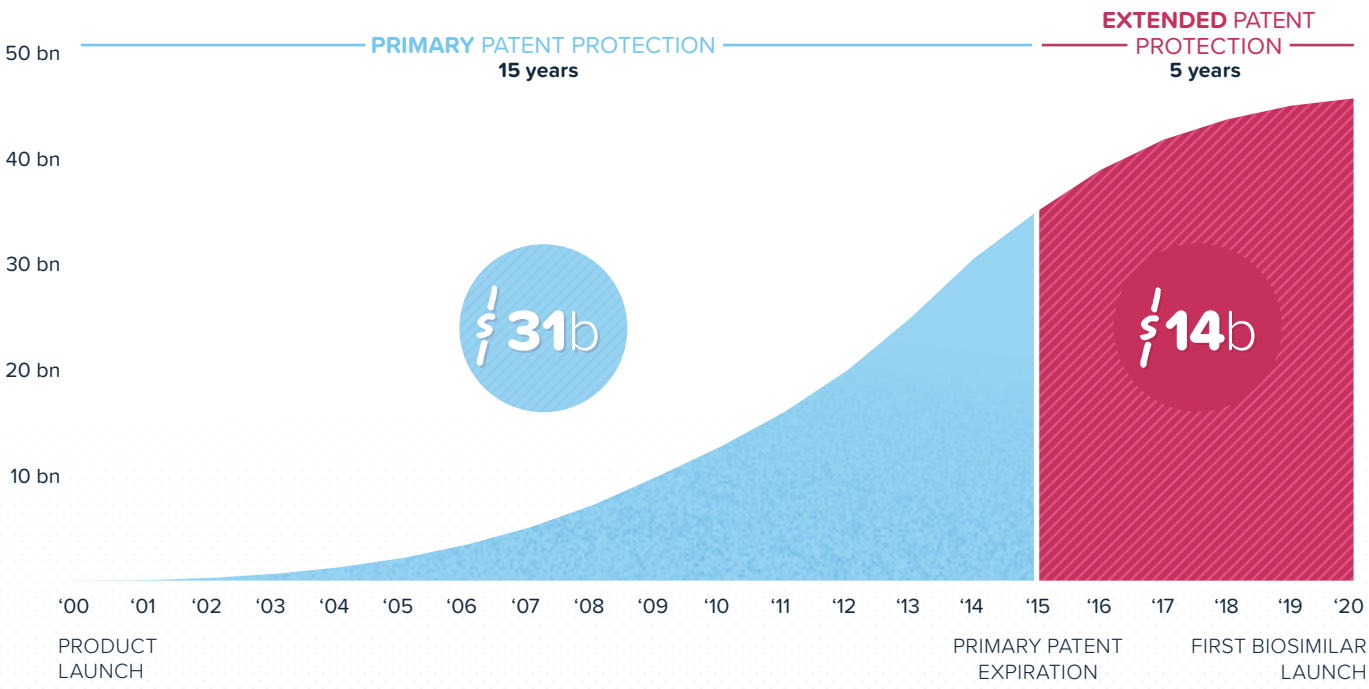


1994
primary patent filed

2000
product launch

2015
primary patent expiry

2020
1st biosimilar launch



ABOUT IMAK

The Initiative for Medicines, Access, and Knowledge (or I-MAK) is a 501(c)(3) organization with a mission to build a more just and equitable medicines system. Our framework integrates deep analytical research to influence policy, education to activate change, and partnerships to drive solutions. We bring decades of private-sector expertise and an evidence based approach to this mission. Our work spans 50 countries and includes engagement with patients, drug manufacturers, patent offices, community leaders, public health professionals, policymakers, scientists, economists, and more.

I-MAK's approach to policy solution development is informed by its **Participatory Changemaking (PCM) process,** a multidimensional assessment of the patent system informed by input from stakeholders who hold or apply for patents, administer the system, and are affected by its decisions. PCM brings together individuals from different geographic, political, personal, and professional backgrounds to generate new ideas on how to modernize the patent system.

I-MAK's work on structural change in the patent system is featured regularly in the national and global press, as well as in Congressional hearings and Committee reports. In early 2021, I-MAK proposed a **10 point plan** to increase equity and competition through the patent system to inform policy solutions going forward. In 2022, I-MAK's patent system reform recommendations supported by the PCM process were **endorsed by the New York Times' Editorial Board.**