Biopharmaceutical Patents 101

Patent protection in the United States gives inventors the exclusive right to sell an invention for a set period of time before others may copy and sell it. The basic patent term is 20 years from the application date, along with any patent term adjustment (for Patent Trade Office delays) or restoration (for regulatory approval process delays). The U.S. Constitution and laws have established a system to grant patents as an incentive for individuals and companies to invest the time, effort and dollars needed to develop new ideas and products. Weakening patents can slow or stifle innovation by making it harder to recoup the investments made to develop the product.

Patent Protection in the Biopharmaceutical Industry Differs from that in Other Industries
Patent protection for biopharmaceuticals is different from protection in other industries for very specific reasons:

• Unlike patents in other industries, biopharmaceutical patents cover products that take a very long time to develop. Patents are not based on having an approved product, and patent applications are made at the time of the invention (relatively early in the drug development process). It takes 10-15 years on average to develop a new medicine from the earliest stages of discovery through FDA approval.

• Significant portions of the patent term for a new drug are lost before a product enters the market, and generic companies can challenge patents as soon as four years after a brand drug enters the market. The average effective patent life for innovative prescription drugs is 12.6 years.¹

• Given the substantial costs in initial investment in biopharmaceutical R&D, strong patent protection provides the potential opportunity to recoup investments made to develop new medicines. The average cost to develop a new medicine has been estimated at upwards of $1.2 billion according to the Tufts Center for the Study of Drug Development.²

The Process of Innovation is Complex: Odds are Almost Overwhelmingly Against Actually Bringing a New Medicine to Patients
The process of innovation is very complex, lengthy and indeed fragile in nature. The stakes are high, with only one in tens of thousands of compounds successfully making it through the discovery, preclinical, clinical trials and FDA review stages of development. Even then, only one in

six approved drugs brings in enough revenue to recoup the average costs of development. Recent biopharmaceutical advances – driven by scientific research and creative genius – would have been impossible without a system of laws that provide the structure, stability and certainty for the needed investment.

**Brand Drugs Face Vigorous Competition Long Before Generic Copies Arrive on the Market**

Notwithstanding patents, brand drugs face vigorous competition long before generic copies arrive on the market. Tufts University researchers have found that the average length of time before a first-in-class drug got its first direct competitor has dropped from 10.2 years in the 1970s to 1.2 years for the period 1990-2003. In fact, there is a race to be first to market: by 1995, nearly all first-in-class medicines had potential competitors in Phase II clinical testing at the time of approval.

**The Research-Based Biopharmaceutical Industry has a Proven Track Record of Bringing Innovative Products to Patients**

The research-based biopharmaceutical industry has a proven track record of bringing innovative products to patients. Prescription medicines have resulted in tremendous medical advances worldwide. In addition, there are currently more than 5,000 medicines in development worldwide, which have the potential to result in needed medical advances against the most costly and challenging diseases and conditions facing U.S. patients.

**Ensuring Strong IP Protections Can Improve People’s Health Worldwide**

Patents are critical to continued medical innovation, ensuring that companies have the potential to recoup the substantial R&D investments needed to develop new medicines and cures that are vitally important to patient health worldwide. In fact, PhRMA members alone invested an estimated $48.5 billion in R&D in 2012, and since 2000 they have invested more than $500 billion. Patents provide a degree of assurance for investors to risk the capital investments necessary in the long development process and to fund new R&D initiatives. Legislative changes that diminish the value of patents could have an immediate detrimental impact on decision makers considering investing in R&D-based ventures, and will negatively affect needed long-term innovation.

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