## A2 Evergreening (One-and-done)

### CP – Patent Tolling

#### CP: The member nations of the WTO should implement a one-and-done approach that extends the patent period for new drugs such that the 20-year period of exclusivity begins only when the drug is brought to market.

#### The counterplan competes—reduction is a net reduction

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Mike Pushkin and Larry Rowe (West Virginia Legislature). House Bill 110. West Virginia Legislature, 2017 First Extraordinary Session. 19 May 2017. JDN. <http://www.wvlegislature.gov/Bill_Status/bills_text.cfm?billdoc=hb110%20intr.htm&yr=2017&sesstype=1X&i=110>

(ii) The term "reduction in force" means a **net reduction** in the number of employees employed by the employer in West Virginia, determined based on total West Virginia employment of the employer’s controlled group;

#### The counterplan’s version of one-and-done is a massive net increase in overall IP protection—timeframe exclusivity o/ws every other aspect of IP, even a few weeks can be worth billions of dollars.

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As noted above, the recuperation of the investments in a new medicine is largely realized in high cost markets. It is estimated that between 80 and 90 per cent of the sales of patented medicine occur in the OECD countries.45 This is where the recovery of costs in research and development takes place, and not in the developing countries. Jean O. Lanjouw and William Jack have pointed out that the developed countries already offered patents on pharmaceuticals before TRIPS, and that ‘the main result of the harmonization of standards required by TRIPS is to strengthen pharmaceutical patent rights in a group of poorer countries.’46 Lanjouw and Jack comments on the effect of extending the patent period: ‘Lengthening patent protection for a couple of weeks in rich countries, for example, could provide returns equivalent to the introduction of 20-year patents in the developing world.’47 This concerns then the compensation for lost sales in developing countries. Another matter is the cost of producing the needed drugs for free supply. Here it is significant that the patent holder will already have its own, or they have out-licensed, ongoing production. The cost of R&D, marketing and testing for approval, as well as setting up production, will be covered by the ordinary patent period and should therefore be kept outside the calculation of cost for the added production. Details need to be worked out regarding the calculation of the cost and the length of the extended patent period, and the companies will most likely need to accept an authorized auditing instrument verifying the data necessary for the calculations. The average effective sales protection is, as shown above, ten years. It is safe to assume that the extension needed for added production is a small fraction of that. Indeed it has been said by Harvey Bale, then the director general of the International Federation of Pharmaceutical Manufacturers Associations, that ‘Companies are able, through sales they make in developed countries, to offset the cost of donating drugs to poor countries.’48 Here we see a strong reason to keep the patent institute in place instead of weakening it. If surplus values generated by extended patent protection could be used to make the donations programs comprehensive, then the patent system, instead of cutting people off from access to essential medicines, actually would be the arrangement that made them accessible to people that could not even afford generic medicines. Lanjouw and Jack in fact concludes that certain medicines should be made available to the very poorest countries free of charge.49 An extended patent period would imply that the introduction of generic drugs and the price competition that follows from it would be slightly postponed. The cost for this, in that the price reduction is delayed in wealthier countries, would come as a result of expanded market protection through TRIPS and not from any new demands from patients in developing countries.

#### And it solves the 1AC because the incentive for patent renewals comes from the fact that more than half the exclusivity period lapses before the drug comes to market

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Chie Hoon Song and Jeung‑Whan Han\* Research Center for Epigenome Regulation, School of Pharmacy, Sungkyunkwan University, Suwon, Republic of Korea Patent cliff and strategic switch: exploring strategic design possibilities in the pharmaceutical industry Song and Han SpringerPlus (2016) 5:692 DOI 10.1186/s40064-016-2323-1 <https://springerplus.springeropen.com/track/pdf/10.1186/s40064-016-2323-1.pdf> -CAT

The pharma industry: an interesting avenue for designing strategies The pharmaceutical industry has a unique approach to its research and development compared to other industry segment. The sector is strongly R&D driven, highly regulated and is characterized by an increasing level of product complexity and quality requirements (Grabowski 2004). It generally takes up more than 10 years and at least $1 billion to successfully develop and achieve a market approval of a new blockbuster drug (efpia 2014). The long development and testing cycles together with uncertain prospects for commercial success make it demanding to delay planning and decision making processes within an organization. Over the years, the pharmaceutical industry has constantly adapted its business model towards the development of a single drug that targets a broader population. This approach has contributed to important advances in pharmacology to treat a wide spectrum of diseases while ignoring the patient’s individual biology. However, as many companies are conducting researches in similar indication areas and working on influencing the same enzyme activity or the interaction with receptors, it seems opportune to file a patent application as early as possible for the discovered drug candidate. This approach has the disadvantage that the patent expiration is expected to occur much earlier than usual and the effective market life of drugs is significantly reduced (Hemphill and Sampat 2012). It takes an average of 12–13 years to complete the research and development activities, from the initial patent filing to the regulatory approval of new drug, thereby reducing the effective time of market exclusivity to 7–8 years (efpia 2014). Grabowski and Moe (2008) emphasized that the shortened exclusivity period offers “insufficient time for most new drugs to recoup the up-front R&D costs and earn a positive return on this investment”. Subsequently, reducing the time necessary to develop and commercialize the product is one of the key success parameters. However, as the innovator-companies generally have a comparatively limited portfolio of innovative products in their pipeline, they can “no longer simply allow post-patent profits to be eroded and rely on new, patented products to replace their lost revenues” (Bruce 2003). In this context, strategic behavior can be expected in a legal framework to promote lifecycle extension strategies. A steady communication between the health care providers and representative of the pharmaceutical industry is seen as an essential element in making the health care more affordable for the payers and profitable for the industry. Thus, the patent cliff might provide a unique opportunity for the participant in the current healthcare system to collaborate and reinvent the current model of drug discovery and drug marketing for the sustainable development of the whole industry sector.

#### Net benefit – the CP removes the perverse incentive to haphazardly race through R&D on the first patent – that’s the best of both worlds: we get new and safe innovations now and in the future.

McDole and Ezell '21

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Intangible assets, such as IP rights, comprised approximately 84 percent of the corporate value of S&P 500 companies in 2018. For start-ups, this means much of the capital needed to operate is directly related to IP (see Teal Bio case study for more on this). IP also plays an especially important role for R&D-intensive industries. To take the example of the biopharmaceutical industry, it is characterized by high-risk, time-consuming, and expensive processes including basic research, drug discovery, pre-clinical trials, three stages of human clinical trials, regulatory review, and post-approval research and safety monitoring. The drug development process spans an average of 11.5 to 15 years.6 For every 5,000 to 10,000 compounds screened on average during the basic research and drug discovery phases, approximately 250 molecular compounds, or 2.5 to 5 percent, make it to preclinical testing. Out of those 250 molecular compounds, approximately 5 make it to clinical testing. That is, 0.05 to 0.1 percent of drugs make it from basic research into clinical trials. Of those rare few which make it to clinical testing, less than 12 percent are ultimately approved for use by the U.S. Food and Drug Administration (FDA). In addition to high risks, drug development is costly, and the expenses associated with it are increasing. A 2019 report by the Deloitte Center for Health Solutions concluded that since 2010 the average cost of bringing a new drug to market increased by 67 percent. Numerous studies have examined the substantial cost of biopharmaceutical R&D, and most confirm investing in new drug development requires $1.7 billion to $3.2 billion up front on average.9 A 2018 study by the Coalition for Epidemic Preparedness found similar risks and figures for vaccines, stating, “In general, vaccine development from discovery to licensure can cost billions of dollars, can take over 10 years to complete, and has an average 94 percent chance of failure.”10 Yet, a 2010 study found that 80 percent of new drugs—that is, the less than 12 percent ultimately approved by the FDA—made less than their capitalized R&D costs. Another study found that only 1 percent (maybe three new drugs each year) of the most successful 10 percent of FDA approved drugs generate half of the profits of the entire drug industry. To say the least, biopharmaceutical R&D represents a high-stakes, long-term endeavor with precarious returns. Without IP protection, biopharmaceutical manufacturers have little incentive to take the risks necessary to engage in the R&D process because they would be unable to recoup even a fraction of the costs incurred. Diminished revenues also result in reduced investments in R&D which means less research into cancer drugs, Alzheimer cures, vaccines, and more. IP rights give life-sciences enterprises the confidence needed to undertake the difficult, risky, and expensive process of life-sciences innovation secure in the knowledge they can capture a share of the gains from their innovations, which is indispensable not only to recouping the up-front R&D costs of a given drug, but which can generate sufficient profits to enable investment in future generations of biomedical innovation and thus perpetuate the enterprises into the future.