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To the United States Senate, Committee on the Judiciary, Subcommittee on Intellectual Property

Subcommittee Hearing on "The State of Patent Eligibility in America, Part II"

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Introduction

Chairman Tillis, Ranking Member Mr. Coons, and Members of the Subcommittee: On behalf of BIO I thank you for the opportunity to testify on the state of patent-eligible subject matter in the United States.

By way of personal introduction, I am Deputy General Counsel and Vice President for Intellectual Property for the Biotechnology Innovation Organization, a major trade association representing over 1,000 biotechnology companies, research institutions, technology incubators, and similar entities in the medical, agricultural, environmental and industrial biotechnology sectors. At BIO I advise the organization's board of directors and BIO's various policy departments on patent and other intellectual property-related matters. Prior to joining BIO in 2006, I was Chief Patent Counsel for MGI Pharma, Inc., in Bloomington, MN. I have more than 20 years of professional in-house experience in the biotechnology industry, having begun my career as a postdoctoral research fellow at Genentech, Inc. in South San Francisco in 1995, and subsequently worked as a research scientist at Guilford Pharmaceuticals Inc. in Baltimore. My research specialty was the biology of age-related degenerative brain disorders; in this role I participated in several drug development programs before becoming a patent lawyer in 2003. I hold an M.S. degree in biology from the University of Ulm in Germany; a Ph.D. in Neuroscience from the University of Lund, Sweden; and a J.D. degree from Georgetown University Law Center where I serve as adjunct professor of law.

Background

Few sectors of the Nation's economy are as dependent on predictable, enforceable patent rights as is the biotechnology industry. Robust patents that are valid and that carry a commercially reasonable scope of protection enable biotechnology companies to secure the enormous financial resources needed to advance biotechnology products to the marketplace, and to engage in the partnering and technology transfer that is necessary to translate basic scientific discoveries into real-world solutions for disease, pollution, and hunger.

Research and development within the biotechnology industry comes at a high cost, and every idea that is funded comes with a much greater risk of failure than success. Investment thus is predicated on an expected return in the form of patent-protected products or services that ultimately reach the market. The typical BIO member company

does not have a product on the market yet, nor a steady source of revenue, and spends tens of millions of dollars on R&D annually. The biotechnology industry as a whole provides employment to over 1.5 million individuals nationwide, and private and corporate biomedical research spending now approaches $70 billion annually. Virtually all of this investment is through private funding.[1] Developing a single therapy requires an average investment ranging from $1.2 billion to over $2 billion, and the clinical testing period alone consumes more than 8 years on average.[2]

Such investments are not only expensive; they are risky. For every successful biopharmaceutical product, thousands of candidates are designed, screened, and rejected after significant investments have been made. The chances that a biopharmaceutical medicine will advance from the laboratory bench to the hospital bedside are approximately one in 5,000.[3] Only a small minority of candidate drugs even advance to human clinical trials, and most of those will never ultimately reach the market. For example, at the time human clinical testing begins, the odds that a biopharmaceutical compound will eventually receive FDA approval are only slightly over 10 percent.[4]

Because such risks and costs cannot usually be borne by any one entity alone, biotech drug development depends heavily on licensing, partnering, and access to capital. Patents allow biotech inventions of great societal value to be passed or shared among parties best suited to unlock their potential at any given stage of development and commercialization – each contributing their part, each sharing the risk of failure, each increasing the odds that a product eventually reaches patients.

If these patents can be invalidated, or patent applications be denied, under overly broad criteria, third parties would be less likely to invest in or license the technology, and major sources of R&D funding would move elsewhere. The result – patients waiting for the next new cure or treatment will have to wait longer, or may not ever get it at all.

For these reasons, uncertainty, drift, and creep in the law of substantive patentability – such as under Section 101 of the Patent Act – is highly relevant to the biotech business model. A small or mid-sized biotech company that today decides to begin development of, for example, an Alzheimer's treatment must look a decade or more into the future. Long-term financial commitments will be required; several hundred million dollars will need to be

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[1] Moving Research from the Bench to the Bedside: Hearings Before the Subcomm. on Health of the House Comm. on Energy and Commerce, 108th Cong., 1st Sess. 47 (2003) (testimony of Phylliss Gardner, M.D) (http://archives.energycommerce.house.gov/reparchives/108/Hearings/07102003hearing990/Gardner1579.htm) ("The biotechnology industry is the most research and development-intensive and capital-focused industry in the world," noting that 98 percent of research and development investment comes from the private sector).

[2] Joseph A. Di Masi and Henry G. Grabowski, The Cost of Biopharmaceutical R & D: Is Biotech Different? Manage. Decis. Econ. 28: 469-479, 2007)(hereafter: "Di Masi and Grabowski").

[3] Secretary of Health and Human Services Tommy G. Thompson, Remarks at the Milken Institute's Global Conference (Apr. 26, 2004), available at www.hhs.gov/news/speech/2004/040426.html

[4] Clinical Development Success Rates 2006-2015, BIO Industry Analysis Report 2016, available at https://www.bio.org/sites/default/files/Clinical%20Development%20Success%20Rates%202006-2015%20-%20BIO,%20Biomedtracker,%20Amplion%202016.pdf

raised; and development partnerships will need to be secured in a situation where the cost of capital is high and the odds of ultimate success are small. Because investment-intensive businesses can tolerate only so much risk, even moderate additional uncertainty can cause business decisions to tip against developing a high-risk, but potentially highly-beneficial, product. This is not an academic consideration. Every biotech executive has stories to tell about promising experimental compounds that had very favorable medicinal properties, but were never developed because their patent protection was too uncertain. And scholars have documented this unfortunate fact. [5]

The past 9 years have seen an unprecedented expansion of common-law exceptions to patentability. These expanded exceptions have swallowed preexisting patents on inventions that were perfectly patentable when the applications describing them were first examined and issued years earlier. All indications are that these exceptions are still expanding, with courts struggling to identify any outer boundaries in the Supreme Court's caselaw. Businesses must rationally assume that patents that are validly issued today can "become" invalid over time, because new creative applications of judicial exceptions may lurk only an appellate decision or two in the future. Nothing could be worse for investment in innovation than changing the rules of patentability after the fact in this way, after large investments have been made in reliance on properly examined and issued patents. If courts continue their current practice of construing judicial exceptions unmoored from the provisions of the Patent Act, without being able to genuinely explain the doctrinal origins of these exceptions or even clearly articulating the policies that are to be achieved, it is no exaggeration to say that investment in biotech innovation will sooner or later be negatively affected. By the time we understand the impact on new tests and treatments that may only become available a decade from now, it will be too late.

The average American today can realistically hope to live into her or his 8th decade. At retirement, one out of five Americans can expect to develop Alzheimer's disease during her or his remaining years. The risk of developing cancer is even greater. While much has been said about inefficiencies in the patent system that affect business costs and prices for consumers in some sectors today, we must keep in mind that that same patent system encourages risk-taking and long-term investment in potential solutions for the biggest problems facing our world and the generations to come: disease, hunger, and pollution. Great care must be taken to ensure that we do not focus too heavily on current complaints about problems in the patent system without appreciating the system's longer-term benefits to society.

It is critical that the future path of our patent system is one that preserves and maintains the incentives for innovation that have made the United States the global leader in medical, agricultural, industrial and environmental biotechnology. With this in mind, I would like to touch on two biotechnology subject matter areas that are affected by recent patent-

[5] Benjamin Roin, Unpatentable Drugs and the Standards of Patentability. Texas Law Review, Vol. 87, pp. 503-570, 2009.

eligibility jurisprudence, before concluding with some observations on the draft reform legislation pending in this Subcommittee.

Preparations of naturally occurring or naturally-derived substances: Among BIO's members, no area of substantive patent law has received more attention over the past several years than the topic of patent-eligible subject matter under Section 101 of the Patent Act. The Supreme Court has weighed in on this subject four times in as many years, and patent practitioners are losing count of the numbers of patents that have been rejected by the PTO or struck down in the lower courts on this ground over the past years alone. While in terms of sheer numbers the impact on software-implemented inventions has been particularly harsh, the patentability of biotechnology inventions relating to products and processes derived from natural sources or materials also has been affected significantly by this ongoing judicial and administrative expansion of non-statutory patent law in the United States. BIO's members are greatly concerned by the significant departure from internationally-accepted norms of patentability that is increasingly manifesting itself in the courts, particularly with regard to industrial, agricultural, and pharmaceutical preparations of naturally-derived substances, compositions, and processes.

Inventive preparations based on naturally-occurring substances have historically been of great importance in biotechnology, and innovation in this area has been spurred, at least in part, by the availability of patent protection. This is true for every sector of biotechnology. Examples include vaccine antigens, crop protection products[6], plant biotechnology and

[6] Numerous commercial crop protection products, such as enriched or purified preparations of selected strains and combinations of *Bacillus thuringiensis* or *B. subtilis* are used in organic insect control; *B. pumilus* is used as a biofungicide. Naturally-occurring fermentation products such as spinosad and avermectin are commercially marketed for insect and mite control.

breeding[7], industrial enzymes[8], immunosuppressive drugs[9], anticancer compounds, and antibiotic drugs.[10]

In the continual search for new therapies, the use of patented, naturally-occurring substances is not just a historical phenomenon but continues to be important today. For example, romidepsin was approved by the U.S. Food and Drug Administration in 2009 for the treatment of cutaneous T-cell lymphoma. It was first reported in the scientific literature in 1994 as an isolate from *Chromobacterium violaceum* from a soil sample obtained in Yamagata Prefecture, Japan (*see* U.S. Patent No. 4,977,138). Two natural marine antitumor compounds, trabectedin and aplidine (*see* U.S. Patent No. 5,834,586) were discovered in the sea squirts *Ecteinascidia turbinata* and *Aplidium albicans*, respectively. Both are in active clinical development, with trabectedin having been approved in 2007 for commercial marketing in Europe under the trade name Yondelis®. In 2012, ingenol mebutate, a natural compound extracted from *Euphorbia peplus* plants, was approved by FDA and EMA under the trade name Picato® for the topical treatment of actinic keratosis (*see, e.g.*, U.S. Patent No. 7,410,656).

As these examples indicate, preparations of novel and unobvious naturally occurring molecules continue to be an important source for drug discovery. Indeed, naturally-occurring molecules and their close derivatives have contributed an estimated 36% of all first-in-class small molecules approved by the FDA between 1999 and 2008. *See* Swinney DC and Anthony J, *How Were New Medicines Discovered?* Nat. Rev. Drug Discov. 10 (2011) 507-519. In oncology, such naturally-derived chemotherapeutic agents have been described as an important second rail in the fight against cancer that supplements the parallel development of highly-targeted oncology treatments using antibodies or fully-synthetic small molecules. *See* Basmadjian et al., *Cancer Wars: Natural Products Strike Back*. Frontiers in Chemistry 2 (2014) 1-18.

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[7] Genetic elements such as promoters, intronic nucleotide sequences, non-coding RNA as well as naturally expressed sequences are widely used in plant biotechnology and breeding activities in major crops including corn, wheat, soybean, rice, tobacco, canola, potato, sugar beet, and others.

[8] Phytase, an enzyme supplement to animal feed, enhances the ability of livestock to digest phytate in grain, thus reducing environmental pollution from fecal phosphate. Progress in this area has been facilitated by the invention of a phytase enzyme from the microbe *E. coli* and patent protection of isolated DNA. *See* U.S. Patent No. 6,190,897. Glucoamylase, an enzyme from the fungus *Trichoderma reesei* that efficiently releases glucose sugars from carbohydrates, allows for better production of biofuels such as ethanol. *See* U.S. Patent No. 7,413,887

[9] Three major immunosuppressive drugs used to prevent organ rejection of transplant recipients were all discovered in natural, soil-dwelling microbes. Cyclosporine A was first discovered in a soil sample from Norway; tacrolimus (Prograf®) is produced by the bacterium *Streptomyces tsukubaensis*, first discovered in a soil sample from northern Japan (*see* U.S. Patent No. 4,894,366), and sirolimus (Rapamune®)(*see* US patent 3,929,992) is produced by the bacterium *Streptomyces hygroscopicus*, which was famously discovered in a soil sample from Easter Island.

[10] A large proportion of early cytostatic drugs were discovered, isolated and derived from botanical or microbial sources, such as vincristine, vinblastine, vinorelbine, vindesine, camptothecin, irinothecan, topothecan, paclitaxel, docetaxel, etoposide, teniposide, doxorubicin, daunorubicin, idarubicin and epirubicin.

Antibiotics represent another area of drug development where naturally-derived products play an important role in addressing critical emerging medical needs. FDA antibiotic approval numbers illustrate the problem. There were 16 new systemic antibiotics approved from 1983 to 1987. Approvals declined to 10 from 1993 to 1997, to five from 2003 to 2007, and to just two between 2009 and 2012. Steve Usdin, *Antibiotics Reset,* BioCentury Nov. 19, 2012.[11] Yet, new antibiotics are urgently needed given the increasing resistance of microbes to existing antibiotics. Naturally-occurring antibacterial substances play an important role in addressing this emerging problem. Among the relatively few new antibiotic drugs that were approved during the past decade, for example, are the bacterial fermentation products daptomycin and fidaxomicin, the latter having been approved as a first-in-class molecule in 2011. Over the coming decade, the importance of naturally-occurring substances as sources for new antibiotic drug development will only increase, as advances in bioprospecting, in understanding microbial physiology and bacterial biosynthetic gene clusters, and in analytical techniques provide fertile areas for critically-needed research to unlock the untapped potential of naturally-occurring antibacterial substances. *See* Wright GD, *Something Old, Something New: Revisiting Natural Products in Antibiotic Drug Discovery*. Can. J. Microbiol.60 (2014) 147-154.

Such historically uncontroversial inventions are now increasingly being rejected in the PTO as unpatentable subject matter under an expanded extra-statutory exception for "natural phenomena," even if they are otherwise novel, unobvious, and useful inventions that, but for the intervention of man, would not have ever been known and put into practically useful forms. By subjecting such inventions to an unstable patent-eligibility analysis that focuses on the "gist" of the invention instead of the specific scope of the patent claim itself, courts are in the process of creating a deep disparity in substantive patent law whereby whole categories of socially beneficial inventions would face obstacles to patent protection in the United States but remain patentable among its major trading partners, with attendant harmful effects on the flow of investment, trade, and cross-border transfer of innovation. BIO urges this Committee continue its comprehensive review of Section 101 jurisprudence and PTO implementation to determine what needs to be done, and to ensure that the patentability of naturally-derived substances, compositions, and processes remains consistent with our nation's best interests.

Methods of using drugs and other substances for therapy, diagnosis or prophylaxis:

Modern biotechnology depends on the ability to harness hard-earned scientific knowledge regarding cellular and biomolecular processes to develop technologies and products that will improve lives. BIO and our member companies are committed to ensuring that the patent system recognizes and encourages these valuable innovations. Absent the ability to protect their discoveries with valid patents, BIO's member companies would lack the necessary

[11] Available at: https://www.biocentury.com/biotech-pharma-news/coverstory/2012- 11-19/gain-act-fda-stance-only-first-steps-to-refilling-antibiotic-pipeline-in-us-a1

incentive to make the risky, expensive, and time-consuming investments in research and development often required to bring new technologies to market.

Yet since the Supreme Court's *Mayo* decision, significant uncertainty has remained as to the patent-eligibility of methods of treatment, diagnosis, and prophylaxis. In the wake of *Mayo* the Federal Circuit has engaged in a difficult case-by-case analysis of how eligible and ineligible subject matter should be identified in the biotechnology context. Many of those decisions have resulted in the invalidation of patents under Section 101, and every diagnostic method patent that has reached the Federal Circuit was struck down. *See, e.g.*, *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, No. 2017-2508, 2019 WL 453489 (Fed. Cir. Feb. 6, 2019) (invalidating method of diagnosing a neurological disorder); *Roche Molecular Sys., Inc. v. Cepheid*, 905 F.3d 1363 (Fed. Cir. 2018) (invalidating method for detecting pathogenic bacterium); *Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369 (Fed. Cir. 2016) (invalidating methods for detecting a coding region of DNA based on its relationship to non-coding regions); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1373 (Fed. Cir. 2015) (invalidating methods for detecting paternally inherited cffDNA in the blood or serum of a pregnant female); *In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755, 761 (Fed. Cir. 2014) (invalidating methods for screening for an altered BRCA1 gene). In other cases, the Federal Circuit has recognized that certain novel methods of treatment, like the iloperidone treatment claimed by Vanda, "are directed to a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome," and are therefore patent eligible. *Vanda*, 887 F.3d at 1136. Because no discernible contours have been drawn between these decisions, the patent user community (and multiple members of the Federal Circuit itself) are concerned about continuing uncertainty, tension in the caselaw, and inconsistent or unpredictable outcomes.

Two developments in the caselaw are particularly notable. First, since the recent expansion of judicial exceptions, the Federal Circuit has not once upheld a patent on a diagnostic method. The claimed methods in these patents range from broad and general methods to specific and particular laboratory processes requiring significant human intervention and manipulation of novel man-made reagents and reaction products . At this point it is unclear whether diagnostic methods are patentable in any meaningful way, a fact that has been noted by industry and scholars alike.[12] In practice, lower courts seem to understand the judicial exception to require 1. the exclusion of nonstatutory subject matter from the claim and 2. an inquiry into whether the claimed method would be patentable or "inventive" without that subject matter. This approach is highly problematic because it means that a newly-discovered natural phenomenon (which is itself a malleable concept) could never support the patentability of a claim. In practice, the patentee would basically have to make a different kind of invention entirely instead of a diagnostic method -- for example, the patentee would have to invent an independently patentable tool that may be useful for the desired diagnosis, such as new laboratory reagents or a new analytical apparatus. But such a requirement would impede development in an area that benefits from the efficiency and predictability of existing tools, technology platforms, and infrastructure into which new biological findings can be applied. In this way patent law would systematically reward the invention of research tools, and deny rewards to those who use these tools to develop real-world diagnostic, prognostic or other socially beneficial biotech processes. If this is indeed the intended policy outcome, no court has ever explicitly said so. At any rate, basic decisions about research and innovation policy such as these should be reserved for Congress.

[12] Rebecca Eisenberg, "Diagnostics Need Not Apply." *J. Sci. & Tech. L.* 21, no. 2 (2015): 256-86.

Second, in an extrapolation of *Mayo*, it is increasingly being argued that the relationship between dose and effect of a drug is, basically, a natural phenomenon or law of nature. But all methods of drug treatment, without exception, depend on the body's reaction to the drug. Continuing judicial expansion of the exceptions to patent-eligibility along such lines would significantly hamper innovation in important biotherapeutic spaces. Illustrative are historical examples of life changing treatments that if patented today, might very well fail under Section 101 jurisprudence. Consider AZT, the first AIDS drug, for example. That product was originally investigated in the 1960s as an anticancer drug. Although AZT failed as a cancer treatment, further research determined it to be efficacious for AIDS. Similarly, fampridine (4-aminopyridine) was known as a vertebrate pesticide before it was developed for the first-ever drug for improving walking in multiple sclerosis patients. Under the ever-expanding judicial exceptions of laws of nature and natural phenomena, the status of AZT and fampridine as known substances would seem to make any methods of treatment using them non-patentable, regardless of the fact that both substances were later discovered to have efficacy in a new treatment. This would undoubtedly discourage biotechnology companies from investing in development efforts related to such abandoned drugs.

Lack of Congressional intervention also threatens developments in personalized medicine, where many inventions arise from the discovery of a relationship between the genetic profile of a specific individual and the optimized diagnosis and treatment of that person for a given disease. A recent success story in this area is gefitinib, first approved in 2003 as a first-generation tyrosine kinase inhibitor for non-small cell lung cancer (NSCLC) tumors. Response rates to the drug were subsequently found to be below 20% in unselected patients. In 2005, the Food and Drug Administration restricted gefitinib from being used to treat all patients with NSCLC. As a result, the manufacturer discontinued marketing the drug, and the pending marketing authorization application in Europe was withdrawn. However, subsequent clinical evidence revealed heterogeneity in response to gefitinib that had previously been unobserved, and by 2008 the presence of an "EGFR" mutation was established as a strong predictor of treatment response. In 2015 FDA approved gefitinib as a first-line treatment in patients with metastatic NSCLC whose tumors have certain EGFR mutations as detected by an FDA-approved test. At the time, the sponsor stated: "In 2003, [gefitinib] was the first EGFR-TKI for patients with non-small cell lung cancer. While some patients showed dramatic benefit, the research at that time did not enable us to identify those patients that would benefit the most from this treatment. . . . Today, our understanding of molecular mutations and molecular targeting has enabled better decision making in the treatment of NSCLC."[13]

Personalized medicine remains one of the most promising areas of research for companies like BIO's members. And they depend on the ability to obtain patents to justify the development of novel treatments. Creating further uncertainty about the validity of such patents through unpredictable expansion of judicial exceptions, risks forestalling this new era of targeted and more cost-effective medicine. Moreover, it threatens the United States' competitive edge in this important area of innovation.

Some observations on objections to Section 101 reform:

Interest groups have made a series of sweeping statements about the consequences of Section 101 reform for medical research and patient care. Fears that the proposal pending before the Subcommittee would permit the patenting of human genes, which would in turn stifle future research, raise medical costs and interfere with medical care are unfounded and difficult to understand given the current state of the legislative working draft. And with

[13] <https://tinyurl.com/gefitinib>

respect to concerns that reforming the law of patentable subject matter would stifle future research, the relationship of patenting and follow-on research has been studied extensively:

- In 2006, David Adelman and Kathryn DeAngelis published a detailed study of over 52,000 biotechnology patents granted in the US between January 1990 and December 2004. In the words of the two authors, their study described "the general trends in biotechnology patenting including patent counts, patent-ownership patterns, and the distribution of biotechnology patents across distinct areas of research and development." They concluded, "This analysis finds few tangible signs of patent thickets that define the anticommons" (Adelman and DeAngelis, The Mismeasure of Innovation in the Biotech Patent Debate, available at https://www.semanticscholar.org/paper/Patent-Metrics%3A-The-Mismeasure-of-Innovation-in-the-Adelman-Deangelis/49c6a84f11798fefb9c141e9650a5ed7990cf6c1)
- A 2006 report by the National Research Council found the "number of projects abandoned or delayed as a result of difficulties in technology access is reported to be small, as is the number of occasions in which investigators revise their protocols to avoid intellectual property issues or in which they pay high costs to obtain intellectual property." Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health at 134 (2006).
- A 2005 survey of academic researchers conducted by Walsh, Cho, and Cohen concluded that "patenting does not seem to limit research activity significantly, particularly among those doing basic research," with only 1% of their random sample of 398 academic respondents reporting a project delay of more than a month due to patents on knowledge inputs necessary for their research, and none reporting abandoning of a research project due to the existence of patents. John P. Walsh et al., Final Report to the National Academy of Sciences' Committee Intellectual Property Rights in Genomic and Protein-Related Inventions: Patents, Material Transfers and Access to Research Inputs in Biomedical Research (Sept. 20, 2005).
- A 2009 Canadian report on researcher perspectives on commercialization and patenting of genomic research similarly found that there is little evidence that the progress of research itself is in fact being seriously hindered or that gene patents are being aggressively enforced. CJ Murdoch et al., "Commercialization, Patenting and Genomics: Researcher Perspectives," Genome Medicine 1:22 (2009), *available at* http://genomemedicine.com/content/pdf/gm22.pdf.
- Another 2006 study (Caulfield, Cook-Deegan, Kieff and Walsh, Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies, Nat Biotechnol. 2006 Sep; 24(9): 1091) surveyed the current scholarship and concluded based upon existing conditions that policy recommendations for patent reform surrounding genetic patents have largely been driven by a small number of high-profile incidents and controversies and that these anecdotes do not accurately reflect the larger realities surrounding patenting in biotechnology. Regarding the oft-stated fears of a developing anticommons logjam, Caulfield et al. concluded that the effects predicted by the anticommons problem are not borne out by the available data.
- The FTC subsequently concluded that concerns that patenting upstream technology, or "research tools," would actually obstruct commercialization of new products and hinder follow-on innovation in biotechnology "has yet to materialize." Emerging Health Care Issues: Follow-on Federal Trade Commission report on follow-on biologics, June 2009, at 32.

- A 2002 study undertaken by the German government, to determine whether patents on DNA molecules impeded entry into particular fields of research in which isolated DNAs had been patented found that DNA patents created no such barriers to entry. The great majority of those interviewed across the entire surveyed group clearly favored the so-called "absolute product patent protection" of genes. Strauss et al., "Genetic Inventions and Patent Law: An Empirical Survey of Selected German R & D Institutions," Max Planck Institute for Intellectual Property, Competition and Tax Law (2002). Similarly, in 2002, the OECD Working Party on Biotechnology Report (OECD Report), despite documenting a number of specific concerns held by researchers, failed to substantiate fears that growth in the number and complexity of biotechnology patents is preventing access to inventions for research purposes. Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 12–15.
- A report by the Australian Law Reform Commission, "Genes and Ingenuity: Gene Patenting and Human Health," ALRC 99 (2004), available at: http://www.austlii.edu.au/au/other/alrc/publications/reports/99/ likewise concluded that " there is little evidence that gene patents have had any significant adverse effect to date on the conduct of genetic research in Australia," Id., at 12.78, and that existing evidence appears limited and anecdotal.
- Of some 40,000 DNA-related patents, only six have been litigated in the diagnostic testing area. "Property rights: The granting of patents on human genes has so far not been the disaster it was predicted to be." 458 Nature 386 (2009).
- In a 2010 series of case studies on the impact of DNA patents on genetic research, diagnostic test development, and patient access to genetic testing services published as a special supplement in Genetics in Medicine (vol. 12 (4), April 2010), the authors, despite identifying several particularized concerns about licensing practices relating to some individual gene patents, found little systemic negative impact of gene patents on genetic research, test development, patient utilization, and pricing of testing services. The full supplement is available at: http://journals.lww.com/geneticsinmedicine/toc/2010/04001
- An exhaustive 2019 study by Sampat and Williams concludes that human DNA patents do not appear to have hindered follow-on innovation, while on the other hand *trade secrecy* protection of human genetic sequences induced measurable declines in follow-on scientific research and product development. The authors write that "this pattern of evidence suggests that changes to patent policy must carefully consider what strategies that firms will use to protect their discoveries in the absence of patents, and that an understanding of the relative costs and benefits of patent protection compared to [the alternative option of trade secrecy] is needed in order to evaluate the welfare effects of patent policy changes." B. Sampat and H. Williams, How Do Patents Affect Follow-On Innovation? Evidence from the Human Genome, *American Economic Review 2019, 109(1): 203–236*

Stated concerns about stifling research also ignore the protection provided to researchers under 35 U.S.C. § 271(e)(1), *see Merck KGaA* v. *Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005), and the common law research exception, *see Whittemore* v. *Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (Story, J.). Regarding the common law research exemption, BIO believes that the scope and applicability of this doctrine is currently both underappreciated and poorly understood, and that it has had insufficient opportunity for caselaw development because patents are simply not being enforced against scientific

research. Throughout the biotech industry, enforcement of patents against unlicensed researchers is widely viewed as irrational, and non-enforcement is the norm. *See, e.g.*, Chandrasekharan et al., *Proprietary Science, Open Science and the Role of Patent Disclosure*, 27 Nature Biotech. 140, 140 (2009). This helps explain why "there is little documented evidence that patents covering genes or indeed any other subject matter have a detrimental impact on the conduct of research in the academic setting." Toneguzzo, *Impact of Gene Patents on the Development of Molecular Diagnostics*, 5 Expert Op. Med. Diagnostics 273, 274 (2011).

Generalized assertions about the effects of diagnostic patents on patient health and access to medical care are also exaggerated. It is easy to argue after an invention has already been discovered, disclosed, and developed for the market that *now* the public would be better off if it were not patented. It is just as easy to single out a particular invention and argue with the benefit of hindsight that patent protection was not necessary for its discovery and development. Such facile arguments ignore the long-term benefits that the public derives from providing patent protection in exchange for the disclosure of new and useful discoveries. These arguments also ignore the fact that patent protection exists for a limited period and, once a patent expires, the invention enters the public domain.

This latter point is particularly pertinent to concerns about "human gene patents." As a general proposition, legislation is prospective. If Congress were to pass Section 101 reform, and assuming for the sake of argument that it would impart patent-eligibility on preparations of newly-discovered genetic sequences going forward, it is hard to envision that many "new human genes" could be discovered or patented in this day and age. The human genome has been heavily studied and published for decades, and an enormous trove of readily-searchable prior art in this field would present a huge obstacle to patenting.

The legislative proposal pending before this Subcommittee:

BIO strongly supports efforts to bring much needed reform to this area of patent law. The legislative proposal recently introduced by Senators Tillis and Coons and Representatives Collins, Johnson, and Stivers is an important stride in the right direction. Importantly, it will return to the legislative branch control over what types of innovations are eligible for patent protection, rather than leaving this critical decision to the courts. It reinforces the notion that while judicial interpretation of the statute may be required in some circumstances, development of common law exceptions to patent-eligibility is not intended. Moreover, it requires courts to look at claimed inventions as a whole rather than dissecting claims into a "gist" and assessing the remaining parts for additional inventive concepts. The draft legislation reflects a considered approach and it is evident that its drafters took into account the concerns and input of a diverse group of participating stakeholders. BIO notes that the draft legislation adds a new definition of utility that introduces the concepts of "fields of technology" and "human intervention," and a revision to Section 112(f). Regarding the first two concepts, BIO believes that the notion of human intervention has long been implicit in U.S. concepts of "useful inventions or discoveries," and it is proper to retain this important concept and make it explicit. Regarding "fields of technology," this language would be new to the Patent Act, though not necessarily alien to U.S. patent law. The United States is a signatory to TRIPS, which uses these same terms. Regarding the proposed revision to Section 112(f), this proposal is a recent addition to the legislative draft, and BIO members have not had the benefit of long deliberation and we will need more time to provide meaningful feedback on this aspect.

BIO remains committed to continuing to work with the Congress to further perfect the proposal and to respond to legitimate concerns and constructive input from stakeholders that have participated in the preceding series of roundtables or that may wish to join the process going forward.

Two points should be made about opposition to this bipartisan effort. First, reform to Section 101 should not be scuttled because some view the current state of the law as an expedient means to defend against infringement cases. Favoring quick means to invalidate broad swaths of patents ignores the collateral damage and unintended consequences of current jurisprudence. Second, the proposed legislation and whichever final form it takes, should not be an invitation to relitigate the merits or demerits of the Supreme Court cases that gave rise to current systemic problems. To the extent that various groups have valid and substantiated concerns about the legislation, they should be invited to participate in the process with constructive proposals.