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

EXECUTIVE SUMMARY

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Biologics represent the future of medicine.
Advances in biotechnology research and development have ushered in scores of new and transformative breakthroughs for patients with unmet medical needs. The potential of this young, largely U.S.-based industry to revolutionize the ways by which we understand, treat, prevent, and eliminate disease is nothing short of extraordinary. The realization of that great potential—and the benefits it stands to bring to patients, our healthcare system, and the U.S. economy more generally—will require a carefully balanced approach to the construction of a regulatory pathway for biosimilars.

In 1984, for small molecule drugs, the Hatch-Waxman Act struck an important balance between promoting 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. Forthcoming biosimilars legislation should seek a similar type of balance between innovation and competition that can best serve the needs of patients now and in the years to come.

Collectively, the sum of the provisions in Hatch-Waxman legislation yielded an average of 12 to 14 years for small molecule drugs to be on the market prior to generic drug market entry.
These provisions include the "sameness" standard for approval of an ANDA (generic drug application), five years of data exclusivity, and patent term restoration (including up to 14 years of effective patent life).

Independent analyses of empirical data consistently corroborate the 12- to 14-year timeframe for small molecules.
Henry Grabowski and Margaret Kyle's extensive analysis of 251 drugs over a ten-year timeframe (1995-2005) found that small molecules' average time on the market prior to generic competition 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. 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.

This 12 to 14 years for small molecule drugs to be on the market prior to generic entry is the cornerstone of the balance struck in Hatch-Waxman legislation and 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 ensure that biologics have parity with small molecules, the provisions in biosimilars legislation will need to differ in some respects from those in Hatch-Waxman to account for the unique characteristics of biologics.
Small molecule drugs derive their average 12 to 14 years of time on the market before generic market entry primarily through the ANDA provision that requires that the generic be the "same" as its reference product. Biologics are far more complex than small molecule drugs, however, and unlike generic small molecule drugs, a "sameness" standard cannot be applied to biosimilars. Among other factors and for various reasons, this inapplicability of a "sameness" standard has potentially serious implications for patents in the biological context, rendering their ability to support a framework that fosters investment in and development of new biologic medicines far less certain.

For biologics, the inapplicability of a "sameness" standard provides a means for biosimilar companies to "work around" patents.

The FDA and others have indicated that scientific limitations imposed by the structural complexity of biologics and other factors make Hatch-Waxman's "sameness" standard not possible to apply to biosimilar drugs. Under the alternative "similarity" standard, a biosimilar manufacturer could potentially 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 nature of patent claims for biologic products differs from that of small molecule products, and as patent claims are increasingly narrowed by courts, the "terrain" available for other manufacturers to work around a patent claim without technically infringing it expands.

This similarity standard and patent work-around scenario mean that biosimilars could come to market well before patents expire, in turn deterring investment in biomedical research and the development of new biologic medicines. The ability of biosimilar companies to work around patents undermines the opportunity for biologics to have at least parity with small molecule drugs in terms of time on the market prior to biosimilar entry.

Data exclusivity of at least 12 to 14 years in biosimilars legislation will make possible parity with the 12 to 14 years Hatch-Waxman legislation yielded for small molecule drugs.

Data exclusivity—a concept included under the Hatch-Waxman paradigm—can most effectively provide the predictability crucial to fostering continued investment in the development of new lifesaving medicines while facilitating market entry for biosimilar drugs after a reasonable and more predictable period of time. Together with patents, 12 to 14 years of data exclusivity for biologics will nurture and reward innovation while also allowing competitors to eventually benefit from the work of an innovator.

Data exclusivity is by definition limited in scope and duration, allowing other manufacturers to bring their products to market under the same process as innovator companies.

Data exclusivity refers to a defined period of time during which the FDA may not rely on an innovator's data to approve another company's product based on limited ("abbreviated") clinical studies. Administered by the FDA, data exclusivity provides a clear and predictable framework for biosimilar approval for both innovators and biosimilar companies. A period of data exclusivity begins upon first approval of a product, and is unrelated to the duration of the patents that cover a medicine or its use. 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.

Ultimately, 12 to 14 years of data exclusivity for innovative biologics is essential to achieving goals fundamental to the success of any balanced pathway forward for biosimilars, among them:

1. **The right balance for patients**. The right balance for patients depends on a framework capable of both promoting the development of new medicines and facilitating the entry of lower-cost versions of them to market after a reasonable and predictable interval. The key to striking the right balance is 12 to 14 years of data exclusivity.
2. **Parity with small molecule products**. We know that biologics can deliver substantial new advances in medicine. Parity with what small molecule products have been afforded under the collection of provisions in Hatch-Waxman is a fair and sound policy goal. The key to achieving parity is 12 to 14 years of data exclusivity.
3. **Maintaining our country's competitive edge**. Americans created and built the biotechnology industry. We lead the world in the discovery and development of new lifesaving medicines with biotechnology companies in all 50 states. However, this leadership is no longer certain as other countries work aggressively to lure biotechnology away from the U.S. We must maintain our competitive edge in biotechnology. To do so will require at least 12 to 14 years of data exclusivity.