Questions for the Record from Representative Issa for Jamie Simpson

"Medicines and IP: Balancing Innovation and Access"

June 4, 2026

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1. Do FDA exclusivity programs that temporarily block competition supplant the need for patent protection to allow innovators to recoup research and development costs?

2. Did the PTAB need to be reined in?

    a. Follow on question: Historically, how does PTAB compare to district courts when it comes to the rate at which they invalidate patents?

    b. Follow on question: What has the available data shown about whether PTAB has accurately adjudicated patent validity over the past 12 years?

3. When a patent is held invalid, that means it does not meet one or more statutory requirements and should not have been granted in the first place. Should patent policies encourage the early and accurate adjudication of patent validity so that invalid patents can be detected and cleared away to avoid obstructing the entry of lower-cost generic and biosimilar medications?

Questions for the Record from Representative Johnson for Jamie Simpson

"Medicines and IP: Balancing Innovation and Access"

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1. In your opening remarks, you stated that the Drug Price Competition and Patent Term Restoration Act (the Hatch-Waxman Act) increased the generic drug market share from roughly 13% in 1983 to approximately 90% today. Please provide peer-reviewed data supporting these figures and a brief summary of the methodology used to produce them.

2. In your opening remarks, you stated that the United States was not the world leader in biopharmaceutical innovation 40 years ago. Please provide peer-reviewed research supporting this claim, including data on the relative shares of biopharmaceutical innovation attributable to the United States and other countries at that time, as well as comparable data for the present day. Additionally, please briefly summarize the methodology used in these studies.

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Before the Subcommittee on Courts, Intellectual Property, Artificial Intelligence, and the Internet
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Hearing on "Medicines and IP: Balancing Innovation and Access"

ANSWERS TO QUESTIONS FOR THE RECORD FROM SUBCOMMITTEE CHAIRMAN ISSA

July 7, 2026

1. Do FDA exclusivity programs that temporarily block competition supplant the need for patent protection to allow innovators to recoup research and development costs?

No. Regulatory exclusivity and patent protection serve different purposes, operate on different timelines, and confer different rights. Congress designed them to work together; one does not substitute for the other.

A patent is a property right: it allows the inventor to exclude others from practicing the claimed invention, including competitors who independently develop the same product or use the same underlying technology. Patents can also protect platform technologies, research tools, manufacturing methods, formulations, delivery systems, and other inventions that may not correspond neatly to a single FDA-approved product. Regulatory exclusivity is narrower. It is a form of regulatory forbearance: for a defined period, FDA may not rely on the originator's approval data to approve an abbreviated generic or biosimilar application. It is tied to the approved product, begins at approval, and expires on a fixed schedule.

That distinction matters because much of a medicine's clinical value often emerges after first approval, through new indications, reformulations, improved delivery systems, or other post-approval research. Most forms of regulatory exclusivity do not provide an ongoing reward for that lifecycle innovation. Patents can, but only when the later invention independently satisfies patentability requirements such as novelty and non-obviousness. In that respect, patent law does exactly what it is designed to do in cumulative-innovation fields: reward real advances that build on prior discoveries.

Nor does FDA exclusivity fully prevent competition in the way patents can. During the exclusivity period, a competitor may be blocked from relying on the innovator's data, but it is not necessarily barred from developing its own data and seeking approval. Once exclusivity expires, only patents continue to protect qualifying inventions and incentivize further research.

For these reasons, FDA exclusivity alone is not sufficient to replace patent protection. Exclusivity fills targeted regulatory gaps, while patents provide broader, invention-based protection that supports both initial investment and later improvements. Innovators rely on the two in combination, not one in place of the other.

2. Did the PTAB need to be reined in?
(a) Follow on question: Historically, how does PTAB compare to district courts when it comes to the rate at which they invalidate patents?
(b) Follow on question: What has the available data shown about whether PTAB has accurately adjudicated patent validity over the past 12 years?

Yes, but in a targeted way. The answer is not to dismantle inter partes review or post-grant review. It is to fix the serial and duplicative challenges that PTAB practice has too often allowed. Since the Leahy-Smith America Invents Act (AIA) created IPRs and PGRs, PTAB practice has shifted repeatedly across administrations and USPTO directors. For much of that history, a patent owner could be forced to defend the same claims multiple times: before the PTAB, in district court, before the ITC, or through multiple petitions filed by related or strategically aligned challengers. In some circumstances, claims could even be challenged again after they had already survived review.

That instability matters because a patent is a property right, and like any property right, it depends on a measure of finality. If the same patent can be subjected to repeated, overlapping attacks, the result is not just litigation burden; it is uncertainty that undermines the stability that inventors and investors need to justify the cost of developing and commercializing new technologies.

The USPTO has recognized this problem and has tried to address it administratively. But that is not enough. Discretionary-denial policy has expanded, contracted, and expanded again depending on the director and the administration. A procedure that can be created by memorandum or rulemaking can also be undone the same way. Patent rights need more durable safeguards than shifting agency practice.

That is why reform should focus on this specific feature of PTAB practice: not whether administrative patent review should exist, but whether the same challenger should be able to pursue repeated or duplicative validity attacks. The PREVAIL Act (H.R. 3160/S. 1553) offers a sensible roadmap. Among other things, it would require many IPR petitioners to have been sued or threatened with suit before filing a petition; require challengers to choose a single forum for their invalidity challenge after institution; and prevent the PTAB from relitigating claims that a court or the ITC has already upheld against the same challenger or its privies.

Those reforms would preserve PTAB review while restoring basic fairness and finality. A challenger would still have a meaningful opportunity to contest validity, but not endless opportunities across multiple forums. That is the right balance: one real chance to challenge a

patent, in the forum the challenger chooses, with rules stable enough to protect the reliance interests that patent rights are meant to support.

(a)

Historically, PTAB invalidation rates were much higher than district court invalidation rates in the Board's early years, but they have since moved closer to the 40–60% range typically observed in fully adjudicated patent-validity disputes.

That comparison requires caution. Patents that reach a final validity decision are not a random sample of all patents. They tend to be commercially important patents that someone thought worth asserting and someone else thought worth challenging. And because clearer cases are more likely to settle, the cases that proceed to judgment are usually the close ones.[1]

That selection effect depends heavily on stable and predictable legal rules. Sophisticated parties settle or litigate based on their expectations about how a tribunal is likely to apply the governing standard. In district court, that standard includes a presumption of validity and a clear-and-convincing-evidence burden.[2] At the PTAB, the burden is preponderance of the evidence, and the procedural setting is different. But once the relevant rules are known and reasonably stable, parties can price those differences into their expectations. The cases that proceed to final judgment should then tend to be the uncertain ones under that forum's governing rules.

That is why it is not surprising, in theory, for district courts and the PTAB to converge toward similar observed invalidation rates even though they apply different standards. The point is not that the underlying standards are the same. They are not. The point is that each standard becomes part of the parties' predictive framework. Once litigants understand the rules of the game, the cases selected for final adjudication should cluster around the margin of uncertainty created by those rules.

District court outcomes generally fit that pattern. The empirical literature is limited, but leading studies have found district courts invalidating patents in roughly the expected range: about 42.6% in a later study of definitive merits rulings in cases filed in 2008–2009.[3] A recent Sunwater Institute review likewise found that district court invalidation rates generally fall within the 40–60% range predicted by litigation-selection theory.[4]

The PTAB's early years looked very different, however. For example, as of 2015, the cumulative percentage of challenged claims that the Board had invalidated in IPRs was 83%, far outside the

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[1] George L. Priest & Benjamin Klein, *The Selection of Disputes for Litigation*, 13 J. Legal Stud. 1 (1984) (seminal paper on this topic); *see also* Sunwater Institute, *Patent Quality in the United States: Findings and Suggestions for Policymakers* (Sept. 2024) (describing the law-and-economics literature and its application to patent cases) (this paper is independent research funded by C4IP).

[2] *See* Priest & Klein, *supra* note 1.

[3] John R. Allison, Mark A. Lemley & David L. Schwartz, *Our Divided Patent System*, 82 U. Chi. L. Rev. 1073 (2015), https://lawreview.uchicago.edu/sites/default/files/01%20Allison%20Lemley%20Schwartz_ART_Online%20REVISED_0.pdf.

[4] Sunwater, *supra* note 1.

range typically associated with fully adjudicated patent disputes.[5] There are many possible explanations for this deviation. One is that the proceedings were new, the legal and procedural rules were still developing, and parties lacked a reliable track record for predicting outcomes. That uncertainty may have disrupted ordinary settlement dynamics, causing cases to proceed to final written decision that might otherwise have settled. The first wave of petitions may also have targeted an accumulated backlog of especially vulnerable patents. And the early PTAB framework included features that appeared favorable to challengers, including broadest-reasonable-interpretation claim construction and a limited practical ability to amend claims.

Over time, however, PTAB outcomes have moved closer to the district-court range. Institution rates have fallen from their early peak, and the Sunwater Institute's review of fiscal years 2019–2023 found institution rates of roughly 47–64% and final-written-decision invalidation rates of roughly 41–61%.[6] Those figures are more consistent with a mature adjudicatory system in which parties understand the applicable rules and settlement behavior filters out many clearer cases.

So, in sum: district courts have long tended to invalidate patents at rates consistent with ordinary litigation-selection theory, while the PTAB's early years were an outlier. As PTAB practice became more settled, its outcomes converged toward the same general 40–60% range—not because the PTAB and district courts apply identical legal standards, but because sophisticated parties learned to account for each forum's rules and standards when deciding which cases to settle and which to take to judgment. Notably, this convergence can occur even if one believes that certain PTAB standards—such as its use of the preponderance-of-the-evidence standard rather than the clear-and-convincing standard applied in district court—are ill-suited to the PTAB's role in the patent enforcement system.

(b)

The available data does not support a confident claim that the PTAB has been either systematically accurate or systematically inaccurate in adjudicating patent validity. The threshold problem is that there is no neutral benchmark against which to measure "accuracy." Patent validity is a legal conclusion reached under a particular burden of proof, on a particular record, applying a particular claim construction. So most proposed measures of PTAB accuracy are really measures of agreement with another decision-maker — the Federal Circuit, a district court, or the ITC, all of whom are effectively second-guessing the USPTO's initial decision — none of which supplies an independent yardstick of correctness.

With that caveat, the data supports two limited observations.

First, the Federal Circuit sustains PTAB decisions on appeal at a high rate — affirming the Board on every appealed issue in roughly 72–75% of cases cumulatively, with reversals-in-whole relatively uncommon.[7] At first blush this may seem hard to square with the settlement-selection

[5] Daniel F. Klodowski et al., *Special Report – PTAB IPR Stats Over Time (Q4 2013 - Q3 2018)*, Finnegan (Nov. 30, 2018), https://www.finnegan.com/en/insights/blogs/at-the-ptab-blog/special-report-ptab-ipr-stats-over-time-q4-2013-q3-2018.html.
[6] Sunwater Inst., *supra* note 1.
[7] Klodowski, *supra* note 5.

dynamics that push fully adjudicated validity disputes toward a rough 40–60% band, and that some observers invoke to characterize first-instance outcomes. It is not, once the premises of that theory are stated with care. The tendency toward the center is a feature of disputes in which the stakes are roughly symmetric to the two parties; it is not a fixed law, and it holds regardless of the governing legal standard because rational parties price the standard into their settlement decisions, so the standard changes which disputes are litigated to judgment rather than the win rate among them. That is also why two first-instance forums applying different burdens (e.g., the PTAB by a preponderance, a district court by clear and convincing evidence) can both fall within the band: the burden is absorbed by selection, not read off the win rate.

The same theory, applied to the appellate stage, can predict a departure from the center rather than convergence to it. The authors of the theory apply the model to the decision to appeal in the same terms as the decision to litigate, and they identify a common condition under which appellate outcomes will diverge systematically from 50%: they assert that appellate stakes are typically asymmetric, because appeals may be disproportionately contested for the value of the resulting precedent, which the parties may not value equally.[8] Likewise, in patent cases, given the substantial cost disparity between taking a case to trial versus appealing a losing verdict, a losing party might be incentivized to appeal despite being aware of a low likelihood of success. The point is not that the theory predicts any particular affirmance figure — the direction and magnitude of the departure turn on where the stakes asymmetry lies, which the theory does not fix from first principles — but that a systematic departure from 50% on appeal is fully consistent with, indeed expected under, the same framework that yields the 40–60% band below.

What the affirmance rate does *not* establish is that the Board was "right." That conclusion is blocked not by selection theory but by the standard of review. The Federal Circuit reviews the Board's legal conclusions *de novo*, but reviews its factual findings only for substantial evidence — a deferential standard that asks whether the Board's result was reasonably supported, not whether the court would have reached the same result in the first instance.[9] That matters for anticipation, which is a question of fact, and for obviousness, where the ultimate legal conclusion rests on factual predicates such as the scope and content of the prior art, the motivation to combine, and a reasonable expectation of success, each reviewed for substantial evidence. A range of records will support the Board's finding whichever way it came out, so affirmance signals durability under deferential review, not correctness. Many affirmances are also entered without opinion under Rule 36 and endorse no reasoning at all.[10] The affirmance rate thus measures how often the Board's decisions survive deferential review, not how often they were substantively right.

Second, there are instances in which the PTAB has reached different decisions than other trial-level forums, but again, disagreement between the PTAB and district courts or the ITC is not necessarily evidence that either forum got the answer wrong. The forums apply different rules. In

[8] Priest & Klein, *supra* note 1.
[9] *Dickinson v. Zurko*, 527 U.S. 150 (1999); *In re Gartside*, 203 F.3d 1305, 1315 (Fed. Cir. 2000); *Consolidated Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938) (substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion").
[10] Fed. Cir. R. 36(a), https://www.cafc.uscourts.gov/home/rules-procedures-forms/federal-local-rules-of-appellate-procedure/.

district court and at the ITC, an issued patent is presumed valid and invalidity must be proven by clear and convincing evidence. At the PTAB, unpatentability need only be shown by a preponderance of the evidence. For petitions filed before November 13, 2018, the PTAB also applied a different claim-construction standard — broadest reasonable interpretation — while courts applied the *Phillips* standard.[11] The Federal Circuit and Supreme Court have both recognized that these differences can lawfully produce different outcomes.

The bottom line is that the data is more useful for understanding institutional behavior than for grading PTAB accuracy. It shows PTAB decisions that are often sustained under deferential appellate review, and lawful divergence from district courts and the ITC because the forums apply different burdens and, historically, different claim-construction rules. It does not establish that the PTAB is categorically more or less accurate than other forums. The more defensible conclusion is that PTAB is a different adjudicatory track, calibrated to different rules, burdens, records, and procedural incentives.

3. When a patent is held invalid, that means it does not meet one or more statutory requirements and should not have been granted in the first place. Should patent policies encourage the early and accurate adjudication of patent validity so that invalid patents can be detected and cleared away to avoid obstructing the entry of lower-cost generic and biosimilar medications?

Yes. When a patent's validity is genuinely in question, resolving that question early and accurately benefits the challenger, the patent owner, and the public. The challenger avoids spending resources designing around or litigating against claims that may not survive. The patent owner obtains greater certainty and can license, invest, and commercialize on firmer footing. And the public receives clearer notice of what is protected and what is not. Uncertainty is costly to everyone, and the longer it persists, the more business and research decisions are made in its shadow.

The structure of the AIA already reflects a preference for front-loaded review. Post-grant review permits broad validity challenges — including eligibility, novelty, obviousness, written description, and enablement — but only during the first nine months after a patent issues. After that window closes, inter partes review remains available for the rest of the patent term, but only on narrower grounds: novelty and obviousness based on patents and printed publications. That design encourages the most comprehensive challenges to be brought early, before reliance interests have fully formed.

But "early" is only half the point. The adjudication must also be reliable. A good validity system should clear away claims that do not satisfy the statutory requirements while confirming claims that do, so that either outcome gives the parties and the public something they can rely on. A system that allows the same patent to be attacked repeatedly, years apart, across overlapping

[11] USPTO, *Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board*, 83 Fed. Reg. 51340 (Oct. 11, 2018), https://www.govinfo.gov/content/pkg/FR-2018-10-11/pdf/2018-22006.pdf.

forums does the opposite. It encourages late-stage uncertainty, increases the risk of inconsistent outcomes, and undermines the finality that property rights require.

Accordingly, the right policy goal is not simply more validity challenges. It is early, accurate, and durable resolution. Invalid claims should be tested and removed through fair procedures, but valid claims should also be quieted against repetitive attacks. That balance protects both competition and innovation by ensuring that patent rights are neither wrongly preserved nor endlessly destabilized.

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Before the Subcommittee on Courts, Intellectual Property, Artificial Intelligence, and the Internet
Committee on the Judiciary, U.S. House of Representatives

Hearing on "Medicines and IP: Balancing Innovation and Access"

ANSWERS TO QUESTIONS FOR THE RECORD FROM SUBCOMMITTEE RANKING MEMBER HANK JOHNSON

July 7, 2026

1. In your opening remarks, you stated that the Drug Price Competition and Patent Term Restoration Act (the Hatch-Waxman Act) increased the generic drug market share from roughly 13% in 1983 to approximately 90% today. Please provide peer-reviewed data supporting these figures and a brief summary of the methodology used to produce them.

These figures track the share of generics used to fill all prescriptions filled at U.S. pharmacies, which has grown dramatically since the 1984 Hatch-Waxman Act.

1983 (about 13%). The Congressional Budget Office reported that in 1983, generics were about 13% of the market for the kind of drugs Hatch-Waxman's generic-approval pathway covered.[1] CBO reached that figure by counting generic versus brand sales in a large sample of U.S. retail-pharmacy data and scaling it up to a national estimate. Independent peer-reviewed research arrives at a similar but slightly lower figure, describing generic use in the early 1980s at around 10%.[2]

Today (about 90%). Today, about 90% of prescriptions are filled with generics.[3] The Association for Accessible Medicines' annual report, prepared by the pharmacy-data firm IQVIA, reports this 90% figure.[4] It is independently corroborated by government claims data: in Medicare's prescription-drug program, where the share is calculated directly from claims, generics reached

[1] CBO, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* xiii (July 1998), https://www.cbo.gov/sites/default/files/105th-congress-1997-1998/reports/pharm.pdf (reporting the percentage of generics for non-antibiotic drugs).
[2] *See* Henry G. Grabowski & John M. Vernon, *Longer Patents for Increased Generic Competition in the U.S.: The Hatch-Waxman Act After One Decade*, PharmacoEconomics (1996).
[3] The exact percentage varies slightly with which prescriptions are counted, for example, retail pharmacies only versus all dispensing settings.
[4] Ass'n for Accessible Medicines, *The U.S. Generic & Biosimilar Medicines Savings Report 2025* (2025), https://accessiblemeds.org/wp-content/uploads/2025/09/AAM-2025-Generic-Biosimilar-Medicines-Savings-Report-WEB.pdf (citing to IQVIA, *The Use of Medicines in the U.S. 2023*, https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2023).

88% to 90% of prescriptions filled in 2016, up from 53% to 63% in 2006.[5] Peer-reviewed research documents the long climb to this level, with the generic share of prescriptions rising from 18.6% in 1984 to 74.5% by 2009.[6]

2. In your opening remarks, you stated that the United States was not the world leader in biopharmaceutical innovation 40 years ago. Please provide peer-reviewed research supporting this claim, including data on the relative shares of biopharmaceutical innovation attributable to the United States and other countries at that time, as well as comparable data for the present day. Additionally, please briefly summarize the methodology used in these studies.

Yes. Peer-reviewed research and related empirical studies support the statement that the United States was not the world leader in biopharmaceutical innovation forty years ago. The evidence shows that, through the mid-1980s, Western European firms collectively led the world in the discovery and introduction of new drugs. Over the following two decades, however, innovation leadership shifted decisively toward the United States.

One clear historical measure is the development of new chemical entities, or NCEs — new drug molecules brought to market. Data compiled by the European Federation of Pharmaceutical Industries and Associations and analyzed by the U.S. International Trade Commission (ITC) show that Western European firms accounted for a majority of global NCEs in the late 1970s and early 1980s.[7] In 1980–1984, European firms still developed substantially more NCEs than U.S. firms. Europe accounted for 126 global NCEs during that period, compared with 63 for the United States and 57 for Japan. In other words, the United States was an important contributor to pharmaceutical innovation, but it was not yet the world leader.

Other measures point in the same direction. Patent-based studies from the period show that European countries collectively accounted for a larger share of pharmaceutical patenting than the United States, even as U.S. strength was beginning to emerge in biotechnology-related fields.[8] Commercial-output measures also show a major shift over time: by the late 1990s, U.S.-

[5] Christine Buttorff, Yifan Xu & Geoffrey F. Joyce, *Variation in Generic Dispensing Rates in Medicare Part D*, 26 Am. J. Managed Care e355 (2020), https://www.ajmc.com/view/variation-in-generic-dispensing-rates-in-medicare-part-d (peer-reviewed analysis of Medicare Part D claims, 2006–2016, documenting high and rising generic dispensing rates in the program).

[6] Ernst R. Berndt & Murray L. Aitken, *Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals in the Quarter Century After the 1984 Waxman-Hatch Legislation*, 18 Int'l J. Econ. Bus. 177, 177 (2011).

[7] European Federation of Pharmaceutical Industries and Associations (EFPIA), *The Pharmaceutical Industry in Figures* (1997), pp. 22, as reproduced in U.S. International Trade Commission, *Review of Global Competitiveness in the Pharmaceutical Industry,* USITC Staff Research Study 25, Publication 3172 (April 1999), Table 2-1, p. 2-3. The table covers four five-year periods from 1975 through 1994. Shares calculated from table totals.

[8] Alfonso Gambardella et al., *Global Competitiveness in Pharmaceuticals: A European Perspective* 38, Table 16 (November 2000) (prepared for the Directorate General Enterprise of the European Commission) (showing data drawn from European Patent Office filings, 1978–1997; inventions assigned by share of inventors' country location).

headquartered firms accounted for a much larger share of the world's top-selling drugs than they had a decade earlier.[9]

Peer-reviewed research similarly found that, comparing the periods of 1982-1992 and 1993-2003, the U.S. share of new chemical entity introductions increased while Europe's share declined.[10] Later research found that European-headquartered pharmaceutical firms experienced a more pronounced decline in research publications from European-based laboratories than U.S.-headquartered firms did from U.S.-based laboratories, suggesting that primary discovery research was increasingly moving toward, or being conducted in partnership with, U.S.-based research sites.[11]

The methodologies used in these studies vary, but they point to the same broad conclusion. Some studies count new drug introductions, which directly measure the output of novel medicines but do not assess their medical impact. Other studies use patent counts and patent citations, which capture earlier-stage inventive activity and the influence of particular research programs, though they can be affected by differences in patent-filing behavior across countries. Still others use commercial measures, such as the national origin of top-selling drugs, which capture real-world impact but are influenced by market size, commercialization strategy, and pricing.

Taken together, these sources support the point made in my opening remarks: forty years ago, global pharmaceutical innovation was led collectively by Western Europe, with the United States playing a major but secondary role. The present-day picture is very different. Over the late twentieth and early twenty-first centuries, the center of biopharmaceutical innovation shifted toward the United States, which is now widely recognized as the world's leading source of new drug discovery and development.

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[9] *Id.* at 33, Table 12 (tracking the fifty best-selling new chemical entities launched in two five-year windows, 1985–1989 and 1995–1999, by the origin of the producing corporation, defined by headquarters location; source data: IMS Health. It shows the United States continuing to grow in terms of producing more of the top 50 NCEs and generating more sales compared to Europe (24 compared to 16) and generating more sales.)

[10] *See* Henry Grabowski and Y. Richard Wang, *The Quantity and Quality of Worldwide New Drug Introductions, 1982–2003*, Health Affairs Ex. 4 (2006) (showing the U.S. adding 32 NCEs to its output during this period while the EU declined by 47).

[11] Ismael Rafols et al., *Big Pharma, Little Science? A Bibliometric Perspective on Big Pharma's R&D Decline*, Technological Forecasting and Social Change Fig. 6 (2014). The study covered the publication output of all R&D laboratories of the world's 15 largest pharmaceutical firms from 1995 through 2009.