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In summary, IP provisions are not uniformly negative in the international patent system. Many countries provide IP protection to pharmaceutical products that ensure a better quality, safety and efficacy for those who use medicines. The IP provisions do not always result in lower prices because they take a long time to implement and require that patents remain in place for a long time. In particular, the high patent term extension on pharmaceuticals in Europe and the USA may result in lower prices for the citizens who use medicines. Paradoxically, patents delay generic medicine access in some countries, but this is currently seen as a positive by many within the international community as they believe this might enable greater access to quality medicines [85]. It is important to keep in mind that any IP protections in trade agreements should not hinder generic medicine entry and minimise the effect of these protections on access to medicines. The IP provisions found in the US and EU trade agreements are unlikely to be beneficial to providing affordable access to new ARVs in developing countries, as a result of the longer patent term extension and the requirement for patent term extensions are maintained for medicines for over 5 years after the patent grant. These findings are supported by several studies that have examined the impact of IP provisions in the US and EU in the context of developing countries. These studies suggested that IP provisions are unlikely to have a significant effect on medicine prices in the immediate term [40, 59, 60, 62, 65, 67, 82, 85].

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the vha formulary is available to all veterans, including those covered by other formularies. as a result, the decisions made by the vha formulary are not in isolation. each pharmaceutical company, public and private, must submit a drug for review and approval by the vha formulary, which may result in higher or lower prices. the pharmaceutical industry is highly competitive, and a number of companies are seeking to gain market share by developing and marketing new products and/or developing new indications for existing drugs. to accomplish this goal, the pharmaceutical industry invests heavily in research and development, marketing and sales [6, 7]. these research and development efforts are aimed at discovering new therapeutic agents that are more effective and/or safer than existing agents. in addition to the discovery of new drugs, the development of new therapeutic agents is becoming more complex because the number of new molecular entities (nmes) has increased significantly, as have the number of indications for which these nmes are being tested [8]. more recently, the number of nmes in late-stage clinical development has been estimated to be at least one-third of the total number of nmes in development, and this number is expected to

increase in the future [9]. pharmaceutical industry revenues and sales have reached record-breaking levels in recent years. in 2016, global pharmaceutical sales were \$1.12 trillion, representing growth of 6.6% from 2015 [10]. the estimated sales value of the global pharmaceutical industry is projected to grow at a compound annual growth rate of 5.1% between now and 2021, reaching an estimated value of \$1.61 trillion [10]. however, these levels are being challenged by increasing demand for prescription drugs across the globe [11, 12]. the projected demand for pharmaceuticals in the us is estimated to increase by 9.1% between now and 2030, to a level of \$1.77 trillion [13]. in contrast, the world health organization predicts that the global pharmaceutical market will grow at a compound annual growth rate of 6.5% between now and 2030, reaching an estimated value of \$2.76 trillion [14]. 5ec8ef588b

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