The Unspoken Cost of Pharma IP Protections from Trade Agreements

For too long, bilateral, plurilateral and multilateral trade agreements have put the interests of the originator pharmaceutical companies over the needs of patients and their access to affordable, safe and effective generic and biosimilar medicines.

KOREA

COST

3-year patent term extension applied in Korea (Q3, 2012) as required by the US-Korea Trade Agreement (KORUS) and a 5-year patent term extension (2015) as required by the EU-Korea FTA

$1.2 BILLION
COMBINED TOTAL LOST SAVINGS

MISSED OPPORTUNITY

If the 3-year patent term extension hadn't been enacted in Korea as a result of KORUS...

7,000+ PATIENTS

COULD HAVE BEEN TREATED WITH TRASTUZUMAB FOR HER2 NEGATIVE GASTRIC CANCER

APPROXIMATELY

650 PATIENTS ACHIEVING DISEASE-FREE SURVIVAL FOR AT LEAST 12 MONTHS

Without the 5-year patent term extension required in the EU-Korea FTA...

7,300+ PATIENTS

COULD HAVE BEEN TREATED WITH DUTASTERIDE FOR BENIGN PROSTATIC HYPERPLASIA; THIS IS VITAL IN A COUNTRY WHERE THE PREVALENCE OF DISEASE IS INCREASING RAPIDLY DUE TO AN AGING MALE POPULATION.

MEXICO

COST

A 5-year data exclusivity term for small molecule medicines implemented in Mexico in 2012 as part of NAFTA

$320 MILLION
TOTAL LOST SAVINGS

MISSED OPPORTUNITY

Without the 5-year data exclusivity term...

OVER 150,000 PATIENTS

COULD HAVE BEEN TREATED WITH FILGRASTIM (TWELFTH-GREATEST LOST-COST-SAVINGS MOLECULE) FOR A LOW NEUTROPHIL COUNT DUE TO HIV/AIDS OR FOLLOWING CHEMOTHERAPY POISONING.

ECUADOR

COST

5-year data exclusivity term implemented in Ecuador in 2017 as EU-Andean FTA requirement

$3.2 MILLION
TOTAL LOST SAVINGS

PERU

COST

5-year data exclusivity term implemented in Peru in 2013 as EU-Andean FTA requirement

$5.4 MILLION
TOTAL LOST SAVINGS

COLOMBIA

COST

5-year data exclusivity term implemented in Colombia in 2013 as EU-Andean FTA requirement

$10.7 MILLION
TOTAL LOST SAVINGS

CANADA

COST

A 2-year certificate of supplementary protection (CSP) regime and other changes implemented in Canada in 2017 as part of the CETA with the EU (estimated increase Canadian drug costs by 6.2% annually beginning in 2023).

USA

COST

Shift from 17-year to 20-year patent term in the United States as TRIPS requirement

$620 BILLION
TOTAL LOST SAVINGS

MISSED OPPORTUNITY

If TRIPS hadn't required the U.S. to extend term to 20 years, approximately **10 million additional patients** could have been treated with a **10-year course** of treatment with the maximum dose atorvastatin. This is a market where approximately 35 million patients are currently on statins and more than 100 million suffer from high cholesterol.

THE TAKEAWAYS

Billions in revenue has gone to the originator pharmaceutical industry and has been **denied to health care systems and patients that badly need treatments.** Countries need to beware before agreeing to provisions in trade agreements: There is a cost.

The study does not suggest intellectual property rights are *not* important. It clearly points to a cost to health system and patients if extending the intellectual property rights of originator companies is given precedence over the broader societal interests.

The elusive balance between supporting innovation and ensuring access to medicines through a competitive market can be found. It just requires **that countries stay within the bounds of the current TRIPS agreement and not seek expanded monopoly rights.**

SOURCE: IQVIA Report: Impact of free trade agreements (FTAs) on generic & biosimilar medicines markets, October, 2020.

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