
I·MAK
The Basics of Drug Patents
PRITI KRISHTEL
05 | 16 | 19


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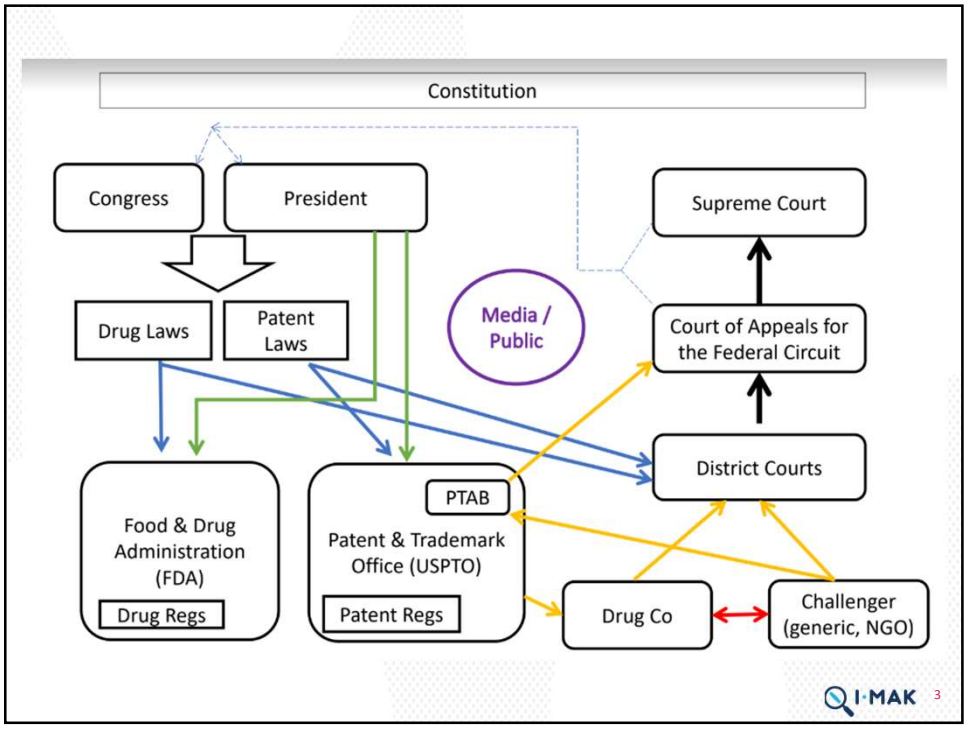
The Patent System


Constitution
Congress
President
Supreme Court
Drug Laws
Patent Laws
Media / Public
Court of Appeals for the Federal Circuit
District Courts
PTAB
Food & Drug Administration (FDA)
Drug Regs
Patent & Trademark Office (USPTO)
Patent Regs
Drug Co
Challenger (generic, NGO)
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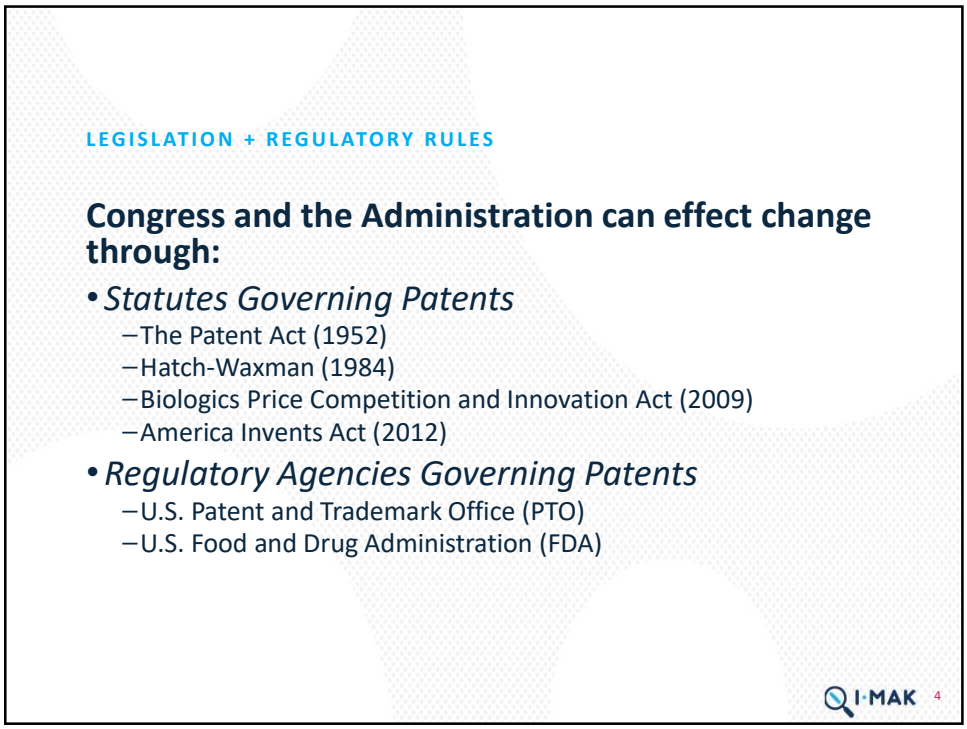
LEGISLATION + REGULATORY RULES
Congress and the Administration can effect change through:
• Statutes Governing Patents
– The Patent Act (1952)
– Hatch-Waxman (1984)
– Biologics Price Competition and Innovation Act (2009)
– America Invents Act (2012)
• Regulatory Agencies Governing Patents
– U.S. Patent and Trademark Office (PTO)
– U.S. Food and Drug Administration (FDA)
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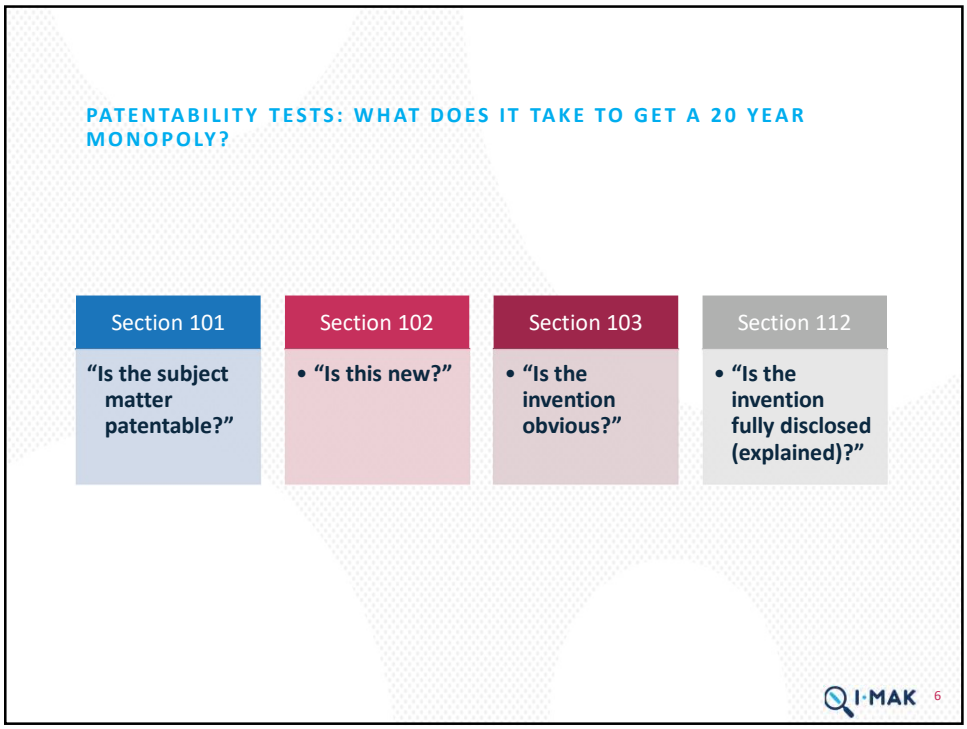
The How
HOW ARE PATENTS GRANTED?
THE STANDARDS OF PATENTABILITY


PATENTABILITY TESTS: WHAT DOES IT TAKE TO GET A 20 YEAR MONOPOLY?
Section 101
"Is the subject matter patentable?"
Section 102
• "Is this new?"
Section 103
• "Is the invention obvious?"
Section 112
• "Is the invention fully disclosed (explained)?"
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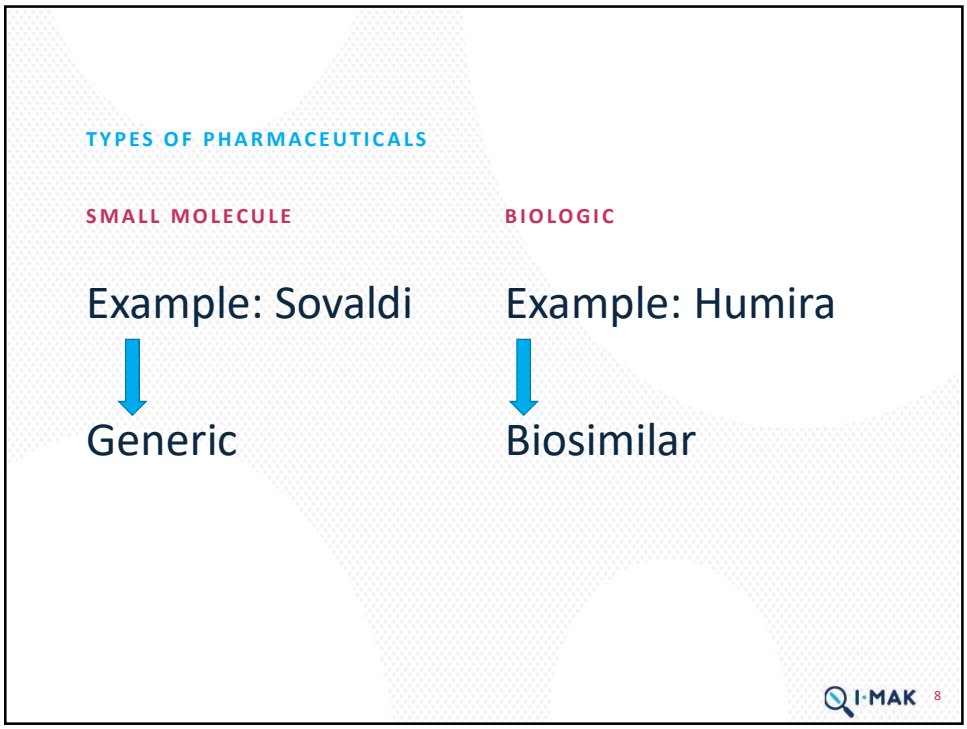
Types of Pharmaceutical Patents


TYPES OF PHARMACEUTICALS
SMALL MOLECULE
Example: Sovaldi
Generic
BIOLOGIC
Example: Humira
Biosimilar
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TYPES OF PHARMACEUTICAL PATENTS

Pharmaceutical manufacturers pursue patents in three areas:

- **Base patents:** These patents cover the core active ingredient or protein sequence/DNA that make up a medicine and are the foundational patents for every pharmaceutical drug.
- **Secondary patents:** derivative compounds that are inherent within the base patent e.g. different crystalline and **substantially pure forms**, enantiomers, formulations, of the base compound, methods of use, new indications (new use), changes in strength or dosage; new dosing route; combinations with other drugs; segmented patient populations; different processes for manufacturing; packaging/patient instructions; pharmaco-kinetic/therapeutic parameters.
- **Tertiary patents:** Using medical devices paired with an active ingredient that may be off patent to prolong market exclusivity.

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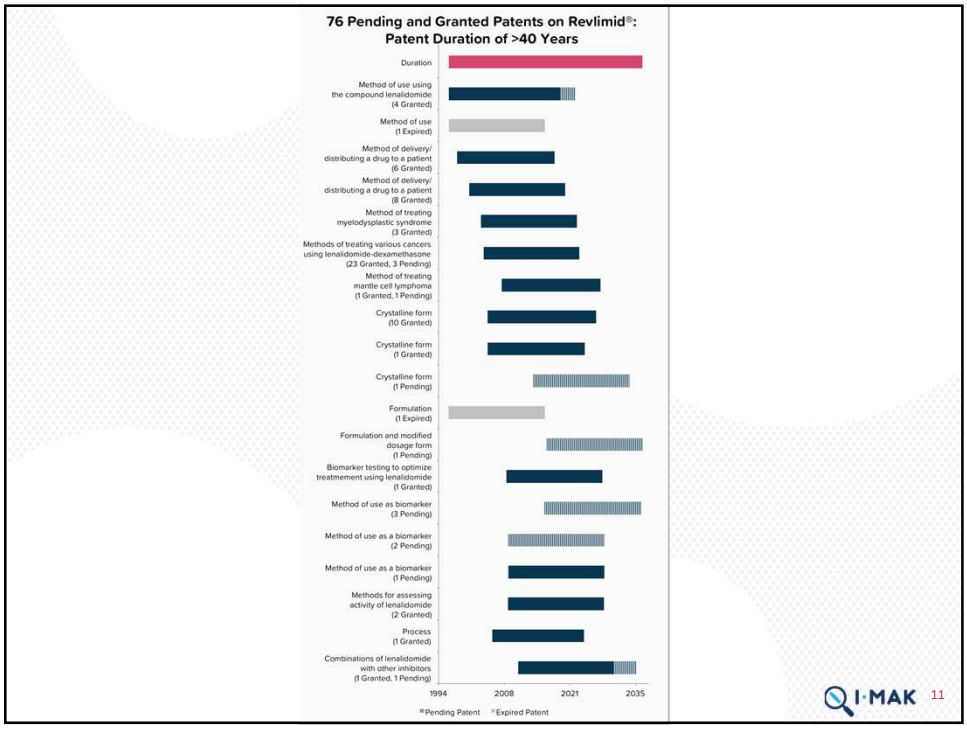
76 Pending and Granted Patents on Revlimid®:
Patent Duration of >40 Years
Duration
Method of use using the compound lenalidomide (4 Granted)
Method of use (1 Expired)
Method of delivery/ distributing a drug to a patient (6 Granted)
Method of delivery/ distributing a drug to a patient (8 Granted)
Method of treating myelodysplastic syndrome (3 Granted)
Methods of treating various cancers using lenalidomide-dexamethasone (23 Granted, 3 Pending)
Method of treating mantle cell lymphoma (1 Granted, 1 Pending)
Crystalline form (10 Granted)
Crystalline form (1 Granted)
Crystalline form (1 Pending)
Formulation (1 Expired)
Formulation and modified dosage form (1 Pending)
Biomarker testing to optimize treatmement using lenalidomide (1 Granted)
Method of use as biomarker (3 Pending)
Method of use as a biomarker (2 Pending)
Method of use as a biomarker (1 Pending)
Methods for assessing activity of lenalidomide (2 Granted)
Process (1 Granted)
Combinations of lenalidomide with other inhibitors (1 Granted, 1 Pending)
1994
2008
2021
2035
Pending Patent
Expired Patent
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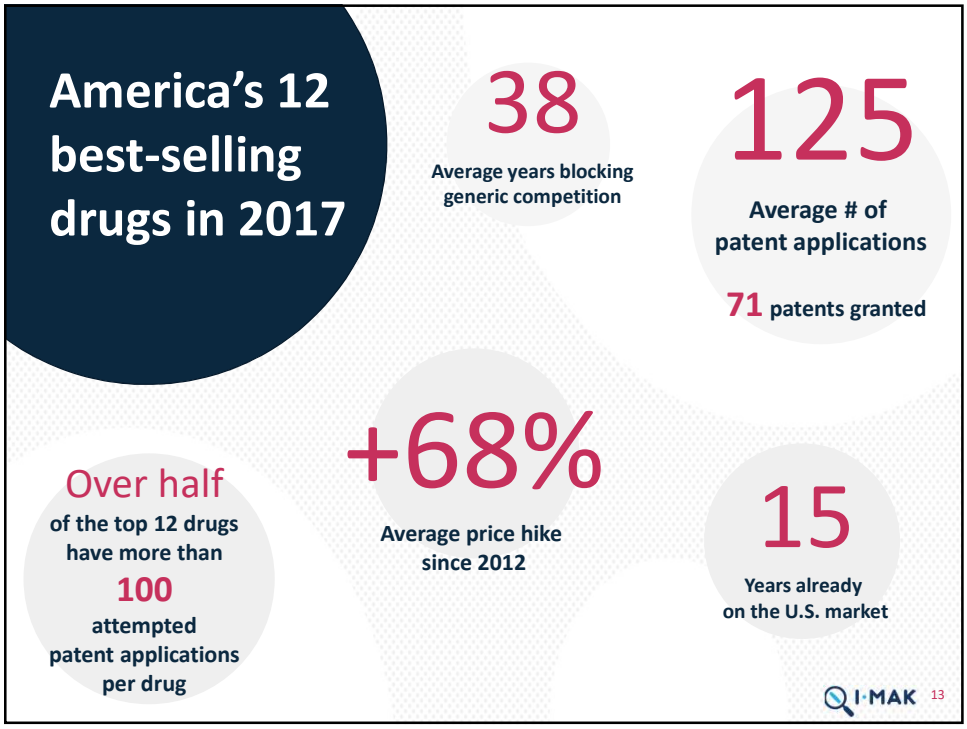
AbbVie
1 HUMIRA
CONDITION(S) TREATED Arthritis
NUMBER OF PATENT APPLICATIONS 247
PRICE CHANGE SINCE 2012 +144%
YEARS BLOCKING COMPETITION 39
ON THE U.S. MARKET SINCE 2002
Biogen/Genentech
2 RITUXAN
CONDITION(S) TREATED Cancer
NUMBER OF PATENT APPLICATIONS 204
PRICE CHANGE SINCE 2012 +25%
YEARS BLOCKING COMPETITION 47
ON THE U.S. MARKET SINCE 1997
Celgene
3 REVLIMID
CONDITION(S) TREATED Multiple Myeloma
NUMBER OF PATENT APPLICATIONS 106
PRICE CHANGE SINCE 2012 +79%
YEARS BLOCKING COMPETITION 40
ON THE U.S. MARKET SINCE 2005
Amgen
4 ENBREL
CONDITION(S) TREATED Arthritis
NUMBER OF PATENT APPLICATIONS 57
PRICE CHANGE SINCE 2012 +155%
YEARS BLOCKING COMPETITION 39
ON THE U.S. MARKET SINCE 1998
Roche/Genentech
5 HERCEPTIN
CONDITION(S) TREATED Cancer
NUMBER OF PATENT APPLICATIONS 186
PRICE CHANGE SINCE 2012 -58%
YEARS BLOCKING COMPETITION 48
ON THE U.S. MARKET SINCE 1998
Pfizer/BMS
6 ELIQUIS
CONDITION(S) TREATED Stroke/ Embolism
NUMBER OF PATENT APPLICATIONS 48
PRICE CHANGE SINCE 2012 +69%
YEARS BLOCKING COMPETITION 34
ON THE U.S. MARKET SINCE 2012
Johnson&Johnson
7 REMICADE
CONDITION(S) TREATED Arthritis
NUMBER OF PATENT APPLICATIONS 123
PRICE CHANGE SINCE 2012 +18%
YEARS BLOCKING COMPETITION 32
ON THE U.S. MARKET SINCE 1998
Roche
8 AVASTIN
CONDITION(S) TREATED Cancer
NUMBER OF PATENT APPLICATIONS 219
PRICE CHANGE SINCE 2012 +16%
YEARS BLOCKING COMPETITION 43
ON THE U.S. MARKET SINCE 2004
Johnson&Johnson
9 XARELTO
CONDITION(S) TREATED Blood Clots
NUMBER OF PATENT APPLICATIONS 49
PRICE CHANGE SINCE 2012 +87%
YEARS BLOCKING COMPETITION 31
ON THE U.S. MARKET SINCE 2011
Bayer/Regeneron
10 EYLEA
CONDITION(S) TREATED Macular Degeneration
NUMBER OF PATENT APPLICATIONS 67
PRICE CHANGE SINCE 2012 +6%
YEARS BLOCKING COMPETITION 34
ON THE U.S. MARKET SINCE 2018
Sanofi
11 LANTUS
CONDITION(S) TREATED Diabetes
NUMBER OF PATENT APPLICATIONS 74
PRICE CHANGE SINCE 2012 +114%
YEARS BLOCKING COMPETITION 37
ON THE U.S. MARKET SINCE 2000
Pfizer
12 LYRICA
CONDITION(S) TREATED Pain
NUMBER OF PATENT APPLICATIONS 118
PRICE CHANGE SINCE 2012 +163%
YEARS BLOCKING COMPETITION 32
ON THE U.S. MARKET SINCE 2004
I·MAK
12


America's 12 best-selling drugs in 2017
38
Average years blocking generic competition
125
Average # of patent applications
71 patents granted
Over half
of the top 12 drugs have more than
100
attempted patent applications per drug
+68%
Average price hike since 2012
15
Years already on the U.S. market
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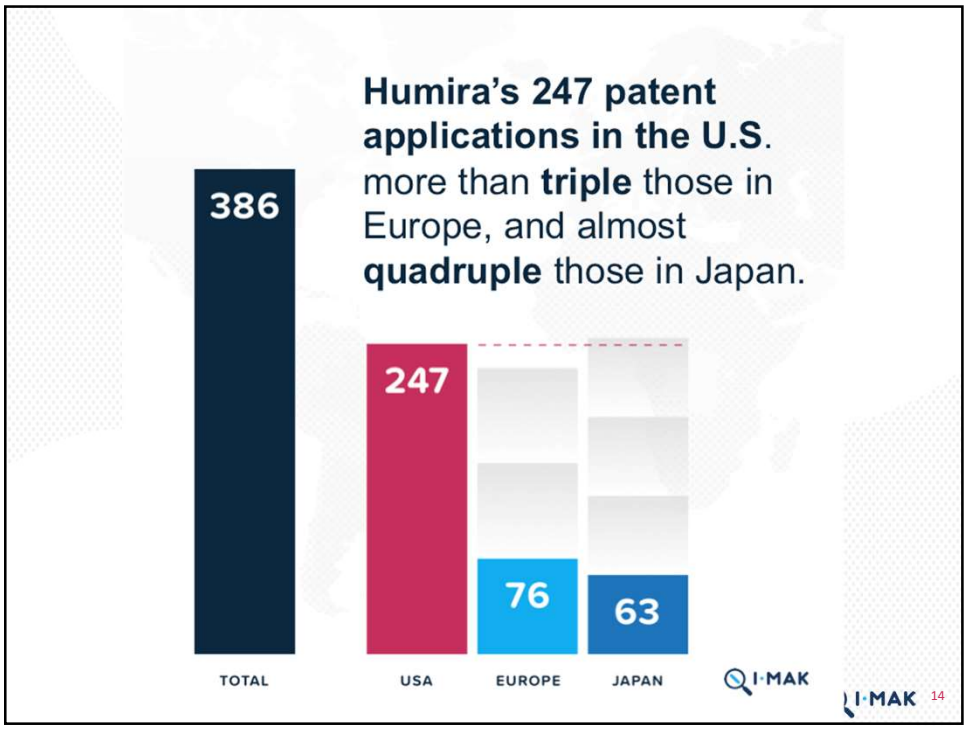
Humira's 247 patent applications in the U.S. more than triple those in Europe, and almost quadruple those in Japan.
386
247
76
63
TOTAL
USA
EUROPE
JAPAN
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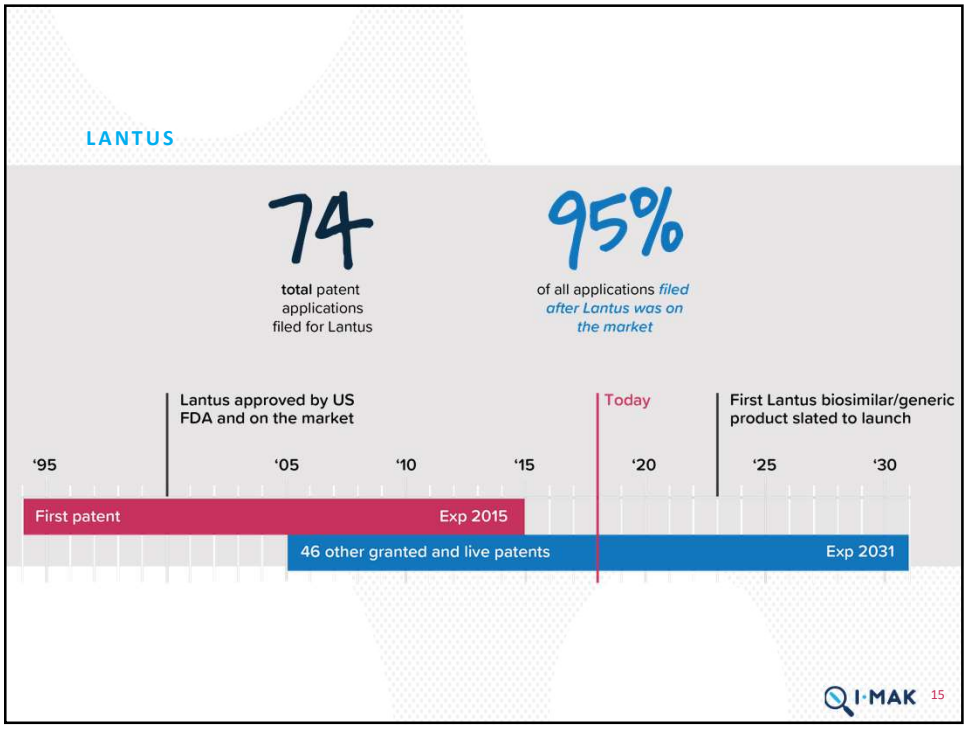

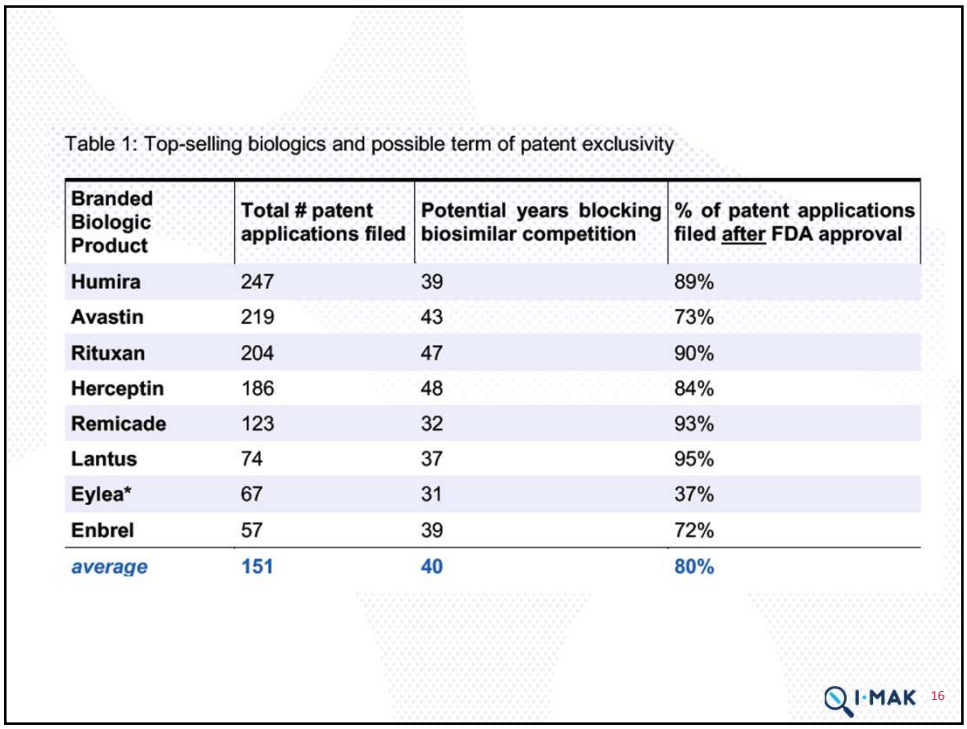

Table 1: Top-selling biologics and possible term of patent exclusivity

Branded Biologic Product	Total # patent applications filed	Potential years blocking biosimilar competition	% of patent applications filed after FDA approval
Humira	247	39	89%
Avastin	219	43	73%
Rituxan	204	47	90%
Herceptin	186	48	84%
Remicade	123	32	93%
Lantus	74	37	95%
Eylea*	67	31	37%
Enbrel	57	39	72%
average	**151**	**40**	**80%**

PATENT GAMES ARE NOT LIMITED TO BIOLOGICS

Brand	Company	FDA Approved	No. of Patent Applications	No. of Granted Patents	Years of potential protection
Copaxone	Teva	1997	137	67	40
Epclusa	Gilead	2016	80	43	32
Truvada	Gilead	2004	72	51	45
Imbruvica	AbbVie	2016	152	83	30

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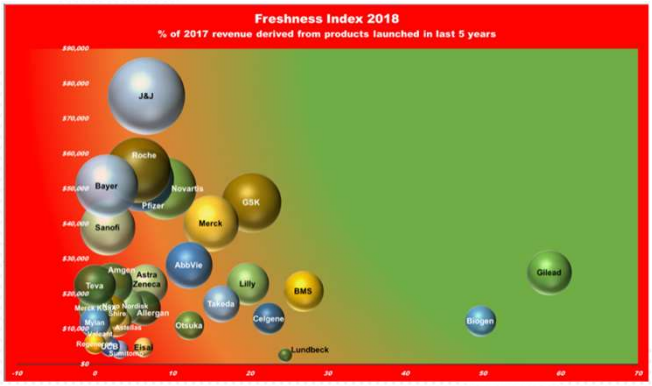
Is the patent system delivering progress?

11% of the pharmaceutical industry's 2017 revenue is coming from **new products**



"For all the talk of innovation in pharma, a term used with loose abandon, and even looser definition, the challenge of seeing 'return on invention' is a significant one"

- Mark Rea, CEO, IDEA Pharma

Source: IDEA Pharma, Pharmaceutical Innovation Index 2018 - Freshness Index

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The need for reform

SOME THOUGHTS

REAL REFORMS FOR REAL CHANGE

- Modify the "inventiveness" standard for patents
- Severely restrict continuation applications at the USPTO

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We can't solve the drug pricing crisis until we solve the drug patent problem

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