

TPP Biologics Exclusivity Period Maintains The Status Quo

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Earlier this month, a final agreement was reached on the Trans-Pacific Partnership that could provide for as little as five years of nonpatent exclusivity for new biologics. In recent months, it was reported that the biologics exclusivity period remained one of the thorniest issues facing the TPP in its last rounds of wrangling. The final agreement is not yet officially available and thus its exact contours are not yet clear. The leaked text of the agreement, however, appears to represent a complicated compromise, allowing countries to choose between an eight-year exclusivity period and a five-year period that may also provide additional protections.

Biologic medicines, also known as biologics, are complex molecules that are made in living cells. They can be contrasted with the more familiar pharmaceutical products known as chemical or small-molecule drugs, which are chemically synthesized. Because biologics are made in living cells, they can at best be similar to already-approved biologics. For this reason, they are known as biosimilars. In 2015, Sandoz's Zarxio, a biosimilar of Amgen's Neopogen medication became the first biosimilar to be approved in the United States.

The text of the TPP, a closely-guarded secret throughout the negotiations, is slated to be made public within 30 days. U.S. Trade Representative Michael Froman has stated that the text is still being finalized in preparation for release. On Oct. 9, however, WikiLeaks released what it claims to be the full intellectual property chapter of the TPP. Article QQ.E.20 of that chapter addresses biologics exclusivity and appears to offer signatories two choices for biologics exclusivity. First, the TPP provides that signatories shall "provide effective market protection [to a new biologic] for a period of at least eight years from the date of first marketing approval." Second, the TPP provides for an alternative "period of at least five years" that may also include protection "through other measures" and which recognizes "that market circumstances also contribute to effective market protection." The text also indicates that whichever path a country chooses, it shall "deliver a comparable outcome in the market."

These provisions will come into effect gradually over the next decade, as the TPP provides for varying transition periods for each signatory. The draft also recognizes that “international and domestic regulation of new pharmaceutical products that are or contain a biologic is in a formative stage and that market circumstances may evolve over time.” It goes on to require the parties to “consult after 10 years, or as otherwise decided by the TPP commission, to review the period of exclusivity.”

The leaked agreement leaves significant choice as to how to provide exclusivity for biologics. Broadly speaking, nonpatent exclusivity comes in two forms: data exclusivity and market exclusivity. Data exclusivity refers to the period during which a biosimilar maker cannot piggy-back off the regulatory data (for example, clinical trials) of the innovator company. For example, in the United States, a biosimilar application may not be submitted to U.S. Food and Drug Administration during the period of data exclusivity. In practice, because the regulatory approval process takes time, a biologic protected by data exclusivity will enjoy a slightly longer effective exclusivity period than one protected by market exclusivity for the same duration. Market exclusivity refers to the period during which a biosimilar cannot be approved for sale, but the biosimilar maker may use the data of the innovator company for review of its regulatory application.

Article QQ.E.20 of the leaked text requires TPP countries to provide exclusivity by implementing Articles QQ.E.16.1 and 16.3, which appear to provide only market exclusivity. Even though those articles refer to “data protection,” it is unclear that they require data exclusivity since both articles appear to bar marketing approval rather than regulatory review of the biosimilar. The leaked draft of the TPP also does not specify how the periods it provides for will be broken down between these two types of exclusivity, if at all. It is unclear, for example, whether the eight years of exclusivity in the TPP refers strictly to market exclusivity or whether some period of data exclusivity can be built into those eight years. It seems likely that any combination of data and market exclusivity should suffice to meet the eight year requirement.

Other provisions of the leaked draft further muddy the waters. It is unclear how exclusivity for new biologics is achieved “through other measures” or what those measures may be. The “other measures” may simply refer to the time it takes a biosimilar to be approved by the relevant regulatory authority. Additionally, the draft’s call for “a comparable outcome in the market” is something of an enigma, given that the TPP apparently provides for both five- and eight-year exclusivity periods; it is hard to see how a three year difference could result in a comparable outcome, particularly if the five-year period is intended to provide market rather than data exclusivity and the biosimilar application therefore can be reviewed and all-but approved during the five-year period.

Regardless of its final details, the compromise represents a setback for the United States, which consistently sought 12 years of market exclusivity during the negotiations. Other nations, such as Australia, pushed for five years of data exclusivity. Under United States domestic law, biologics enjoy 12 years of exclusivity — four years of data exclusivity during which a biosimilar maker cannot submit its biosimilar application to the FDA, followed by eight years of market exclusivity. Australia has five years of data exclusivity without any additional market exclusivity; the regulatory process itself, however, adds on another year or more of effective market exclusivity depending on how long it takes for the biosimilar product to be approved.

After a half-decade of negotiations, the TPP’s provisions on exclusivity for biologics may do little more than maintain the status quo. The United States will not have to shorten its current 12-year period. Other TPP countries will also not have to make changes. Japan and Canada provide eight years of exclusivity under their domestic laws and will be able to stay with that number. Australia and New Zealand, both vocal during the negotiations about their opposition to the United States’ 12-year proposal, have indicated that their five-year exclusivity periods meet the TPP’s requirements and will not be lengthened by the final agreement. In fact, it is possible that only one TPP signatory, Brunei, which currently provides less than five years of exclusivity, will

have to enact new protections. In effect, then, the TPP may simply codify the exclusivity regime that already exists around the Pacific Rim.

Because the TPP largely maintains the status quo, its effect on pharmaceutical innovation may be limited. Had the United States' 12-year proposal been adopted, investment in developing new biologics likely would have increased, as pointed out by the Biologics Industry Organization. BIO released a statement expressing disappointment that the TPP failed to include a 12-year exclusivity period. BIO called the move "short sighted" and argued that 12 years of exclusivity "is a prerequisite to attract the investment required to continue medical innovation and develop new biological cures and therapies." BIO pointed out that while the TPP agreement will not impact the 12 year exclusivity period in the United States, it may "chill global investment" and slow development of new biologics. PhRMA, the Pharmaceutical Research and Manufacturers of America, expressed similar disappointment. PhRMA noted that 12 years of exclusivity was "not a random number, but the result of long debate in Congress."

Advocates for shorter exclusivity periods are not happy with the deal either, though for different reasons. Hillary Clinton, for example, has said that "pharmaceutical companies may have gotten more benefits and consumers got fewer." But the TPP is hardly a win for the pharmaceutical industry, since it likely will not increase exclusivity for biologics in most TPP countries and offers much less exclusivity than the United States sought. For this reason, Orrin Hatch, a long-standing supporter of a 12-year exclusivity period, has expressed concern that the deal does not provide enough protection to foster global innovation. As to Clinton's concerns that the TPP may raise prices, they appear to be misplaced, given that the TPP largely maintains status quo.

Furthermore, a shorter TPP exclusivity period, while having a chilling effect on investment in new biologics, may not have significantly reduced costs. Although generic versions of small-molecule drugs tend to be priced at a deep discount to their brand-name counterparts, biosimilars have so far represented only a modest savings over innovator biologics. Sandoz priced Zarxio, the first biosimilar approved in the United States, about 15 percent lower than Neupogen, the innovator product. Spending on Zarxio in the first six months will be even closer to Neupogen — just under 3 percent less — as a result of how the Affordable Care Act sets reimbursement for biosimilars.

Now that the talks have concluded, the TPP should soon be made available in its final form. Once that happens, the Obama administration will submit the agreement to Congress, which must give it an up-or-down vote. Debate is all but certain to stretch into next year, with a final ratification vote expected in early 2016.

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