Achieving the Right Balance between Innovation and Competition: The Role of Data Exclusivity

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Introduction

Biologics are revolutionizing medicine today, fueling breakthroughs that are changing our understanding of disease and making possible extraordinary advances in a vast range of therapeutic areas for which there remain pressing unmet needs. America's biotechnology companies have led this revolution in medicine: Today, the industry has a presence in every state and accounts for approximately 6.9 million jobs nationwide.[1] Smaller biotechnology companies (all but the top ten) comprise more than 90 percent of the industry, account for two-thirds of the industry's future product pipeline,[2] and have created thousands of jobs in an extensive and diverse list of communities throughout the country.[3] The industry's larger companies—many of which were start-ups themselves not many years ago—also play an important role in the development of new biologics and a major role in supporting smaller companies through partnerships, licensing arrangements, and acquisitions. Altogether, U.S. biotechnology companies have produced nearly 300 approved therapies for patients to date[4] and have more than 600 new medicines in pipeline development.[5]

> *"Biological products often represent the cutting-edge of biomedical research and, in time, may offer the most effective means to treat a variety of medical illnesses and conditions that presently have no other treatments available." – U.S. Food & Drug Administration*[6]

Increasing utilization of biologic therapies has prompted Congress to consider ways to increase access to lower-cost "biosimilar"[7] versions of these important treatments, while maintaining a system that promotes and rewards innovation. More than 20 years ago, for "small molecule" drugs, the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act) struck an important balance between promoting the research and development of new medicines and facilitating the entry of lower-cost versions of them to the market. Both innovative and generic manufacturers of small molecule drugs have had opportunities to succeed as a result, and patients have benefited enormously.

Collectively, the sum of the provisions in the Hatch-Waxman legislation—including the "sameness" standard for approval of an ANDA (generic drug application), five years of data exclusivity,[8] and patent

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[1] Estimated total employment impact based on 2006 statistics: Includes estimates of direct and indirect employment. Archstone LLC and Lawton Burns. The Biopharmaceutical Sector's Impact on the U.S. economy: Analysis at the National, State, and Local Levels. March 2009.

[2] The Boston Consulting Group. "Rising to the Productivity Challenge: A Strategic Framework for Biopharma." July 2004. Available at http://www.bcg.com/impact_expertise/publications/files/Rising_to_the_Productivity_Challenge.pdf.

[3] Battelle analysis of BLS, QCEW data from the Minnesota IMPLAN Group. From the report "Technology, Talent and Capital: State by State Bioscience Initiatives 2008." Available at http://www.bio.org/local/battelle2008/.

[4] Biotechnology Industry Organization statistics. "Biotechnology & Health." Available at http://bio.org/healthcare/.

[5] "2008 Report: Medicines in Development—Biotechnology." Available at http://www.phrma.org/files/Biotech%202008.pdf.

[6] "FDA 101: Biological Products." July 25, 2008. Available at http://www.fda.gov/consumer/updates/biologics062608.html.

[7] The term "biosimilar" refers to a product that is demonstrated to be highly similar to an innovative product and that is approved by the FDA based on abbreviated clinical trials and reliance on the innovator's data and findings.

[8] In addition, where patent protection exists, innovator drugs are ensured regulatory exclusivity during generic challenges until the earlier to occur of a court decision or the expiration of 30 months from notice by the generic to the innovator.

term restoration (providing up to 14 years of effective patent life[9])—yield an average period of approximately 12 to 14 years for small molecule drugs to be on the market prior to generic drug market entry.[10]

This 12 to 14 years for innovative products is the cornerstone of the balance struck in Hatch-Waxman legislation and provides the most appropriate reference point from which to construct comparably balanced biosimilars legislation capable of sustaining and fostering continued advancements in biotechnology for the benefit of patients.

To achieve this balance, however, the provisions included in biosimilars legislation must differ in some respects from those in the Hatch-Waxman Act. An alternative approach is necessary to account for the unique issues raised by biologics relative to small molecule drugs. Specifically, small molecule drugs derive their average 12 to 14 years of time on the market before the start of generic drug entry to the market primarily from the application of their patents, the patent-term restoration rules, and Hatch-Waxman's requirement that a generic drug approved through the ANDA provision be the "same" as its reference product.

The biological context is different, however. Biologics are far more complex than small molecule drugs and, unlike generic small molecule drugs, a "sameness" standard cannot be applied to biosimilars. In addition, as explained in more detail below, the protective value of patents is often less certain for biological products. Any framework for biosimilars must take into account these and other considerations specific to biologics. To ensure that biologics have parity with small molecules in terms of time on the market prior to generic entry, such a framework should build upon the concept of data exclusivity put forward in Hatch-Waxman and apply it for a duration that provides, at a minimum, parity with small molecules: 12 to 14 years.

> *"There is general recognition that the idea of 'sameness', as the term is used in the generic drug approval process under the Federal Food, Drug, and Cosmetic (FD&C) Act and applied to small molecules, will not usually be appropriate for more structurally complex molecules of the type generally licensed as biological products under the Public Health Service (PHS) Act."*
> *- Janet Woodcock, MD, FDA Deputy Commissioner, Chief Medical Officer, March 26, 2007*[11]

To understand the importance of a 12- to 14-year data exclusivity period to a balanced biosimilars framework, it is useful to look more closely at the difference between the "sameness" standard applied to generic drugs and the "similarity" standard applied to biosimilars, at patents and at data exclusivity, both in general terms and as they relate specifically to biologics. The discussion that follows in a Question and Answer format aims to provide that closer look at each of these factors, followed by explanation of why at least 12 to 14 years of data exclusivity is uniquely necessary to achieve and maintain the right balance of innovation and competition in this vitally important area of healthcare.

[9] The patent term restoration provisions allow an innovator to receive, under certain conditions, a half day of restored patent life for every day its product is in premarket clinical trials. In addition, an innovator can receive day-for-day restoration of patent life for the time the marketing application is under FDA review. Restoration periods cannot exceed five years, and cannot provide an effective patent life (meaning patent term following product approval) in excess of 14 years, regardless of how much of the effective patent term is lost due to time spent in clinical testing and review.

[10] Charles Clift. "The value of patent term extensions to the pharmaceutical industry in the USA." *Journal of Generic Medicines*, Volume 5, Number 3, 11 April 2008, pp. 201-208 (8); Henry Grabowski and Margaret Kyle. "Generic Competition and Market Exclusivity Periods in Pharmaceuticals." *Managerial and Decision Economics* 2007, vol. 28, issue 4-5, pages 491-502; Congressional Budget Office, *A CBO Study: How Increased Competition from Generic Drugs Has Affected Prices & Returns in the Pharmaceutical Industry*, July 1998, Chapter Four, "The effects of the Hatch-Waxman Act on the Returns from Innovation." Available at http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf.

[11] Testimony before the Committee on Oversight and Government Reform, US House of Representatives. Available at http://www.fda.gov/ola/2007/protein32607.html.

UNDERSTANDING THE SIMILARITY STANDARD AND PATENTS— THE PROBLEM OF UNCERTAINTY FOR BIOLOGICS

What is the FDA standard for regulatory approval of generic small molecules as outlined in Hatch-Waxman?

Under the Hatch-Waxman Act, a generic (ANDA) applicant must demonstrate that its active ingredient is ***identical*** to that of the innovator or "reference" product to which it corresponds. Generally, this "sameness" standard required for approval of a generic, together with the patents for small molecule drugs, have provided a reasonable level of predictability for small molecule innovators and their investors until the point of patent expiration.

How is the standard for regulatory approval of biosimilars likely to be different from the standard for generic drugs in Hatch-Waxman?

The FDA and others have indicated that scientific limitations imposed by the structural complexity of biologics and other factors make a "sameness" standard not possible to apply to these products. It is likely that biosimilar manufacturers will instead be required to demonstrate that their products are "highly similar" to the corresponding reference products. As explained below, this similarity standard has the potential to considerably diminish the predictability of patent protection for innovator biologics.

"Biosimilars" are products that are demonstrated to be highly similar to existing ("reference") biologic products, and that are approved on the basis of their own abbreviated clinical studies and at least some of the data submitted in support of a reference product. Due to the complexity of biologics, a biosimilar product can only be made "similar" to its reference product, and not identical.

Generally speaking, what role do patents play for the pharmaceutical and biotechnology industries?

The patent system is intended to promote innovation for the social good; to this end, a patent is a reward for inventing something new, useful and unobvious, and disclosing it to the public. Certain subject matters, such as "products of nature" or materials already in the public domain, are not eligible for patenting, even though they may show promise for development into therapeutic products. Once granted, a patent provides its owner with the right to exclude others from making, using, or selling the invention for a specific period of time—usually 20 years from the day the patent application is filed.

Pharmaceutical and biotechnology companies, unlike companies in most other industries, cannot just sell their inventions; they must first secure FDA approval to do so. This approval process requires companies to invest heavily in generating massive amounts of clinical and other data to support a finding of safety and effectiveness that is necessary for, but does not guarantee, FDA approval. Not surprisingly, a significant part of patent life is used up during this data generation and approval process. Patent term restoration is available to partially compensate for this delay. For companies requiring FDA approval,

the so-called "effective patent life" is substantially shorter than 20 years. For an innovative small molecule drug, this period ranges from 12 to 14 years on average.[12]

What data corroborate the 12 to 14 years for small molecule drugs?

Independent analyses of empirical data consistently corroborate this timeframe.[13] Henry Grabowski and Margaret Kyle's extensive analysis of 251 drugs over a ten-year period (1995-2005) found that small molecules' average time on the market prior to generic drug entry to the market ranged between 12 and 15 years. Charles Clift's short-range analysis of the 40 top-selling drugs in 2006 determined that average duration of effective patent life to be approximately 12.8 years.[14] Older data captured by the Congressional Budget Office closely correspond to this number as well, indicating 11.5 years of average effective patent life for 51 drugs approved between 1992 and 1995.[15]

What guarantees does a patent provide?

Although patents are of primary importance to fostering innovation, they provide no guarantees. The rights a patent grants an innovator during its term are only as effective as the owner's ability to enforce the patent. That ability, in turn, depends on the nature of the potential infringer's product, the scope and breadth of the patent claims, and the validity and enforceability of the patent claims. Compounding these factors—which alone create significant uncertainty—is the uncertainty inherent to patent litigation in the federal courts. A recent statistical study reports that patentees successfully enforce their patents in court in only 39% of all cases.[16] This uncertainty has significant implications for smaller biotechnology companies that are highly dependent on external financing to carry out their research efforts, as the uncertainty created by relying solely on patents will likely chill venture investment in biomedical research and development.

How do patents work to support investment in and development of small molecules versus biologics?

Patents for small molecule drugs generally claim the entire molecule itself—as well as a broad class of related molecular structures—providing predictability for investment in and development of small molecule products until the patents expire.

Biological products are much larger in size and far more complex in their structures than small molecule drugs. In some instances, they may be based on "products of nature" or materials otherwise in the public domain for which little or no patent protection is available. If patentable, patents granted to them may

[12] Charles Clift. "The value of patent term extensions to the pharmaceutical industry in the USA." *Journal of Generic Medicines*, Volume 5, Number 3, 11 April 2008, pp. 201-208 (8); Henry Grabowski and Margaret Kyle. "Generic Competition and Market Exclusivity Periods in Pharmaceuticals." *Managerial and Decision Economics* 2007, vol. 28, issue 4-5, pages 491-502; Congressional Budget Office, *A CBO Study: How Increased Competition from Generic Drugs Has Affected Prices & Returns in the Pharmaceutical Industry*, July 1998, Chapter Four, "The effects of the Hatch-Waxman Act on the Returns from Innovation." Available at http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf.

[13] Sources of the empirical data relied upon in the studies cited here include IMS, the US Patent and Trademark Office, and the US Food & Drug Administration.

[14] Clift. "The value of patent term extensions to the pharmaceutical industry in the USA." *Journal of Generic Medicines*, Volume 5, Number 3, 11 April 2008, pp. 201-208 (8).

[15] Congressional Budget Office, *A CBO Study: How Increased Competition from Generic Drugs Has Affected Prices & Returns in the Pharmaceutical Industry*, July 1998, Chapter Four, "The effects of the Hatch-Waxman Act on the Returns from Innovation." Available at http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf.

[16] Aron Levko, Principal, PricewaterhouseCoopers. FTC Hearing on "The Evolving IP Marketplace – The Remedies." February 11, 2009. Available at http://www.ftc.gov/bc/workshops/ipmarketplace/feb11/docs/alevko.pdf.

cover only certain aspects of its basic structure, a small range of variations to that structure, and/or how the product is made. The more limited scope of patents used to support investment and development for biologics makes it potentially easier for a biosimilar manufacturer to design a product with a very similar medical effect, but that does not infringe the patent—in patent parlance, to "design around" or "work around" the patent. Investors analyze patents and the risk of "working around" them as they review the value of particular molecules and create a risk profile for potential investment.

How is the patent landscape different today from the patent landscape in 1984, when the Hatch-Waxman Act was passed? What bearing does this have on biologics?

The vulnerability of biological patents to "work-arounds" is exacerbated by the fact that the scope of patent claims for new medicines is increasingly narrowing. Since 1984, and in recent years in particular, the U.S. Supreme Court and the Court of Appeals for the Federal Circuit have handed down decisions that narrow patent claims significantly.[17] This narrowing of patent claims is a particular challenge for biologic medicines because, just as a property deed defines an owner's interest in an area of land, each patent's scope is limited to its allowed "claims," which specify the boundaries of the patent's protection. So, as a patent claim narrows, the "terrain" available for another manufacture to work around the patent claim without infringing it expands. This trend affects small molecule drugs, but it makes the degree of commercial exclusivity provided by patents for biologics even more uncertain, thus increasing the level of risk associated with biotechnology investment and thus encumbering the pace and extent of biomedical innovation.

How does the similarity standard for biosimilars relate to patents on biologics?

Under a similarity standard, a biosimilar manufacturer could work around the innovator's patent claims to make a version of the product that is "close enough" to win FDA approval (using an abbreviated biosimilar pathway and relying on the innovator's data in the process) while at the same time "different enough" to avoid patent infringement. The similarity standard and patent work-around scenario means that biosimilars could come to market well before patents expire.

If companies can "work around" or circumvent innovator patents, what will happen to biologics?

Patent uncertainty for innovator biologics, absent other mechanisms to offset this risk, will translate most immediately to reduced investment in biomedical research and development, a large measure of which is carried out by small biotechnology companies highly dependent on venture capital and other sources of external financing. This reduction in investment in turn will affect research scientists and students interested in biomedical research, their academic centers, as well as the communities where biologics are developed and produced and the employees who do this work. Ultimately, those who stand to lose most are the patients in the United States and around the world who need the new and better treatments only a thriving innovator biotechnology industry can provide.

[17] See, e.g., KSR International Co. v. Teleflex, Inc., 127 S. Ct., 2007 WL 1237837.

What can help mitigate patent uncertainty for innovators to ensure a proper balance of innovation and competition in biosimilars legislation?

In light of the patent uncertainty to which biologics are particularly subject, data exclusivity—a concept included under the Hatch-Waxman paradigm—can most effectively provide the predictability that is essential to encouraging continued investment in biotechnology, while also making possible the introduction of biosimilars after a defined period of time. In the same way that patents and related provisions have functioned for small molecules under Hatch-Waxman, 12 to 14 years of data exclusivity, together with patents for biologics, will nurture and encourage research for medical breakthroughs while also allowing biosimilar manufacturers to eventually benefit from the work of an innovator.

DATA EXCLUSIVITY OF 12 to 14 YEARS IS NEEDED FOR BIOLOGICS TO ADDRESS THE UNCERTAINTY OF PATENTS CAUSED BY THE SIMILARITY STANDARD

What is data exclusivity? How does it work?

Data exclusivity refers to a defined period of time, beginning upon FDA approval, during which the FDA may not rely on the data submitted by an innovator, or its findings about the innovator's product, to approve another company's product based on limited ("abbreviated") clinical trials.[18] The data exclusivity period begins upon first approval of the product, and is unrelated to the duration of the patents that cover the medicine or its use.

Data exclusivity provides a clear and predictable framework for biosimilar approval for both innovators and biosimilar companies. It is implemented through administrative action by the FDA and does not need to be enforced through litigation, which can be expensive and the results of which are unpredictable. Even during a period of data exclusivity, provided patents are not infringed, another manufacturer can submit its own, independently generated data to support approval of its product by the FDA. Accordingly, while data exclusivity is very narrow, it is certain, only protecting each innovator from the use of its own data by a would-be competitor, and then only for the length of the exclusivity period.

Data exclusivity is not market exclusivity and does not provide a company with a monopoly in a market. Manufacturers who develop their own data to secure FDA approval of their products can enter the market even if another company has data exclusivity.

What are the "data" referred to in data exclusivity?

The "data" in data exclusivity include the extensive array of information an innovator company must generate to show that its drug is sufficiently safe and effective to merit FDA approval for sale in the United States. The data package submitted to FDA, developed at substantial expense over a period of many years, and with no guarantee of product approval, includes information pertaining to the product's chemistry, manufacturing and controls, non-clinical pharmacology and toxicology, clinical trials, safety update reports, and other information.

[18] For generic small molecule drugs, FDA makes an "assumption" that the generic product is safe and effective based on its finding that the reference product is safe and effective, and knowing that the generic drug's active ingredient is the same. Thus, both FDA and the generic drug company are "relying on" the data obtained by the innovator company. This "reliance on the innovator's data" is only possible after data exclusivity periods have ended.

Why is data exclusivity so necessary?

Ultimately, the advancement of biomedical research and development depends heavily on data exclusivity of a duration appropriate to balance innovation and competition. Indeed, data exclusivity is the regulatory solution required to keep the drivers that fuel R&D intact and in motion.[19] At the same, data exclusivity's expiry allows biosimilar manufacturers to benefit from this work, thereby allowing the FDA to rely upon the innovator's data and its findings about the innovator's product to bring less-expensive versions of the medicine to the marketplace. On both sides of this balance, the most important beneficiaries are patients.

> *"An abbreviated approval pathway for biosimilars or follow-on biologics that does not provide adequate data exclusivity for innovator products and which enables challenges to innovator intellectual property in an unbalanced fashion, would deter investment and undermine incentives for the development of innovative, new biotechnology drugs, impeding patient access to these lifesaving therapies. - National Venture Capital Association"*[20]

For biologics, what duration of data exclusivity is necessary to achieve the right balance of innovation and competition? Why?

A data exclusivity period of at least 12 to 14 years for innovative biologics will achieve the fundamental goal of improving patient care and public health (through encouragement of research for medical breakthroughs) while reducing cost over time (through timely market entry of lower-cost biosimilars). As the multiple studies cited here confirm,[21] 12 to 14 years is the length of time required to provide at least parity with small molecule drugs under the Hatch-Waxman framework.

How would a data exclusivity period of at least 12 to 14 years help encourage research into the potential of a biologic medicine to treat additional diseases?

Very often, biologic medicines can be used to treat a wide range of diseases. From available examples today, a single biologic can treat conditions ranging from rheumatoid arthritis to Crohn's disease to severe psoriasis; another, colorectal cancer and lung cancer and breast cancer. The process to determine a biologic's full therapeutic potential is extremely time-intensive, often requiring many additional years of basic research and clinical evaluations, and a level of investment commensurate with and sometimes even exceeding that required for initial approval for treatment of a single condition.[22] Investment in new-disease research for an approved biologic will drop off substantially if data exclusivity and patents do not provide a reasonable amount of time to research a biologic's potential to treat additional diseases where it may have the potential to provide benefit. Given this fact, and the value that this research brings to patients, a 12- to 14-year data exclusivity period is especially important to make this research possible.[23]

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[19] Investment in development of a new biologic is both expensive and risky. Development of the data to support FDA approval can take 10 to 15 years and cost more than $1.2 billion on average. This investment—borne by investors—does not ensure approval; many products fail during clinical trials. See Joseph DiMasi and Henry Grabowski. "The Cost of Biopharmaceutical R&D: Is Biotech Different?" Managerial and Decision Economics 28(4-5), pages 469-479 (2007).

[20] Letter, NVCA to the Honorable Frank Pallone, Jr. May 2, 2008. Available at http://www.nvca.org/pdf/NVCA_Follow-on-Biologics_Responses.pdf.

[21] Grabowski and Kyle; Clift; Congressional Budget Office.

[22] Maya Said, Charles-Andre Brouwers, Peter Tollman. "Continued Development of Approved Biological Drugs: A Quantitative Study of Additional Indications Approved Postlaunch in the US." December 2007. Available at http://www.bcg.com/impact_expertise/publications/files/Biologics_Dec07_final.pdf.

[23] Not only is a 12- to 14-year data exclusivity period important to make this research possible, but a strong argument can be made that an additional period of data exclusivity of one to two years should be added to the base exclusivity period to encourage significant new disease research.

The FDA refers to a product's approved clinical uses as its "indications." The first disease or condition for which the FDA approves a product for clinical use is called its "initial indication." When a product is approved for clinical use in treating multiple conditions, it is said to have "additional indications." Additional indications approved after the initial indication are often referred to as "new indications."

How would 12 to 14 years of data exclusivity encourage the availability of biologics that have therapeutic potential but no patent protection?

There are a large number of unapproved molecules with therapeutic potential for which patents have expired or are otherwise unavailable.[24] In some cases, the therapeutic potential of a patented molecule was understood only as science advanced, after the patent expired or the remaining patent life was too short to protect the investment needed for development. In other cases, molecules were disclosed or mentioned publicly, or the patent office concluded the molecules were based on prior published scientific publications or patents, thus preventing them from being patented at all regardless of their potential to treat diseases. Many molecules with the potential to advance medicine have gone undeveloped simply because the patent system did not provide sufficient protection to invest in and pursue these important research opportunities.

In these situations, a data exclusivity period of the appropriate duration—12 to 14 years, would provide opportunities for today's researchers to pick up where past researchers left off and to fully explore how molecules that lack patent protection might play a role in novel approaches to disease treatment.

On the economics side, are there other arguments to support 12 or more years of data exclusivity for innovator biologics in biosimilars legislation?

There are a number of important and relevant economic arguments to support 12 or more years of data exclusivity for innovator biologics, one of which centers on what economists refer to as "break-even analysis," or the point at which innovator biotechnology companies no longer operate at a loss after making the enormous investment in a portfolio of potential therapies, many of which fail in early and late stages and never make it to market. This is an important consideration, especially given the extent to which biotechnology companies necessarily depend on external financing to carry out their research for breakthrough new medicines, and the high technical and commercial risks associated with biotechnology investing.[25]

An analysis of average break-even lifetimes for biologics conducted by Duke University economist Henry Grabowski determined the appropriate period of data exclusivity to be 12.9 to 16.2 years, based on the estimated period of time it takes a portfolio of biologics marketed by a mature company to earn back the average cost of R&D needed to bring a new biologic to market.[26]

[24] Benjamin Roin. "Unpatentable Drugs and the Standards of Patentability." Available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1127742.

[25] Compounding these risks are the biotechnology industry's higher development costs, longer development timelines, and lower success rates relative to most other industries.

[26] Henry Grabowski. "Follow-On Biologics: Data Exclusivity and the Balance between Innovation and Competition." *Nature Reviews: Drug Discovery*. Vol. 7. June 2008."

How can 12 to 14 years of data exclusivity help maintain US global competitiveness in biotechnology?

While we have been the world leader in biotechnology to date, continuation of this leadership is not guaranteed. Many other countries are challenging our leadership and providing incentives to advance biotechnology in their countries.

> *"The United States has built a system of scientific innovation that simultaneously trains our own best and most talented people and attracts the best and brightest from around the world. We have 'in-sourced' talent, combined it with our own and pushed the boundaries of innovation for our economy and, indeed, the world. But today, China, India, Singapore and others have adopted biomedical research and the building of biotechnology clusters as national goals…. We may be creating a climate where our position as the primary destination for the best and brightest researchers from around the world may be challenged." – Drew Gilpin Faust, Harvard University President*[27]

The European Union has provided 10 years of data exclusivity for innovators, with one additional year for discovery and approval of a significant new clinical use. To maintain U.S. competitiveness and leadership in this area, it is appropriate to include in U.S. biosimilars legislation a data exclusivity period that is more favorable to innovation than the period provided in Europe and elsewhere.

> *"We must recognize that the foundation of our prosperity in this global world is to remain on the cutting edge of technology and medical and scientific breakthroughs in the years ahead and translate those advances into reliable products and services…. America has always been a world leader in research and development, but we can no longer take our success for granted."*
> *– Senator Edward Kennedy*[28]

Conclusion

Congress has a significant opportunity to carry forward the kind of balance achieved in the Hatch-Waxman Act, this time with a new paradigm that appropriately accounts for and reflects the unique challenges and promises associated with biologic therapies. For biologics, the key to achieving balance for the benefit of all interests lies in the allocation of 12 to 14 years of data exclusivity: parity with what Hatch-Waxman has yielded for small molecule drugs in terms of time on the market prior to generic entry. Twelve to 14 years of data exclusivity in biosimilars legislation would yield benefits for stakeholders across the board. This amount of data exclusivity, together with patents, would afford all parties—regulators, payers, providers, investors, innovator and biosimilar manufacturers, and patients—a high level of predictability regarding the timing of entry of lower-cost biosimilars to the market.

This clear and predictable framework will promote continued investment in biologics research in the U.S., helping especially smaller biotechnology companies highly dependent on outside funding to facilitate their important research and development efforts, which in turn will benefit patients waiting for

[27] Testimony of Drew Gilpin Faust, Harvard University President, before the Senate Committee on Health, Education, Labor and Pensions. March 11, 2008. Available at http://www.brokenpipeline.org/fausttestimony.pdf.

[28] Address at Northeastern University: "Globalization and the American Dream." February 22, 2006. Available at http://www.tedkennedy.com/content/710/senator-kennedy-on-globalization.

innovative new medicines. It also opens the door for lower-cost biosimilars, allowing biosimilars manufacturers and patients to thrive just as generic manufacturers and patients have under the Hatch-Waxman Act.

Ultimately, the allocation of at least 12 to 14 years of data exclusivity for biologics is essential to the enduring success of any biosimilars framework enacted by Congress. It is the key to strike the right balance for patients, to achieve parity for biologics with small molecule drugs, and to maintain America's competitive edge in biotechnology, allowing us to continue to lead the world in bringing forth new lifesaving medicines.