

A New Age in Intellectual Property

BY FRED D. MASON

American officials are currently finalizing the a major new trade deal, known as the Trans-Pacific Partnership agreement. The TPP involves some of this country's most fruitful trade partners, including Chile, New Zealand, Singapore, and Australia.

One of the main issues at the center of these negotiations are ways to strengthen protections for intellectual property rights.

These protections are especially important for leading-edge research firms in Maryland and across the country. Bringing a new treatment to market is hugely expensive, often requiring an investment of \$1 billion dollars or more before generating a penny of revenue. Firms only take on such risks if they are assured that what they develop will remain their own property, certainly long enough to realize a return on their investment.

A key protection for research firms is the principle of "data exclusivity." While it might sound esoteric, data exclusivity actually has profound implications for the health and well-being of millions of people. If officials miss this chance to put the appropriate protections in place, this country will lose out on new medicines -- and Maryland will lose out on jobs.

Data exclusivity bars other drug makers from accessing the clinical trial data of a competitor's new drug for a preset period of time. Such data can be useful in creating knock-off versions of the original.

Data exclusivity is particularly important for an advanced class of drugs called "biologics." Unlike traditional chemical drugs, biologics are derived from living organisms. They're significantly more complex, which also makes them significantly more effective in combating disease.

Biologics have shown unprecedented promise in the treatment of pressing diseases like Alzheimer's,

cancer, and cardiovascular illness. They've also proven effective against traditionally hard-to-treat conditions like Parkinson's.

For biologics especially, patent protections alone are insufficient. If companies can obtain access to the research data for a biologic, they can use that information to create a drug that serves generally the same therapeutic purposes -- without actually being an exact copy, thus skirting patent protections. The new

*Here in Maryland,
the pharmaceutical
industry accounts for
more than 100,000
direct and indirect jobs.
Although biotech is a
relatively new field, it's
a vital for our state.*

knock-off drug will cut into the original biologic's market share, making it that much more difficult for the inventor to realize a return on their investment, or even break even.

When setting the length of data exclusivity, trade officials need to strike the right balance between lowering drug prices through the introduction of copycat treatments and preserving the financial incentives that drive innovation. A broad body of research suggests that the length that best meets those conflicting aims is 12 years.

Setting exclusivity any lower than that is deeply dangerous. Europe already has a 10 year data

provision in place. If the American standard is only five or even seven years, the United States would immediately become less competitive. Highly mobile pharmaceutical firms will relocate their operations across the Atlantic.

Incorporating strong data exclusivity protections in the TPP will help ensure that the next generation of life-saving biologics gets manufactured on American soil.

When drug makers start new drug research programs, they create new jobs -- from the scientists who research and test new compounds, to the manufacturers of lab tools and the construction workers who build facilities.

Currently, the American pharmaceutical industry supports over 4 million jobs. And these biotech positions are good ones, paying 75 percent more than the average wage.

Here in Maryland, the pharmaceutical industry accounts for more than 100,000 direct and indirect jobs. Although biotech is a relatively new field, it's a vital for our state. Between 2001 and 2008, biotech jobs in Maryland grew more than 10 times faster than the overall job-growth rate -- climbing 46 percent!

A wise TPP is essential for nurturing this industry.

Strong protection for data exclusivity means new drugs. New drugs mean new jobs in Maryland and in America. During the TPP negotiations, American officials need to push for years of data exclusivity that are at least equal to or better than the European countries with which America competes.

Intellectual property protection is the hallmark of countries that lead the world in innovation.

Fred D. Mason is the president of the Maryland and DC AFL-CIO.