



May 19, 2021

Rep. Carolyn B. Maloney
Chairwoman of the Committee on Oversight and Reform
U.S. House of Representatives

Rep. James Comer
Ranking Member of the Committee on Oversight and Reform
U.S. House of Representatives

Re: Request for statement for the record in hearing on Unsustainable Drug Prices (Part III), May 18, 2021

I am the Director of Knowledge Ecology International (KEI), a non-profit organization that works globally to promote reforms in the incentives for drug development. I have followed drug pricing disputes for several years, and undertaken research on possible reforms of the incentive system for inducing investments in research and development. More information about KEI can be accessed here: <https://keionline.org>.

Under the current system, governments provide a number of direct and indirect subsidies for drug development, plus incentives. The primary incentives are time limited sets of exclusive rights to make and sell products. These incentives include exclusive rights in patented inventions and a growing number of regulatory barriers to entry by generic or biosimilar products, including three to twelve years of exclusive rights in regulatory test data and seven years of exclusivity for orphan drug designations, as well certain possible extensions of those rights. This hearing is to examine the excessive nature of those incentives and the impact of high prices on patients and health systems.

As the hearing has demonstrated, there is no connection between the incentives needed to induce investments in biomedical innovation and the ultimate cost of the incentives, and the impact of the patent system of the temporary monopoly is arbitrary, with a wide range of possible outcomes as regards the number of years before a company faces competition for generic or biosimilar versions. (See Annex)

Professor Robin Feldman has proposed a “one-and-done” reform, that would limit companies to “one period of protection,” with a company choosing which patent exclusivity would set the cap at the time the FDA approves the drug. (Feldman 2019, Feldman 2018). This could also be done by Congress setting a cap, for example at 12 or 14 years from the first US FDA registration for the product. After the cap is reached, companies could still benefit from rights in patents, but through reasonable royalties on open licenses, rather than exclusive rights. Such a reform would work particularly well if it were accompanied by required technology transfer, so that biologic drugs did not have greater barriers to entry than do small molecule drugs, following the period of intended exclusivity (designed to induce investments in R&D).

Such a standardized cap on the period of exclusivity would avoid cases where some drugs have seven years of exclusivity while others enjoy 27 years, only due to the complex and arbitrary nature of determining the validity and scope of patent claims. It would not, however, address other concerns about the incentive system; namely, that the system can wildly over reward some innovations and under reward others.

Humira, a drug that had sales of more than \$171 billion through the end of 2020, is an example of a case where the incentive was excessive, but there are many other products that have monopoly sales revenue that far exceeds any efficient subsidy, and where the exclusivity effectively imposes enormous fiscal toxicity and access barriers from high prices.

Any cap on exclusivity could have more than one dimension, and include both time and global sales. In comments on dozens of NIH proposed exclusive patent licenses, KEI has asked that any exclusive rights terminate when global revenues exceed certain benchmarks, (<https://www.keionline.org/nih-licenses>) a condition that is relatively straightforward to implement, particularly for cases where exceptionally high prices are tolerated due to rare diseases or conditions, or for blockbuster drugs where there is a significant mismatch between the incentive and the expected cost of further development of the licensed technology. KEI has also addressed the need to consider global revenues as a trigger for interventions for excessive pricing in an April 30, 2019 memorandum to Congress. (Knowledge Ecology International 2019)

If caps on exclusivity were implemented as a legislative reform, there would be a small reduction in the incentive for drug developers, and this would be a negative for research and development investments. The quantitative impact of the change in the incentive on R&D outlays requires some challenging modeling, but one aspect is not difficult. The present value of one dollar received 15 years in the future,

discontinued at low trend inflation rate of 2 percent and a real discount rate of 10.5 percent (the discount rate used in Joseph DiMasi's 2016 paper), would be 17 cents. For each 17 cents in future revenue, one would deduct expected costs of manufacturing, marketing and rent seeking lobbying and litigation activities, as well as excessive compensation for executives. Let's just assume that it would consume about one quarter of the sales in revenue, making the present value of one dollar in net revenue in year 15 to be 13 cents. To this one can further discount the odds of a product actually having an effective exclusivity longer than 14 years, under the patent system as we know it, and the uncertainty of a superior alternative appearing on the market. And for each additional year of exclusivity, the present value of the incentive is discounted even more, and exponentially. For example, Humira's year 25 revenue would have a present value of 5 cents on the dollar, and year 30 revenue would have a present value of less than 3 cents on the dollar, before even taking into account the costs of goods, marketing, litigation, taxes, etc, or discounting further the remote chance that an effective exclusivity will actually exist that far out.

Table 1: Present value of 1 dollar, discounted at 12.5 percent

Year	Present value of \$ 1 in future revenue	75% of PV
15	.1709	.1282
16	.1519	.1139
17	.1350	.1013
18	.1200	.0900
19	.1067	.0800
20	.0948	.0711
....		
25	.0526	.0395
30	.0292	.0219

Compensating for impact on R&D

Even with such discounting, the possibility of a long exclusivity period is of some value of the investors. To offset the reduction in incentives, Congress could undertake any number of measures that will more than compensate. For example, **the Orphan Drug Tax Credit** on qualifying clinical trials could be restored to 50 percent (the value of the credit from 1983 to 2017), or **the NIH budget** could be increased, two measures that would have a much bigger impact on innovation than long periods of

exclusivity. The Congress could also fund **new market entry rewards**, as cash payments to developers of products useful in areas of priority, such as new antibiotic drugs, or more generally, for products that improve health care outcomes, rather than match them.

As an incentive mechanism, market entry rewards have a number of advantages over extended exclusivity. Market entry rewards provide monetary rewards to firms earlier, do not induce as much spending on marketing and rent seeking lobbying and litigation, having a higher present value to a firm, and can be directed to achieve policy objectives, such as to reward the development of products to address the greatest needs, with the most significant efficacy, or that establish new approaches to treating or preventing diseases or conditions.

Congress could also introduce the cap on exclusivity to apply only to products that have either high prices (when the cost of a treatment exceeds per capita incomes) and/or large cumulative sales revenue.

A combination of (1) a fixed target for exclusivity (based upon years on the market, with or without revenue triggers), followed by the non-exclusive licensing of inventions, data, know-how and cell lines, and (2) market entry rewards or other R&D subsidies, provides for a more holistic reform that both reforms the incentive and preserves or enhances innovation. This combination can be introduced initially with a long period of exclusivity, such as 14 years, and over time, decreasing exclusivity periods and increasing market entry rewards, providing a feasible and enabling pathway for delinking R&D incentives from legal monopolies and high prices.

Sincerely,

A handwritten signature in blue ink that reads "James Packard Love". The signature is written in a cursive, flowing style.

James Packard Love
Director, Knowledge Ecology International
<http://keionline.org>, email: james.love@keionline.org

Bibliography

- Feldman, Robin. 2018. "May your drug price be evergreen." *Journal of Law and the Biosciences* 5, no. 3 (December): 590-647. <https://doi.org/10.1093/jlb/lisy022>.
- Feldman, Robin. 2019. "'One-and-done' for new drugs could cut patent thickets and boost generic competition." *Stat News*, February 11, 2019. <https://www.statnews.com/2019/02/11/drug-patent-protection-one-done/>.
- Knowledge Ecology International. 2018. "Drug approvals from 1995-2005, number of competitors for biologic BLA and NDA." <https://docs.google.com/spreadsheets/d/1YIKf0Nybi8ByWSo7hJmuzGQR-ySY4h6dugRWrf19lPA/edit?usp=sharing>.
- Knowledge Ecology International. 2019. "KEI Memo on U.S. Legislation to cap price increases on prescription drugs and to enhance the transparency of R&D costs." <https://www.keionline.org/30578>.

ANNEX How common is extended exclusivity?

How many products currently benefit from extended exclusivity? There are few studies on this point. KEI studied the probability of entry for drugs first approved by the FDA from 1995 to 2005, by the end of 2017. For drugs approved in 2005, this was a 12 year period. For drugs approved in 1995, it was 22 years. For the 350 Type 1 NDA small molecule products first approved by the FDA from 1995 to 2005, 215, or 61 percent, faced entry by at least one product with the same API by the end of 2017. The odds of entry were higher for products approved earlier. For the Type 1 products approved from 1995 to 2003 under an NDA, 64 percent faced competition from products with the same API, compared to 47 percent for the drugs approved in 2004 or 2005. For biologic products, entry was less common, just 17 percent of products registered under a BLA faced a competitor with the same API.

Among the products that faced competition from products with the same API, the average time before entry was 10.5 years for the NDAs, and 16.4 years for the BLAs. Among the 215 Type 1 NDA products in the study that faced competition from a product with the same API, roughly half faced competition within 10 years, and 77 percent faced competition within 14 years. KEI is currently updating this study to include data on entry through the end of 2020.