Overview of the USPTO Drug Exclusivity Report

USPTO Report: Selected Key Quotations

(1) Simply counting granted patents does not provide a meaningful assessment of the patent landscape nor is it indicative of the length of exclusivity:

"The results illustrate that simply quantifying raw numbers of patents and exclusivities is an imprecise way to measure the intellectual property landscape of a drug product because not every patent or exclusivity has the same scope . . . ***[S]imple counts of patents can be misleading when every patent is counted equally***, because the number of patents does not provide a clear picture of the landscape without a review of the scope of the claims in each patent." (p. 57)

(2) Follow-on patents do not "extend" earlier patents and do not block the introduction of generics:

"[T]his study identifies several examples of such follow-on patents . . . In some of these examples, ***the data indicates that a generic competitor drug was approved and launched, while later patents directed to follow-on innovation and listed in the Orange Book were still in force***. For example, a generic competitor launched a competing product to LIPITOR, before all the patents expired." (p. 5)

"In other cases, **later patents may have claims directed only to specific aspects of the [innovator company's] product, and may not block a generic** from launching a competing product once the earlier patents have expired." (p. 6)

(3) Only issued patents, not pending or abandoned applications, provide patent exclusivity:

"The study includes only granted patents and does not include pending or abandoned patent applications. Abandoned applications do not result in granted patents, and thus, do not pose a barrier to competition. The study also does not discuss pending patent applications, because they are not listable in the Orange Book and may never become patents, and if no patent is granted, there is no enforceable right. As a result, ***the total of all abandoned and pending applications is not a meaningful metric***." (p. 13)

(4) Most innovative products, not only pharmaceuticals, are covered by multiple patents:

"With respect to multiple patents that cover a single product, multiple patents associated with a single marketed product are not unique to the pharmaceutical industry and are a common practice in many innovative industries, especially for complex products." (p. 58)

USPTO Report: USPTO Data Shows That There Is No Clear Correlation Between the Number of Orange Book Patents and When a Generic Enters the Market

Of the 25 new drug applications (NDAs) the USPTO reviewed, 13 had generic products enter the market during the study period. These NDAs are listed under their branded product name below, along with the number of Orange Book patents listed for those products during the USPTO's study period of 2005-2018.

The average period of exclusivity across these products is 11.4 years — less than the 20-year length of a full patent term. Although the USPTO cautioned that it was not reviewing a statistically significant sample, its findings are in line with other research in this field.[1] As the USPTO concludes, "The results illustrate that simply quantifying raw numbers of patents and exclusivities is an imprecise way to measure the intellectual property landscape of a drug product." (p. 57).

Product	Orange Book-listed Patents	Total Exclusivity (Years)
AMBIEN tablet	1	14.4
AMBIEN CR	2	5.1
NORVASC	2	14.7
MIRAPEX ER	3	5.8
LYRICA	3	14.6
LYRICA solution	3	9.6
LYRICA CR	5	3.5
INTERMEZZO	4	4.3
MIRAPEX	4	12.5
LIPITOR	5	15
KALETRA solution	14	16.4
KALETRA tablet	20	15.6
REVLIMID	27	16.2

[1] *See, e.g.*, Erika Lietzan & Kristina Acri née Lybecker, *Solutions Still Searching for a Problem: A Call for Relevant Data to Support "Evergreening" Allegations*, 33 Fordham Intell. Prop., Media & Ent. L.J. 41 (forthcoming) (11.3 years of average market exclusivity based on review of 224 NDAs) (collecting other studies in footnote 237); Henry Grabowski et al., *Continuing Trends in U.S. Brand Name and Generic Drug Competition*, 24 J. Med. Econ. 908 (2021) (for new molecular entities with over $250 million/year, the average time to generic entry was 13 years, which "has changed relatively little over the past decade and remains lower than for all [new molecular entities] (14.1 years).").

I-MAK Patent Data: The USPTO Report Shows that I-MAK Overstates the Patent Barriers to Generic Market Entry

Per the USPTO report, there is no simple correlation between the total number of patents and the length of exclusivity. Simple patent counts are not predictive of when a generic can or will enter the market.

I-MAK's overall patent count includes patents not listed in the Orange Book. As the USPTO Report states, "Whether a patent is listed in the Orange Book is an important distinction because only patents listed in the Orange Book can affect the timing of FDA approval of a generic drug. Patents that are not listed in the Orange Book do not impact the timing of FDA approval of a generic drug application." (p. 13). The USPTO Report, which catalogues the number of Orange Book patents, provides a more realistic picture of when generics can enter the market—although generics can also attempt to enter the market earlier if they plan to challenge Orange-Book-listed patents.

I-MAK's top-line patent count further includes abandoned and pending patent applications, neither of which can be used to block products from the market through patent litigation.

	Total Patents		Exclusivity (years)	
Product	Orange Book (USPTO)	I-MAK	Until Actual Generic Entry	I-MAK Data
Lyrica capsule	3	68	14.6	32
Lyrica solution	3	68	9.6	32
Lyrica CR	5	68	3.5	32
Revlimid	27	206 total (83 abandoned, 79 active, 38 expired, and 6 pending)	16.2	40.0
Biktarvy	9	73 total (26 abandoned, 32 active, 12 expired, and 3 pending)	N/A	20.9
Eliquis	3	43 total (19 abandoned, 19 active, 3 expired, and 2 pending)	N/A	34.0
Imbruvica capsule	27	195 total (85 abandoned, 96 active, and 14 pending)	N/A	22.3
Imbruvica tablet	27	195 total (85 abandoned, 96 active, and 14 pending)	N/A	18.0
Xarelto	5	30	N/A	31
Xarelto tablet	3	30	N/A	31

Sources: USPTO Report (Orange Book patents and their expiration dates, FDA approval dates, dates of actual generic entry) (data provided for 2005-2018); I-MAK, The Drug Patent Book (I-MAK data for Revlimid, Biktarvy, Eliquis, and Imbruvica (separate products analyzed collectively)) (data appears current as of June 2022); I-MAK, Overpatented, Overpriced (2018) (I-MAK data for Lyrica and Xarelto (for both, separate products analyzed collectively)).

Other Data: 2023 Top Patentees Are Concentrated in Tech, Not Pharma

The Intellectual Property Owners' Association (IPO) 2023 annual report of the top 301 patentees in the United States shows that the tech sector dominates the list:[2]

- Publicly-traded tech companies comprise nearly 100 entities on the list compared to only 6 biopharma companies (2%).[3]
- The total number of patents (9036) granted to the top patentee (Samsung Electronics) is over three times the number of patents granted to the biopharma companies on the list *combined* (2748).

[2] The full list is available at IPO's website in an interactive form, and also available here: https://ipo.org/wp-content/uploads/2024/01/2024-Patent-300-IPO-Top-Patent-Owners-List.pdf. To assign sector designations, entities from the IPO list were cross-referenced with the sector designations assigned by Morningstar for publicly traded companies (https://www.morningstar.com/). Biopharma companies were identified by reference to Morningstar's industry sub-designation of "Drug Manufacturers – General" or "Biotechnology" under the "Healthcare" sector designation.

[3] These biopharma companies are: Bayer AG, Johnson & Johnson, Merck, Regeneron, Roche, and Sanofi.