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Comments of the Pharmaceutical Research and Manufacturers of America in Response to the USPTO's Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights (Docket No. PTO-P-2022-0025)

February 1, 2023

I. Introduction

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit these comments in response to the United States Patent and Trademark Office's (USPTO) Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, 87 Fed. Reg. 60,130-60,134 (Oct. 4, 2022).

PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA's member companies have invested more than $1.1 trillion in the search for new treatments and cures, including an estimated $102.3 billion in 2021 alone. The biopharmaceutical industry is committed to working every day to discover and develop new treatments and cures for patients battling serious and life-threatening diseases such as Alzheimer's, heart disease, cancer, and, most recently, COVID-19, while also anticipating and preparing for the next pandemic. These new treatments and cures are made possible by the American system of intellectual property (IP) protections.

Given the increasing cost of bringing a biopharmaceutical product to market and the percentage of products that fail to reach the market, IP protections are now more important than ever to promote investment in biopharmaceutical research and development (R&D). Strong and predictable IP protections in the United States are essential to the U.S.'s economic well-being, and these protections signal to other jurisdictions the critically important economic benefits of IP. The substantial investments related to biopharmaceutical R&D also fuel the U.S. economy. IP-intensive manufacturing industries drive economic progress and collectively support 57.6 million American jobs,[1] including more than 4.4 million jobs supported by the biopharmaceutical industry, and contribute approximately $1.1 trillion in economic output when direct and indirect effects are considered.[2]

The USPTO is seeking public input regarding various initiatives to "bolster[] the robustness and reliability of patents" and "ensure that the patent rights granted by the USPTO fulfill their intended purpose of furthering the common good, incentivizing innovation, and

[1] PhRMA, IP in the Economy (last visited Jan. 30, 2023).

[2] TEConomy Partners, LLC, *The Economic Impact of the U.S. Biopharmaceutical Industry: 2020 National and State Estimates*, at 1, 14-15 (Mar. 2022).

promoting economic prosperity."[3] PhRMA agrees with this goal. PhRMA has concerns, however, about the increasingly harsh and in our view, unfounded, criticisms of the U.S. patent system that are cited in the Request for Comments. Patents provide critical incentives for biopharmaceutical companies to make the costly and high-risk investments necessary to research and develop new medicines for patients particularly in areas of high scientific uncertainty, and reduced patent protections would lead to fewer therapeutic choices for health care providers and patients. We believe that current IP laws and policies are functioning as intended and that the criticisms of the American patent system are unfounded. They are also based on flawed data and false narratives.

A. The Patent Laws and Policies Provide Critical Incentives for Innovative New Medicines

Developing a new medicine begins long before any patent applications are filed, with basic and other preclinical research, before progressing into long and costly clinical trials, obtaining FDA approval, and then bringing a drug to market—a long and increasingly expensive process. The time required to develop a drug and bring it to market averages 10 to 15 years.[4] Furthermore, R&D costs have increased by approximately 8.5% per year over the past decade.[5] The average cost of R&D per new drug is $2.6 billion, which includes the cost of laboratory research, clinical trials, and expenditures for drugs that do not reach the market.[6] This estimate does not include expenditures related to often significant FDA post-approval requirements nor does it include the substantial investments related to post-approval advances including, but not limited to, new indications, new forms of administration, and novel combination products.

On top of increasing costs, the risks of biopharmaceutical R&D are significant: most investigational biopharmaceuticals fail to obtain FDA approval.[7] Approvals are also getting harder to obtain. More than 20% of drugs developed in the 1980s and 1990s were ultimately approved by FDA, but now fewer than 12% of drugs that enter Phase I clinical trials are approved by FDA and marketed.[8] Further, an analysis of investigational drugs developed for nine different cancers between 1998 and 2020 revealed that 1,315 investigational drugs were

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[3] 87 Fed. Reg. 60,130, at 60,130 (Oct. 4, 2022).

[4] PhRMA, *The Dynamic U.S. Research and Development Ecosystem*, at 1 (2021). Protocols for clinical trials have become significantly more complex in recent years. For example, Phase II and III protocols involve 263 procedures per patient, supporting approximately 20 endpoints, and the number of procedures per patient has increased 44% since 2009. *See Rising Protocol Design Complexity is Driving Rapid Growth in Clinical Trial Data Volume*, GLOBALNEWSWIRE (Jan. 12, 2021). Phase III clinical trials generate an average of 3.6 million data points, which is three times the amount collected 10 years ago. *Id.* All of these additional complexities contribute to the increasing cost of biopharmaceutical research and development.

[5] Research and Development in the Pharmaceutical Industry, Congressional Budget Office, at 16 (Apr. 2021).

[6] Joseph A. DiMasi, Henry G. Grabowski, Ronald W. Hansen, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20-33, at Abstract (2016) (in 2013 dollars).

[7] PhRMA, *The Dynamic U.S. Research and Development Ecosystem*, at 2 (2021).

[8] Research and Development in the Pharmaceutical Industry, Congressional Budget Office, at 16-17 (Apr. 2021).

unsuccessful, and only 111 gained FDA approval.[9] These statistics reflect a uniquely complex and uncertain R&D pathway for biopharmaceuticals compared to innovative products in other fields of technology. In part due to these complexities, most drugs do not enter the market until years after a patent is issued, which typically results in an effective patent life that is significantly shorter than 20 years.[10] Thus, a biopharmaceutical product often does not enjoy the full 20 years of patent protection, which reinforces the need for patent protection that is available to be reliable and robust.

After a drug product is approved, biopharmaceutical sponsors often continue to innovate with respect to that drug product, and clinical research on new uses of approved products has revolutionized the treatment of many diseases and conditions. In some cases, additional research determines that a medicine can also be used to treat different states of the same disease, such as earlier stages of cancer. Additional research may also demonstrate the medicine can be used to treat completely different conditions including different forms of cancer, or different diseases altogether. In other cases, additional research may lead to increased safety or effectiveness, or new dosage forms, or new forms of administration of a medicine that can improve patient adherence or convenience, leading to better patient outcomes. Without patents to safeguard the investments made to research and develop additional uses, which may require a significant investment and take three to twelve years to develop,[11] there would be little incentive to continue R&D on a drug product after it has been approved. Indeed, IP protection for post-approval R&D should be strengthened, not weakened. FDA already generally permits follow-on applicants—which includes both generic and biosimilar applicants—to omit patent protected indications from their labeling while obtaining approval for other indications.[12] However, their products nevertheless may be used for the protected indication, including through automatic substitution

[9] *See* PhRMA, *Researching Cancer Medicines: Setbacks and Stepping Stones*, at 3 (2020). For example, setbacks in Alzheimer's disease medicine development highlights the complexity of Alzheimer's research—there is just a 2% success rate in treatments. Between 1998 and 2021 there were 198 unsuccessful investigational drugs for Alzheimer's disease. *See* PhRMA, *Researching Alzheimer's Medicines: Setbacks and Stepping Stones*, at 1 (2021). And between 1998 and 2017, 146 investigational medicines that were in clinical development to treat and potentially prevent Alzheimer's were halted while only four new medicines were approved to treat symptoms of the disease. *See* PhRMA, *Researching Alzheimer's Medicines: Setbacks and Stepping Stones*, at 3 (2018).

[10] *See* 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., at 41 (forthcoming) (finding that 224 new drug applications averaged 11.3 years of market exclusivity and new chemical entities averaged 13.34 years).

[11] Erika Lietzan, *Paper Promises For Drug Innovation*, 26 GEO. MASON L. REV. 168, 177-78 (2018); Benjamin N. Roin, *Solving the Problem of New Uses*, at 5 (Oct. 14, 2016).

[12] *See* FDCA § 505(j)(2)(A)(viii); 21 C.F.R. § 314.127(a)(7); Public Health Service Act § 351(k)(2)(A)(i)(III); FDA, Draft Guidance for Industry, Biosimilars and Interchangeable Biosimilars: Licensure for Fewer Than All Conditions of Use for Which the Reference Product Has Been Licensed, at 3-4, 8 (Feb. 2020) ("an applicant may choose to seek licensure of a proposed biosimilar or interchangeable biosimilar for fewer than all of the reference product's licensed conditions of use based on an assessment by the applicant that one or more of the reference product's licensed conditions of use is protected by patent").

for generics.[13] Any new policies should avoid further undermining of the incentives for development of new uses of approved drugs.

As previously noted, the biopharmaceutical industry is committed to working every day to discover and develop new treatments and cures for patients battling serious and life-threatening diseases while also working to anticipate and prepare for future challenges. Further, rare diseases often affect fewer than 10,000 people, but the total impact of rare diseases is much broader; cumulatively, rare diseases affect 30 million Americans, and these individuals often have significant unmet needs.[14] New treatments and cures are made possible by the American system of IP protections. Given the increasing cost, complexity, and unpredictability of bringing a biopharmaceutical product to market and the increasing percentage of drugs that fail to reach the market, IP protections are more important than ever to protect the investment in biopharmaceutical R&D. PhRMA applauds the USPTO's recognition of the importance of patents in incentivizing R&D directed to cancer via the Moonshot Program.[15] This recognition emphasizes the key role that patents play in promoting continued investment necessary to develop new drugs and bring them to market.[16] Incentives for innovation and investment in biopharmaceuticals are equally important in other areas of medicine.

The accomplishments of the United States in promoting development of both innovative and follow-on (i.e., generic and biosimilar) biopharmaceuticals are due in no small part to the balance Congress struck in both the Hatch-Waxman Act and its Amendments and the Biologics Price Competition and Innovation Act (BPCIA). Both Acts were intended to promote competition by establishing a pathway for abbreviated applications while preserving incentives for innovation.[17] Before the enactment of Hatch-Waxman, generic drugs were only about 19% of all dispensed prescriptions,[18] but Hatch-Waxman has been an overwhelming success in enabling generic access. Generics currently comprise up to 92% of all drug prescriptions dispensed, up from 75% in 2009.[19] Biosimilar products also are providing patients with additional choices. Interchangeable biologics have recently been approved, and the biosimilar market has expanded rapidly in recent years. Growth in the biologics and biosimilar market is

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[13] *See* Jesse C. Vivian, *Generic Substitution Laws*, U.S. PHARMACIST (June 19, 2008) (describing automatic substitution for generic drugs)).

[14] *See* PhRMA, *Meeting the Need: Rare Diseases and the Orphan Drug Act*, at 5 (2019).

[15] *See, e.g.*, *USPTO announces Cancer Moonshot Expedited Examination Pilot Program* (Dec. 8, 2022) (providing "expedite[d] examination for a broad scope of technologies to prevent cancer and cancer mortality . . . to help accelerate the patenting of key technology to bring [cancer] solutions to market and end [] cancer once and for all").

[16] Moreover, PhRMA supports initiatives to ensure patent quality through measures that aim to provide the USPTO and examiners with sufficient resources and capabilities for robust examination. For example, providing examiners additional access and assistance in identifying relevant prior art may help ensure the quality of issued patents.

[17] *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417. 98 Stat. 1585; Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148 §§ 7001-7003, 124 Stat. 804.

[18] *See* PhRMA, What is Hatch-Waxman? (June 2018).

[19] IQVIA Institute for Human Data Science, *The Use of Medicines in the U.S. 2022: Usage and Spending Trends and Outlook to 2026*, at 39 (Apr. 2022); IQVIA Institute for Human Data Science, *Medicines Use and Spending in the U.S. A Review of 2018 and Outlook to 2023*, at 5 (May 2019).

projected to continue, suggesting that the carefully balanced incentives of the BPCIA are working as intended.[20] Accordingly, both laws have robustly facilitated competition from follow-on products in the U.S. marketplace.

Indeed, incentives for innovation should be strengthened, particularly for novel drugs and innovative uses of existing drugs. Although some commentators have alleged that generic products are unnecessarily delayed from market entry, data do not support this allegation. For example, innovator drugs in a 1995-2019 cohort have been found to have an average market exclusivity period (MEP) from market launch of the innovator drug to the launch of the first generic of between 12.2 and 14.6 years.[21] In addition, since enactment of Hatch-Waxman in 1984, patent challenges from generic companies (in the form of paragraph IV certifications and subsequent Hatch-Waxman lawsuits) have been filed more frequently and earlier in the lifecycle of the innovator drug. Generic companies often file such challenges as soon as possible under the law—in the case of a new chemical entity, as early as four years after approval—and recent data show a trend towards new molecules experiencing fewer years from brand launch to the first Paragraph IV filing.[22]

To maintain a thriving market for both novel and follow-on drug products, innovator companies must continue to have incentives to make the risky, substantial investment in R&D necessary to bring new drugs to market. In the absence of such incentives, fewer new drugs may make it to FDA approval, to providers, and to patients, which would upset the balance intended by Hatch-Waxman and the BPCIA. The U.S. is a global leader in biopharmaceutical R&D and, as a result, patients in the U.S. generally enjoy the fastest and broadest access to innovative medicines in the world.[23] This access to biopharmaceutical products has the ability to offset other, much more significant and long-term costs related to adverse health outcomes. Without robust R&D, fewer medicines would be available, which could lead to worse health outcomes and, ultimately, more expensive medical care.

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[20] *See* Global Biosimilars Market Growing to Exhibit a Noteworthy CAGR of 22.9% by 2033, Key Drivers, Growth and Opportunity Analysis - Research Nester, GLOBAL NEWS WIRE (Oct. 12, 2022); The Global Biologics Market Is Projected to Grow at a CAGR of 8.82% By 2032: Visiongain Reports Ltd, GLOBAL NEWS WIRE (Oct. 12, 2022).

[21] Henry Grabowski et al., Continuing trends in U.S. brand-name and generic drug competition, 24 J. MED. ECON. 908, 911 (2021); *see also* 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., at 41 (forthcoming) (finding that 224 new drug applications averaged 11.3 years of market exclusivity and new chemical entities averaged 13.34 years). Arguments that "patent thickets" are extending patent protection are misplaced. As the data shows, innovator drugs, on average, receive less than 20 years of market exclusivity.

[22] Henry Grabowski et al., Continuing trends in U.S. brand-name and generic drug competition, 24 J. MED. ECON. 908, 914 (2021).

[23] *See* Kevin Haninger, New analysis shows that more medicines worldwide are available to U.S. patients, PHRMA (June 5, 2018).

B. Criticisms of the Patent System Underlying the Request for Comments Are Unwarranted

PhRMA has concerns about unsubstantiated allegations about the U.S. patent system, some of which are referenced in the Request for Comments. The June 8, 2022 letter from Senators Leahy, Cornyn, Blumenthal, Collins, Klobuchar, and Braun alleges that "large numbers of patents that cover a single product or minor variations on a single product, commonly known as patent thickets . . . are primarily made up of continuation patents and can stifle competition."[24] The letter also alleges that "continuation applications, rather than being closely scrutinized because of these harmful incentives, are granted at *higher* rates than original applications."[25] But the Senators do not cite any evidence for these allegations, and continuation applications are not subject to different patentability standards. Moreover, such a contention suggests that the USPTO is not carefully examining patents of certain types or in certain technology areas. No evidence has been cited questioning the quality of the USPTO's examination process; to the contrary, the USPTO applies the same rigorous standards regardless of the application type or relevant industry. Notably, a letter from Senator Tillis, Ranking Member of the Senate Judiciary Committee Subcommittee on Intellectual Property, explained that "several of the main sources driving the narrative that patents are to blame for high drug prices do not appear to . . . be based on accurate facts and data from reliable, unbiased sources."[26] Indeed, despite the strong rhetoric, there is no sound evidence that excessive numbers of patents are being issued, or that they are improperly stifling competition in the biopharmaceutical arena, nor is there reliable evidence that continuation applications are subjected to more lenient patentability standards than original applications.

First, all patent applications are examined and are issued as patents only if they meet the same rigorous standards. The statutory text makes no distinction between the patentability requirements for applications directed to different technologies or for different application types. Consistency in the USPTO's examination of all applications is key to ensuring the continued success of the U.S. patent system, as well as to ensuring consistency with the country's treaty obligations regarding technology neutrality as discussed below. Indeed, the Patent Public Advisory Committee understands that "[w]ith a reliable and durable patent right, inventors (and those that invest in patented technology) have confidence in the system . . . ."[27]

Second, narratives about the quantity of patents and the families of patents comprising so-called "patent thickets" are driven by questionable data and misunderstandings about patent coverage. A newly issued patent does not extend the term of an old one. And a single patent covers only the subject matter set forth in its claims, and claims in different patents cannot be identical. Thus, multiple distinct inventions relating to a particular product lead to multiple patents. Further, if related yet distinct claims are prosecuted via a continuation patent, the grant

[24] Letter from Sens. Leahy, Cornyn, Blumenthal, Collins, Klobuchar, and Braun to Kathi Vidal, at 1 (June 8, 2022).

[25] *Id.*

[26] Letter from Sen. Thom Tillis to Dr. Janet Woodcock and Mr. Drew Hirshfeld, at 1 (Jan. 31, 2022).

[27] Patent Public Advisory Committee, 2022 Annual Report, at 3 (Nov. 1, 2022).

of the continuation patent does not extend the expiration date of either patent. Unless otherwise extended as allowed by statute,[28] a patent's term expires 20 years from its "effective filing date," which, for a patent issuing from a continuation, continuation-in-part, or divisional application, is the filing date associated with the earliest-filed non-provisional application to which it claims priority.[29]

There are fewer patents in the biopharmaceutical industry than there are in many other industries. For example, between 2016 and 2021, the five companies with the most issued patents were all high-tech companies, not biopharmaceutical companies.[30] Data from the Intellectual Property Owners Association demonstrate that in 2021, the top 20 patent owners with the largest numbers of patents were not biopharmaceutical companies, and fewer than 3% of the top 300 patentees are biopharmaceutical companies.[31] The top 20 patent owners have an average of 0.55 patents per million of R&D spend based on 2021 figures; in contrast, biopharmaceutical companies in the top 300 patent owners have an average of 0.05 patents per million of R&D spend.[32] Indeed, there tend to be fewer patents per medicine than for many other marketed products, ranging from golf balls and golf clubs to cell phones to certain athletic shoe technology.[33]

Lawmakers and academics are increasingly recognizing that narratives about patent thickets have been built on seriously flawed data. For example, I-MAK has alleged that biopharmaceutical companies "maintain[] market control by exploiting an outdated patent system" and "secur[ing] hundreds of patents to block competition."[34] I-MAK's data are often cited by individuals in academia, witnesses at congressional hearings, and by policymakers. Yet I-MAK has been repeatedly criticized for its lack of transparency as regards the underlying data

[28] *See, e.g.*, 35 U.S.C. § 154(b) (Patent Term Adjustments); § 156 (Patent Term Extensions).

[29] 35 U.S.C. § 154; 35 U.S.C. § 100(i)(1).

[30] *See* Prableen Bajpai, *Who Led the Patent Race in 2021?*, NASDAQ (Jan. 12, 2022).

[31] *See* Top 300 Organizations Granted U.S. Patents in 2021, 39th Annual Listing (Jan. 6, 2022).

[32] Moreover, the combined total number of patents issued to the eight biopharmaceutical companies on the list was less than half of the total number of patents issued to the top patentee. If the number of patents issued to these eight biopharmaceutical companies were combined, they would place fourth on the list. *See* Top 300 Organizations Granted U.S. Patents in 2021, 39th Annual Listing (Jan. 6, 2022), and publicly available R&D figures.

[33] *See, e.g.*, Titleist Patent Marking (last visited Jan. 30, 2023) (noting, for example, 41 patents covering the 2019 Pro V1 golf balls and 48 patents covering the 2019 Pro V1x golf balls); Building a Better Golf Ball, Popular Science (Nov. 24, 2008) (noting that a golf ball may contain as many as 70 separate inventions); TaylorMade Golf Patent Marking (listing over 100 patents for certain golf clubs); Apple-Samsung Case Shows Smartphones as Legal Magnet, New York Times (August 25, 2012) ("By one estimate, as many as 250,000 patents can be used to claim ownership of some technical or design element in a smartphone."); LG Patent Marking (last visited Jan. 30, 2023) (listening hundreds of patents as covering LG's smartphones); Alison Noon, *Puma Must Face Nike's Flyknit Patent Infringement Claims*, Law360 (Oct. 10, 2018) ("Nike claimed to have acquired more than 300 utility patents to protect the knit-upper shoe trend it launched in 2012.").

[34] I-MAK, *Overpatented, Overpriced: Curbing patent abuse: Tackling the root of the drug pricing crisis*, at 10 (Sept. 2022).

and methodology as well as its flawed and inaccurate data and conclusions.[35] For example, in its methodology for counting "total patents," I-MAK "includes not just patents, but also pending patent applications, and even fully abandoned patent applications."[36] A recent article by Adam Mossoff states that "I-MAK's reported numbers of issued patents, patent applications, and exclusivity periods for drugs are infected with serious questions of reliability and accuracy," and he observes "repeated and vast discrepancies between I-MAK's numbers and the numbers found in official, publicly available governmental sources like the FDA's Orange Book and court opinions."[37] Professor Mossoff notes that I-MAK cites exclusivity expiry dates for medicines that extend far beyond actual generic entry for these medicines. I-MAK thus has inflated the purported number of patents covering biopharmaceutical products and has extended their predictions of loss of exclusivity dates beyond reality.[38] And I-MAK itself has stated that branded drugs make up only 8% of prescriptions, while generic drugs make up 92% of prescriptions.[39]

The reliability of conclusions drawn from the U.C. Hastings Evergreen Drug Patent Database (the "Hastings Database") [40] has also come into question. Scholars Erika Lietzan and Kristina Acri analyzed the accuracy of the Hastings Raw Dataset of expiry dates for patents and statutory exclusivities for drug products and identified significant deficiencies in the inferences drawn from it in the Hastings Database. Based on generic launch dates reflected in FDA's Paragraph IV Patent Certifications List, the article authors demonstrated that the Hastings Database's "latest protection end date" listings do not accurately capture when generic drugs enter the market. Instead, based on the authors' dataset, many generic drugs were launched *before* the listed latest expiry date—in many cases, years earlier. Specifically, Lietzan and Acri found that "generic competition launched on average 84 months (seven years) before the Hastings Database implies it would."[41] In addition, "79 new chemical entities in our dataset experienced generic competition on average 68 months (or more than five years) before the date the Hastings Database implies they would."[42] Accordingly, the authors conclude that the "Hastings inference"— that until the last protection end date, the brand company may have

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[35] *See, e.g.*, Adam Mossoff, *Unreliable Data Have Infected the Policy Debates Over Drug Patents* (Jan. 2022); Letter from Sen. Thom Tillis to Dr. Janet Woodcock and Mr. Drew Hirshfeld (Jan. 31, 2022); Letter from Sen. Thom Tillis to Dr. Robert Califf and Mr. Drew Hirshfeld (Apr. 1, 2022).

[36] Letter from Sen. Thom Tillis to Dr. Robert Califf and Mr. Drew Hirshfeld, at 2 (Apr. 1, 2022).

[37] Adam Mossoff, *Unreliable Data Have Infected the Policy Debates Over Drug Patents*, at 5-6 (Jan. 2022).

[38] *See, e.g.*, *Statement of Corey Salsberg, Vice President and Global Head Intellectual Property Affairs for Novartis regarding "Listening Session on Joint USPTO-FDA Collaboration Initiatives,"* at 6 (Jan. 19 2022) (noting how I-MAK included "44 *abandoned* patent applications that never issued as patents, as well as a variety of patents that don't cover our drug."); *see also Comment – Adam Mossoff*, at 2-5 (raising "[q]uestions of [u]nreliability in I-MAK's [p]atent [d]ataset").

[39] *See* I-MAK, *Overpatented, Overpriced: Curbing patent abuse: Tackling the root of the drug pricing crisis*, at 2.

[40] *See* Evergreen Drug Patent Database.

[41] 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., at 1 (forthcoming).

[42] *Id.* at 1-2 (forthcoming).

limited generic competition and monopolized a drug product—is invalid, and "that the 'latest protection end date' [in the Hastings Database] should not be used as a proxy for the likely generic entry date."[43]

A focus on the number of years of exclusivity obtained from patents is also misguided. Patents allow an inventor to exclude others from making or using the claimed invention, but not all patents relating to a biopharmaceutical product actually prevent generic or biosimilar products from entering the market. For example, as Lietzan and Acri note, some patents relate to "discrete products or to conditions of use that can (generally) be carved from a generic drug's labeling, allowing generic entry before expiry of the last protection period."[44] FDA also generally permits carve-outs of patented information for biosimilars.[45] Thus, the existence of patents does not necessarily prevent the approval and subsequent marketing of follow-on products. Approval and launch of biosimilars and interchangeable biologics have contributed to growth in the biologics and biosimilar market, which is projected to continue.[46]

Any changes made to USPTO policy should be based on factual evidence, not unreliable data lacking transparency and divorced from real-world impact. Further, to the extent that the USPTO seeks to implement any specific policy changes regarding patents, any policy changes should be technology neutral. The U.S. patent system was established without regard to the type of technological advancements; that is, the U.S. patent system is technology-neutral and does not favor certain technologies over others.[47] Technology-specific initiatives or rules directed at only one industry could conflict with the technology-neutral U.S. patent system and could be contrary to the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).[48] Thus, any technology-specific policy changes should not be implemented.

As the USPTO grapples with the important patent policy questions set forth in the Request for Comments, it should recognize that biopharmaceutical innovation is lengthy, complex, and unpredictable, and so flexibility in the patent application process is important. Besides rendering patent prosecution adaptable to the reality of discoveries, such flexibility also allows for efficient prosecution of patents. The National Patent Planning Commission recommended a "policy that patentability shall be determined objectively by the nature of the contribution to the advancement of the art, and not subjectively by the nature of the process by

[43] *Id.* at 46-47 (forthcoming).

[44] *Id.* at 48 (forthcoming).

[45] FDA, Draft Guidance for Industry, Biosimilars and Interchangeable Biosimilars: Licensure for Fewer Than All Conditions of Use for Which the Reference Product Has Been Licensed, at 3-4, 8 (Feb. 2020).

[46] *See Global Biosimilars Market Growing to Exhibit a Noteworthy CAGR of 22.9% by 2033, Key Drivers, Growth and Opportunity Analysis - Research Nester*, GLOBAL NEWS WIRE (Oct. 12, 2022); *The Global Biologics Market Is Projected to Grow at a CAGR of 8.82% By 2032: Visiongain Reports Ltd*, GLOBAL NEWS WIRE (Oct. 12, 2022).

[47] *See* U.S. Const., Art. 1, § 8.

[48] TRIPS Agreement, art. 27.1.

which the invention may have been accomplished."[49] And courts have recognized the importance in affording an applicant flexibility in how patents are prosecuted. Indeed, the ability to pursue different claim sets with respect to the number of claims, scope of claims, and terminology used in describing claims, for example, is a key aspect of the U.S. patent system.[50]

The U.S. Patent Act encourages broad disclosure of inventive subject matter precisely because it permits a patent applicant to secure over time the full scope of patent protection that is supported by a patent application. Patent applicants may choose to seek such protection for their inventions via continuation or divisional practice, and these divisional and continuation applications can claim priority to the originally-filed application.[51] As currently established, continuation and divisional practices allow patent applicants to choose which claims to prosecute in a particular application. Indeed, both the Patent Act itself and courts have endorsed such practices, and any USPTO policies should maintain them. In addition, patent applicants may also choose to file a terminal disclaimer. Despite some of the negative commentary regarding terminal disclaimers, a terminal disclaimer is not an admission that patent claims are patentably indistinct. Instead, filing a terminal disclaimer is often for administrative purposes and in the interest of prosecution efficiency. Continuation applications, divisional applications, and terminal disclaimers thus help promote flexibility and efficiency in the patent prosecution process. Accordingly, the U.S. patent system should be focused on incentivizing innovation and encouraging disclosure of inventive subject matter rather than on attempting to restrict flexibility and protection for inventions.

II. Continuation Applications Advance the Patent System's Goal of Early, Robust Disclosures to the Public (Questions 4(f), 8-10)

Authorized under 35 U.S.C. § 120, continuation applications help advance the *quid pro quo* principle of public disclosure. Continuation applications encourage inventors to disclose their innovations fully and promptly without the fear that some inventions disclosed, but not claimed, in the original application might not be able to be protected. Put another way, continuation applications allow an applicant, based on what was originally disclosed in the parent application, to pursue different claims to cover different inventive elements in different

[49] Efforts to Establish a Statutory Standard of Invention, Study of the Subcommittee on Patents, Trademarks, and Copyrights of the Committee on the Judiciary, at 2 (1958).

[50] *See, e.g.*, *In re Wakefield*, 422 F.2d 897, 900 (C.C.P.A. 1970) (acknowledging an applicant's flexibility with respect to the number of claims and the scope of claims); *In re Chandler*, 319 F.2d 211, 225 (C.C.P.A. 1963) (acknowledging an applicant's flexibility with respect to the terminology used to characterize the scope of claims).

[51] *See, e.g.*, 35 U.S.C. § 120 ("An application for patent for an invention disclosed in the manner provided by section 112(a) (other than the requirement to disclose the best mode) in an application previously filed in the United States, or as provided by section 363 or 385, which names an inventor or joint inventor in the previously filed application ***shall have the same effect, as to such invention, as though filed on the date of the prior application***, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.") (emphasis added); 35 U.S.C. § 121 ("If the other invention is made the subject of a divisional application which complies with the requirements of section 120 ***it shall be entitled to the benefit of the filing date of the original application.***") (emphasis added).

ways to ensure adequate patent protection is available commensurate with the scope of their disclosure. Thus, an applicant can decide, over time, what to claim from the original disclosure and does not need to claim every conceivable iteration of what is disclosed in the original specification in the first application. Continuation practice, therefore, encourages applicants to describe their inventions fully and robustly in the first-filed application.

Accordingly, continuation applications (and patents issuing therefrom) help foster the patent system's goal of promoting innovation and earlier disclosure in the original application of the underlying research that resulted in that innovation. To be a proper continuation application, claims in a continuation application must be supported by the original disclosure of the earliest utility application in the chain. Continuation applications have the same disclosure as their parent applications, and any claims in a continuation application must be supported by that disclosure and satisfy all other statutory requirements for patentability before they can issue as patents. Thus, the original (i.e., first-filed) application provides the public and competitors with notice of what was discovered and invented by the applicant and thus what can be claimed in continuation application(s). This framework is fair and equitable and strikes the right balance between protecting inventors and providing social benefits. Such a system differentiates the patent system from other means of intellectual property protection, such as trade secret protection, by rewarding innovators who disclose their inventions.

Limiting continuation practice would ***not*** promote innovation and progress in science. Inventors would be disincentivized from robustly disclosing their inventions if there was uncertainty around whether they could receive the benefit of patent protection for the full scope of the disclosed innovation. Accordingly, any changes restricting continuation practice and limiting the inventor's ability to protect aspects of the inventions disclosed but not claimed in the original application would be a disservice to the public and to technological development.

A. The USPTO Should Not Subject Continuation Applications to Second Looks or Heightened Scrutiny (Questions 8 and 9)

The USPTO's Request for Comments asks about the possibility of changes that would require second looks and heightened scrutiny for certain continuation applications. Such changes would not promote efficiency or patent quality; indeed, there is no basis or authority for applying different standards in examining different types of patent applications. Furthermore, such changes potentially would hinder continuation practice and thus hinder the early, fulsome disclosures associated with continuation practice.

1. Second Looks Would Not Promote Efficiency

Special second-look examination practices, as mentioned in Question 9, would create inefficiencies and duplication, including because they would require at least two examiners to learn the applicant's disclosures and technology. For example, the examiner who has examined a continuation application has already reviewed the application to ensure it satisfies the patentability requirements, which include the requirements of 35 U.S.C. § 112. If the same examiner reviewed the parent application and the continuation application, then the examiner was already familiar with the specification, technology, and terminology prior to beginning

examination of the continuation. Adding further review, e.g., by a team of patent quality specialists, would place a burden on the USPTO's limited resources and require unnecessary duplication of efforts because these specialists would need to become familiar with the application's disclosures, just as the assigned examiner already would have done.

Moreover, whether the application satisfies the § 112 requirements is equally relevant for any application, such as an original application that receives its notice of allowability on its first office action. The Request for Comments does not provide evidence suggesting that continuation applications (especially those that would be issued in the first office action) tend to have more § 112-related concerns relative to any other type of application.

2. Heightened Examination Scrutiny May Hinder Early, Robust Disclosures of Inventions and Discoveries

Similarly, suggesting that continuation applications face a "heightened examination"[52] standard would risk upsetting the current balance that encourages early, robust disclosures of information in original applications. Any heightened examination applying new or different standards for patentability to certain types of applications would be untethered to the statutory requirements and case law and thus would create uncertainty; such new or different standards also would violate the statute. Introducing a new "heightened examination" standard for patentability—one not defined in the Request for Comments—in certain types of applications could also suggest that other applications may not have been fully reviewed (or reviewed with less scrutiny), thus eroding public trust in the patent system, particularly with respect to those patents not subject to a heightened examination standard. Moreover, if any heightened examination depends on field of technology, it would run afoul of TRIPS. Indeed, the USPTO should apply the same standards and the same level of scrutiny to all patent applications, regardless of the type or history of the application.

a) The Patent System Recognizes that Innovation May be Incremental

The heightened scrutiny suggested by Question 9 is aimed at "ensur[ing] that minor modifications do not receive second or subsequent patents." But the patent system recognizes that innovation may be incremental (*see* III.D., *infra*) and protects such innovation, including through the structure of § 102. For example, § 102(b), as enacted in the AIA, ensures that prior patents or applications that name a different inventor *but* are from the same owner/joint research partner only qualify as prior art under § 102(a)(2) (like pre-AIA § 102(e)) as of their *publication date*, not their filing date. This provision recognizes that applicants seek to patent developments in their research, and intentionally limits the prior art that applies to those applicants. Similarly, § 102(b) allows a patent owner to file sequential applications before the publication of a prior

[52] The Request for Comments does not describe how an examiner would apply "heightened examination," whether "increasing the scrutiny" is intended to change the standards for patentability or the evidentiary standard for examination and, if not, what it would entail.

application.[53] The patent laws do not allow an applicant to patent an invention already claimed in another patent. Similarly, if an examiner views a claimed invention as an obvious variant of a claim in a prior patent, the patent system allows the examiner to reject that claim under obviousness-type double patenting (OTDP).

B. Limiting the Timing for Filing Continuation or Divisional Applications Would Not Promote the Patent System's Goal of Robust Disclosures (Questions 4(f) and 10)

As an initial matter, continuation and divisional applications may only claim subject matter that was disclosed in the parent application. Therefore, any inventions that will be claimed in a continuing application are necessarily disclosed in the original application. What changes in a continuation or divisional application is simply what the applicant elects to claim. Once all of the inventions have been presented in the original disclosure, applicants should not be subject to any arbitrary deadline for claiming any previously disclosed subject matter.[54] As discussed in more detail below, if limitations on timing of continuing applications were implemented, entities would be forced to make decisions about the scope of protection early in a product's development cycle without full information, and entities with limited resources might not be able to afford filing claims to cover all of the disclosed innovations that they wished to cover with patent protection at the time of the original filing. The suggested approach would hinder the patent system's *quid pro quo* principle of public disclosure.

Applicants should not have to make a final determination on claim scope upon the initial disclosure of their inventions to the public. Indeed, instead of penalizing applicants for robust disclosures, the patent system should seek to reward and encourage them. Accordingly, undue procedural restrictions on the ability to pursue claims based on subject matter disclosed in an original application is not a fair bargain for the applicants' disclosure to advance the progress of science.

1. The Timing to File Continuation Applications Should Not be Limited

For as long 35 U.S.C. § 120 has been in effect, applicants have been free to seek continuation applications if a parent application was still pending. [55] Setting a time limit, as

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[53] The AIA legislative history shows clear intent behind § 102(b). For example, the 2011 House Judiciary Committee Report's section-by-section analysis for the AIA noted that "[n]ew section 102(b) preserves the grace period, ensuring that during the year prior to filing, an invention will not be rendered unpatentable based on any of the inventor's own disclosures, or any disclosure made by any party after the inventor has disclosed his invention to the public." Matal, A Guide to the Legislative History of the America Invents Act., at 475, citing H.R. REP. No. 112-98, at 71 (2011). This comment refers to the entire § 102(b), including § 102(b)(2).

[54] 87 Fed. Reg. 60,130, at 60,134 (Oct. 4, 2022).

[55] *See, e.g.*, *In re Henriksen*, 399 F.3d 253, 254 (C.C.P.A. 1968) ("We hold here that under that section of the statute, in view of its long-standing interpretation by the Patent Office and the patent bar, there is no statutory basis for fixing an arbitrary limit to the number of prior applications through which a chain of copendency may be traced to obtain the benefit of the filing date of the earliest of a chain of copending applications, provided applicant meets all the other conditions of the statute.").

noted in Question 10, would introduce a hurdle not provided for in the statute and would disrupt this longstanding practice. Prosecution decisions would come early in the development timeline, when applicants may not have complete information as to which inventions to protect and which to dedicate to the public. Many applicants may not have the financial resources to file and prosecute multiple continuation applications simultaneously to ensure compliance with any time limit. For those that did decide to prosecute multiple applications simultaneously, the USPTO would be required to examine more applications in parallel.

With a time limitation, the decision of whether to file any continuation application would come earlier in the product development cycle and would require an applicant to make the decision of which subject matter to pursue with less information (and potentially before financing and/or licensing deals can be completed) in order to avoid a loss of potential patent rights. For example, over time an applicant who discovered and adequately disclosed a genus of compounds may later learn that particular disclosed species are more valuable and may want to pursue narrow claims covering those species. This is especially true for companies whose research and development process needs to progress, for example, from cell to animal to human testing, before being able to market a commercial product.[56] As research and development progresses, these companies may learn which disclosed species or sub-species are safe, effective, and commercially viable to justify pursuing narrower claims. PhRMA's members in particular would be disproportionately impacted. This is because the pharmaceutical industry has a long product development cycle where new information continues to be learned after the original application is filed.

In another example, an applicant may be limited in the number of claims and applications they can file due to funding or other resource constraints. Given this, an applicant may elect to pursue broader claims, for example, in the hopes of securing funding. After funding is secured, the applicant may then seek narrower claims to protect particular aspects of the invention. If the system required all continuation applications to be filed early, that would especially impact small inventors with limited funding and others with limited resources: strictly frontloading prosecution costs and decisions could hinder investment and disclosure in patents and, accordingly, innovation.

Suggestion of a timing requirement also fails to acknowledge the practicalities of continuation practice. Applicants may have some allowable and some rejected claims, and they may not wish to delay issuance of the allowed claims. Instead, they may file a continuation application to continue prosecution on those rejected claims. Such issues may not be foreseeable upon initial application filing and may develop over time—for example prior art may be discovered later or patentability principles may change, such as development of § 101 and § 112

[56] Such a timing limitation on filing continuation applications would be particularly prejudicial to the biopharmaceutical industry whose products often need to go through clinical trials before they may be marketed. As disclosure requirements for clinical trial protocols continue to change, including requiring ever-earlier disclosure of such protocols, applicants, to avoid information about these protocols constituting prior art, must file their patent applications before the protocols are disclosed. But as clinical studies progress, an applicant's focus on what subject matter originally disclosed is most valuable may change and therefore result in continuation applications being filed to claim additional earlier disclosed subject matter.

case law. Applicants should be afforded flexibility to address such developments. Moreover, requiring any continuation application to be filed within a set timeframe of the original parent application would be inconsistent with applicable law. Under 35 U.S.C. § 2(b)(2) the USPTO "may establish regulations, not inconsistent with law." Here, however, changes restricting timing of continuation applications would be inconsistent with 35 U.S.C. § 120, and the USPTO lacks the statutory authority to engage in the substantive rulemaking that would be required to implement such a limitation.[57] Such a change would arguably be akin to the previously-rejected "number" rule that the court in *Tafas v. Dudas*, 541 F Supp. 2d 805 (E.D. Va. 2008), determined was a substantive rule that the USPTO lacks authority to make.[58]

The text of § 120 makes clear that the time period for filing a continuation application is during the pendency of the parent application. [59] The language that "[n]o application shall be entitled to the benefit of an earlier filed application under this section ***unless an amendment containing the specific reference*** to the earlier filed application is submitted ***at such time*** during the pendency of the application ***as required by the Director"*** (emphasis added) only provides the Director with the authority to articulate the requirements for the amendment to the child application containing the "specific reference" to the parent application, not for the overall timing of filing the child application.

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[57] *See Merck & Co, Inc.. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996) ("Congress has not vested the Commissioner with any general substantive rulemaking power"); *id.* (determining that 35 U.S.C. § 6(a) only authorizes the Director to promulgate procedural but not substantive regulations); *see also Eli Lilly & Co. v. Bd. of Regents of Univ. of Wash.*, 334 F.3d 1264, 1269 n.1 (Fed. Cir. 2003) (same).

[58] *See also In re Henriksen*, 399 F.2d 253, 254 (C.C.P.A. 1968) ("We hold here that under that section of the statute, in view of its long-standing interpretation by the Patent Office and the patent bar, there is no statutory basis for fixing an arbitrary limit to the number of prior applications through which a chain of copendency may be traced to obtain the benefit of the filing date of the earliest of a chain of copending applications, provided applicant meets all the other conditions of the statute.").

[59] Section 120 provides:

> An application for patent for an invention disclosed in the manner provided by section 112(a) (other than the requirement to disclose the best mode) in an application previously filed in the United States, or as provided by section 363 or 385, which names an inventor or joint inventor in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, ***if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application*** and if it contains or is amended to contain a specific reference to the earlier filed application. ***No application shall be entitled to the benefit of an earlier filed application under this section unless an amendment containing the specific reference to the earlier filed application is submitted at such time during the pendency of the application as required by the Director***. The Director may consider the failure to submit such an amendment within that time period as a waiver of any benefit under this section. The Director may establish procedures, including the requirement for payment of the fee specified in section 41(a)(7), to accept an unintentionally delayed submission of an amendment under this section.

35 U.S.C. § 120 (emphasis added).

Such a reading is consistent with the Federal Circuit's original decision in *Tafas v. Doll*, 559 F.3d 1345, 1360 (Fed. Cir. 2009), *vacated*, 328 F. App'x 658 (Fed. Cir. 2009).[60] There the Federal Circuit determined that § 120 "unambiguously states that an application that meets [the] four requirements [of § 120] '*shall* have the same effect, as to such invention, as though filed on the date of the prior application.'" (quoting 35 U.S.C. § 120) (emphasis in original).[61] As the Court pointed out, the use of "shall" indicates that these are the exclusive requirements, and that all applications that meet these requirements must receive the benefit provided by § 120.

2. The Timing to File Divisional Applications Should Not be Limited

Divisional applications often result from complying with an examiner's restriction requirement limiting examination in an application to one invention and requiring separate and distinct inventions to be prosecuted in separate, divisional applications.[62]

Requiring a set date by which all divisional applications must be filed, which is suggested in Question 4(f), would not promote efficiency, innovation, or competition. Instead, it would require prosecuting more divisional applications in parallel, which at times may be unnecessary, may increase (and would certainly frontload) prosecution costs.[63] For example, sometimes a restriction requirement is withdrawn, and the restricted claims are rejoined and examined in one application.[64] It would not be efficient to require early prosecution of divisional applications when ultimately all of the claims may be rejoined and prosecuted in one application.

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[60] The Federal Circuit took this case *en banc*, which vacated its panel decision. However, because the USPTO withdrew its proposed rule change prior to the Federal Circuit issuing its *en banc* decision, the full Federal Circuit never addressed this issue. The now-vacated panel decision still provides guidance as to why the USPTO would lack the ability to substantively change continuation practice.

The remaining non-vacated decision on the matter is the Eastern District of Virginia's decision. *See Tafas v. Dudas*, 541 F. Supp.2d 805 (E.D. Va. 2008). There the District Court found that the USPTO could not engage in substantive rulemaking that limited the number of continuation applications an applicant could file. *Id.* at 811.

[61] Those four requirements are: "[1] the invention claimed in the application must have been properly disclosed in a prior-filed application; [2] the application must have been filed by inventor(s) named on the prior-filed application; [3] the application must have been 'filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application'; and [4] the application must contain or be amended to contain a specific reference to the prior-filed application." *Id.*

[62] 35 U.S.C. § 121 ("If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions . . .")

[63] Indeed, the European Patent Office (EPO) implemented a time limit on when divisional applications could be filed. *See* *OJ EPO 2009, 296 - Decision of the Administrative Council of 25 March 2009 amending the Implementing Regulations to the European Patent Convention (CA/D 2/09)* (Mar. 25, 2009). EPO "divisional" applications include subsequent applications that are similar to applications that would be described as "continuations" under U.S. practice. Such a change, however, resulted in an increase in the number of divisional applications "because applicants have preferred to file divisionals before the end of the 24-month time limit, as a precaution" and the EPO ultimately removed the 24-month limit. Ruth Sanchez, *Divisional applications may again be filed as long as the parent application is pending*, Lexology (Oct. 23, 2013).

[64] *See* MPEP § 821.04.

Such potential changes would also likely increase and frontload patent procurement costs for all types of applicants, which disproportionately impacts individual inventors and small entity applicants. By way of example, it is not uncommon in the biotech space to receive a five- to ten-way restriction requirement as a first office action in an application. Many applicants may not have available the financial resources to file and prosecute five to ten divisional applications in parallel. If there were a time limit on filing divisional applications, however, an applicant would have no choice but to file a divisional application directed to the subject matter of each restricted group prior to the USPTO-implemented deadline to obtain the full scope of patent protection for the disclosed inventions. Accordingly, in response to the hypothetical five- to ten- way restriction requirement, the applicant would be forced to file five to ten separate applications or else forfeit patent protection that may have otherwise been supported by the breadth of the disclosure. Many members of the biotech ecosystem are small companies and universities that do not have the financial resources to frontload prosecution costs and pursue several applications in parallel. This lack of resources is especially acute for inventions that require longer development life cycles to allow for the identification of the particularly valuable aspects, such as in the pharmaceutical and biotech space. If applicants are unable to bear the expected burden associated with more stringent restriction requirements (which may be especially burdensome for small and micro entities), they may choose to narrow their disclosure in patent applications, which would hinder the progress of science by disrupting the balance of disclosing information in exchange for the opportunity to secure patent protection. Under the current system, however, an applicant may wait to determine whether to pursue patent protection over subject matter subject to a restriction requirement and/or to gather additional resources to cover costs.

Moreover, § 121—the statute governing divisional applications—does not provide any discretion for the Director to establish timing rules for when a divisional application must be filed. Instead, it states that "[i]f the other invention is made the subject of a divisional application which complies with the requirements of section 120 it shall be entitled to the benefit of the filing date of the original application." As discussed above, § 120's timing requirement provides that the application only needs to be filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and the USPTO therefore does not have the authority to limit the time period in which a divisional application may be filed.[65]

3. More Information is Necessary Before Discussing Potential Changes to Restriction Practice (Question 4)

The USPTO's potential changes to restriction practice (i.e., the other aspects of Request for Comments Question 4) are ideas that could warrant further review, but this Request for Comments is not the appropriate process for that. The Request for Comments does not get into the level of detail necessary for the public to thoroughly engage in any potential changes.

[65] *See* 35 U.S.C. § 120 ("An application for patent for an invention disclosed in the manner provided by section 112(a) . . . if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application").

Any changes to restriction practice should be assessed and balanced against maintaining a continuation and divisional practice that ensures the incentives of the patent system remain properly aligned. The USPTO should ensure that applicants will still be able to obtain claims commensurate with the full scope of their disclosures through continuation or divisional practice.

III. The Current Obviousness-Type Double Patenting/Terminal Disclaimer Practice Ensures the Balance and Efficiency of the Patent System and Promotes Innovation and Disclosure and Should Not be Modified or Eliminated (Questions 4(h), 6-7)

At the outset, it is important to distinguish obviousness-type double patenting (OTDP) from statutory double patenting. ***Statutory double patenting*** under 35 U.S.C. § 101 prevents an inventor from obtaining more than a single patent that covers the identical subject matter. ***OTDP***, on the other hand, is a judicially-created equitable doctrine developed to address two perceived potential harms: (1) extension of patent term by a patent whose claims are obvious in view of a claim of an earlier-expiring patent, and (2) infringement suits by multiple owners of different patents whose claims are obvious variants of one another.[66] For OTDP to apply, the two patents must have at least one common owner, have a common applicant or inventor, be commonly assigned or owned, or be subject to certain joint research agreements. Under the current law, applicants may be able to overcome an OTDP rejection by filing a terminal disclaimer (TD) specifying that the patents will have the same expiration date and common ownership, thus addressing the two potential harms the doctrine was designed to avoid. Terminal disclaimers cannot be used to overcome statutory double patenting. The OTDP and TD practice reflects the realities that innovation is often incremental, the crucial importance of encouraging innovation and early disclosure, and the practical need to promote efficiency of the patent system.

A. The Patent System Should Promote Rather than Limit Applicants' Flexibility (Question 4(h))

The use of TD to overcome OTDP issues properly affords applicants flexibility in presenting and pursuing claims. As discussed in sections I.B and II.B (*supra*), flexibility has been long recognized as important for maintaining the *quid pro quo* of the U.S. patent system. Any potential limitations on applicant flexibility should be carefully considered and balanced against the need to encourage participation in the patent system with its accompanying benefits to public knowledge and innovation.[67] Flexibility is also especially important for innovations in the biopharmaceutical industry, which often face extraordinary unpredictability and a long development timeline. Dictated by the reality of R&D and resource constraints, applicants may prefer or need to pursue claims of varying scope at different times, e.g., as they learn more about practical advantages of disclosed subject matter and secure resources to pursue further patent protection. In addition to flexibility in continuation practice, in order to fully disclose and protect their innovations, applicants may also have multiple patent families on related inventions. For example, different applications may affix different priority dates to the claims, which can

[66] *In re Van Ornum*, 686 F.2d 937, 943-44 (C.C.P.A. 1982).

[67] *See*, n.55.

impact the scope of the prior art. Different specifications may also differ in the § 112 support they provide for the claims, for example, as research progresses and further data are available to disclose. Moreover, the examination process before the USPTO can reveal further differences between applications in view of the claims at issue and provide guidance to the scope of allowable subject matter.

Applicants should be afforded flexibility to obtain claims covering the subject matter that they invented and chose to disclose to the public. Therefore, a common applicant or assignee should not be required to include all patentably indistinct claims in a single application or to explain why they are instead choosing to separate purportedly patentably indistinct claims into two or more applications, as the USPTO contemplates in Question 4(h).

B. The Current USPTO Practice and Case Law Already Addresses TD and OTDP (Questions 4(h), 6, and 7)

There is no need to change the current TD/OTDP practice in the way the USPTO potentially suggests in the Request for Comments Questions 4(h), 6, and 7. As discussed in section II.A.2. (*supra*), the criteria for patentability are set forth in United States Code Title 35 and related case law; the USPTO should not and may not create additional patentability hurdles by eliminating or restricting the availability of terminal disclaimers.

First, OTDP is a judicial doctrine grounded in the stated rationale of preventing unjustified term extension, and enforcement by multiple assignees of patents on obvious variants. TDs are specifically designed to—and do—address both of these identified potential harms by requiring a common expiration date and common ownership of disclaimed patents. Therefore, stipulating that claims of different patents are not patentably distinct would not address any purported harm associated with OTDP.

Second, existing case law already addresses how to treat patents that are tied together with a terminal disclaimer. The Federal Circuit has found that "a terminal disclaimer is a strong clue that a patent examiner and, by concession, the applicant, thought the claims in the continuation lacked a patentable distinction over the parent." *SimpleAir, Inc. v. Google LLC*, 884 F.3d 1160, 1168 (Fed. Cir. 2018). Courts have followed that "strong clue" and further determined TD-tied patents to be "patentably indistinct." *See, e.g.*, *Indivior Inc. v. Dr. Reddy's Lab'ys*, S.A., 752 F. App'x 1024, 1035 (Fed. Cir. 2018). However, *SimpleAir* also emphasized that "as our precedent indicates, that strong clue does not give rise to a presumption that a patent subject to a terminal disclaimer is patentably indistinct from its parent patents." *SimpleAir* at 884 F.3d 1168.[68] Thus, the law addresses patents linked by TDs, while also recognizing that a TD is not an admission that the patents should rise and fall together. This framework allows for the requisite prosecution flexibility provided by terminal disclaimers; it also ensures consistency with the law of obviousness. Requiring applicants seeking patents on purportedly obvious variations of prior claims to stipulate that the claims are not patentably distinct as a condition of

[68] Indeed, citing multiple precedents, the court reiterated that "our cases foreclose the inference that filing a terminal disclaimer functions as an admission regarding the patentability of the resulting claims." *SimpleAir*, 884 F.3d at 1167.

filing a terminal disclaimer (as suggested in Question 4(h)) or treating the filing of a terminal disclaimer as an admission of obviousness and having patents tied by TD stand and fall together (as suggested in Question 7) are not only unnecessary revisions to a functioning practice, they also potentially overstep the authority of the USPTO and could create unintended consequences as discussed in detail below.

C. Potential Changes to TD and OTDP Practice Are Not Consistent with Existing Law (Questions 4(h), 6, and 7)

As an initial matter, neither the imposition of an OTDP rejection nor the filing of a TD implies anything about the *entire patents* tied together with a TD. As with all other rejections, OTDP is analyzed with respect to the individual claims of patents. Some claims of these patents may not be even alleged to be obvious variants over any claims in any other patent, so it would not make sense for every claim in a patent to fall as a result by default. In addition, any changes that would make a TD an admission of patentable indistinctness or require patents linked by a TD to rise and fall together are not consistent with the current law on obviousness and presumption of validity. Therefore, the USPTO may exceed its authority if it were to promulgate such changes, which would amount to inappropriate rulemaking.

First, a change that would cause patents linked by a TD to "stand and fall together," as contemplated in Question 7, would run afoul of the long-standing law of obviousness. For example, a patent with a genus claim may be found obvious based on OTDP over another patent claiming a lead compound within the genus. Those patents may be linked by a TD to overcome OTDP. Consider another prior art patent describing a subgenus that encompasses the lead compound but does not specifically identify it. The genus patent may be found obvious in view of the subgenus, but the compound patent may not be obvious, especially when the lead compound has unexpected properties over the subgenus. In this case, it would be contrary to the law of obviousness for the genus patent and the lead compound patent to both fall in view of the prior art when the prior art does not render the lead compound patent invalid. This issue may also exist within a single patent. For example, the first claim may be a genus claim and the next nine claims may be related to a particular species within the genus, where each species has unique and unexpected properties. Even if there were an OTDP issue with respect to the genus claim, it would be improper that claims 2-10 must stand and fall together with the OTDP reference patent as well.

In addition, 35 U.S.C. § 282 unequivocally sets forth that a patent shall be presumed valid, and that the burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.[69] The presumption of validity is a fundamental principle of the U.S. patent law. To have patents "stand and fall together," as contemplated in Question 7, would essentially deprive a duly issued patent of such presumption of validity and is inconsistent with the law.

[69] *Microsoft Corp. v. I4I Ltd. P'ship*, 131 S. Ct. 2238, 2239 (2011)

Second, Questions 4(h) and 6 both contemplate keeping OTDP, but eliminating terminal disclaimers, and prohibiting patents that are obvious variations of each other. This rule change would practically nullify 35 U.S.C. §§102(b)(2)(C)/102(c) and, importantly, run afoul of the Congressional intent behind these statutes as well as behind the pre-AIA 35 U.S.C. §103.

The statute 35 U.S.C. §§ 102(b)(2)(C)/102(c) ensures that prior patents or applications that only qualify as prior art under § 102(a)(2) (or pre-AIA §102(e)) and are from the same owner/joint research partner are prior art as of their *publication* date, instead of the filing date. The function of §102(b)(2)(C) /§102(c) to allow a patent owner to file sequential applications before the publication of a prior application is supported by clear legislative intent.[70] According to the bill summary from the Congressional Research Service, the Omnibus Reform Act revises the condition of patentability to make clear that subject matter developed by another person, which qualifies as prior art only in certain circumstances, "***shall not preclude the granting of a patent*** on an invention with only obvious differences where the subject matter and claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person." Thus, "[t]he effect of the amendment is to ***allow an applicant to receive a patent*** when an invention with only obvious differences from the applicant's invention was described in a patent granted on an application filed before the applicant's invention, provided the inventions are commonly owned or subject to an obligation of assignment to the same person."[71] The changes contemplated in Questions 4(h) and 6 are contrary to this clear legislative intent.

*Third***,** the patent statute as a whole contemplates that an applicant may receive multiple patents on similar concepts from the same inventors or inventive entity. This was recently reaffirmed by Congress with the AIA, which preserved this framework. For example, 35 U.S.C. § 121 acts like its pre-AIA predecessor provision and permits restrictions to one distinct invention per application, while separate and additional inventions may be made the subject of divisional applications. For example, an applicant who submits an application with claims directed to a product and a method of using that product may obtain a restriction requirement and pursue those categories of claims in two divisional applications that may result in two or more patents.

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[70] The AIA provisions §§ 102(b)(2)(C) /102(c) descended from the pre-AIA § 103(c). On November 29, 1999, the Intellectual Property and Communications Omnibus Reform Act of 1999 amended § 103 of the patent statute to exclude not only commonly-owned § 102(f) and § 102(g) prior art, but also § 102(e) prior art from being used by the USPTO to reject an application based on obviousness.

[71] H.R. Rep. No. 106-287, at 69 (1999) (emphasis added). As further evidence, the section-by-section analysis of the Omnibus Reform Act that Senator Lott introduced into the record in 1999 also states that "[t]he bill amends §103(c) by adding a reference to §102(e), which currently bars the granting of a patent if the invention was described in another patent granted on an application filed before the applicant's date of invention. The effect of the amendment is ***to allow an applicant to receive a patent*** when an invention with only obvious differences from the applicant's invention was described in a patent granted on an application filed before the applicant's invention, provided the inventions are commonly owned or subject to an obligation of assignment to the same person." *Id.* (emphasis added). The legislative intent to remove §102(e) prior art from §103(c) was therefore to "***allow an applicant to receive a patent***" even when an invention is deemed obvious over a patent granted on an application filed before the applicant's invention but share common ownership or are subject to an obligation of assignment to the same entity. *Id.* (emphasis added).

Critically, 35 U.S.C. § 102(b)(2)(C) states "[a] disclosure ***shall*** not be prior art to a claimed invention under subsection (a)(2) if … (C) the subject matter disclosed and the claimed invention, not later than the effective filing date of the claimed invention, were owned by the same person or subject to an obligation of assignment to the same person." (emphasis added). These statutes therefore recognize that innovation is iterative[72] and applicants seek to patent developments in their research, which may include claims that are obvious variations of earlier claims pursued by the applicant, and intentionally limits the prior art that applies to those applications. They provide a benefit and a protection to applicants by eliminating certain of applicants' applications as prior art when they file sequential applications before the publication of a prior application.

The potential changes contemplated in Questions 4(h) and 6 would defeat that benefit because the subsequent applications may face OTDP rejections, and therefore would practically be prohibited without the option of terminal disclaimers. If TDs are not available, the provisions in § 102(b)(2)(C) / § 102(c) would be all but rendered meaningless, because a patent owner could not file sequential applications before the earlier applications publish as permitted by the statute, since it may be prohibited by OTDP.

Further, because these contemplated rules would change existing law, the USPTO lacks the authority to make such a change through rulemaking.[73]

D. Potential Changes to TD and OTDP Practice Could Stifle Innovation and Discourage Early Disclosure (Questions 4(h), 6, and 7)

First, if terminal disclaimers were not available, as considered in Questions 4(h) and 6, it would create uncertainty and discourage innovation and disclosure because innovators might not be able to obtain adequate protection from the patent system for continued innovation due to OTDP extending far beyond the stated reasons for its creation by the courts. If a TD required a stipulation that the claims are not patentably distinct (as mentioned in Question 4(h)) or if disclaimed applications were forced to "rise and fall together" (as contemplated in Question 7), then an applicant might not receive sufficient value from additional disclosures, which would reduce incentives to further develop and disclose improvements of existing inventions. All of these changes would distort the balance of the U.S. patent system and discourage continuous and incremental innovation, including post-approval R&D, and disclosure of inventions in patent applications to promote the progress of science.

Moreover, to avoid OTDP rejections, innovators might refrain from filing patent applications until they believe they are in complete possession of all related subject matter and can include all such subject matter in the initial filing. This creates tension with the first-to-file system. Indeed, such OTDP rejections arise purely because such claims are pursued in separate patent applications, not because they are unpatentable over the prior art. Furthermore, where applicants' disclosure of their innovation is delayed, this also delays the public's access to their

[72] *See, e.g.*, Sandeep Kishore, *The Power of Incremental Innovation*, (last visited Jan. 30, 2023).

[73] *See* § III.B, *supra*.

invention and underlying research. This would frustrate the patent system's goal of encouraging timely sharing with the public (and other innovators as well as competitors) the underlying research that resulted in that innovation.

Needless to say, in this time of highly developed and sophisticated sciences and technologies, U.S. society crucially relies on continuous and incremental innovations to advance technology, healthcare, and the economy. But innovators require some degree of certainty in their ability to protect continued investment in new and improved inventions. And indeed, other innovators need to access the existing innovations first before they can collectively build on and keep improving new technologies. Because the potential changes would render OTDP much harder to overcome, they may discourage the original innovators from continuing innovations. And because the potential changes may discourage early disclosure, they may also prevent other innovators from timely building on the innovation. This would defeat the purpose of the patent system.

Second, the potential changes may lead to more complex patents that include numerous different inventions. Eliminating or discouraging patents that are obvious variants (or may be construed as obvious variants by the Office) may encourage prosecution of more expansive patents with more claims to capture disclosures that are currently prosecuted in different patent families with different specifications to ensure that all subject matter can be claimed. However, more complex patent specifications with more claims do not practically provide any benefits over multiple patents that expire on the same date. Indeed, they may lead to longer application pendency and less examination efficacy.

The Request for Comments references the expense of challenging multiple patents in post-grant proceedings or district court as the first reason for the purported need to reconsider terminal disclaimer practice. PhRMA, however, is unaware of data supporting the contention that litigation costs are higher to challenge multiple patents with terminal disclaimers than to challenge fewer, but more complex patents (at the PTAB or in district court litigation). And the fee for challenging patents before the PTAB is set by the USPTO. So even if this reason were accepted, it could be addressed by fee adjustment instead of completely reworking the current OTDP/TD practice and upsetting the balance of promoting innovation and disclosure and encouraging competition. In addition, because arguments in post-grant challenges are presented on a claim-by-claim basis, whether additional claims appear in a single patent or multiple patents may not substantially affect efficiency in post-grant practice. Moreover, Congress has already enacted an efficient, targeted litigation system allowing generic or biosimilar applicants to challenge relevant pharmaceutical or biotechnology patents through the enactment of the Hatch-Waxman Act and the BPCIA. These litigation systems provide advantages to the participants including because they are designed to allow for the resolution of litigation prior to any damages being incurred, thus reducing the potential risk and number of issues to litigate.

E. Potential Changes Would Decrease Efficiency (Questions 4(h), 6, and 7)

The potential changes to constrain or eliminate TDs would also decrease efficiency of the U.S. patent system. Under current practice, even if the claims are arguably patentably distinct, many applicants choose to file a TD in response to an OTDP rejection to avoid the burden and

expense of arguing the merits of an OTDP rejection to the USPTO and potentially on appeal. Modifying the practice would discourage at least these applicants from using TDs to moot OTDP rejections, thereby increasing the burden on applicants and the USPTO, and potentially reducing benefits to third parties of earlier expiration dates and required common ownership of TD patents.

F. Some Potential Changes are Based on Rules Not Suited for the Context of TD/OTDP (Question 4(h))

Some potential changes are based on other existing rules that are not suited for the context of TD/OTDP:

For example, Question 4(h) suggests rejecting claims that are not patentably distinct as "unduly multiplied under 37 CFR 1.75." 37 C.F.R. § 1.75(b) states that more than one claim may be presented in an application provided the claims differ substantially from each other and are not unduly multiplied. This aims to avoid claims that are "repetitious and multiplied, the net result of which is to confuse rather than to clarify." MPEP § 2173.05. An "undue multiplicity" rejection previously has been based on § 112(b) or pre-AIA § 112, second paragraph. This is different from the context of double patenting. *Id.*

If 37 C.F.R. § 1.75(b) were to be repurposed for rejecting claims for lacking patentable distinctness, that would amount to rulemaking from the USPTO and should follow appropriate procedures. If they are the same claims, they will be rejected under statutory double patenting, which cannot be resolved with a TD. If the claims are not unduly multiplied, but simply (in the opinion of the examiner) reflect obvious variants of each other, then they will be rejected under the applicable doctrine (OTDP), not a different basis. It would be unclear whether or how an applicant could overcome an undue multiplicity rejection for claims that are deemed an obvious variation of others. This would cause confusion with respect to the scope of patentable subject matter and may amount to inappropriate rulemaking, thus undermining participation in the patent system via the early disclosure of research and discouraging innovation. *See* III.D, *supra*.

Question 4(h) cites 37 C.F.R. § 1.78(f)[74] and suggests a common applicant or assignee might be required to include all patentably indistinct claims in a single application or to explain a good and sufficient reason for retaining patentably indistinct claims in two or more applications. Broad enforcement of such a provision would be burdensome and present the potential for arbitrary and inconsistent application. 37 C.F.R. § 1.78(f) permits but does not mandate consolidating claims, stating that elimination of claims from all but one application "may be required" absent "good and sufficient reason." However, neither the rule nor the MPEP provides an explanation of the justification for requiring consolidation of claims, nor what might be considered "good and sufficient reason" that would justify retention of claims in multiple applications. The lack of any rationale or clear standard seems to allow for a burdensome requirement without clear reasoning and further allow arbitrary and potentially inconsistent decision-making from patent examiners. Applicants' flexibility in pursuing patent claims should

[74] 37 C.F.R. § 1.78(f) concerns co-pending applications and does not apply to claims of granted patents.

not be limited (*see* III.A, *supra*), let alone in a manner without clear rationale or standard, subject to individual examiners' views and enforcement with respect to whether claims should be consolidated. More broadly deploying 37 C.F.R. § 1.78(f) would promote uncertainty for patent applicants, which undermines a goal of the patent system. The potential change would also promote inefficiency. Requiring written statements providing a reason for retaining patentably indistinct claims in two or more application would be problematic and burdensome, as discussed in III.E. And, as previously discussed in Question 4(h), arguing over whether claims are patentably indistinct (e.g., claims subject to an OTDP rejection) discourages efficiencies promoted by current practice.

IV. Requiring Applicants to Identify Support for Claims Is Inefficient and Burdensome for Examiners and Applicants (Questions 2(a)-2(f))

At the outset, such a practice seems to be an improper form of burden shifting to applicants. As *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992) explains, "the examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant. . . . If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent." *See also In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984). Consistent with this legal principle, claims are presumed to have adequate written description support upon filing,[75] and originally presented claims "are part of the original specification and in many cases will satisfy the written description requirement." *Mentor Graphics Corp. v. EVE-USA, Inc.*, 851 F.3d 1275, 1297 (Fed. Cir. 2017).[76] Thus, the burden is and should be on the examiner to issue rejections under 35 U.S.C. § 112 when claims lack sufficient support, rather than requiring, at the outset, that the applicant identify support in each case. Likewise, it is the examiner's burden to deny priority claims (i.e., under 35 U.S.C. §§ 119, 120, 121, or 365) when there is insufficient disclosure or support in the earlier-filed application for the claimed subject matter. [77] By requiring an applicant to identify or describe the support for claims upon their original presentation or upon any subsequent amendment, the applicant would necessarily be making such identifications/explanations in the absence of an examiner's rejection, which is not only inconsistent with the patent law, but unduly burdensome.

[75] *See* MPEP § 2163.04 (citing *In re Wertheim*, 541 F.2d 257, 263 (C.C.P.A. 1976) (noting "that the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims")); *see also In re Alton*, 76 F.3d 1168, 1175 (Fed. Cir. 1996).

[76] Indeed, the applicant's original claim set often demonstrates that "the applicant[] had in mind the invention as claimed," that is, the applicant had possession of the claimed invention, as of the filing date. *See Crown Packaging Tech., Inc. v. Ball Metal Beverage Container Corp.*, 635 F.3d 1373, 1381 (Fed. Cir. 2011).

[77] *See, e.g.*, MPEP § 2163; *see also Wertheim*, 541 F.2d at 263; *Alton*, 76 F.3d at 1175.

A. Burdening Applicants with Identifying Supporting Disclosure Would be Prejudicial, Burdensome, and Unnecessary (Questions 2(a)-(c), (e)-(f))

For several reasons identifying and explaining claim support in the specification upon original presentation of the claims or in continuation applications, in the absence of a rejection under § 112, would be unnecessarily burdensome, inefficient, and may be prejudicial to applicants.

First, the entirety of the specification must be considered in assessing whether a claim complies with 35 U.S.C. § 112.[78] If the applicant were required to identify certain portions of the written description providing claim support at the outset, the examiner might place undue emphasis on the identified portions at the expense of considering the disclosure as a whole. Likewise, the identification of certain support in a priority application could place undue emphasis on the applicant-identified portions. Furthermore, as explained above (*see* IV, *supra*), such a practice would be an improper form of burden shifting to applicants. Requiring applicants to provide detailed analysis showing support for genus or Markush claims and explain or identify the corresponding support in the written description for each species encompassed in the claimed genus means that applicants would have an initial burden to establish they have met the requirements under § 112 in the absence of any rejection by the examiner; such an exercise is inconsistent with the patent law.

Second, such changes would be overly burdensome and thus could discourage participation in the patent system by stifling broad invention disclosures and would not foster innovation, competition, or access to information. In particular, it would be unnecessarily burdensome to require applicants to provide a detailed analysis showing written description support for genus or Markush claims, to identify each claim limitation that is a genus, or to explain or identify the corresponding support in the written description for each species encompassed in the claimed genus. For example, it is a well-established practice in claiming chemical compounds to disclose a generic formula for a class of compounds in the specification and thereafter claim the genus of compounds that would be encompassed by the formula. Those of skill in the art would understand the class of compounds encompassed by the disclosed generic formula without the need to specifically identify in a prosecution submission every compound that could be encompassed by the formula. Requiring such a submission would defeat the drafting efficiencies afforded by use of Markush structures and become a burdensome addition to the file history, with no practical purpose in terms of fostering innovation or patent quality. This extra burden on applicants could also discourage applicants from pursuing extensive research programs in the United States that rely on the potential for broad patent protection to justify the risks and expenses of pursuing such research programs.

Relatedly, the USPTO should also consider to what extent such a rule could result in duplicative efforts and additional burdens. For example, with respect to Markush claims, requiring additional submissions or other written disclosures relating to Markush species in every

[78] *See, e.g.*, *In re Tropp*, 748 F. App'x 1022, 1023 (Fed. Cir. 2018) ("[F]ailure to consider the totality of the record in assessing written description constitutes legal error.") (citing *In re Alton*, 76 F.3d 1168, 1176 (Fed. Cir. 1996)).

case at filing would be unnecessary and a further barrier to the patent system, especially for individuals, small business owners, and academic institutions. Indeed, Markush claims already list alternative species explicitly, readily enabling the examiner to raise questions or rejections if support appears to be lacking for some or all of the claimed alternatives. And MPEP § 2117 already includes the "improper Markush claim" rejection and provides that such a rejection should be made in the first action on the merits. Accordingly, under current USPTO practice, examiners are instructed to assess each member of Markush claims from the earliest stages of examination.

The suggestion about requiring identification of support could, therefore, end up chilling innovation in cutting-edge areas that rely on these types of claims for meaningful patent protection. Such concerns would be particularly acute for smaller and resource-constrained applicants, who may be particularly sensitive to the additional burdens and costs, e.g., associated with disclosing and identifying during prosecution support for every species potentially within the scope of a claimed genus. In response, such applicants may opt out of pursuing patent protection for genus inventions. This could ultimately frustrate the goals of fostering innovation and public disclosure of inventions.

Third, current prosecution practice already encourages applicants to identify support in the original disclosure for amended claims. For example, MPEP § 714.02 provides that an "Applicant should [] specifically point out the support for any amendments made to the disclosure" while MPEP § 2163 provides that "[w]ith respect to newly added or amended claims, applicant should show support in the original disclosure for the new or amended claims."

Universally requiring additional identification or explanation of support or species in the absence of a rejection would create additional burden on applicants and examiners without any corresponding benefit. For example, in the absence of a pending rejection, applicants may adopt an overly broad approach and try to address every conceivable issue for every pending claim. This would result in further administrative burden for both the applicant and Examiner. By responding to the specific issues that an examiner raises in a rejection, the applicant can present appropriately focused, responsive, and informative comments and arguments that further clarify claim scope and meaning in view of the specification.

Moreover, unless an application claims the benefit of priority applications under 35 U.S.C. § 119 (i.e., foreign or provisional applications), or is a continuation-in-part (CIP) application claiming priority under 35 U.S.C. § 120 (in which case the presented claims would not be entitled to claim the benefit of the filing date of the priority application if such claims rely on new matter added in the CIP application), no such showing should be required as to earlier-filed parent applications of which the pending application is a continuation or divisional application since the specifications for the parent and pending application are necessarily the same.

B. 37 C.F.R. § 1.75(d)(1) Should Not be Modified by Replacing "or" With "and" (Question 2(d))

Under current practice, "clear support or antecedent basis in the description" under 37 CFR § 1.75(d)(1) generally is treated as one requirement, which exists "so that the meaning of the terms in the claims may be ascertainable by reference to the description." 37 C.F.R. § 1.75(d)(1).[79] This expresses the tenet that the words of the claim must be supported by the specification, because the claims of a patent must be interpreted in light of the specification.[80]

The MPEP reinforces this understanding from the case law. For example, MPEP § 608.01(o) explains that the "clear support or antecedent basis" language in 37 C.F.R. § 1.75(d)(1) and consistency between the claims and specification is "necessary in order to [e]nsure certainty in construing the claims in the light of the specification" and "so that the meaning of the terms in the claims may be ascertainable by reference to the description." This further exemplifies that "clear support" and "antecedent basis" are treated as one collective concept for the purposes of 37 C.F.R. § 1.75(d)(1) under U.S. law—that the meaning of claim terms should be clear by reference to the specification.

Given these settled interpretations and practices, the USPTO, contrary to its suggestion in Question 2(d), should not introduce uncertainty by changing any language in 37 C.F.R. § 1.75(d)(1). Any rule change purporting to change the interpretation or meaning of these concepts in the context of 37 C.F.R. § 1.75(d)(1) would be a substantive change and the USPTO would lack the authority to adopt such a rule. Section 112 has no requirement that the specification provides antecedent basis for claim terms. Adopting this as a requirement would amount to substantive rulemaking, which the USPTO is not authorized to engage in.[81] In addition, a stringent rule that requires the specification to provide verbatim support for all claim terms would be contrary to current law. The Federal Circuit has held that "the description requirement does not demand any particular form of disclosure, or that the specification recite the claimed invention *in haec verba*." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010) (*en banc*).[82]

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[79] *See, e.g.*, MPEP § 608.01(o) ("While an applicant is not limited to the nomenclature used in the application as filed, he or she should make appropriate amendment of the specification whenever this nomenclature is departed from by amendment of the claims so as to have *clear support or antecedent basis* in the specification for the new terms appearing in the claims.") (citing 37 C.F.R. § 1.75) (emphasis added) .

[80] *See, e.g.*, *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316–17 (Fed. Cir. 2005) (*en banc*) (citing 37 C.F.R. § 1.75(d)(1) and its requirement to provide "clear support or antecedent basis" as a justification for a court "to rely heavily on the written description for guidance as to the meaning of the claims").

[81] *See Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1336 (Fed. Cir. 2008) (citing *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549–50 (Fed. Cir. 1996)); *see also Tafas v. Doll*, 559 F.3d 1345, 1352 (Fed. Cir. 2009).

[82] *See also Bd. of Trs. of Leland Stanford Junior Univ. v. Chinese Univ. of Hong Kong*, 860 F.3d 1367, 1375 (Fed. Cir. 2017) ("Substantial evidence supports a finding that the specification satisfies the written description requirement when the essence of the original disclosure conveys the necessary information—regardless of *how* it conveys such information, and even when the disclosure's words [a]re open to different interpretation[s].") (emphasis in original, internal quotation marks and citations omitted).

V. Requests for Continued Examination Promote Efficiency and Should Not be Modified in a Way that Would Hinder Such Efficiency (Question 3)

A. Requests for Continued Examination Serve Multiple, Important Roles During Patent Prosecution

Requests for Continued Examination (RCEs) function as a way to expedite prosecution through providing the applicant with an opportunity for further amendment and argument as a matter of right. For example, after an application is allowed but before it issues as a patent, an applicant may become aware of additional, relevant prior art. Through filing an RCE the applicant is allowed to disclose this additional prior art and have this art considered by the examiner. In addition, there may be instances where an application is close to allowance and, through an RCE, the applicant could refine the application to be in condition for allowance. While the applicant could achieve this goal through filing a continuation application, filing an RCE would be a more efficient route.

For example, based on the USPTO's statistics in December 2022, it took an examiner approximately 1.9 months to issue an office action after an RCE was filed, while it took an examiner 16.4 months to issue a first office action in a new application.[83] Accordingly, a patent applicant may resolve patentability issues faster through RCE practice than filing a continuation. Thus, to foster competition and public notice, as well as applicants' ability to protect their inventions in exchange for disclosing them in patent applications, encouraging RCE practice (which tends to result in faster issuance compared to continuation or appeal) would better serve the USPTO, applicants, and the patent system.

RCEs, while serving as a way to expedite prosecution, also have significant fees associated with them. These fees (in which the second and any subsequent RCE is more expensive than the first filed RCE) create a financial hurdle that helps regulate the use of RCEs. RCEs also count against patent term adjustment (PTA), which also helps to regulate their use.

B. Any Changes to RCE Practice Should Carefully be Considered and Balanced with the USPTO's Goals (Question 3)

Implementing a mandatory internal process, as mentioned in Question 3, that changes once the number of RCEs filed in an application reaches a certain threshold, would create inefficiencies, while not fostering innovation or competition. There may, however, be some instances where involving additional examiners may advance the USPTO's goals, but such transfer should not be strictly tethered to a threshold number of RCEs being filed.

For example, transferring the application to a new examiner or increasing the scrutiny given in the examination of the application when an applicant believes the application is close to allowability would create new inefficiencies. Transferring the application to a new examiner after a threshold number of RCEs are filed would require the new examiner to get up to speed on the entire prosecution history before deciding upon further action. There may also be instances

[83] USPTO, Patents Pendency Data December 2022 (last visited Jan. 30, 2023).

where the examiner and applicant, through amendments and interviews, are getting closer to agreement on allowable subject matter and switching examiners based solely on a threshold number of RCEs being filed could require inefficient duplicative efforts. Similarly, it would be inefficient if an applicant becomes aware of additional prior art, files an RCE to submit it, and then has the application transferred to a new examiner. The original examiner would be much more up to speed on the application and any issues of patentability, and thus could determine more efficiently if the additional prior art raises any new issues.

Furthermore, if an applicant has needed to submit multiple RCEs to progress prosecution to a certain point, this suggests repeated rejections by the examiner, indicating that the application already has been scrutinized rigorously. "Increasing the scrutiny"[84] applied to RCEs after a certain threshold number of RCEs could violate the statutory and case law and create confusion by introducing the concept that patents may be allowed under different standards of patentability. For example, "[i]ncreasing the scrutiny" raises the question of whether the USPTO would apply a different evidentiary standard to a particular group of applications but not to others. The evidentiary standard used by the USPTO during *ex parte* patent examination should be a preponderance of evidence, regardless of application type. The patentability requirements themselves also must be applied consistently across all examined applications, and creating new or disparate patentability standards is not permitted under the Patent Act and would amount to improper substantive rulemaking. In addition, "increasing scrutiny" on a particular subset of patent applications raises the question of whether other types of patent applications would be subject to less scrutiny and therefore potentially result in patents with less quality. Consistent with the statute, the USPTO should apply the same standards and the same level of scrutiny to all patent applications, as required under law, regardless of the type or history of each patent application. In addition, if any increased scrutiny depended on field of technology, it would run afoul of TRIPS.

To the extent the USPTO seeks to change RCE practice, one such approach could be to require an interview after a certain number of RCEs have been filed. Interviews play an important role in improving patent quality because they facilitate constructive dialogue between the examiner and the applicant, help the examiner to understand the claimed invention, and assist the applicant to appreciate the issues identified by the examiner. Mandating an interview with the examiner, and potentially additional examiners or supervisors, after a certain threshold number of RCEs are filed would allow an applicant and examiner(s) to discuss their different views about the claimed inventions.

An additional change that could further the USPTO's goals would be to allow the applicant, after a threshold number of RCEs are filed, to request intervention from a Supervisory Patent Examiner (SPE). Where an applicant and examiner are unable to reach agreement with respect to allowable subject matter, allowing the applicant to involve the SPE and/or switch examiners could reduce the instances where an applicant must file an appeal. Indeed, appeals

[84] The Request for Comments does not describe how an examiner would "increase the scrutiny," whether "increasing the scrutiny" is intended to change the standards for patentability or the evidentiary standard for examination and, if not, what it would entail.

can be filed precisely to involve an SPE and other members of an appeal conference in the evaluation.

VI. Conclusion

PhRMA appreciates the USPTO's efforts to bolster the robustness and reliability of patents and to incentivize and protect new and nonobvious inventions while facilitating the broader dissemination of public knowledge to promote innovation and competition. PhRMA and its member companies are committed to contributing to the dialogue between the USPTO and stakeholders on important patent issues.

Respectfully submitted,

/s/	/s/
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