Biologics are a small part of the pharmaceutical market, but are its fastest growing component. Patents on most current biologics have expired or will expire during the period from 2009 to 2024. There is mounting pressure from governments, insurers, and patients’ groups to reduce costs of pharmaceuticals and biologic drugs are major targets for cost savings.

The developments facilitating the generic version of a biologic, called *follow-on biologics* (FOBs), are gaining momentum. The *Pathway for Biosimilars Act* proposes that brand name drug makers of an original biologic get twelve years of market protection and exclusivity before generic versions can compete. While critics claim the longer exclusivity period will unnecessarily slow the entry of low-cost alternatives to the biologics market, others see the twelve-year term as necessary to preserve incentives for innovation and development of these complex, cutting edge products. It takes $1.2 billion to develop the average biologic and another $250-$450 million to produce it. Most biologics won’t recoup costs until on the market 12.9 to 16.2 years. Cost analyses reveal that companies cannot recoup costs in under twelve years; biologic developers would soon begin operating at a loss. Research on potential biologics might be halted.

Biologics are much more costly, time consuming, and difficult to produce than standard pharmaceuticals. Shortening the patent time to less than half of that of standard pharmaceuticals would compromise quality and quantity. The decision to establish guidelines and twelve years of patent exclusivity is in the best interest of patients.