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Executive Summary of Technical Report

Documentation of Group Modeling Design and Research

INTERNATIONAL EXPERT GROUP ON BIOTECHNOLOGY, INNOVATION AND INTELLECTUAL PROPERTY

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DOCUMENTATION OF GROUP MODELING DESIGN AND RESEARCH[1]

Executive Summary of Technical Report

Céline Bérard
L. Martin Cloutier
Luc Cassivi

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I. RESEARCH PROCESS

1. Introduction

Within the context of the project, the principles of group model building using system dynamics (SD) were applied to the intellectual property (IP) system, to inquire about its mechanisms within the biotechnology context for human health and agriculture, from legal, ethical, economic and managerial standpoints. The research method followed is based on the established approach in the literature in SD. SD includes a set of principles allowing to represent qualitatively the structure of feedback loops and to quantify the impact of decision over time using sensitivity or scenario analyses of potential decisions. This modeling process is well-established and documented in the literature.

1. Problem definition;
2. Formulation of dynamic hypotheses;
3. Design and elaboration of simulation model;
4. Evaluation of model;
5. Formulation of new strategies and results.

This document introduces briefly each of the five (5) steps followed to model the IP system in the biotechnology context for human health and agriculture: 1) problem definition, 2) dynamic hypothesis specification, 3) the design and elaboration of the model, 4) evaluation of model, and 5) formulation of new strategies and results.

2. Problem Definition

At this first step, the problem, dynamic hypotheses, and objectives of the model were defined and specified. These are based on the work already reported in previous publications[1] and final Report of the International Group of Experts in Biotechnology, Innovation and Intellectual Property[2].
The seven probes and IP subsystem (IP "box") included in the modeling process are as follow:

- Intellectual property rights include patents, authors' rights, industrial secret, know-how, trademarks.
- Distributive justice takes into account elements relative to the distribution of benefits and burdens generated by biotechnology innovations.
- Innovation management as a function of the management or governance of innovation systems.
- Knowledge management relates to issues relative to the diffusion of information and how organizations transfer knowledge.
- Integrity of living things takes into account the manner by which the system influences perceptions and life of living organisms.
- Economic efficiency concerns a series of issues relative to the conception of patent policies aimed at improving economic efficiency.
- Risk management related to the evaluation of scientific, analysis and management of risks related to the environment and potential impacts on biodiversity.
- Legal sovereignty takes into account the international legal and political context.

3. Formulation of Dynamic Hypotheses

This second step consists in elaborating the dynamic hypothesis of the model represented using an influence diagram (ID). This is to highlight the set of variables associated with the causal links of the model. This simplified representation shows the feedback loops of the model. Such a system is deemed complex because of feedback loops that illustrate the microstructure of the system. A complex system is structured with feedback loops in interactions. Reinforcing feedback loops are labelled "R", amplify the reinforcing macro-behaviour of the system, and balancing feedback loops labelled "B" introduce inertia toward equilibrium, thus limiting the actions of the reinforcing loops. Feedback loops within systems do not behave in isolation of one another, they generate alternative feedback loops interactions at different points in time and act on time delays in the system.

To design the ID, group modeling sessions were conducted during which members of the International Experts Group were directly involved in its development process. Given participants were not necessarily initially familiar with the modeling techniques, a preliminary ID was prepared to guide and facilitate the elaboration of the qualitative model. More precisely, group modeling sessions were conducted in three steps: 1) elaboration of an ID for each probe and the

IP "box", 2) the integration of probes and IP "box" as subsystems into a unified ID, 3) the validation of an ID with required adjustments.

Each subsystem was taken into account in the ID include a large number of variables that interact with one another and with subsystems that interact with each other. The general conceptual structure of the ID (see figure 1) shows the links and variables included into two subsystems. To this day, the IS includes 117 variables, 361 links and over 6 000 feedback loops, of which most of them are reinforcing feedback loops. As examples, two excerpts are shown in figure 2.

This stage of the research process is useful to help the group involved in the development and design of the model acquire the common vocabulary by the documentation of a variable dictionary, in which each variable of the ID is defined. This dictionary, along with the causal links are reproduced in APPENDIX A AND B.

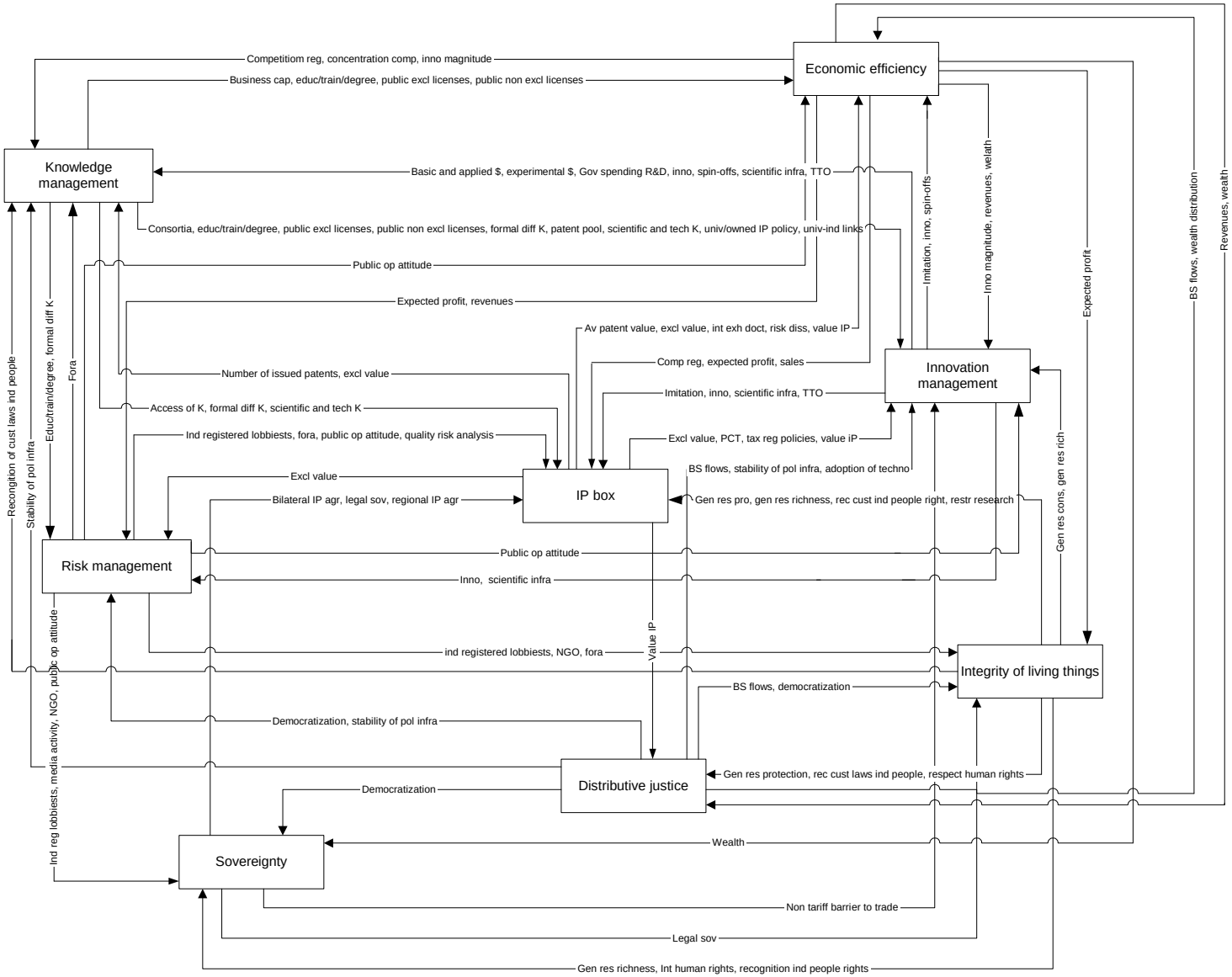


Figure 1 - General structure of the intellectual property system model for biotechnology

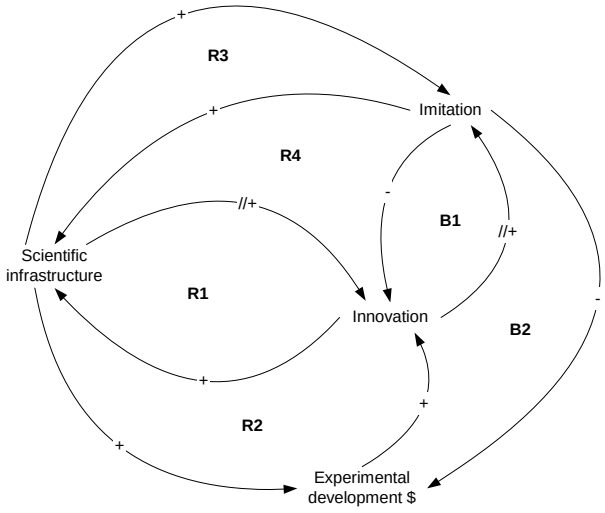


Figure 2a

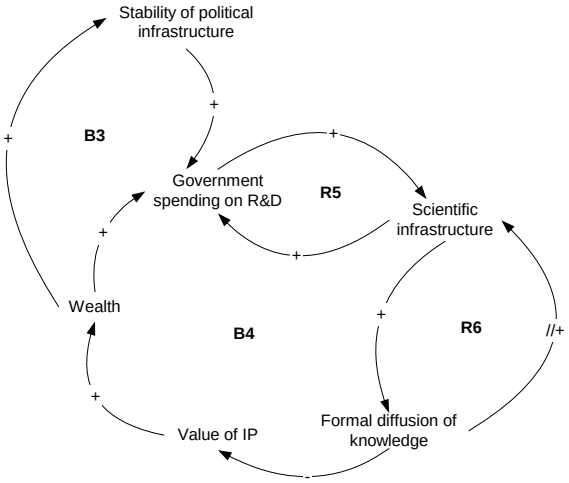


Figure 2b

Figure 2 - Excerpts from the influence diagram (ID)

Figure 2a represent an excerpt of the ID from the innovation management and imitation, that involves four reinforcing loops and two balancing loops. The scientific infrastructure is one of the most determining factors for innovation: it contributes directly (loop R1), or indirectly with expenses on experimental development (loop R2), to the virtuous benefit cycle into which the number of innovative products is augmenting (loops 3 and 4). Innovation and imitations are closely knitted. However, a strong number of imitative products can become risky to the extent that it reduces not only the extent of innovation of a country (loop B1), but also investments in R&D (loop B2). This structure translate the problem of the limits to growth archetype of the SD literature as defined by these reinforcing processes, that are slowed down by balancing loops emerging involuntarily.

Figure 2b shows a portion of the ID related to the development of scientific infrastructure. Expenses in R&D by the government are key as a mean to an end in the development of infrastructure (loop R5). The formal diffusion of knowledge can help facilitate this reinforcing behavior (loop R6). Given a strong degree of diffusion of knowledge could alter expected benefits, given its negative influence on the value of IP, and thus the country's wealth, the stability of its political infrastructure (loop B3) and government investment (loop B4). The formal diffusion of knowledge could lead to unintended consequences to the functioning of the system: the underlying dynamics is described by the "fix that fails" archetype in the Sd literature to exemplify that short-term solutions are at times unwarranted given long-term consequences, making the initial situation worse.

4. Design and Elaboration of Simulation Model

The formulation of the ID aims to the design and elaboration of the quantitative model, often called a level-rate model. The representation of this model was conducted with the use of the Powersim© software.

In what follows, there is a short introduction to the research activities conducted at this step. More details will be provided in the complete technical report.

4.1. Formulation and calibration of the simulation model

The formulation and calibration of the simulation model was based on an extensive data collection conducted in part by members of the International Experts Group and has required that the ID model be translated into a level-rate model using first-order difference equation. Some of these equations were the object of statistical estimation used in the quantification process of the level-rate model.

4.2 Data collection

The scope of the data collection includes 17 countries spread over five regions (see table 1) and covers a historical period from 1995 to 2007.

Table 1 Regions and countries covered by the data collection

Region	Countries
Africa	South Africa Algeria Kenya
South and Central America	Argentina Brazil Mexico
North America	Canada United States
Asia-Oceania	Australia India Indonesia Japan New Zealand
Europe	France Russia Turkey Great Britain

Publicly available data bases were consulted to obtain quantitative data and information and to calibrate the model using most of the variables identified by the International Experts Group. For example, there were data used from the OECD, the WTO, the WIPO, etc.

Out of 117 variables, 87 were inserted into the model. The remainder of the variables was not included because of the lack of data and of empirical research on the topic, in particular on IP and biotechnology[3].

4.3 System translation into level variables and rate variables

SD principles include different types of variables to represent a system: level variables, rate variables, and parameters. Such a quantitative model can be visualized on a computer screen. Level variables are accumulators of past decisions and can be measured in currency, in goods accumulated, and information that report the state of the system. The state of the system can serve as a basis for making decisions. Rate variables are measure by period of time, and augment or deplete level variables over time. They can either be inputs and outputs and compute change in a system by taking into account time delays. On this basis, and using the ID as the reference system for quantification, the model includes 33 level variables, 87 rate variables, and 54 parameters.

4.4 Formulation of decision rules

The formulation of decision rules is a translation in a mathematical form of the effect of one or more variables on a given variable. Decision rules were statistically estimated for rate variables and a certain category of parameters called « auxiliaries". The formulation of statistical equation was based on statistical techniques and more precisely on mixed model methods using the SPSS software.

4.5 Model calibration

Following the translation of the ID into level and rate variables and the development of the mathematical equations (using statistical methods and games), the input parameter and initial value of level variables were calibrated.

The model calibration was based on historical time series data from 1995 to 2007. Then, the level-rate model was initialized for the current year (2008). This quantification process is based on results generated by the model during simulations that have allowed for the anticipation of the behavior of the system from 2008.

4.6 Model evaluation

This step consists in making sure the model is appropriate for the task at hand. It is necessary to evaluate the model and many tests were executed. These tests, both qualitative and quantitative, are important to help build

confidence in the model's results. The more tests that can be conducted, the greater the community of users can help improve the system that they are interested in. Six tests were conducted on the model: 1) boundary appropriateness test, 2) structure evaluation test, 3) parameter evaluation test, 4) behavior reproduction test, 5) extreme condition test, and 6) integration error test.

II. SIMULATION MODEL INTERFACE

The simulation model can allow for testing modifications in the system and to observe over time the impact of potential decisions under consideration. This model includes a computer simulation model, designed within the software Powersim© with an Excel interface. One interface per country has been designed.

The procedure followed (material used, the model, etc.) accounted for: 1) user-friendly interface to facilitate the ease of modification of the parameter(s) and variable (s) of interest and access to results by using a navigating menu, 2) making sure someone with no prior familiarity with this type of modeling could quickly proceed with simulation runs.

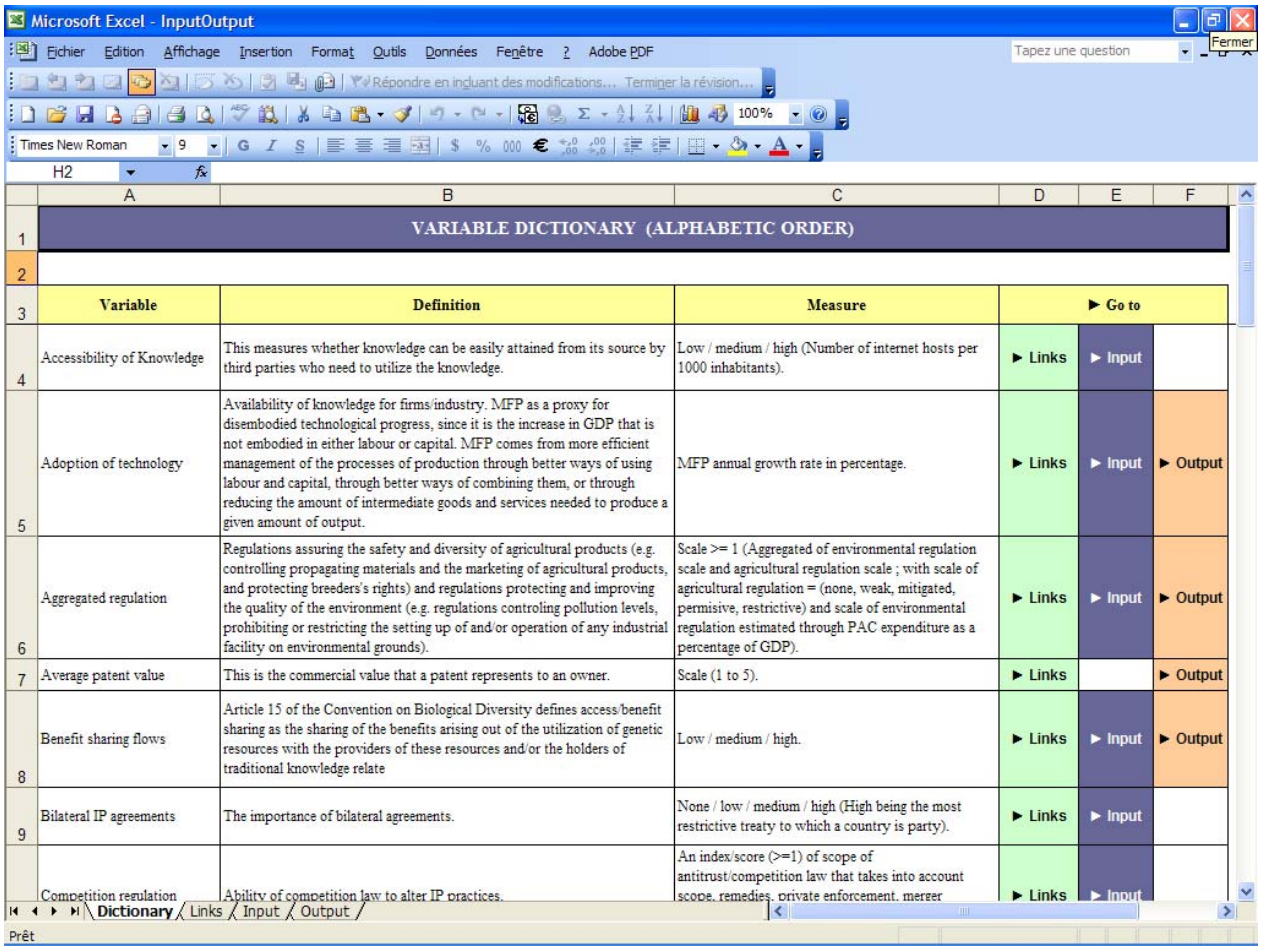
The Excel interface is identical for all countries, and includes four (4) tabs: 1) variable dictionary, 2) the causal loops link definitions, 3) inputs, and 4) outputs. Each tab in the Excel document is presented and briefly described below with the interface for Canada as an illustrative example.

1. « Dictionary » Tab

The first tab of the model is the variable dictionary of the model quantitative simulation model. In the Excel file, the variable dictionary is restricted to the variables quantified in the model, and, thus, is less detailed than the variable dictionary of the influence diagram (ID).

On this tab, the variable names, their definition and measures, are defined and listed in alphabetical order (see figure 1).

To facilitate the ease of navigation on the interface, a click on the boxes labelled « *Links* », « *Input* », « *Output* » allows for a navigation between tabs on the targeted variable.



Variable	Definition	Measure	► Go to		
Accessibility of Knowledge	This measures whether knowledge can be easily attained from its source by third parties who need to utilize the knowledge.	Low / medium / high (Number of internet hosts per 1000 inhabitants).	► Links	► Input	
Adoption of technology	Availability of knowledge for firms/industry. MFP as a proxy for disembodied technological progress, since it is the increase in GDP that is not embodied in either labour or capital. MFP comes from more efficient management of the processes of production through better ways of using labour and capital, through better ways of combining them, or through reducing the amount of intermediate goods and services needed to produce a given amount of output.	MFP annual growth rate in percentage.	► Links	► Input	► Output
Aggregated regulation	Regulations assuring the safety and diversity of agricultural products (e.g. controlling propagating materials and the marketing of agricultural products, and protecting breeders's rights) and regulations protecting and improving the quality of the environment (e.g. regulations controling pollution levels, prohibiting or restricting the setting up of and/or operation of any industrial facility on environmental grounds).	Scale >= 1 (Aggregated of environmental regulation scale and agricultural regulation scale ; with scale of agricultural regulation = (none, weak, mitigated, permisive, restrictive) and scale of environmental regulation estimated through PAC expenditure as a percentage of GDP).	► Links	► Input	► Output
Average patent value	This is the commercial value that a patent represents to an owner.	Scale (1 to 5).	► Links		► Output
Benefit sharing flows	Article 15 of the Convention on Biological Diversity defines access/benefit sharing as the sharing of the benefits arising out of the utilization of genetic resources with the providers of these resources and/or the holders of traditional knowledge relate	Low / medium / high.	► Links	► Input	► Output
Bilateral IP agreements	The importance of bilateral agreements.	None / low / medium / high (High being the most restrictive treaty to which a country is party).	► Links	► Input	
Competition regulation	Ability of competition law to alter IP practices.	An index/score (>=1) of scope of antitrust/competition law that takes into account scope, remedies, private enforcement, merger	► Links	► Input	

Figure 1 Interface of the simulation model – « Dictionary » tab

2. *« Links » tab*

The « links » tab shows, in textual form, the links and the causal direction of influence between the variables included in the model (see figure 2). Each variable, listed in alphabetical order, can be examined for their causal relationship (from independent to dependent variables).

It is also possible from that tab to consult the definition of a targeted variable by clinking on the box labelled « *Dictionary* ».

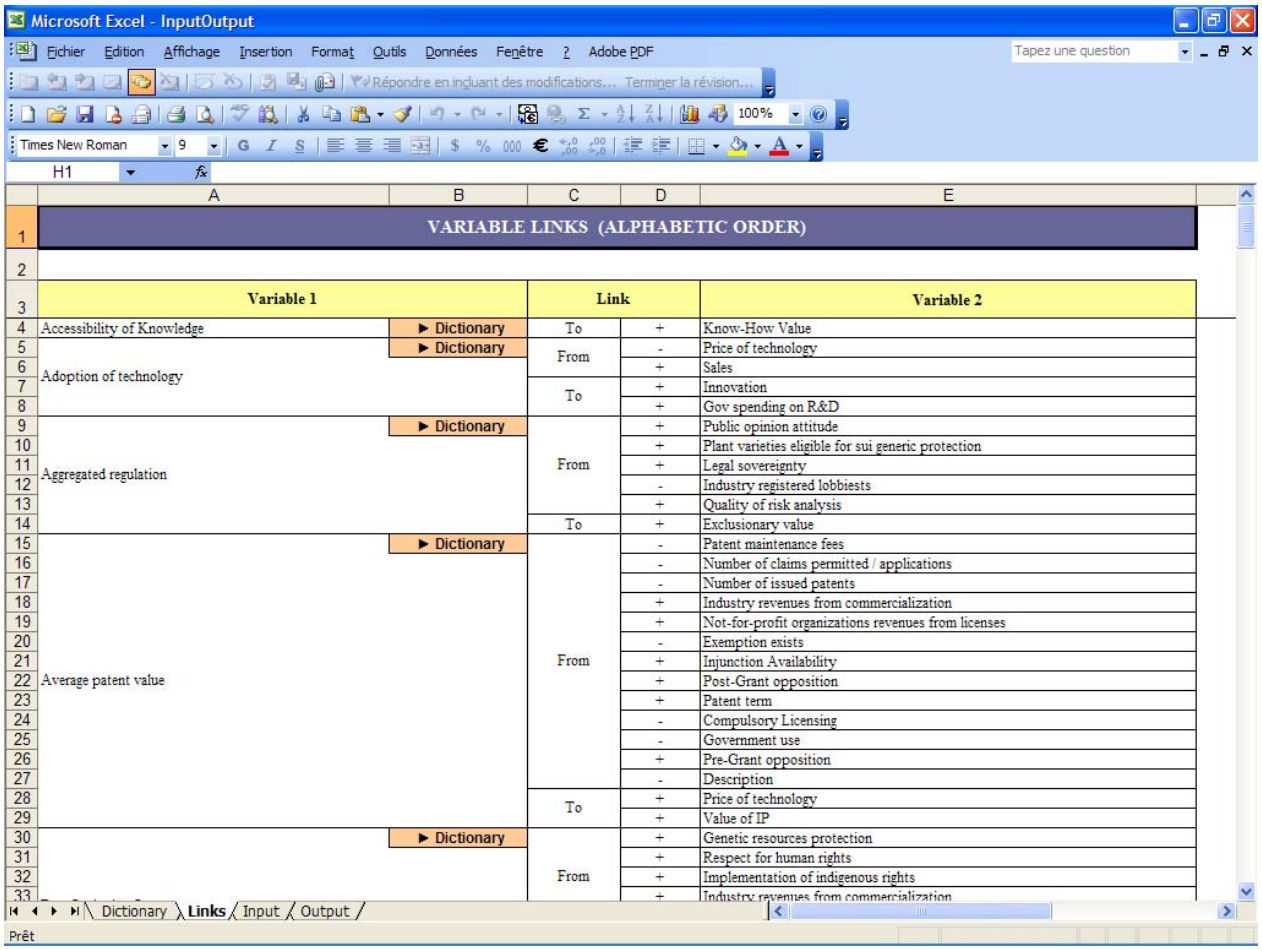


Figure 2 Interface of the simulation model –« Links » tab

3. « Input » tab

The input tab allows the user to modify one or more parameters of the systems and to specify a sensitivity analysis or a scenario.

On the « Input » tab, the variables that can be modified are listed according to their belonging to one of the eight probes of the IPMG model, specified as eight subsystems of the simulation model. The browsing from one to another of these subsystems can be done using an interactive menu (see figure 3).

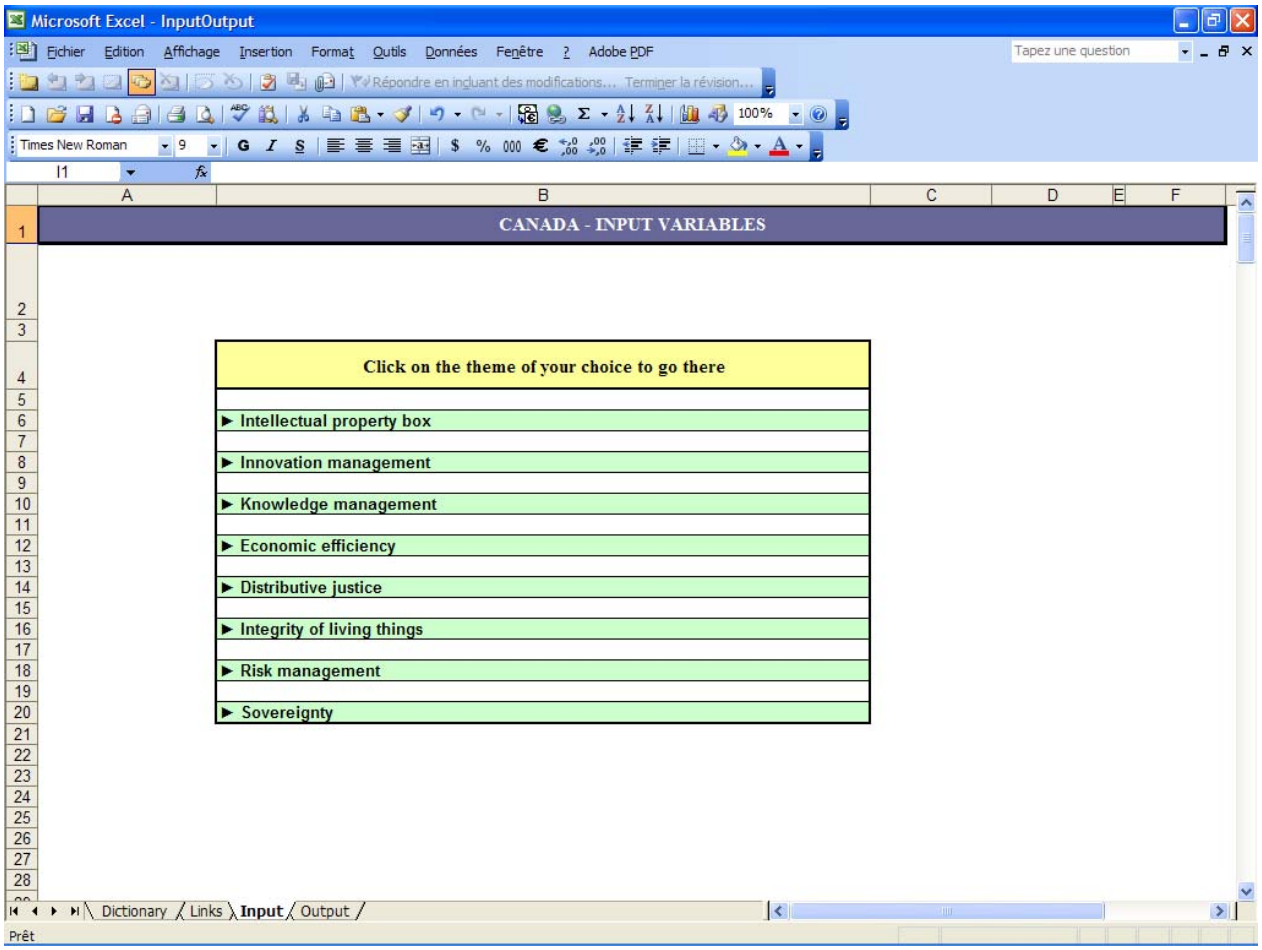


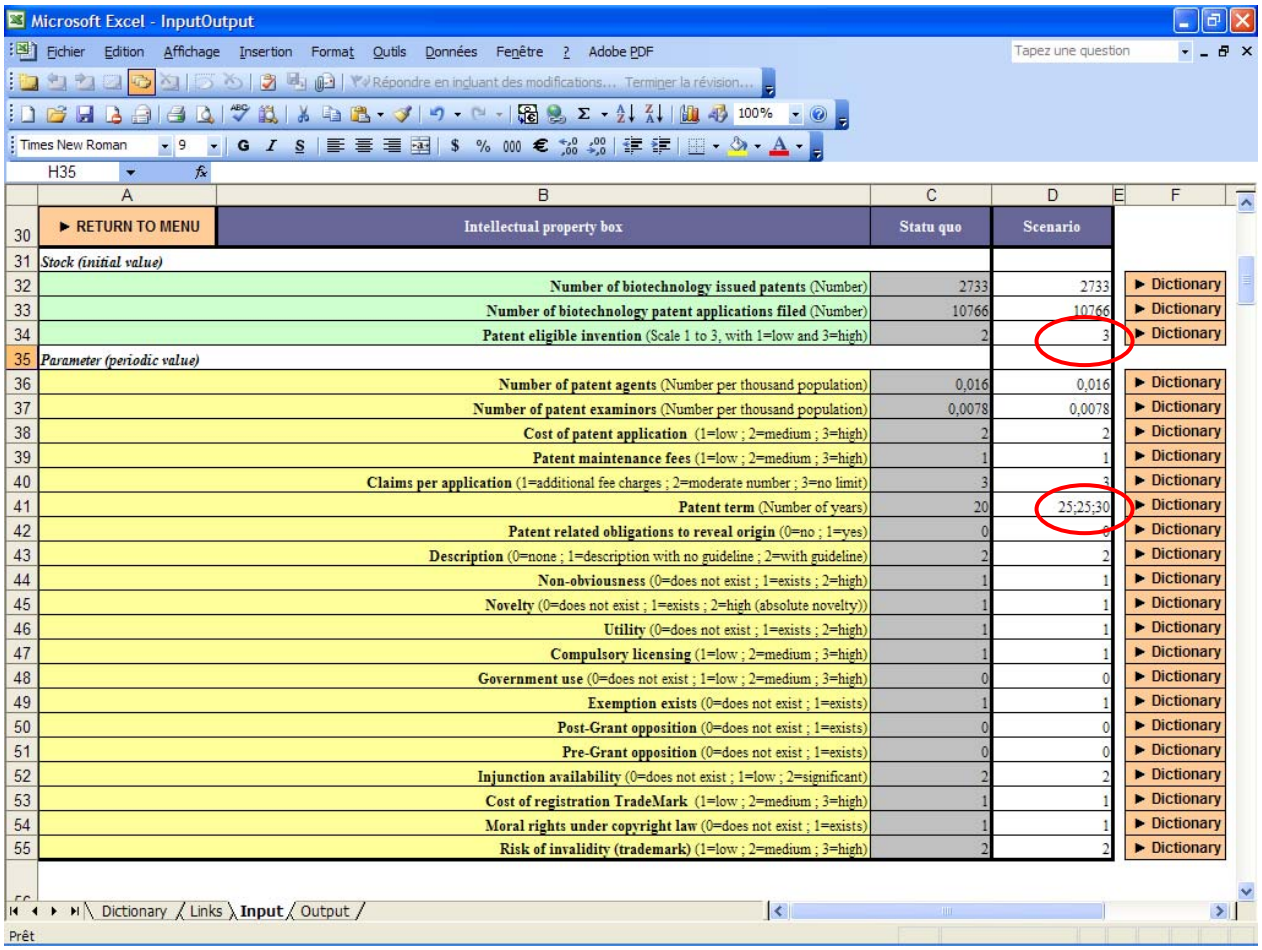
Figure 3 - Interface of the simulation model – Menu of the « Input » tab

After clicking on the box for selecting one of the probes for simulating a change in parameter, the list of parameters within the subsystem selected will appear on the screen. If the user wants to modify one or more parameter related to the IP system, the screen on figure 4 will appear.

For each variable two columns are displayed. The columns « *Status quo* » is fixed and cannot be modified: this value correspond to the initial specification of the model, from which the model was calibrated. The column « *Scenario* » is the one than can be used to modify a value and to specify a sensitivity analysis or a scenario. By default, the entries remaining (not modified) in this column are identical the ones of the status quo column.

The sensitivity analyses and scenarios can be performed on two distinct types of variables: 1) stocks or level variables, and 2) parameters. In system dynamics, the level variables are specified at the start of the simulation, time series parameter specifications can be redefined during the course of a simulation (for example, a time delay that would become shorter).

The user can consult the « *Input* » tab at any point in time to select another subsystem within which another entry could be modified by clicking on the « *Return to menu* » box. From this tab, it is also possible to consult the definition of the variable of interest by clicking on the « *Dictionary* » box. In case there is a desire to see the probe to which a variable is associated, it is possible to navigate from the tab of the variable dictionary (where variables are listed in alphabetical order) and to click on the box « *Input* » associated to the variable of interest.



	A	B	C	D	E	F
30	► RETURN TO MENU	Intellectual property box	Statu quo	Scenario		
31	*Stock (initial value)*					
32		**Number of biotechnology issued patents** (Number)	2733	2733		► Dictionary
33		**Number of biotechnology patent applications filed** (Number)	10766	10766		► Dictionary
34		**Patent eligible invention** (Scale 1 to 3, with 1=low and 3=high)	2	3		► Dictionary
35	*Parameter (periodic value)*					
36		**Number of patent agents** (Number per thousand population)	0,016	0,016		► Dictionary
37		**Number of patent examinors** (Number per thousand population)	0,0078	0,0078		► Dictionary
38		**Cost of patent application** (1=low ; 2=medium ; 3=high)	2	2		► Dictionary
39		**Patent maintenance fees** (1=low ; 2=medium ; 3=high)	1	1		► Dictionary
40		**Claims per application** (1=additional fee charges ; 2=moderate number ; 3=no limit)	3	3		► Dictionary
41		**Patent term** (Number of years)	20	25;25;30		► Dictionary
42		**Patent related obligations to reveal origin** (0=no ; 1=yes)	0	0		► Dictionary
43		**Description** (0=none ; 1=description with no guideline ; 2=with guideline)	2	2		► Dictionary
44		**Non-obviousness** (0=does not exist ; 1=exists ; 2=high)	1	1		► Dictionary
45		**Novelty** (0=does not exist ; 1=exists ; 2=high (absolute novelty))	1	1		► Dictionary
46		**Utility** (0=does not exist ; 1=exists ; 2=high)	1	1		► Dictionary
47		**Compulsory licensing** (1=low ; 2=medium ; 3=high)	1	1		► Dictionary
48		**Government use** (0=does not exist ; 1=low ; 2=medium ; 3=high)	0	0		► Dictionary
49		**Exemption exists** (0=does not exist ; 1=exists)	1	1		► Dictionary
50		**Post-Grant opposition** (0=does not exist ; 1=exists)	0	0		► Dictionary
51		**Pre-Grant opposition** (0=does not exist ; 1=exists)	0	0		► Dictionary
52		**Injunction availability** (0=does not exist ; 1=low ; 2=significant)	2	2		► Dictionary
53		**Cost of registration TradeMark** (1=low ; 2=medium ; 3=high)	1	1		► Dictionary
54		**Moral rights under copyright law** (0=does not exist ; 1=exists)	1	1		► Dictionary
55		**Risk of invalidity (trademark)** (1=low ; 2=medium ; 3=high)	2	2		► Dictionary

Figure 4 Interface of the simulation model –« Input » tab

4. *« Output » tab*

For a given specification for a sensitivity analysis or a scenario, a simulation can be run from the Powersim© software by clicking on the menu the command circled in red (see figure 5). The model will compute time series for the entire set of variables of the model for up to 2050.

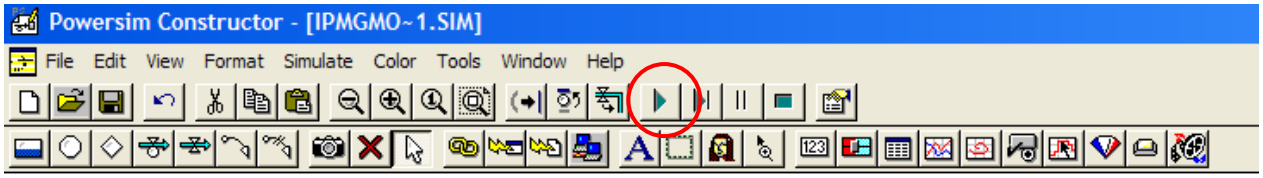


Figure 5. - Running a simulation

The results can be viewed on the « *Output* » tab. The variables are listed according to their association with one of the eight probes (subsystems) some of these probes are further split into sub-probes. It is possible to consult results in table or graph formats. The viewing of results uses an interactive menu as seen in figure 6.

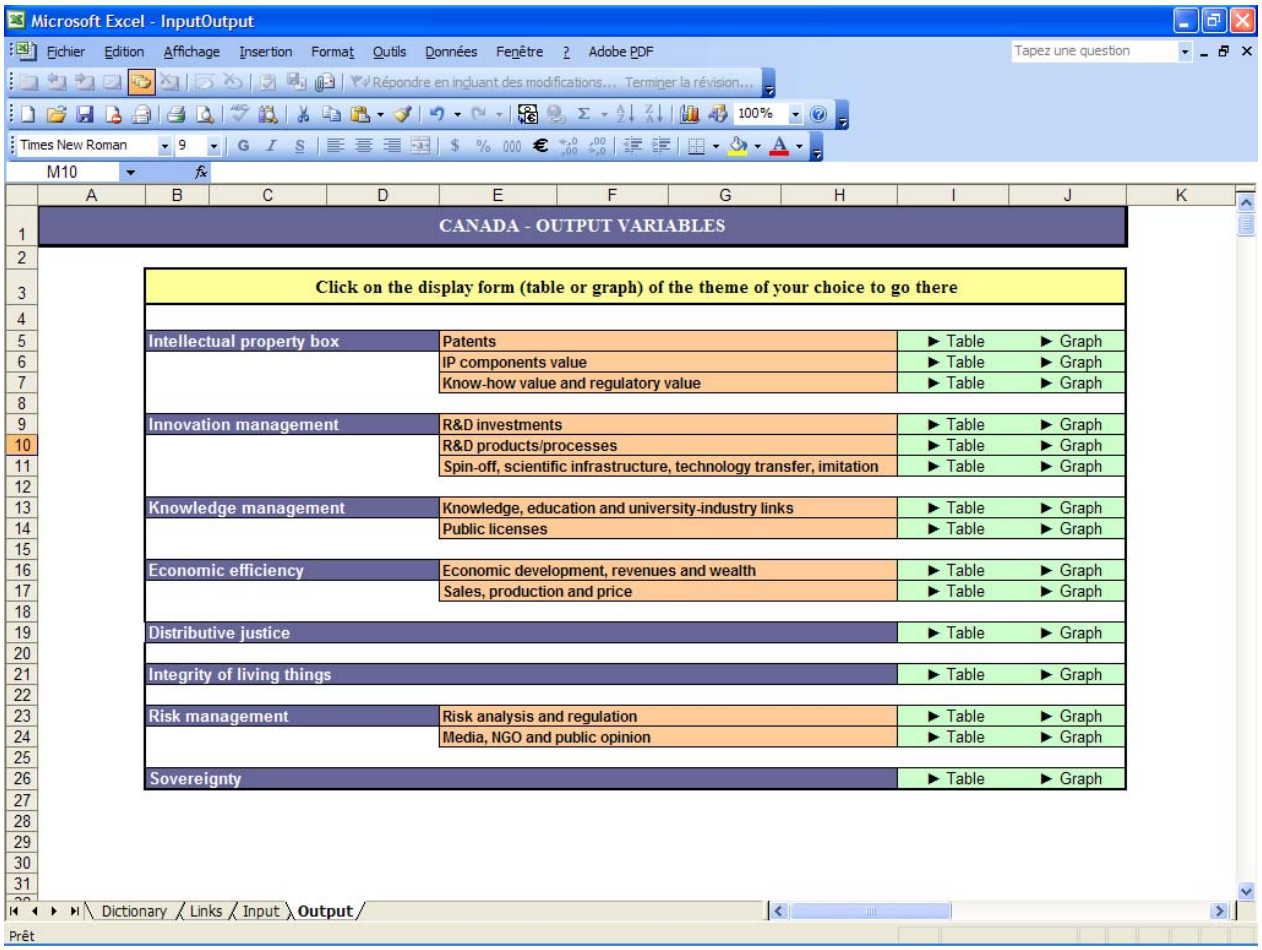
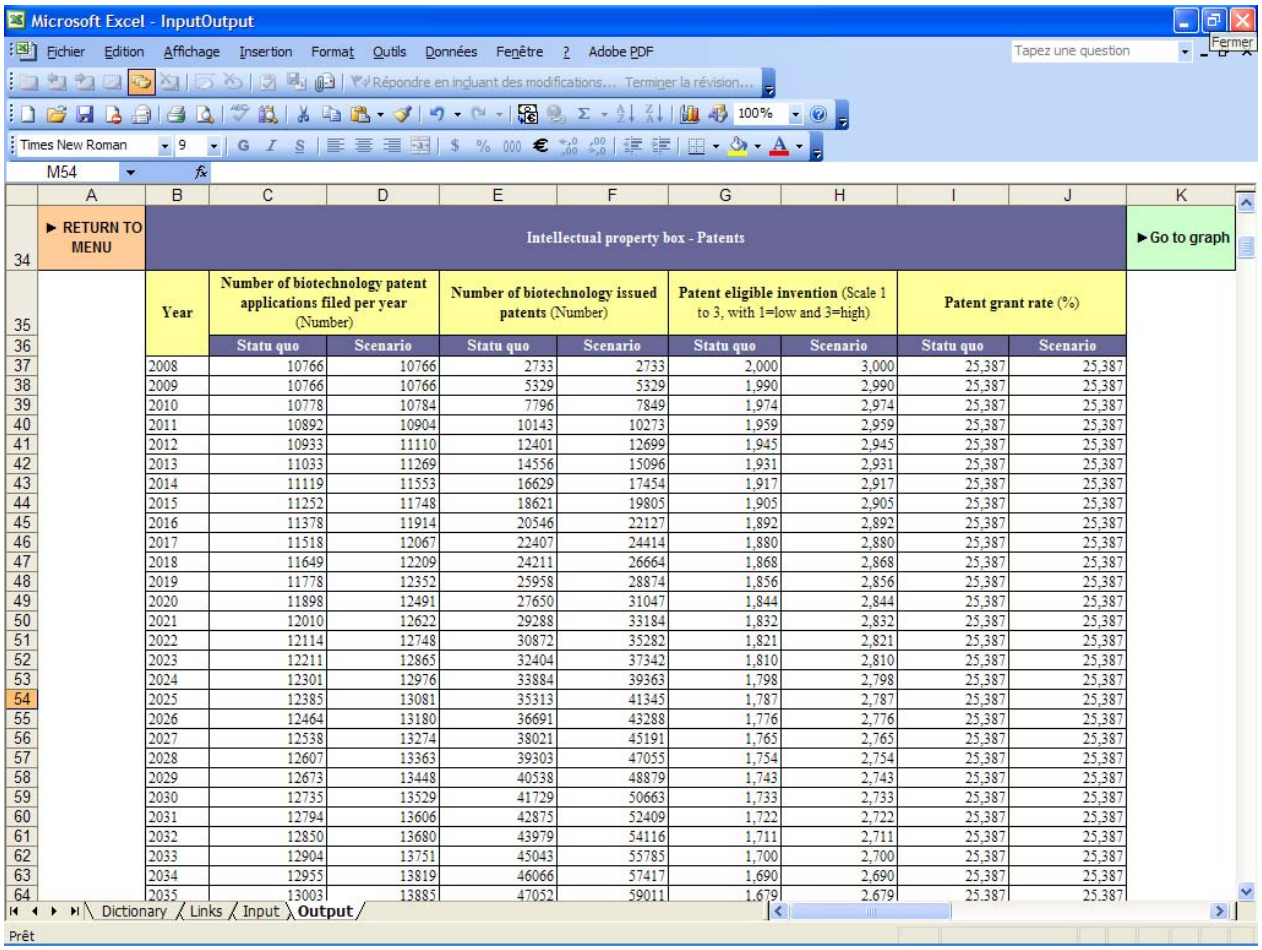


Figure 6 - Interface of the simulation model –« Output » tab

After selecting a format to view results (« *Table* » or « *Graph* ») in the probe or sub-probe to which variables or parameters are associated, results from the simulation run « *Scenario* » can be compared with « *Status quo* » results if no new changes were introduced to the model. For example, if a user wants to examine results for the sub-probe of patents, the screen showed on figure 7 or on figure 8 will display according to the selected format.

The user can go back to the « *Output* » tab to select another sub-probe by clicking on the box (« *Return to menu* »). From this tab, it is also possible to navigate from a format of data to another by clicking on « *Go to graph* » or « *Go to table* ». In case there is a doubt for the probe to which the variable or parameter belongs, it is possible to go back to the variable dictionary (where variables are listed in alphabetical order) and to click on the « *Output* » box associated with the element under consideration.



Microsoft Excel - InputOutput

► RETURN TO MENU

Intellectual property box - Patents

► Go to graph

Year	Number of biotechnology patent applications filed per year (Number)		Number of biotechnology issued patents (Number)		Patent eligible invention (Scale 1 to 3, with 1=low and 3=high)		Patent grant rate (%)	
	Statu quo	Scenario	Statu quo	Scenario	Statu quo	Scenario	Statu quo	Scenario
2008	10766	10766	2733	2733	2,000	3,000	25,387	25,387
2009	10766	10766	5329	5329	1,990	2,990	25,387	25,387
2010	10778	10784	7796	7849	1,974	2,974	25,387	25,387
2011	10892	10904	10143	10273	1,959	2,959	25,387	25,387
2012	10933	11110	12401	12699	1,945	2,945	25,387	25,387
2013	11033	11269	14556	15096	1,931	2,931	25,387	25,387
2014	11119	11553	16629	17454	1,917	2,917	25,387	25,387
2015	11252	11748	18621	19805	1,905	2,905	25,387	25,387
2016	11378	11914	20546	22127	1,892	2,892	25,387	25,387
2017	11518	12067	22407	24414	1,880	2,880	25,387	25,387
2018	11649	12209	24211	26664	1,868	2,868	25,387	25,387
2019	11778	12352	25958	28874	1,856	2,856	25,387	25,387
2020	11898	12491	27650	31047	1,844	2,844	25,387	25,387
2021	12010	12622	29288	33184	1,832	2,832	25,387	25,387
2022	12114	12748	30872	35282	1,821	2,821	25,387	25,387
2023	12211	12865	32404	37342	1,810	2,810	25,387	25,387
2024	12301	12976	33884	39363	1,798	2,798	25,387	25,387
2025	12385	13081	35313	41345	1,787	2,787	25,387	25,387
2026	12464	13180	36691	43288	1,776	2,776	25,387	25,387
2027	12538	13274	38021	45191	1,765	2,765	25,387	25,387
2028	12607	13363	39303	47055	1,754	2,754	25,387	25,387
2029	12673	13448	40538	48879	1,743	2,743	25,387	25,387
2030	12735	13529	41729	50663	1,733	2,733	25,387	25,387
2031	12794	13606	42875	52409	1,722	2,722	25,387	25,387
2032	12850	13680	43979	54116	1,711	2,711	25,387	25,387
2033	12904	13751	45043	55785	1,700	2,700	25,387	25,387
2034	12955	13819	46066	57417	1,690	2,690	25,387	25,387
2035	13003	13885	47052	59011	1,679	2,679	25,387	25,387

Figure 7 - Interface of the simulation model –« Output » tab / tables

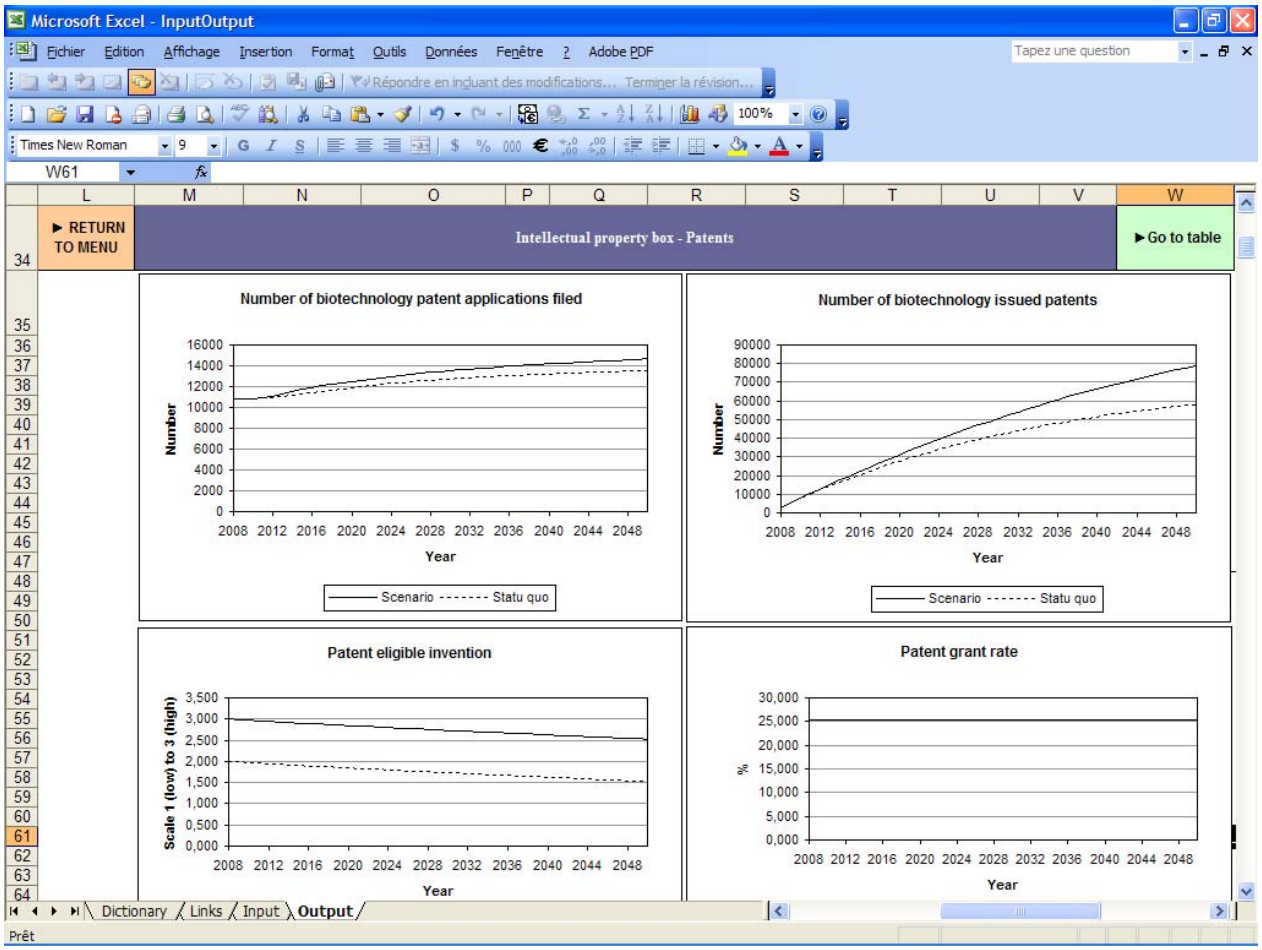


Figure 8 - Interface of the simulation model –« Output » tab / graphs

[1] E. Richard Gold *et al.* "The Unexamined Assumptions of Intellectual Property: Adopting an Evaluative Approach to Patenting Biotechnological Innovation" 18 Public Affairs Quarterly 299.

[2] See generally: www.theinnovationpartnership.org for research findings of the International Experts on Innovation, Biotechnology and Intellectual Property.

[3] Lorie Bouchard, Luc Cassivi, L. Martin Cloutier, *Intellectual Property Modeling in Health and Agricultural Biotechnology: Documentation of Variables, Measures, and Data. Documentation Report*, University of Quebec at Montreal [forthcoming October 2008].

The Innovation Partnership
3800A St-Hubert, Montreal, Quebec H2L 4A5 Canada
www.theinnovationpartnership.org

Centre for Intellectual Property Policy
Faculty of Law - McGill University
3644 Peel Street, Montreal, Quebec H3A 1W9 Canada
www.cipp.mcgill.ca