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A Mathematical Model to Assess the Health and Economic Impacts of Voluntary Licensing Through the Medicines Patent Pool

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Abstract – This paper evaluates the health and economic consequences of Medicines Patent Pool (MPP) licensing schemes for products with voluntary licensing through a theoretical model of the diffusion and impact of MPP licensed products against a baseline where such licenses do not occur. The justification for the study stems from the fact that MPP licenses have been around for a while, and it is therefore about time that someone sought to put a figure on the value of such licenses by way of the impact they have on the number of patients being served, the costs involved and the resultant health outcomes. It incorporates epidemiology data, treatment uptake ratios, drug cost, and health status; it employs differential equations to model the interactions between price cuts, treatment rates and deaths. Specific factors including the incidence of the disease, the price drop resulting from generic entry, and the elasticity of demand for treatment were obtained from international health care research and literature. The evaluation of the results shows that between the years 2017 to 2032 the MPP license dolutegravir new license for the drug generated an extra of 15.5 million patients' year of treatment, averting 151,839 deaths, and amounting to $3.07 billion in economic saving. Likewise, the license for daclatasvir between 2015 and 2026 helped treat more 428,244 patients, preventing 4,070 death and saving $107.6 million.

Keywords – Intellectual Property Rights, Medicines Patent Pool, Bristol Myers Squibb, Disability Adjusted Life Years, Trade-Related Aspects.

I. INTRODUCTION

In contrast to the remedy employed by 'investors' to minimize non-appropriability, Intellectual Property Rights (IPR) [1] play a crucial role not only in securing the required appropriability, and incentives to technological knowledge generation, but also in enabling the knowledge tradability. Lacking robust IPR, 'inventors' could attempt to conceal the information they have created, depending on secrecy that may significantly impede the development of new technical knowledge [2]. Patents, even when limited to exclusive property rights, do effectively communicate the presence of new technical knowledge. An alternative approach to provide inexpensive access to high-quality medications for the continuing COVID-19 epidemic is the implementation of voluntary licensing that is non-exclusive of IPR in the access-based structure [3].

The World Health Organization's (WHO) roadmap for accessibility to vaccines, medications, as well as other health goods includes licensing as a tactic to promote wider accessibility to health items [4, 5]. A study conducted by the WHO Commission on CIPIH (Intellectual Property, Innovation and Public Health) in April 2006 found that patents do not have a significant role in promoting research and development or introducing new ideas into a market with low buying power [6]. Therefore, the establishment of efficient public healthcare relies on the shared but varied spectrum of buying power among people, which is influenced by their affiliation with low-income developing nations or profit-driven industrial sectors. This is apparent from **Table 1**, which presents a comparison of the proportion of therapeutic sectors in retail sales in a developing nation, namely India, using data from the global market [7]. Consequently, pharmaceutical companies would rather concentrate their research efforts on enhancing drugs that generate the highest sales in the global market, which is mostly composed of developed countries, rather than developing drugs that are most needed in developing countries [8]. This is because the disease most common in a developing country does not attract the highest sales in the global market.

Table 1 offers a juxtaposition of the financial outlay on public healthcare in nation-states classified as developing and industrialised, as of 2000 and 2001 [9]. This suggests that low income developing nations allocate a much less proportion of their GDP to healthcare spending compared to industrial countries. This suggests that the ability of the government to enhance its healthcare infrastructure, accessibility, and assistance to the most economically disadvantaged people is intrinsically linked to the average per capita income and subsequent buying power of citizens in that particular nation. Higher per capita income in a nation corresponds to increased government investment in healthcare provision for its population [10]. Within low-income developing nations, the responsibility for healthcare expenses is mostly assumed by the population. Hence, implementing a strict system of patents will further exacerbate this problem without yielding concrete advantages in terms of innovative and efficient treatments, as seen by the ongoing pattern of pharmaceutical corporations neglecting underdeveloped nations in their pursuit of research for novel medications [11].

Table 1. Comparison of the Pharmaceuticals Market in India to The Global Market Shares

Therapeutic Segment	Share of Retail Sales (World: 2001) %	Rank (India: 2000)	Share of Retail Sales (India: 2000) %
Cardiovascular System	19.7	4	8.0
Central Nervous System (CNS)	16.8	6	6.7
Alimentary Tract and Metabolism	15.2	2	13.4
Respiratory System	9.4	5	7.4
Anti-infectives	6.1	1	15.9
Musculo-skeletal	6.1	3	9.6
Genito-urinary	5.7	7	3.1
Cytostatics and Immunosuppressants	4.0	13	0.3
Dermatologicals	3.3	8	3.0
Blood and Blood-forming Agents	3.1	10	3.9
Sensory Organs	2.3	9	3.0
Diagnostic Agents	1.8	12	1.2
Systemic Hormonal Products	1.5	11	1.6
Others (including Parasitology)	-	-	5.4

Note: Global sale shares are from the IMS purchases of drugs

In addition, the Lancet commission on fundamental medicine policies has included patent-based measures, which include promoting voluntary licensing and establish a pool of patents, as part of its suggested policies to lower the costs of vital medications. In Low-Income and Middle-Income Countries (LMICs), Lee et al. [13] and Kesselheim [14] have endeavoured to elucidate the impact of voluntary licencing and the availability of generic pharmaceuticals for essential medications. The Medicines Patent Pool (MPP) was launched in 2010 to facilitate the provision of affordable generic copies of patented ARV medicines in LMICs through negotiating voluntary licenses with patent owners. The MPP works with the WHO and other stakeholders to prioritize HIV medicines for inclusion in the list of patents. It negotiates licences with significant holders of patents, grants non-exclusive subsidiary licences to several manufacturers of generic medicine and enables them to produce and sell off generic versions of patented medicines [16]. Later on, the MPP collaborates with these manufacturers to quickly develop and make available high-quality medications for use in LMICs [17]. The MPP often organizes meetings with its sub-licensee in order to evaluate the regulatory submission and approval of each of the products under the licensed agreement.

The current assessment warrants identifying the additional health and economic value of voluntary-based licensing agreements supported by the MPP, which aims to increase the availability of more affordable, quality-based medicines in LMICs. Although the importance of such licensing in enhancing treatment coverage has been acknowledged, little information exists on the downstream effects of such licensing strategies on patients' outcomes and healthcare costs. Therefore, the aim of this study is to establish and implement a mathematical model to determine the impact of MPP licenses for the critical drugs, including dolutegravir and daclatasvir on the treatment coverage, mortality rates, and economic savings in the subsequent years and decades. The rest of this study has been organized as follows: Section II gives a detailed explanation and justification of the mathematical model employed for computation in this research study. Section III provides the data and methods for the Model calculations. In Section IV and V, the results will be discussed in detail. Finally, Section VI summarizes the conclusion of the paper that voluntary licensing is playing a positive role in increasing access to essential medicines and improving global health.

II. MATHEMATICAL MODEL

Impact assessment in the 21st century is actively evolving and facing significant challenges [18]. For the sake of sustainable development and intergenerational justice, researchers, practitioners, and policymakers in the field of International Affairs are working diligently to guarantee the precision, efficiency, and enforceability of impact assessments. They are doing this task within ever intricate environmental, economic, social, and policy frameworks [19]. Given the current circumstances, the data and guidance provided by IA have become more vital, with consequences that extend well beyond assessment

reports or jurisdictional regulations. Indeed, the choices made by our current generation render us responsible not only to our peers, but also to our offspring, their offspring, our shared future [20].

In the impact assessment model described in the research, the primary goal is to estimate the health and economic outcomes resulting from access-oriented, voluntary licensing agreements through the MPP. The model evaluates the additional uptake of medicines, health outcomes, and cost savings by comparing scenarios with and without MPP licensing. This approach relies heavily on mathematical expressions that combine epidemiological data, economic cost parameters, and health outcome metrics to deliver robust predictions.

Let us begin with Eq. (1) for patient-years treated. The model computes the number of patient-years treated with the MPP-licensed medicines as shown in Eq. (1).

$$P_{MPP} = \sum_{t=2014}^{2032} \left(N_{t,MPP}(t) \cdot Y_{td}(t) \right) \tag{1}$$

where P_{MPP} represents the total patient-years treated under the MPP licensing scenario, $N_{t,MPP}(t)$ denotes the number of patients treated in year t under MPP, and $Y_{td}(t)$ is the average treatment duration per patient in year t. This is computed for each year within the license duration period (e.g., 2014 to 2032 for dolutegravir). For comparison, the same equation is applied for the counterfactual scenario, P_{CF}, which excludes MPP licensing. The difference between the two gives the additional uptake due to MPP licensing as shown in Eq. (2).

$$\Delta P = P_{MPP} - P_{CF} \tag{2}$$

Next, the cost savings are calculated by estimating the difference in costs between purchasing generic medicines under the MPP license and purchasing non-generic versions. This involves Eqs. (3) and (4) for total procurement costs under each scenario:

$$C_{MPP}(t) = \sum_{i=1}^{N} (P_{MPP}(t,i) \cdot Price_{MPP}(i,t)) \tag{3}$$
$$C_{CF}(t) = \sum_{i=1}^{N} (P_{CF}(t,i) \cdot Price_{CF}(i,t)) \tag{4}$$

Here, $C_{MPP}(t)$ is the total cost of treatment under the MPP scenario in year t, where $P_{MPP}(t,i)$ represents the patient-years for medicine i treated under the MPP license, and $Price_{MPP}(i,t)$ is the price per patient-year for the generic version of medicine i. Similarly, $C_{CF}(t)$ is the total cost for the counterfactual scenario, using $Price_{CF}(i,t)$, the price of the non-generic medicine i. The cost savings for year t is computed using Eq. (5).

$$S(t) = C_{CF}(t) - C_{MPP}(t) \tag{5}$$

and the cumulative cost savings over the entire licensing period becomes Eq, (6):

$$S_{total} = \sum_{t=t_0}^{t_n} S(t) \tag{6}$$

where t_0 and t_n represent the start and end years of the licensing period, respectively. This cumulative savings can be substantial, as the model shows cost reductions ranging from billions of dollars. The health outcomes, such as deaths averted and disability-adjusted life years (DALYs) saved, are modelled based on epidemiological inputs. The number of deaths averted due to MPP licensing is expressed as:

$$D_a(t) = \Delta P(t) \cdot R_{MR}(t) \tag{7}$$

where $D_{averted}(t)$ is the number of deaths averted in year t, $\Delta P(t)$ is the additional uptake of medicines due to MPP in year t, and $R_{MR}(t)$ is the mortality reduction rate of the medicines in that year. The total number of lives saved over the license period is provided by Eq. (8).

$$D_{Ta} = \sum_{t=t_0}^{t_n} D_a(t) \tag{8}$$

Similarly, the number of DALYs saved is modeled using Eq. (9)

$$DALYs_{saved}(t) = \Delta P(t) \cdot R_{DALYs_{\frac{saved}{patient-year}}}(t) \tag{9}$$

where $R_{DALYs_{\frac{saved}{patient-year}}}(t)$ represents the rate at which DALYs are saved in every patient in year t. The overall DALYs saved is therefore calculated as shown in Eq. (10).

$$DALYs_{T-saved} = \sum_{t=t_0}^{t_n} DALYs_{saved}(t) \tag{10}$$

The model also includes the number of patients experiencing virological failure and number of MTCT prevented. For virological failures the formula used is Eq. (11).

$$V_{fa}(t) = \Delta P(t) \cdot R_{vfr}(t) \tag{11}$$

The function $R_{vfr}(t)$ represents probability of virological failure per patient in year t, and the total virological failures averted are given by Eq. (12).

$$V_{tfa} = \sum_{t=t_0}^{t_n} V_{fa}\,(t) \tag{12}$$

For mother-to-child transmissions, the model applies a similar formula, elaborated in Eq. (13).

$$M_{ta}(t) = \Delta P(t) \cdot R_{tr}(t) \tag{13}$$

$R_{tr}(t)$ represents the mother-to-child transmission rate per patients in year t, and the total transmissions that are averted in Eq. (14).

$$M_{tta} = \sum_{t=t_0}^{t_n} M_{ta}\,(t) \tag{14}$$

We identify a complicated relationship that the model emulates to estimate the economic and health effects of the MPP voluntary licencing. The drivers of each variable used in the equations are derived from empirical data, assumptions and sensitivity analysis and enable the model to estimate the direct and indirect benefits of extending affordable, high-quality medicines to low- and middle-income countries. This is because the model constructs hypothetical situation that features different degrees of generic competition and prices to offer detailed perception of the influence of licensing arrangements on global health.

III. DATA AND METHODS

The approach used in this study is underpinned by evaluating the health and economic effects of VBAs in the context of the MPP [21]. The approach uses a quantifiable model that measures the utilization and impact of the MPP licensed medicines against what would have been the case if such licenses were not available. These are epidemiological characteristics, treatment conformity, medicine costs, and therapeutic results. To illustrate the dynamics of these parameters, the model estimates the total patient years of treatment, total deaths prevented and the total cost savings over a period.

The approach involves collection of data from various sources as part of the methodology [22]. Demographic information including disease incidence, mortality, and Years Lived Disabled (YLD) or lost are collected from different health related databases, health surveys and literature. The treatment coverage and patient uptake rates are based on recorded clinical trials and health systems reports and the drug pricing data is obtained from the public domain including price bulletins, procurement sources and country expenditure surveys. In terms of time horizon for each medicine under consideration, the research covers the period that starts from the granting of MPP license up to five years after patent expiry to capture all dynamic effects.

The mathematical model is therefore developed utilizing a system of differential equations that define the temporal evolution of price cuts, treatment utilization, and health status. The equation used to model the uptake of medicines licensed under MPP is provided by Eq. (15).

$$U(t) = U_0 + \int_0^t \left(\frac{dP(t)}{dt} \cdot \eta(t)\right) dt \tag{15}$$

where $U(t)$ is total patient-years of treatment at time t, U_0 is the number of patients initially treated, $\frac{dP(t)}{dt}$ is the rate of change in price because of generic competition, and $\eta(t)$ is elasticity of demand for treatment at time t of price changes. This equation enables us to simulate the behaviour of the number of patients who are treated given the price of the medicine that comes with competition from several producers of generic medicine. Savings are estimated by comparing the price of the MPP-licensed medicine to the price of the patented version in the counter factual scenario. The cost savings at time t can also be defined as should in Eq. (16).

$$C_s(t) = \left(P_{patent}(t) - P_{generic}(t)\right) \cdot U(t) \tag{16}$$

where $C_s(t)$ is the total cost savings, $P_{patent}(t)$ is the price of the patented version, $P_{generic}(t)$ is the price of the MPP licensed generic version and $U(t)$ is the total patients treated by the MPP licensed drug. Health impacts are then evaluated by calculating the number of mortalities and DALYs saved because of a better uptake of medicines. This is done through providing an understanding of the basic trends and patterns between treatment coverage and health status with parameters obtained from clinical trials and epidemiological analysis. The number of deaths prevented at time t is given by Eq. (17).

$$D_a(t) = \int_0^t (\lambda(t) \cdot U(t))dt \quad (17)$$

where $D_a(t)$ represents the cumulative number of deaths averted, $\lambda(t)$ is the rate of decline of mortality for every additional patient treated and $U(t)$ is the cumulative number of patient years of treatment. The same procedure is applied to estimate DALYs averted, and the rate of DALY reduction is a function of the clinical impact of the drug in question. Due to several unknown factors including price sensitivity to drug prices and impact of generics on prices, the model has a sensitivity analysis section. Using ranges for these parameters, this analysis creates low, central, and high estimates of the potential effects of the MPP licenses under various market conditions. Moreover, the model also includes information about the availability of drugs by regions and by income level. For instance, the model distinguishes between countries in low income and those in middle income by using different uptake rates and pricing scenarios according to the World Bank. This is evidenced by the health and economic effects observed across the various regions, thereby demonstrating the differential effect of MPP licenses. **Table 2** below indicates the major input parameters that were used in the model.

Table 2. Key Input Parameters

Parameter	Value	Source
Initial price of patented drug	$500 per patient per year	Pharmaceutical pricing databases
Price reduction due to generics	70%	Market reports on generic competition
Elasticity of treatment uptake	1.5	Health economics literature
Mortality reduction per patient	0.0025 deaths averted per patient-year	Clinical trial data

These inputs are then incorporated into the model to produce outputs of cumulative patient years to be treated, cost savings, and health impacts for each medicine. The model is used on both dolutegravir and daclatasvir to determine their respective effects under the MPP licenses. The last stage of the methodology is related to the assessment of the model outputs with the actual available data. For example, actual trends of generic dolutegravir uptake in LICs are employed to verify the findings of the model. Any discrepancies between the model and observed data are addressed by adjusting the model's parameters or assumptions, ensuring the robustness and accuracy of the results.

IV. RESULTS

The initial dolutegravir licensing by ViiV Healthcare administered for Medicines Patent Pool (MPP) in 2014, shortly after the FDA (Food and Drug Administration) in the U.S. approved the original products, and subsequent subsidiary licensing to several generic manufacturers, has facilitated the rapid adoption of generic versions that are both qualitatively guaranteed and cost-effective [23].

This includes the once-daily oral fixed-dosage integration of 50 mg dolutegravir, 300 mg lamivudine, and 300 mg tenofovir disoproxil fumarate. These generic versions can be found in the MPP. ViiV's licence for dolutegravir with the MPP has an anti-diversion provision that mandates the use of “jurisdiction-specific packaging” for pediatric medications sent to countries that are not covered by their own licence for adult formulations [24]. This involves implementing distinct packaging for pediatric dosages of dolutegravir 50mg as a means for ViiV to enforce the license's geographical scope and prohibit residents in these nations from obtaining the general form of the medication. 11 generic produces, by June 2020, had introduced quality-oriented dolutegravir products to the marketplaces [25]. These products were distributed to 106 countries following significant and swift price reductions. These reductions were triggered by the preliminary conveyed pricing for generic dolutegravir, lamivudine, and tenofovir disoproxil fumarate, which was set at USD $75 per individual per annum in 2017.

Collectively, from 2017 to 2032 (i.e., until a period of 5 years after the patent expires in 2026 and 2027), the framework forecasted 332.60 million patients-years designed with dolutegravir by incorporating an extra 15.50 (ranging from 14.41 to 15.50) million patients-years of dolutegravir-centred products, in comparison to the theoretical foundations. The framework generated a cumulative prediction of 151,839 fatalities prevented (34,575-212,973) and a total savings of $3,074 billion using the MPP license for dolutegravir that is available in MedsPaL. In addition, it was projected that 1.086 (0.250 – 2.24) million DALYs, 4555 (907 – 9437) transmissions from mother to child, and 1.39 (0.29 – 2.79) million virology failures would be prevented during this span, with data broken down by national income group and environmental location.

Fig 1 presents the uptake of dolutegravir in patient-years administered in LMICs, with/without MPP licensing, and examined in the core scenario per annum. We derived high, low, and middle economic and health effect cases for the cumulative number of fatalities prevented, as shown in **Fig 2**. **Fig 3** presents the cost savings resulting from the license application. These scenarios were based on a range of values for important generic competition and healtth factors. MPP stands for Medicines Patent Pool. The license for Daclatasvir was granted to MPP in 2015 by Bristol-Myers Squibb [26]. The MPP, in collaboration with Bristol Myers Squibb (BMS), has facilitated the treatment of more than one million patients with DAC (daclatasvir), a curative remedy for HCV infection when employed with other drugs, since granting permissions to produce and market generic varieties of the medicine in 2016 [27]. The licencing agreements between MPP and BMS initially included 112 nations, but have recently expanded to include 28 nations, such as Argentina and Brazil as of 2021.

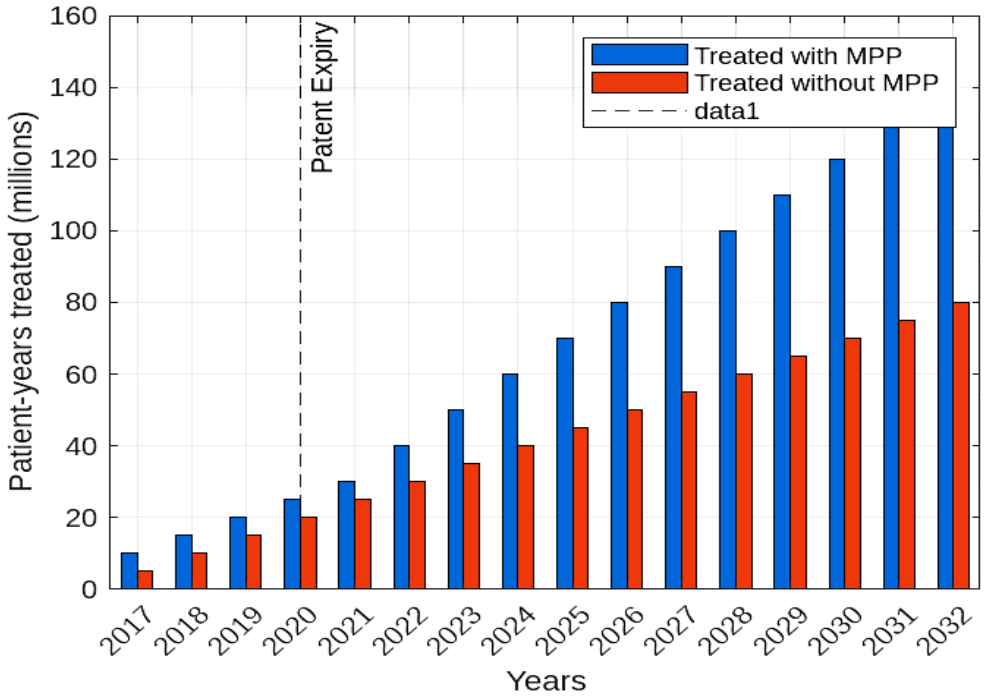

Fig 1. Uptake of Dolutegravir

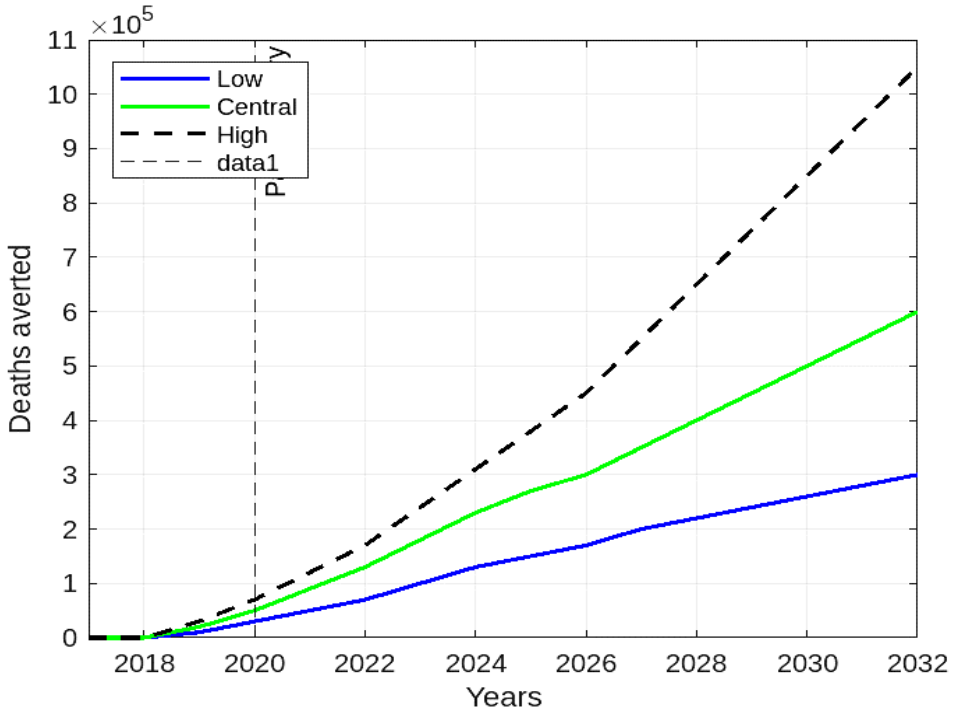

Fig 2. Cumulative Number of Fatalities

A total of thirty-four nations have received DAC (60 or 30 mg) either alone or in conjunction with SOF (sofosbuvir) from licensees of the MPP. The most recent additions to this group of countries are Turkmenistan, Timor-Leste, Tanzania, Tajikistan, Philippines, Moldova, Ethiopia, Cuba, and Armenia. In November 2015, MPP entered into a royalty-free agreement with BMS to allow for the generic production of DAC. In January 2016, MPP launched its first sublicences. Currently, there are four manufacturers (Viatris, Laurus, Hetero, and Cipla – through Mylan subsidiary), which have obtained World Health Organization (WHO) Prequalification. These manufacturers are available to provide DAC (60 or 30 mg) and Mylan additionally offers a WHO certified SOF/DAC fixed-dose integration [28].

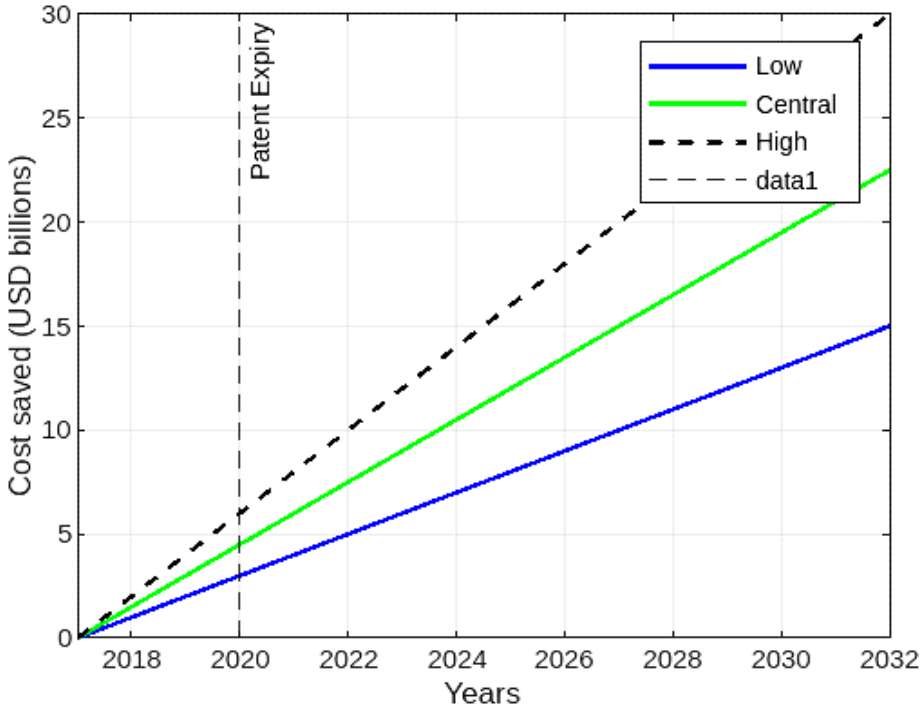

Fig 3. Cost Savings

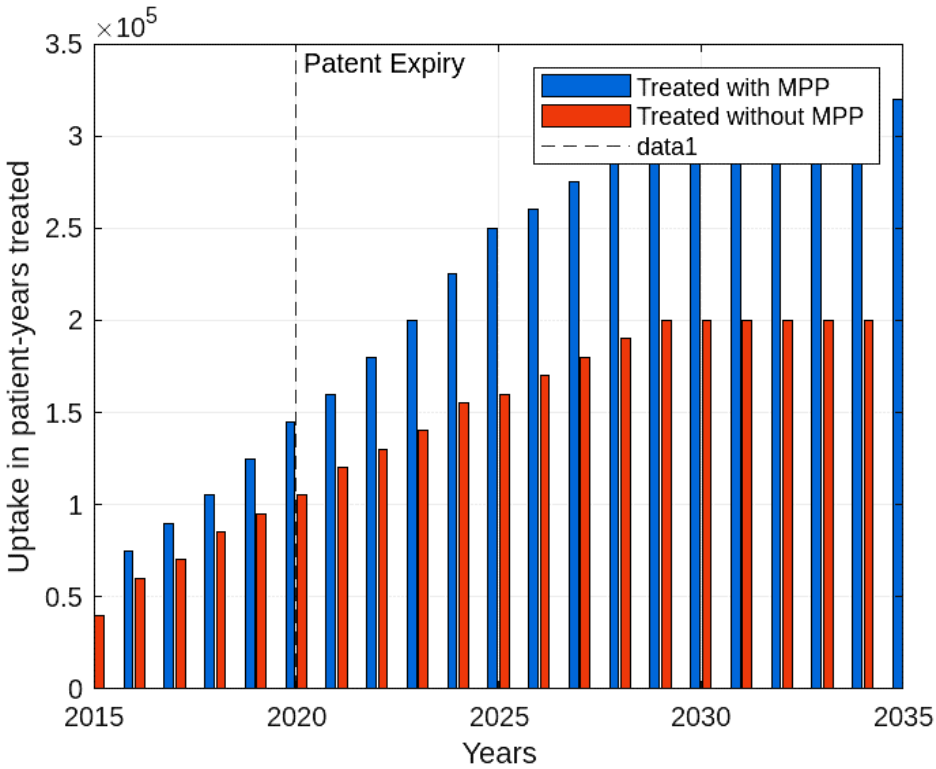

Fig 4. Medication Adherence to Daclatasvir

Charles Gore, Executive Director of MPP, emphasized that obtaining more than 1 million individuals for HCV treatment is a noteworthy achievement and evidence of voluntary licencing efficacy in enhancing the availability of quality-based and safe HCV treatment [29]. This enables nations as well as their government to purchase essential medications for a larger population. “We are pleased to observe the continued emergence of novel nations ordering daclatasvir annually.” If we want to eradicate HCV by 2030, it is imperative that a greater number of LMICs expand their availability of HCV therapies for those affected by this potentially fatal virus [30]. The model projected that between 2015 and 2026, a total of 2.48 million patients would receive treated with a 60 mg oral daclatasvir once daily, which would be under MPP licensing.

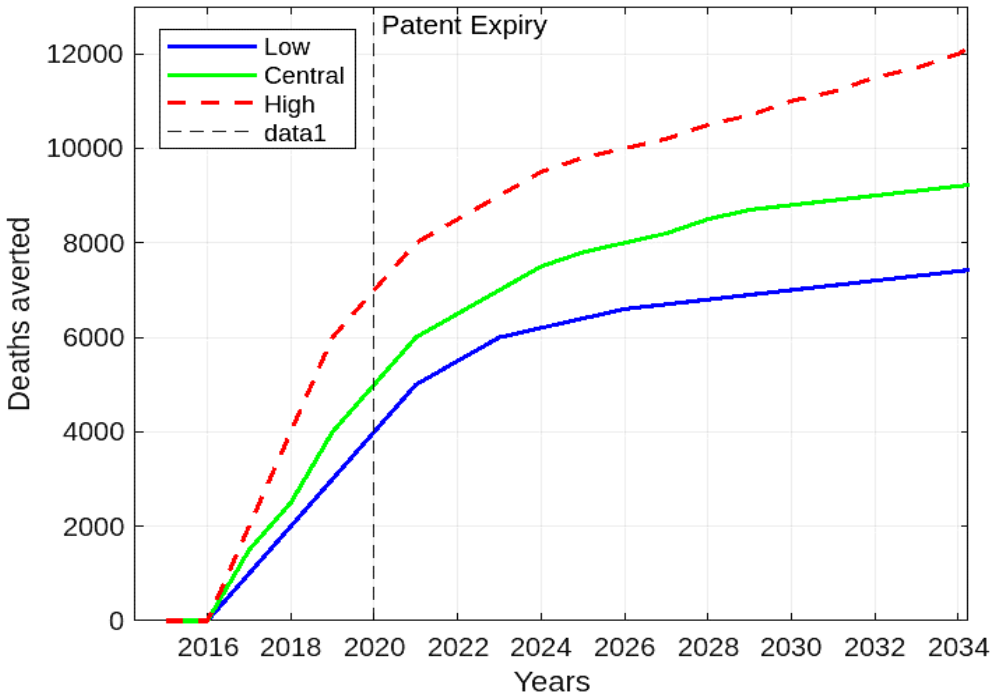

Fig 5. Cumulative Number of Fatalities

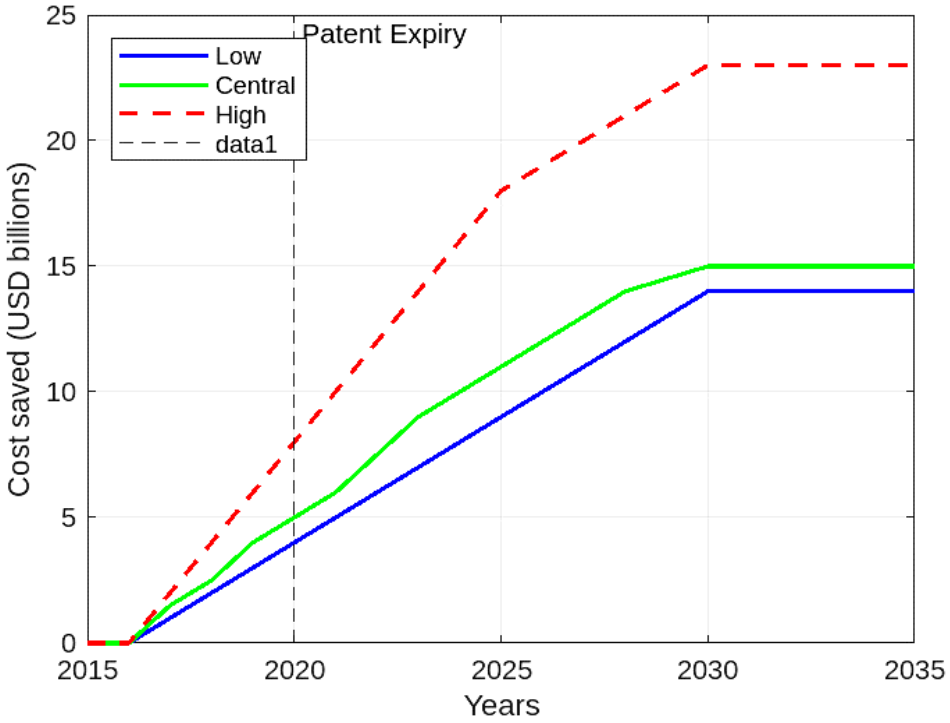

Fig 6. Costs Savings

This would be achieved by increasing the number of patients receiving treatment with daclatasvir products by 428 244 (range 127 584–636 270) compared to the counterfactual scenario. This counterfactual setting includes 14 002 (1609 – 43 765) individuals with HCV who may not have received treatment at all. The framework also forecasted that the MPP licensing for daclatasvir would save 4070 deaths (225–6323) and save $107.593 (30.377–121.284) million. Furthermore, the study incorporated intermediate health impact areas, which encompassed 1766 (320 – 6031) compensated cirrhosis instances, 165 (32–694) decompensated cirrhosis instances, and 136 (27 – 467) hepato-cellular carcinoma prevented instances. This resulted in an additional $20·233 (2.043–34.32) million in healthcare system expenses linked to the advancement of HCV illness evaded. The data is further detailed in **Fig 4-6**, with an analysis of the data categorized by national income group, and environmental location. **Fig 4** describes the medication adherence to Daclatasvir among individuals receiving treatment in LMICs, with or without MPP licensing, categorized by year in the core setting. **Fig 5** derived low, middle, and high economic and health effect setting for the cumulative number of fatalities prevented and costs savings resulting from the license

applications, as depicted in **Fig 6**. These scenarios were based on a range of values for important generic competition and health factors. MPP stands for Medicines Patent Pool.

V. DISCUSSION

By 2030, the licences previously conveyed by the MPP [31] are projected to have saved between 170,000 lives worldwide and USD 3.5 billion. These findings are based on a recently published peer-reviewed research paper in The Lancet Public Health, which validates a novel approach for assessing the effects of MPP licenses. Critical estimations of public health and financial effect of two types of MPP licenses, as case scenarios, are provided in modelling research on the public health and financial effect of IPR of LMICs [32]. This approach has now been employed for licensing to report on the general implications of MPPs licencing portfolio. The implementation of access-based voluntary licensing for optimum therapies yields economic and health advantages for individuals living in LMICs, resulting in cost savings and life-saving measures. In 2020, MPP, with the financial backing of its creator and primary sponsor Unitaid, made the decision to undertake a very ambitious endeavour to commemorate its tenth anniversary [33]. Focused on its historical methodological reporting on economic savings, MPP has now developed its impact assessment approach to integrate novel health impact parameters [34]. This approach acknowledges the health advantages of accessing optimum treatments than sub-optimum alternatives and incorporates more nuanced hypotheses concerning the impacts of MPP licensing on the uptake of drugs at a national level.

Assessment of research impact is a recently developed scientific discipline that usually evaluates effects using a combination of approaches such as study of publications and citations, interviews with peer evaluation, primary investigators, document analysis, and case studies [35]. The body of literature is distinguished by an excessive dependence on bibliometric approaches for evaluating the influence of research. Enhancements to future impact assessment procedures might be achieved by regularly include the end-users of studies in interviews and evaluation procedures. In order for multidimensional study impact assessment protocols to be extensively adopted by research funders and academic institutions, it is crucial to establish the appropriate equilibrium between comprehensiveness and practicality. Houssamo, Locment, and Sechilariu [36] introduced the impact assessment approach so far used by MPP. The presented model provided a direct approach to calculate the expenses associated with acquiring comparable quantities of certain items if MPP permits had not been obtained. The method offered a straightforward and reliable approach to assessing the effects on various goods and illnesses, therefore offering valuable understanding of the financial burden that governments would have had to bear in order to get equivalent health results in the absence of MPP licenses [37].

Soeteman et al. [38] calculated the costs savings associated with the MPP by deducting the anticipated pricing of ARV medicines resulting from the MPP licenses from a hypothetical scenario where the MPP rarely exist. Estimated cost reductions were projected from 2010 to 2028, coinciding with patents expiration for all of these medicaments [39]. The presence of the MPP is believed to influence the pricing of Antiretroviral Drugs (ARVs) in the nations that have the ability to get this pricing. The number of people living with HIV (PLHIV) obtaining antiretroviral therapy (ART) from 2010 to 2028 is determined using the actual figures published by UNAIDS to 2015 [40] and the estimates of HIV reporting predicted under the UNAIDS Fast Track case thereafter [41]. An analysis of the cost-benefit ratios was conducted by creating a comparison of the real and anticipated savings with the real and anticipated MPP running costs for a similar timeframe. Based on this methodology, the authors projected that the cost reductions resulting from MPP licencing for HIV medications from 2010 to 2028 could amount to USD $2.29 billion, which is comparable to 24, 000, 000 patients' years of HIV treatment (considered 'first line') based on the expenses of these therapies in 2016 [42].

Within both primary and secondary care, the dissemination of new drugs is influenced by interacting factors. The absence of early prescribers [43, 44, 45] does not imply that the acceptance of novel medications is essentially arbitrary. Rather, adoption differs across prescribers based on the specific attributes of the prescriber, patient, practice, and medication. The 35 qualifying studies [46, 47, 48] demonstrated many, albeit overlapping, features that were essential in the process of adopting novel drugs and reliably predicted their uptake. Francoeur et al. [49] explicitly state the consistent features across different classifications of drugs. In many instances, however, there is inconsistency within the literature. While Denissen et al. [50] identified a certain characteristic as relevant, others found little evidence supporting its predictive ability. Moreover, the correlations shown by Stillhart et al. [51] between a specific variable and the absorption of new drugs did not always exhibit the same sign. Adler-Milstein et al. [52] did not include any information on healthcare outcomes and presumed that the adoption of these medications without MPP licenses could have been the same, irrespective of the corresponding prices.

Chagas et al. [53] investigated the influence of licencing on the adoption of HCV medications as a means to accurately assess the health consequences of expanding treatment programs. Balmford et al. [54] examined the differences in license implementation across different years and countries. Using 35 interventions and LMICs from 2004 to 2016, Lam et al. [55] evaluated the uptake of HCV treatments in the absence and presence of voluntary licensing. Their basic model (S1) demonstrated that the relationship between licencing and treatment was modest but statistically significant during its introduction and became stronger with time see **Fig 7**. Following the correction for possible confounding factors (S2 and S3), the licensing impact was only evident in the years following its implementation, rather than in the year of its inception. The effect was most pronounced in the second year after the introduction. The results of the leads-falsification test indicated that the parallel tendency hypothesis was supported, as specified by the lack of major correlations between licencing and treatments adopted before the advent **Fig 7**.

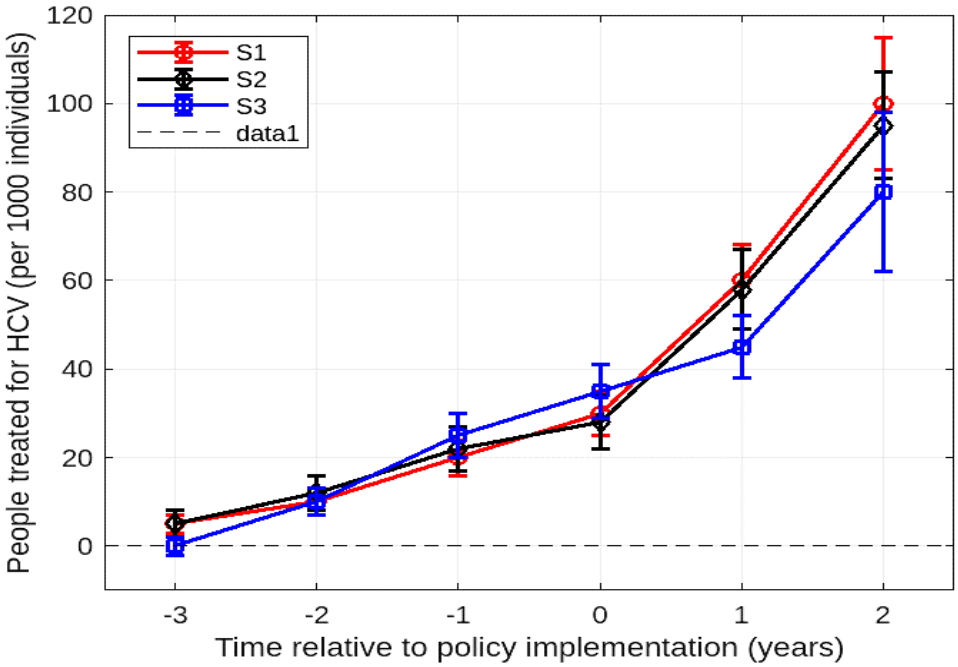

Fig 7. People Treated for HCV In Relation to Policy Implementation

Voluntary licenses were shown to result in an annual increase of 54 (range 26–82) in the number of individuals receiving such drugs per 1000 diagnosed cases. An observable delay after the license agreements was noted, with a tendency towards a growing impact over time. This conclusion was derived from a limited period of observation spanning a few years, utilizing data accessible till 2016, without any longer-term perceptibility. The observation did not document the subsequent health consequences of providing treatment to a larger number of individuals. Despite the fact that market competition resulting from the availability of several generic HCV and HIV medications has significantly lowered LMICs, prices it is crucial to acknowledge the advantages not only of affordable drugs, but also of initial accessibility to medications with greater effectiveness, higher side-effect profiling, enhanced observance, decreased treatment resistance chances, mortality and failure over time, or an integrat`ion of these aspects.

Over 16 million more individuals meet the criteria set by the latest World Health Organisation (WHO) recommendations to begin antiretroviral therapy (ART). Furthermore, the demand is transitioning from the relatively affordable antiretrovirals (ARVs) that facilitated this expansion to more recent, costlier alternatives with less adverse effects or those suitable for those who have acquired resistance to initial therapy [56]. Nevertheless, the presence of patents on these novel medications might impede the vigorous competition from generic alternatives and, as a result, hinder the lowering of prices facilitated by economies of scale. Different approaches to tackle this problem have been envisioned or put into practice, such as utilizing the flexibilities issued by the Agreement on TRIPS, implementing systematic widespread voluntary licensing, exemplified by the MPP, and applying varying prices in different countries, known as tiered pricing. In this study, Yang et al. [57] elucidate the influence of patents on market competition for ARVs and examine many strategies now accessible to mitigate this influence.

The licensing terms and conditions can affect market competition levels and, consequently, the resultant equilibrium pricing. Therefore, MPP licensing guarantee the incorporation of provisions aimed at maximizing cost savings, promoting generic competition, and impacting the health of the general public [58]. These provisions include a wide geographical coverage (often including countries where over 90% of individuals living with HIV in LMICs), inclusivity, rapid growth of generic versions, capacity to design FDCs, technological transfer from patents holders of general producers, and compliance with health protection specified with WTO (World Trade Organization) Agreements on TRIPS [59], integrating a government's authority to provide compulsory licenses. To promote competition and guarantee sufficient supply of antiretroviral drugs (ARVs) in LMICs, MPP is pursuing sub-licenses with several generic companies.

This work introduces a comprehensive modelling framework, which incorporates a real evaluation of alternative case. Its purpose is to not only generate costs savings estimate but also to provide insights into the health impacts resulting from earlier availability and faster adoption of quality-based, cheaper optimal treatment in LMIC. We demonstrated that the sequence of events connecting licensing at the beginning of the process to the final results can be represented in a model to provide reliable numerical estimations of the health and economic consequences resulting from voluntary licensing focused on access. This model is based on the assumption that competition among generic drugs leads to lower prices that influence procurement decisions, hence facilitating quicker and wider availability of medications, resulting in positive health and economic outcomes. The impact of access-based voluntary license measures on cost savings and health outcomes relied on several factors, including the timing and scope of the adoption of generic drugs within the country, the competition level

(and the resulting discounting of prices), the extent of the licensed areas, the remaining duration until the patent expires, and the medical advantages of the licensed medications [60].

The duration of MPP licences is contingent upon the commencement of the MPP agreements with patent holders, the time required for MPP to award sub-licences to generic manufacturers, the time required for generic manufacturers to introduce the product to the market, and the duration of a blocking patent [61]. To establish the onset of the influence of MPP, we used the assumption that for ARVs with prevalent general equivalents on the marketplace, the effects of the license start in the year when the patent holders enter into an agreement with MPP. Derived from empirical evidence, we anticipated that general producers would promptly enter into sub-licences subsequent to MPP acquiring a license from the patent holders. For antiretroviral medications (ARVs) for which generic versions are not yet present, a delay of 1-3 years was considered from the duration of MPP agreements with patents holders to the realistic introduction of a generic product onto the market [62]. This time was allowed for a generic producer to design the product and get governing clearance.

To prevent an overestimation of the effect, a cautious approach was used in few cases when formulating the assumptions for the model. Among the research examined to determine the impact of the number of generic firms on costs, the chosen research was the most cautious, resulting in reduced projected cost reductions from MPP licensing [63]. Furthermore, the number of competing generic producers having MPP at the nation level is not the same as the overall MPP licensees, and the framework often adopts a cautious method to this hypothesis. For instance, whereas MPP had 17 licenses for dolutegravir and 11 firms manufacturing quality-guaranteed goods, the model took into account a mere four rival generics at the county level. This premise was based on the fact that not all licensees have engaged in product development, not all have officially listed the products in a certain nation, and not all are willing or prepared to provide the product to a certain nation at any particular moment. Licensing hypotheses in the counterfactual cases acknowledge likely access programs the original corporations might have implemented [64]. For instance, nations that could have used generic dolutegravir without the MPP licencing, only marginal costs savings are taken into account due to the somewhat stronger rivalry with the MPP-licenced drug. No health impact is accounted for, as it is assumed that these nations could have already transitioned to dolutegravir-oriented regimens without the MPP license.

Under some circumstances, an MPP license might reduce the quantum of royalty expenditures, which were owed by generic firms to originator firms under prior agreements [65]. Prior to the implementation of the MPP license, some generics producers were granted a voluntary licence for 95 nations by Gilead. This licence required them to remit to Gilead a 5% royalty for all sales made on TDF. As a consequence of MPP talks, the royalty rate for manufacturers who maintained a bilateral license with Gilead was reduced to 3% [66]. In addition, after MPP reached a deal with Gilead, generics producers that transitioned to MPP licenses were exempt from paying any royalty provided they took use of the distinctive flexibility of terminating TDF as stipulated in the agreement. The majority of generic firms who transitioned to the MPP license used this adaptability. Zekos [67] expected that generic manufacturers would transfer 50% of any savings in royalties to lower costs for Travel Duty Free (TDF). This is a cautious hypothesis given the very TDF's competitive market, where producers are actively vying for market share via price reductions.

The theoretical capacity and flexibility of the framework were constrained by practical restrictions and limits. The findings were based on hypotheses on the impact of licencing on generic competitions, pricing generic competition, pricing on uptake, and specific outcomes uptake. The hypotheses were derived from research that offered plausible estimates for the impacts under investigation. Additional variables related to the rate and extent of adoption (like the incorporation of medication in WHO as well as other clinical procedures, the industrial capability to meet the expected demand, financial support from global donors, and government-led and other initiatives facilitating expansion) were exogenously addressed. Details concerning how important variables influenced the magnitude and configuration of the projected impact and sensitivity analysis for a number of aspects are provided in the appendix. Furthermore, the presence of uncertainty in some crucial input variable quantity was acknowledged by employing several (high, central, and low) economic and health effect scenarios, which defined the approximated ranges in the simulated results.

VI. CONCLUSION

Using a mathematical model, the study evaluated the impact of MPP licenses for drugs like dolutegravir and daclatasvir by simulating treatment uptake, mortality reduction, and cost savings over time. The results revealed that MPP-licensed dolutegravir led to an additional 15.5 million patient-years of treatment between 2017 and 2032, averting over 151,839 deaths and saving $3.07 billion. Similarly, the license for daclatasvir in the time span of 2015 to 2026 resulted in an additional 428,244 patients treated, 4,070 deaths averted and $107.6 million in total savings. These outcomes suggest that MPP licenses can indeed contribute to a greater number of people gaining access to treatment as well as to a reduction in the cost of medicines that favors generics. MPP can solve an aspect of economic burden difficulties on the healthcare systems when adopted in voluntary licensing for the same population, since it offers a shot at increasing population mortality and future health. The same model shows how these licensing agreements could be even more beneficial when more countries and more pharma firms are involved. Consequently, this study offers strong arguments in support of voluntary licensing as a viable solution to alter the status quo in global health inequity, increase access to essential medicines, and foster public health goals of diseases for which exceedingly costly and scarcity remain crucial hurdles in treatment.

CRediT Author Statement
The author reviewed the results and approved the final version of the manuscript.

Data Availability
No data was used to support this study.

Conflicts of Interests
The author(s) declare(s) that they have no conflicts of interest.

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