

Draft version 18-06-2006

Development of a Model to Assess the Impact of Changes in IPRs

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Justification and objectives of the project.

The TRIPS Agreement on the trade related intellectual property rights promoted by the WTO (World Trade Organization) has led to a world-wide upwards harmonization of the regimes of intellectual property rights (IPR). For most countries TRIPS meant that, in order to gain access to international markets for their exports and to the assumed benefits of free trade, they have to introduce or to reinforce the legislation on patents and other IPR. This trend is likely to benefit developed countries, which finance most research and development (R&D) and generate most of the new knowledge and innovations, but harm the developing countries, than could previously access easily and to a low cost to innovation and new knowledge. Medicines, together with agriculture and software, is the area where this process has created a greater controversy, as the introduction of product patent and the establishment of a minimum duration of twenty years for patent protection has increased the exclusivity position and the market power of innovating companies, with negative effects on access to medicines and the viability of the national industries. Innovative pharmaceutical companies and representatives of a great part of the developed countries where these companies are concentrated claim that a strong protection of IPR is an essential condition for ensuring the continuity of innovation and that in the long run it will also benefit developing countries, as strong IPR will generate innovation in medicines for tropical and neglected diseases and because they will also promote technology transfer, research and foreign investment in these countries. Nevertheless, most of the developing countries and organizations concerned with access to medicines oppose the reinforcing of IPR, because they fear that they will raise the prices of drugs and restrict the access to essential medicines, with very negative effects on the health, specially in low-income populations (Baker and Chatani, 2004; Doctors without Borders, 2004). Many independent researchers and organizations institutions also criticize the present trends to indiscriminately increase the protection of IPR (Waxman, 2005; CIPR, 2002; Stiglitz, 2005). The report of the CIPR (Commission on Intellectual Property Rights) of the United Kingdom had a great international impact, because it originated in a country with a long tradition of protection of IPR. Although the evidence still is not conclusive, there is a growing consensus that reinforcing IPR favours developed and maybe some emerging countries, but probably not developing countries, which should be allowed to adjust the level and timing of IP protection to their development needs and conditions, as developed countries were able to do in the past. Joseph Stiglitz (2005) in a recent article stated that without patents the incentives for the R&D would be probably be weakened, but that the costs associated to patents are very high and that the "open source" movement in Internet demonstrates that even products of enormous commercial value can be produced without IP protection. On the other hand, he highlights the problems associated to the monopoly power derived from IPR, that allows the monopolist to eliminate competitors and limits, in some cases, the rate of innovation. Stiglitz concludes that the IPR regime that a developing country needs is different from the one that can be optimal for a developed country.

Although the DOHA declaration seemed to have established the priority of the objectives of public health over commercial interests and to have put a halt to the extension and intensification of IPR in the field of medicines, in fact the process has continued through the negotiation in regional and bilateral commercial agreements – usually called Free Trade Agreement (FTA) - where industrialized countries have habitually been able to introduce the issue of IPR, forcing developing countries to accept more restrictive clauses than the minimum standards required by TRIPS, usually known as TRIPS plus. Many countries in the region of the Américas and elsewhere have been or are likely to be involved in this type of negotiations in the future (Doctors without Borders, 2004) In this context, it is essential that FTA negotiators have a the necessary tools and information to obtain a clear understanding of the likely impact of TRIPS plus clauses - or any other measure or agreement that directly or indirectly affects

market competition - can have on public health and, in general, on economic development and on the future well-being of the population.

People who are against TRIPS plus agreements and other measures that can worsen the access to medicines from the perspective of the right to health sometimes suggest that exercises aimed at the quantification of the impact should not be carried out, because it somehow constitutes a sign that a country is prepared to negotiate, which weakens the position of the defenders of the access to medicines. This is probably a legitimate and ethically justifiable option, although experience shows it is hardly sustainable. The recent history of bilateral trade agreements shows that many countries end up accepting to a greater or lesser extent the demands of stronger IPR from developed countries due to pressures of external and internal interest groups. This would perhaps have been more difficult if the positive and negative effects of these agreements for the country had been identified and quantified. With appropriate information on the impact of specific changes in IPR, politicians and negotiators, as well as public opinion, could be able to assess in a more rational form what changes in the IPR have negative but acceptable effects within the framework of a negotiation or a global policy and when they are unacceptable, given its potential impact on the health and well-being of the population.

It is paradoxical that the pro-access groups has moved from systematically attacking TRIPS, to defending it as a beneficial agreement for developing countries and to concentrate their efforts in opposing TRIPS plus modifications. Probably the defence of the right to health requires a more proactive strategy, not limited to trying to maintain TRIPS as if it was an irreversible situation. It should rather take the initiative to change the most negative aspects of the present status quo and to introduce strategies at the national and international level aimed at moving to pre-TRIPS situations.

The origin of this project was a result of the recommendations agreed at a meeting of the AIHO Working Group on Aspects of the TRIPS Agreement and the Access to Medicines that took place in Managua, Nicaragua, from the 14 to the 16 of April of 2004 (Working Group on TRIPS and Access to Medicines, 2004). Recommendation 5 of the report of this meeting suggested the convenience of carrying out independent studies on the impact of the TRIPS on the access to medicines, using indicating like the variation of prices, the incorporation of generic medicines to the market, the introduction of new medicines for neglected diseases, etc. The AIHO, in alliance with other organisations, was asked to develop a baseline model for carrying out this type of studies. The primary target of the project has been to develop a simulation model of the impact of measures that lead to changes in the regime of intellectual property rights in relation to the access to medicines. A complementary guide is aimed at helping users applying the model and customising it to the specific needs and conditions of the different countries. The model tries to be user-friendly and easy to understand and apply users that are not experts in modelling and programming. So far the model has been applied to three countries: Colombia, Guatemala and Costa Rica. In order to facilitate the identification and collection by local experts of the country information required for running the model a template was developed.

In the case of Colombia the application of the model was facilitated by the fact that national experts had a substantial previous experience in the analysis of the impact of the changes in the IPR that might derive from the approval of the FTA. Therefore, the application of the model did not require much support from the authors of the model. The national expert from Guatemala and Costa Rica attended a two days training workshop where they were able to understand the model and start preliminary analyses. The three country applications are available as a companion report to this paper. These applications have allowed to assess the capacity of the model and its flexibility in being adjusted and applied to different settings and decision makers needs.

Introduction

Literature review.

Several studies have tried to assess the impact of changes in IPR systems. The aims and results of some of the most relevant ones according to their potential utility for the development of the model developed.

Schondelmeyer (1995) considered the effect of the increase in the duration of patents in the U.S.A. that resulted from the adoption of the GATT, which benefited patents in force by 8th June 1995 (109 products), whose duration was retrospectively extended to 20 years. The time horizon of the impact estimation covered the period 1996 to 2012. The study did not consider the impact derived from the increase in the duration of the patents for patents approved after 1995. The study estimated the additional costs to the consumers and to the federal and state governments, as well as the unexpected benefits obtained by the companies. Unfortunately, the report available to the authors does not provide a detailed specification of the model used for the estimation.

Scherer and Weisburst (1995) used an aggregated time series approach to assess the effect of the introduction of pharmaceutical patents in Italy in 1982. The authors compared by means of econometric methods the observable trends in the period previous to the introduction of the patents and they extrapolated it to the later years, and compared the results with the real data of this period. They concluded that the introduction of patents did not result in local companies investing more in R&D nor innovating that could have been otherwise expected.

La Croix and Kawaura (1996) analyzed the effects of the change of IPR that took place in 1996 in Korea, that at that time happened to have only process patent for medicines, but not product patent. The work focussed on the effect that this change had on the benefits profits Korean companies. As in the former study an econometric model was applied. The time horizon was one year.

Spain introduced the product patent for pharmaceuticals the 7th October of 1992. A study by the Ministry of Industry and Energy (1999) analyzed with great profusion of data the evolution of patenting before and after this introduction, but it does not deepen in the impact on the prices or other variables of interest for our work.

Suh and others (2000) analyze the evolution of prices in markets with a single product under exclusivity conditions when the exclusivity period ends and generic competitors starts. Although the results, referred to the U.S.A., can not be directly extrapolated to other countries, it provides a potentially useful methodology to model one of the most important aspects of our model, that is, the behaviour and reactions of prices of competing products in a market in the transition from exclusivity to competition. A good knowledge of this type of situation is very relevant to our study, as it is precisely a type of adjustment that can be delayed as a result of TRIPS plus provisions.

A study by Nicol and Nielsen (undated) tried to evaluate the impact of the introduction of patents on innovation in the case of the Australian biotechnological industry. The analysis was based on the answers to a questionnaire sent to research institutions and to pharmaceutical and biotechnology companies, both public and private. The answers suggest that the incentives provided by the present patent system is beneficial for the biotechnological industry in Australia and some changes are suggested.

The case of India has been analyzed by several authors using different methodological approaches.

Lanjouw (1998) discussed the theoretical implications of the TRIPS agreement in relation to the potential medicine patents and their effects and tried to assess the magnitude of the effects that the adoption of agreements TRIPS would have, by means of a literature review, interviews and questionnaires.

Fink (2000) studies the same subject focussing on the effects on the pharmaceutical industry, by simulating the impact that the introduction of a more protective regime of patents would have on the structure of the industry and the well-being of the consumers.

Other authors who approached the subject more recently, Chaudhuri, Goldberg and Jia (2003), empirically investigated the arguments of the defenders and detractors of the TRIPS. They studied the price-elasticity, cost and other parameters of supply for the group of fluoroquinolones and used this information to simulate a counterfactual scenario to determine which would have been the prices, the profits (of the domestic companies and the multinationals) and the consumer surplus in case these molecules had been patented in India, as they were in the United States at this time. Their estimations suggest negative effects in form of loss of well-being of the Indian economy of the order of US\$713 million annually, of which 50 million correspond to reduced profits for the local industry, and the rest to a loss of well-being for the consumers. Foreign companies would have obtained additional profits of the order of US\$57 million.

There are several studies on the impact of the patents in countries of Latin America. These studies have been sponsored by the national governments at the occasion of the negotiation of FTA. They generally predict substantial increases in drug expenditure and negative effects on the access to medicines and on the domestic industry.

Colombia: Zuleta and Lylian (1999), IFARMA (2004), Centro de Investigaciones para el Desarrollo y Universidad Nacional de Colombia, 2005), Fedesarrollo y Fundación Santa Fe (2005) Peru: Ministry of Health of Peru (2005), APOYO Consultoría (2005), Ecuador: CORDES (undated)

When to evaluate the impact

The impact of changes in DPI might be studied either prospectively (before of its introduction) or retrospectively (after its introduction). The two options are useful and complementary and the approach and model developed in this project can be applied as both. For decision makers the crucial time for evaluating the impact of a change in the IPR is when this change is being considered, for example, in the negotiations of a FTA that is likely to include IP aspects. This type of prospective evaluation requires future projections of effects and tendencies and can be supported with models of simulation and scenario building aimed at predicting the course of the events under the different options open to negotiation. The prospective estimation of the impact can also be useful in order to identify options that can be interesting for a country and can therefore be included in the design of national policies or in a future agenda of international negotiation.

It is also important to retrospectively evaluate the impact of changes in DPI, i.e. when the effects already have taken place. It might be desirable to compare the decisions that were taken at a given point of time with other options that were open at that time. Retrospective analysis allows obtaining the evidence necessary for predicting the future effects of decisions. Impact evaluation, even if it is done retrospectively, usually requires some form of modelling, because

the estimation of the impact requires not only the observable real data, but also the construction of the counterfactual, i.e. a scenario that represents what would have happened if the change assessed had not been implemented; that is, if the previous policy had been maintained or other strategies had been adopted. One advantage of a retrospective analysis is that one of the scenarios compared is the real observable evolution of a phenomenon, whereas in prospective analyses all the scenarios are hypothetical. A retrospective application can be used to partially validate a model, verifying if it allows to suitably represent the past evolution of the variables implied.

Options to evaluate

The scope of options policy makers might want to evaluate includes any variation of DPI, such as the introduction of the product patent, test data protection, the duration of patent protection, the introduction of the Bolar exception, etc (see table 1). Options might be defined as a combination of changes in several aspects of the IP regime. Given the IP regimes include manifold elements or aspects that can be combined of many different forms, it is advisable that the model can evaluate the impact of complex changes in IPR. For example, the maintenance of the present situation (baseline scenario) might be compared with 1) a scenario A that represents an extension of the duration of the patent, 2) a scenario B that represents a restriction to issuing compulsory licenses, 3) a scenario C that implies both measures simultaneously. The model should ideally be able to evaluate policy changes in, for example, the characteristics and operation of the drug registry, the administrative price control mechanisms, that are not directly related to IPR, but impact the same variables affected by IPR, and might be part of a global policy or of a FTA negotiation.

BOX 1. LIST OF TRIPS PLUS PROVISIONS
TEST DATA PROTECTION
INCREASE IN THE DURATION OF THE PATENT BEYOND 20 YEARS
EXTENSION OF THE DURATION OF THE PATENT IN THE CASE OF DELAYS IN APPROVAL ATTRIBUTABLE TO THE PATENT OFFICE
ELIMINATING OR RESTRICTING EARLY WORKING (BOLAR) EXCEPTION
ELIMINATING OR RESTRICTING COMPULSORY LICENSES
PATENTS FOR SECOND USE (INDICATION)
ESTABLISHMENT OF A MINIMUM TIME FROM PATENT APPROVAL BEFORE COMPULSORY LICENSES CAN BE ISSUED
EXTENSION OF THE OBJECT OF THE PATENT (ELIMINATION OF RESTRICTIONS TO PATENTABILIDAD)
ELIMINATING OR RESTRICTING THE POSSIBILITY OF PREVIOUS OPPOSITION TO PATENTS

ELIMINATING OR RESTRICTING CAUSES FOR REVOCATION OF PATENTS

LINKAGE BETWEEN REGISTRATION AND PATENT OFFICE

ELIMINATING OR RESTRICTING THE USE OF THE INN

ELIMINATING OR RESTRICTING PRICE CONTROL

ELIMINATING OR RESTRICTING PARALLEL TRADE

ELIMINATING OR RESTRICTING INTERVENTIONS AGAINST ABUSE OF PATENTS

OTHER MARKET EXCLUSIVITY CONDITIONS

How to evaluate the impact

Decision makers must make choices under uncertainty and limited information on the impact of their decisions. Simulation models provide a rigorous and a transparent tool for exploring future trends and the likely impact of alternative courses of action and of future or past changes in policies. Simulation models are not substitutes to alternative approaches (e.g. quantitative models) that analyze real experiences, nor to the opinions of experts.

Simulation models allow to combine multiple sources of evidence and opinion in a transparent way, which is susceptible of evaluation and criticism. This makes them superior to the plain judgements and opinions of experts that are stated without a rigorous specification of the underlying reasoning and assumptions. Simulation models also have some advantages over statistical and econometric models, which can only make projections by means of the extrapolation of the historical tendencies of the data on which they are based. Simulation models allow for a greater flexibility in using the best sources of evidence available. They also allow a mechanistic formulation of the phenomenon based on our knowledge on the relationships among the different variables that explain the analyzed phenomenon, even when no observable historical data of all these variables are available. Simulation models also allow to extrapolate previous experiences from the same or from other settings to the time and context relevant for the decision maker.

A simulation model is not a kind of crystal ball that tells the future course of the events, but only an instrument that allows integrating in a coherent and logical structure all the information available, making it easier to judge the validity and robustness of the results.

Finally, a simulation model does not have to be judged solely by its predictive capacity, as it has other valuable uses; for instance, in our case:

- a) It might help in the conceptualization of the process that relates the changes in the IPR to the impact
- b) It helps to identify the information and data required to assess the impact of IPR changes.
- c) It forces the analyst to specify the theoretical and factual assumptions, as well as the technical and value judgments that justify a certain position or recommendation in relation to a decision that must be taken.

Impact variables

Changes in IPR have multiple effects on variables related to the well-being of society. The selection of the impact variables depends on the perspective of the user of the results of the analysis. Some effects might be a priori relevant to most stakeholders.

1. First, the changes in the IPR affect the degree of competition-exclusivity in the pharmaceutical markets, which, in its turn, determine the prices. A higher level of protection of IPR will usually lead to higher prices.
2. Price increases affect pharmaceutical expenditure and access to medicines. If the price-elasticity of the demand is high, the impact will be on expenditure, whereas if it is low, the predominant effect will be on access and utilization and, finally, on the health state of the population. The effect will be more pronounced for lower income groups, which usually have a more elastic demand. When drugs are financed by a third party payer, higher prices might not change utilization, but they might endanger the financial sustainability of the health system.
3. Changes in IPR also affect the competitiveness and, consequently, the market share of the innovative and the non-innovative sectors of the industry. In countries where the local industry is restricted to the formulation of final products and has a limited or null innovating capacity, it is foreseeable that stronger IPR will reduce production and employment and worsen the pharmaceutical trade balance. One can also expect a reduction of the manufacturing capacity of the multinational companies in the country, because they will probably try to take advantage of economies of scale and concentrate production in a few plants, probably located in the countries of origin.
4. Finally, changes in IPR affect the incentives for R&D. Although the defenders of strong IPR regimes claim that it will favour the investment in R&D in the countries concerned as well as in the diseases that afflict those countries, the evidence does not seem to clearly support this assumption.

Presentation of the model of Impact of Changes in the IPR

Structure and general characteristics of the model of Impact of Changes in the IPR

The model developed in this project is limited to the impact generated by changes in the intensity and duration of the conditions of market exclusivity in the drug market. Stronger and longer exclusivity conditions are assumed to rise prices and, hence, expenditure and to reduce access. They are also assumed to negatively affect domestic production. No assumption has been so included on an eventual positive impact of stronger IPR on innovation by the domestic industry nor on the global R&D innovation rate.

The logic of the model is based on the construction of a baseline scenario that represents the evolution of the pharmaceutical market during a specified period of time under a given IPR regime, and the construction of alternative scenarios that simulate the evolution of the market under different hypothetical combinations of changes in IPR-related conditions. For each scenario (both the baseline and the alternative ones) the model calculates the percentage of active ingredients (AI) in the market that are in situation of exclusivity due either to (product) patent or to test data protection. The model also calculates the distribution of the market without exclusivity conditions between products with INN (generics, in the more restrictive interpretation of this term) and “branded” generics. The model assumes that under conditions of exclusivity the AI would have a higher price than under non-exclusivity (competition) and that branded generics have a higher price than generics sold under INN.

The differences in market share among the mentioned segments determines in the model the difference of average prices between two scenarios. These differences, in its turn, determine the impact in terms of consumption (access) and cost or value of the market. In order to relate average price to consumption and expenditure, a constant price-elasticity demand curve is specified. The distribution of the market between the segments with and without exclusivity determine the market share of the domestic industry, which is assumed to maintain a fixed market share of the segment under non-exclusivity.

The scope of the market can be defined in different ways, according to the purposes of the analysis. It might refer to all the medicines sold in a country, or be restricted to a therapeutic group (antiretrovirals, ACE inhibitors, statins, etc) or even to a single active ingredient (amoxicilin). The two options that seem more logic are:

- a) to include all medicines (aggregated or macroeconomic approach)
- b) to include a product group that shows a high degree of sustitubility among the products included (microeconomic criterion of market).

A second criterion for defining the market is the source of financing. One option would be to consider all the products consumed in a country. However, in many countries there are several health subsystems that define several segments of the drug market (social insurance systems, private insurance, OTC market, etc). A decision maker might be mainly interested in the analysis of the segment of the market under his/her responsibility. Moreover, many parameters of the model, prices, demand functions, list of AI, etc) are probably different for each segment. For example, the public and the social insurance systems usually have a lower number of AI and face lower prices than the private sectors. Moreover, price-elasticity is likely to be lower in systems where the consumer pays a lower share of the cost of the drug, as medicines usually are total or partially subsidized, whereas in private markets the consumer often pays the full price.

The geographic scope of the analysis can be defined in different ways. The most relevant type of jurisdiction for the purposes of the present project is likely to be a whole country,

IPR regimes and FTA negotiations, as well as, pharmaceutical policies in general which have a national scope. However, nothing prevents the model to be applied to a smaller geographic area: region, municipality, district. The previous criteria can be combined to carry out, for example, a simulation of the market of antiretrovirals financed by the public sector in region X.

However, in the case the scope is restricted to a sub national area, the impact on the industry, as it is specified in the model, might not make much sense, because the domestic industry might be unevenly distributed across a country.

Operation of the model

The application and operation of the model is described in detail in Appendix 1: Model Specification and in the Users' Manual (English translation pending). The most essential aspects of the model are described in the next paragraphs.

Defining the time horizon

The analyst must define the time horizon of the application. The initial year might be the one when the IPR changes which impact is being assessed were introduced. The final year must be the distant enough to capture the full effects of the change, taking into consideration the lags between the introduction of the change and the occurrence of the effects (For instance, if product patent is introduced in year 2000, patented products might not enter the market until 2008-2012). Under plausible assumptions the share of the market under exclusivity and under competition tend to stabilize some time after the change in IPR. The time horizon should be long enough to reach the year when stabilization takes place. Based on the experience of the initial applications a time horizon of 40 years seems sufficient for the key variable of the model, the proportion of AI in exclusivity to stabilize.

Calculating the proportion of AI under exclusivity

The model calculates first number of AI existing in the market every year of the time horizon, starting from the number of AI in the initial year and by adding the number of AI entering the market and subtracting the number leaving the market every year.

Then the model calculates the number of AI that are in the market with patent-protection exclusivity. Similarly to the previous case, the number of AI with patent-protection exclusivity is computed by adding to those existing at the initial year the number of those entering the market with patent protection and subtracting the number of AI that lose exclusivity protection each year.

The model assumes that if product patent is introduced in year i , the first AI to enter the market with patent exclusivity will do so in year $i+DT$, DT being the average time elapsed between filling a patent and market entry. DT is the additional time required on average to finalize the R&D of the product plus the duration of the registration process.

The model calculates next the number of AI that lose every year the condition of exclusivity. The period of exclusivity is computed by adding to the period of effective patent protection:

1. The average extension of the nominal duration of the patent due, for example, to the compensation for delays in the process of patent approval, that might benefit a certain proportion of patented AI.
2. The period required for generics to enter the market after the period of patent protection (including any extension) has expired
3. The additional average delay of generic entry due to the linkage mechanism (i.e. making registration decision) that might benefit a certain proportion of AI.

The model calculates the periods of exclusivity for different groups of AI that enter the market every year and the number of AI that will be under patent exclusivity each year.

The model makes a follows a similar procedure in order to compute the number of AI that will be every year in the market in situation of exclusivity due to test data by protection (or to equivalent causes). In this case the procedure is simpler, because it must only consider the year when the provision is introduced and the duration of the period of exclusivity due to of test data protection.

The model calculates the total number of AI in situation of exclusivity by any of the two possible causes as the sum of both previous concepts and it also calculates the proportion of AI in exclusivity situation dividing the previous number by the total of AI in the market.

It is assumed that an eventual simultaneous exclusivity granted by patent and by data protection does not increase the market power of an AI in relation to being protected by only one factor of exclusivity.

The previous procedure is repeated for all the scenarios considered.

Calculating the impacts on consumption, expenditure, and domestic production

The expenditure or value of the market (in real terms) in the baseline scenario is obtained by applying a constant rate of growth to the expenditure of the initial year.

For the alternative scenarios the procedure of calculation of the expenditure and the impact on consumption is the following one:

The model calculates a price index of the alternative scenario for every year, that relates the average price in the alternative scenario to the average price in the baseline scenario. The value of the index is, by definition, one for the baseline scenario every year. The index for an alternative scenario in a given year reflects the weighted price differentials between AI with and without exclusivity and between the AI sold as branded generics and INN generics.

A constant price-elasticity demand function is postulated in order to calculate the impact that the increase of the price index will have on the quantities consumed and on expenditure.

The demand curve has the form:

$$q = k p^e, \quad \text{or} \quad \ln q = \ln k + e \ln p,$$

where k and e are constant and $k > 0$ and $e < 0$

Constant price-elasticity of demand: e						q = k p ^e e <= 0					
e = -2			e = -1			e = -0,5			e = 0		
P ^x	q	MV ^x =P ^x q	P ^x	q	MV ^x =P ^x q	P ^x	q	MV ^x =P ^x q	P ^x	q	MV ^x =P ^x q
1	1	1	1	1	1	1	1	1	1	1	1
1,1	0,826	0,909	1,100	0,909	1,000	1,100	0,953	1,049	1,1	1	1,1
1,2	0,694	0,833	1,200	0,833	1,000	1,200	0,913	1,095	1,2	1	1,2
1,3	0,592	0,769	1,300	0,769	1,000	1,300	0,877	1,140	1,3	1	1,3
1,4	0,510	0,714	1,400	0,714	1,000	1,400	0,845	1,183	1,4	1	1,4
1,5	0,444	0,667	1,500	0,667	1,000	1,500	0,816	1,225	1,5	1	1,5

The previous table shows that for higher values of the price-elasticity the reduction in consumption is larger and the increase in expenditure is smaller.

Finally the model calculates the value of the sales of the domestic industry in the market, assuming that the domestic industry has a fixed market share in the segments under exclusivity

and under competition. For countries with an industry that has a low innovative capacity, the market share in the market under exclusivity is assumed to be smaller than in the market under competition or maybe zero. These market shares are assumed constant over time.

Translating IPR changes into model parameters

The list of IPR provisions that might change as a result of FTA negotiations or internal policy decisions is large, as Table 1 shows. A key aspect in the application of the model is to determine how actual changes of these IPR provisions and of other aspects of pharmaceutical policies can be introduced in the model in the form of quantitative parameters.

1. Nominal duration of the patents or variations of this duration.

In this case there is an obvious translation of the provision into the corresponding parameter of the model.

2. Duration of the exclusivity due to test data protection or variations of this duration.

As in the previous case, there is an obvious correspondence with the parameter of the model

3 Compensation by delays in the approval of the patent and delays in the registry of generic due to "linkage" between the registration and the patent office.

These aspects are considered in the model in the form of an increase of the period of exclusivity for a certain proportion of AI. The information will have to be obtained from countries that already have introduced and experienced these type of provisions for a certain time.

4. Existence or removal of the Bolar exception.

It can be modelled as an certain increase of the period of exclusivity. If the Bolar exception is applied this increase is probably close to zero. If the Bolar exception is not applied, the increase will have a positive value. These values can be estimated by observing the delays in generic entry in countries with and without the Bolar exception. In countries with a strong aggressive generics industry (like the US and the UK) the lag should be expected to be shorter than in countries with a weak generic industry.

5. Variations of the patentability of the subject matter.

The impact of a variation of these aspect might be implemented in the model by means of an increase of the proportion of new AI that enter the market with patent protection. The value of this parameter must be estimated from the experience of countries with a subject matter similar to the one that is being assessed.

6. Variations or restrictions in the use of INN, generic substitution policies and other measures that affect the relative importance of INN vs. branded generics.

This type of measures might be modelled by means of assumptions on the expected impact in the market share of INN generics vs. branded generics.

7. Introduction of patents for second uses or for small improvements.

A possible way to modelling these changes can be by means of an extension of the period of exclusivity. This option might however require the introduction of an additional price differential, as patents for second uses might not provide the same the same excluding effect and level of protection than the original patent.

This section tried to show how changes in different IPR provisions might be incorporated in the present version of the model or in slightly modified versions. As a matter of fact, the structure of the model has been revised several times in order to accommodate it to new requirements of the users. Other policy decisions and agreements such as those related to parallel imports or compulsory licensing might require major additional changes in the structure of the model.

Moreover, finding valid and reliable values for the parameters, requires empirical analyses of the performance of the IPR system in countries that have introduced the changes to be assessed.

Definition and calculation of impacts

Impacts are defined and calculated as the difference in a given outcome variable between the baseline and an alternative scenario

The final impacts considered in this model are:

the variation in total expenditure or in the value of the market in monetary units

the relative variation of consumption/utilization in units

the variations in the sales of the national industry in monetary units

In order to calculate these outcomes the model calculates several intermediate outcomes, such as the market share of three categories of drugs (drugs under exclusivity, branded generics and INN generics. Off-patent original drugs are implicitly included in the category of branded generics, and assumed to be priced accordingly, a clearly oversimplifying assumption.

Other key intermediate outcomes include the average price differential attributable to the change of IPR conditions implied by given scenario. However, the model does not try to assess the variation of prices over time.

Key assumptions of the model

The model assumes a constant price differential between the AI under exclusivity and AI under competition. It also assumes that when the period of exclusivity expires the price of the AI immediately falls from the average exclusivity price to the average competitive price. This is obviously a strong assumption that is not supported by empirical evidence: prices tend to adjust over a certain period of time. However, it is assumed that releasing this assumption would not dramatically affect the results of the model.

By modelling the market in an aggregate way the analysis cannot consider the fact that the market share of AI varies enormously, and implicitly assumes that all AI have the same market share, which is the same along the whole product life.

The demand curve has the form $q = k p^e$, which implies a constant price-elasticity. This means that at any point of the demand curve a certain variation of the price will produce the same variation of the quantity demanded.

Finally, in order to calculate the impact on the production of the national industry, the model assumes that the market share of the domestic vs. that of the foreign industry remains constant over time in the submarket under competition and the submarket under exclusivity. Therefore, the variation in the share of the total market held by the domestic industry is directly related to the variations in the relative size of these two markets.

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Appendix 1: Model Specification

Fixed parameters

YI: Initial year of simulation period

YL: Last year of simulation period

TAP_{t₀}: Number of existing active ingredient (AI) in the market in the beginning of the initial year

MV_{t₀}: Total sales/expenditure of the relevant market in year t₀

α: annual rate of growth of MV

d: discount rate

k_{de}: market share of domestic industry in markets under exclusivity

k_{dc}: market share of domestic industry in markets under competition

Scenario dependent parameters

YP: initial year of product patent enforcement

YDP: initial year of data protection enforcement

PD: Nominal patent duration

DT: Time from patent filing of an AI to market registration (approval) of the original product

PDE: Average extension of nominal patent duration due to delays in patent approval

pPDE: Proportion of AI entering the market with an extension of nominal patent duration due to delays in patent approval

TTC: Time from patent expiration to generic entry due to generic development time in absence of Bolar clause

DGE: Average delay in generic entry due to linkage between patent and registration

pDGE: Proportion of AI for which generic competition is delayed due to linkage

DE: Duration of exclusivity due to test data protection

All the durations are defined in years and must be expressed as integers

RPec: Relative weighted average price of an AI under exclusivity vs. its price under competition

RPbd: Relative weighted average price of an AI under competition with brand name vs the respective average price of an AI under competition with INN (international non-proprietary name)

e: price-elasticity of demand

The following parameters must be entered manually for each year

AI_i: Number of AI entering the market in year i

AO_i: Number of AI exiting the market in year i

AIPPI: Number of patented (prod. patent) AI entering the market in year i

AIDPI: Number of AI entering the market with test data protection in year i

pdi: proportion of AI with no exclusivity that are sold under INN (international non-proprietary name) in year i.

Variables

EEP: Effective exclusivity period linked to patent protection

$$EEP = PD - DT + PDE + TTC + DGE$$

TAP_i: Number of existing AI in the market in year i

$$TAP_i = TAP_{i-1} + AI_i - AO_i$$

AOPPI: Number of AI losing exclusivity linked to patent protection in year i

$$\begin{aligned} \text{AOPPi} = & \text{pPED} * \text{pDEG} * \text{AIP}_{i-(\text{PD-DT}+\text{PDE}+\text{TTC}+\text{DGE})} \\ & + (1-\text{pPED}) * \text{pDEG} * \text{AIP}_{i-(\text{PD-DT}+\text{TTC}+\text{DGE})} \\ & + \text{pPED} * (1-\text{pDEG}) * \text{AIP}_{i-(\text{PD-DT}+\text{PDE}+\text{TTC})} \\ & + (1-\text{pPED}) * (1-\text{pDEG}) * \text{AIP}_{i-(\text{PD-DT}+\text{TTC})} \end{aligned}$$

TAIPi: Number of AI with exclusivity linked to patent protection in year i

$$\text{TAIPi} = \text{TAIP}_{i-1} + \text{AIPi} - \text{AOPi}$$

AODPi: Number of AI losing exclusivity due to test data protection in year i

$$\text{AODPi} = \text{AIDP}_{i-\text{DE}}$$

TAIDPi: Number of AI with exclusivity due to test data protection in year i

$$\text{TAIDPi} = \text{TAIDP}_{i-1} + \text{AIDPi} - \text{AODPi}$$

TAIEi: Number of AI with market exclusivity in year i

$$\text{TAIEi} = \text{TAIPi} + \text{TAIDPi}$$

pei: share of the relevant market under exclusivity in year i

$$\text{pei} = \text{TAIEi} / \text{TAPi}$$

MVi: Total sales/expenditure of the relevant market in year i.

$$\text{MV}_i = \text{MV}_{i-1} * (1 + \alpha)$$

Σ MVi: Cumulative sales/expenditure of the relevant market over time horizon.

Σ dMVi: Discounted cumulative sales/expenditure of the relevant market over time horizon.

Variables for alternative scenarios x are indicated by the superindex (x)

P^xi: price index of scenario X in relation to baseline scenario in year i
 (Pi = 1)

$$P^x_i = [1 + (\text{pe}^x_i - \text{pei}) * (\text{RPec} - 1) + (1 - \text{pe}^x_i) * (\text{pdi} - \text{pd}^x_i) * (\text{RPbd} - 1)]$$

The demand curve has the form:

$$q = k p^e, \quad \text{or} \quad \ln q = \ln k + e \ln p,$$

where k and e are constant and k > 0 and e < 0

This demand curve has a constant price-elasticity e.

The first derivative (dq/dp = k α p^{e-1}) is negative when e < 0 and k > 0:

MV^xi: Total sales/expenditure of the relevant market in year i under alternative scenario x

$$\text{MV}^x_i = \text{MV}_i * P^x_i{}^{e+1}$$

Demonstration:

$$\text{MV}^x_i / \text{MV}_i = k(P^x_i)^{e+1} / k(P_i)^{e+1} = (P^x_i)^{e+1}$$

as Pi is by definition Pi = 1, then MV^xi = MV_i * P^xi^{e+1}

Impact of scenario x on consumption

RC^XI: Relative reduction in consumption (units) in year i (from baseline scenario)

$$RC^X I = P^X I^E - 1$$

Demonstration:

$$rC^X i = (q^X i - q_i) / q_i = q^X i / q_i - 1 = (k P^X i^e / k P_i^e) - 1$$

as P_i is by definition P_i = 1, then rC^Xi = P^Xi^e - 1

Four cases are worth considering regarding the effect of the value of **e** on **q** and on **MVI**:

1. If e = 0, q does not change and expenditure (p*q) increases proportionally to price increases when price p goes up.
2. If e = -1, q comes down and expenditure does not change (p*q = k) when price p goes up.
3. If e < -1 (e.g. e = -2), q comes down and expenditure (p*q) decreases when price p goes up. This is called an elastic demand
4. If e > -1 (e.g. e = -0,5), q comes down and expenditure (p*q) increases when price p goes up. This is called a rigid or inelastic demand

Constant price-elasticity of demand: e						q = k p ^e e ≤ 0					
e = -2			e = -1			e = -0,5			e = 0		
P ^x	q	MV ^x =P ^x q	P ^x	q	MV ^x =P ^x q	P ^x	q	MV ^x =P ^x q	P ^x	q	MV ^x =P ^x q
1	1	1	1	1	1	1	1	1	1	1	1
1,1	0,826	0,909	1,100	0,909	1,000	1,100	0,953	1,049	1,1	1	1,1
1,2	0,694	0,833	1,200	0,833	1,000	1,200	0,913	1,095	1,2	1	1,2
1,3	0,592	0,769	1,300	0,769	1,000	1,300	0,877	1,140	1,3	1	1,3
1,4	0,510	0,714	1,400	0,714	1,000	1,400	0,845	1,183	1,4	1	1,4
1,5	0,444	0,667	1,500	0,667	1,000	1,500	0,816	1,225	1,5	1	1,5

ΣMV^Xi: Cumulative sales/expenditure of the relevant market over time horizon under alternative scenario x.

ΣdMV^Xi: Discounted cumulative sales/expenditure of the relevant market over time horizon under alternative scenario x.

Impact of scenario x on sales/expenditure

IMV^XI: Impact of scenario x on total sales/expenditure of the relevant market in year i.

$$IMV^X i = MV^X i - MV_i$$

ΙΣM^XV_i: Impact of scenario x on cumulative sales/expenditure

$$ΙΣM^X V_i = ΣMV^X i - ΣMV_i$$

ΙΣdMV^Xi: Impact of scenario x on discounted cumulative sales/expenditure

$$ΙΣdMV^X i = ΣdMV^X i - ΣdMV_i$$

Impact of scenario x on domestic industry sales

MVD_i: Market sales of domestic industry in year i under baseline scenario

$$MVD_i = k_{de} * pe_i * MV_i + k_{dc} * (1-pe_i) * MV_i$$

MVD^x_i: Market sales of domestic industry under scenario x

$$MVD^x_i = k_{de} * pe^x_i * MV^x_i + k_{dc} * (1-pe^x_i) * MV^x_i$$

RMVD^x_i: Reduction in market sales of domestic industry under scenario x

$$RMVD^x_i = MVD_i - MVD^x_i$$

$$RMVD^x_i = k_{de} * pe_i * MV_i + k_{dc} * (1-pe_i) * MV_i$$

$$- (k_{de} * pe^x_i * MV^x_i + k_{dc} * (1-pe^x_i) * MV^x_i)$$

k^x_i: market share of domestic industry under scenario x

$$k^x_i = k_{de} * pe^x_i + k_{dc} * (1-pe^x_i)$$

Data required for the application of the IPR Impact Model to a given country

1. Initial year of the simulation
2. Final year of the simulation
3. Monetary value of the market (pharmaceutical expenditure) at consumer prices or at the price paid by the relevant financing institution (e.g. National Health Service, Social Insurance). Ideally the market in the 5 or 10 last years would be required in order to estimate the growth of the market. If there are several independent health systems (e.g. Ministry of Health, Social Insurance, private market) it would be better to make separate estimates for each sector. Values can be provided either in US\$ or in local currency
4. Exchange rate over the period considered in point 3. (In case values are given in local currency)
5. Available estimates of the growth rate of the relevant markets. Indicate if it refers to US\$ values, or if it is given in current or constant local prices.
6. Total number of active ingredients (AI) in each market. Indicate as well, if available, the number of AI that account for 50, 80 and 90 % of the market. Ideally these data should be provided for several years as in point 3.
7. Number of AI registered each year in the last 5 – 10 years. If possible provide estimates of the expected number of AI that will be registered (that will enter the market) in the next 5-10 years.
8. Number and market share of AI that are less than 5, 5-10 and more than 10 years old. Provide if possible figures for the last 5-10 years.
9. Year when product patent protection started or will start.
10. Year when data protection and other forms of market exclusivity started or will start
11. Annual number and market share of AI registered with patent protection in the last 5-10 years, if applicable.
12. Annual number and market share of AI registered with data protection or other forms of exclusivity in the last 5-10 years, if applicable.
13. Nominal patent life
14. Nominal duration of test data protection and other forms of market exclusivity
15. Average time between patent filling and registration for products that entered the market in the last 5-10 years
16. Average time between patent expiration and generic competition (if applicable)
17. Total population and population covered by the various health insurance schemes (if applicable) and expected trends in coverage.
18. Short description of the country health system (describe the main traits of the existing insurance schemes: eligibility, financing mechanism, benefit package, co-payments)
19. Per capita expenditure in health services and in pharmaceuticals in each insurance scheme.
20. Distribution by income levels (e.g in deciles) of the population covered by the insurance schemes as well as of the non-insured.
21. Describe the co-payment mechanisms/rules for pharmaceuticals in each insurance scheme
22. Estimates of price-elasticity of the demand for pharmaceuticals if available.
23. Value of pharmaceutical production in the country. Market share of national and foreign manufacturers in each market. Market share in the submarket under exclusivity conditions.
24. Local production (including foreign firms with manufacturing plants in the country) going to the national markets.
25. Export and import of pharmaceuticals (separate finished products and AI)

26. Cost structure of national and foreign firms. Especially relevant is the share of imported AI and other inputs.
27. Employment in the national and foreign companies.