

**Meeting with Peter Van Loan,
Minister of International Trade
Ottawa, February 15 2011**

**The Potential Impact on the Costs of Brand-Name
Drugs of the European demands in the context of
Canada-European Union CETA Negotiations**

By Marc-André Gagnon*, PhD

Assistant Professor, School of Public Policy and Administration (Carleton University)
Researcher with the Pharmaceutical Policy Research Collaboration
Research Fellow with Edmond J. Safra Foundation Center for Ethics (Harvard University)
Researcher with the Centre for Intellectual Property Policy (McGill University)
ma_gagnon@carleton.ca

*Current research funded by Fonds de Recherche sur la Société et la Culture, Faculty of Public Affairs (Carleton University), Edmond J. Safra Foundation Center for Ethics (Harvard University), Health Canada, Canadian Health Coalition, The Innovation Partnership and Assemblée Nationale du Québec.

OUTLINE

- Part 1: The Political Economy of Big Pharma: A Problematic Business Model
- Part 2: Costs and Benefits of CETA on the Canadian Pharmaceutical Sector

List of Big Pharma Companies, Sept. 30 2008

Company	Country	FT Global 500 Rank	Market Value (Billion \$)
1- Johnson and Johnson	US	10	193.6
2- Novartis	Switzerland	25	138
3- Roche	Switzerland	26	134.3
4- Pfizer	US	31	124.3
5- GlaxoSmithKline	UK	38	112.6
6- Genentech	US	53	93.6
7- Abbott Laboratories	US	58	88.8
8- Sanofi-Aventis	France	59	86
9- Merck	US	77	67.6
10- AstraZeneca	UK	83	63.5
11- Amgen	US	85	62.7
12- Bayer	Germany	106	55.6
13- Eli Lilly	US	111	50.1
14- Wyeth	US	115	49.3
15- Bristol-Myers-Squibb	US	150	41.3
16- Takeda Pharmaceutical	Japan	155	40.3
17- Schering Plough	US	220	30
Total	-	-	1431.6

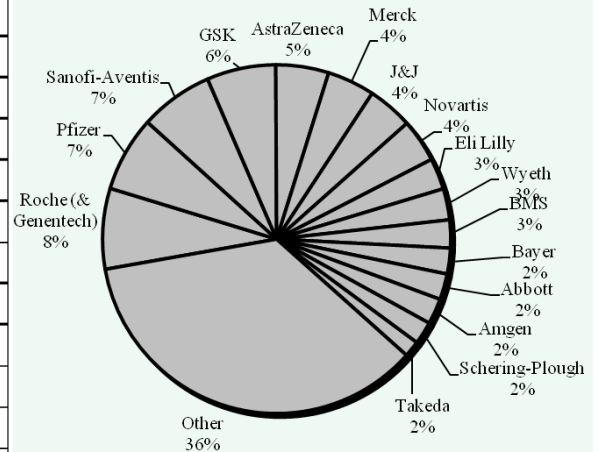
Source: FT Global 500, Fortune Global 500

Mergers and Acquisitions



Big Pharma = 64% of world sales

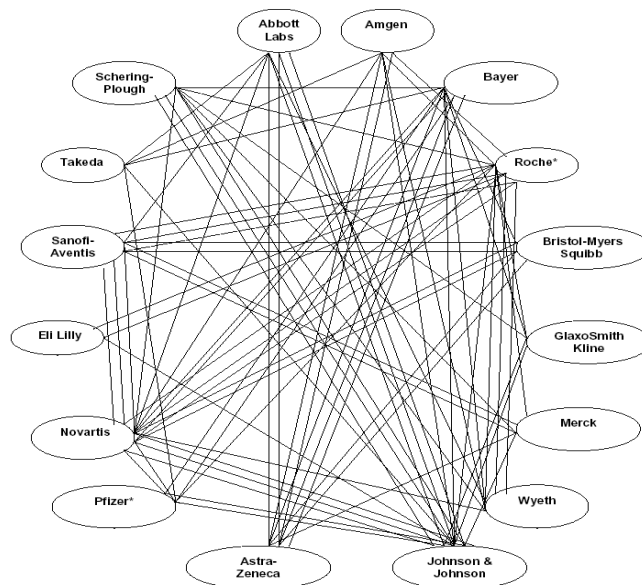
Drug Sales as a Share of Total Market, 2007



Sources: Cowen and Co. (Investext), Takeda and Bayer corporate websites

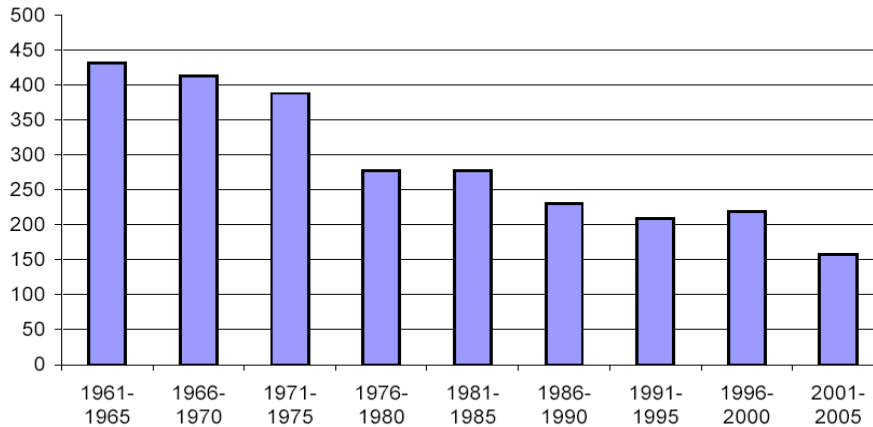
On-going cooperation agreements between Big Pharma Companies (May 2008)

Source: Bioscan



Innovation crisis

**Global Introductions of New Chemical Entities
1961-2005**



Sources:

1961-1985: Erika Reis-Arndt (1987) cited in Redwood (1987)

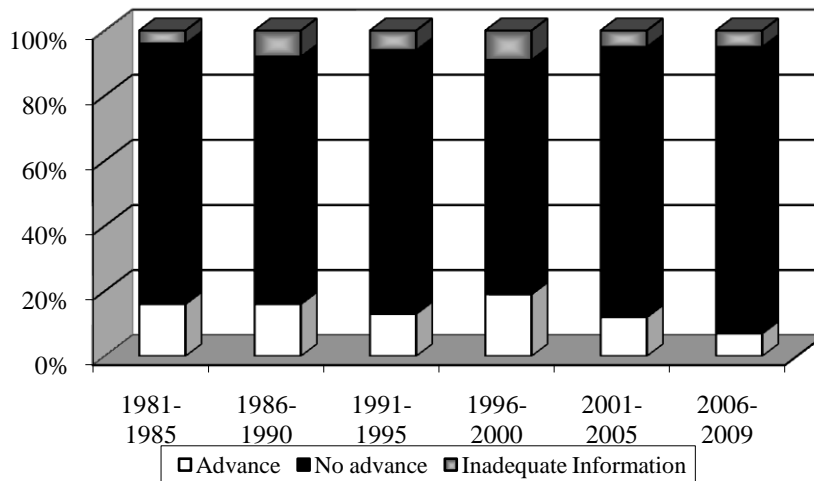
1986-2003: IMS Lifecycle New Product Focus Database cited in Grabowski and Wang (2006)

2004-2005: IMS Lifecycle New Product Focus Database cited in IMS Health Canada (2006).

What about quality? First-in-class or me-too drugs?

Percentage of New Drugs Representing a Therapeutic Advance in the French Pharmacopoeia, 1981-2009

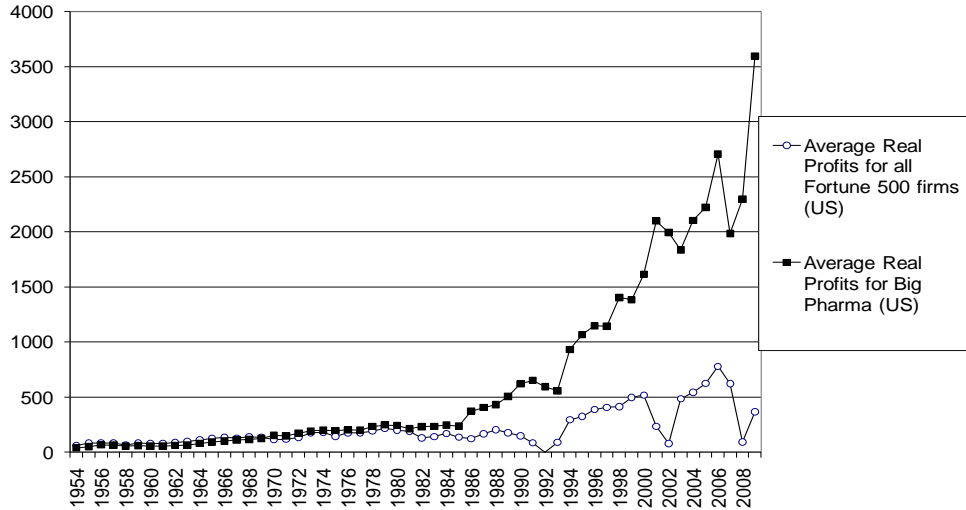
Sources: *Prescrire* (#213 p.59; #224 p.56, #280 p.142; #304 p.139; #316, p.139).



According to the independent medical journal *Prescrire*: In 2009, 104 new drugs were introduced in France; 3 were considered a (minor) therapeutic advance; 95 did not bring anything new to the existing pharmacopoeia; 19 were harshly criticized by doctors since they represented potential danger to health. For the first time, *Prescrire* talks in terms of regression, instead of improvement of the pharmacopoeia.

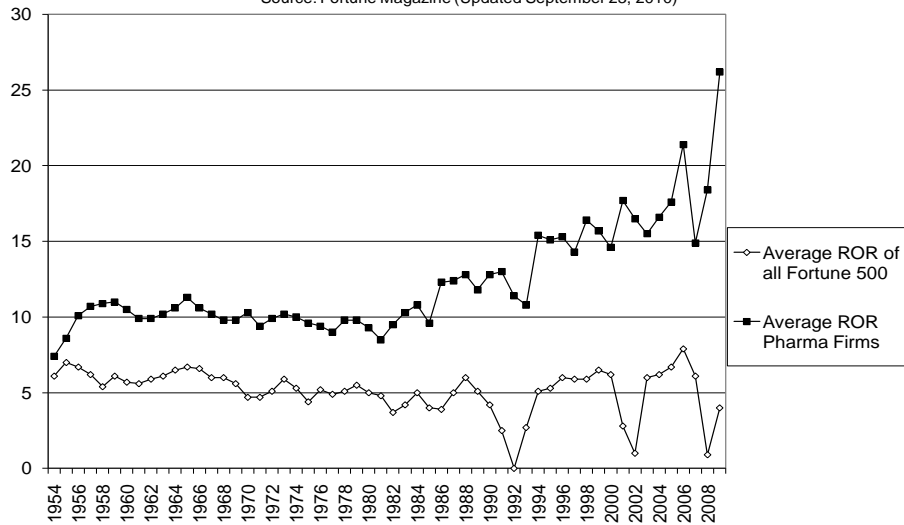
Differential Accumulation for US dominant pharmaceutical companies as compared to all Fortune 500 firms (Evolution of profits in constant 1984 US\$; 1954-2009)

(Updated September 23, 2010)



Differential Returns on Revenues (ROR, Profit per unit) Between Big Pharma and Fortune 500, 1954-2009

Source: Fortune Magazine (Updated September 23, 2010)



High pricing of Patented Drugs as Innovation policy:

Patented Medicine Price Review Board

- “External Benchmarking”: Patented drug prices are capped based on median prices of 7 countries: Switzerland, United States, Sweden, Germany, France, United Kingdom and Italy.
- Countries with important ratio of Pharma R&D expenditures as compared to sales: By providing the same price, maybe Canada will enjoy the same R&D outcomes? In response, to generous patent and pricing policies, the Pharmaceutical Industry agreed in 1987 to spend 10% of their sales in R&D.
- Since United States, Germany, Sweden and Switzerland are the countries with the most expensive patented drugs, Canada always aims at being the world’s fourth most expensive country.

Comparing Canada with comparable countries used, or not, as reference countries by PMPRB

Sources : PMPRB 2006; PMPRB 2009; EFPIA 2009; Medicines Australia

	Countries	Average foreign prices for patented medicines as compared to Canada, 2005 (Market exchange rates)	« R&D expenditures on sales at ex-factory price » ratio, 2006-2007
	Canada	100%	8.1%
Comparable countries used by PMPRB	United States	169%	19.4%
	Switzerland	109%	105%
	Sweden	97%	30.7%
	Germany	96%	22.1%
	United Kingdom	90%	39.8%
	France	85%	16.4%
	Italy	75%	6.8%
Comparable countries not used by PMPRB	Finland	88%	12.9%
	Netherlands	85%	10.9%
	New-Zealand	79%	n.d.
	Austria	78%	15.8%
	Australia	78%	10.9%*
	Spain	73%	6.7%

*: Data for 2005-2006.

Artificially inflated prices of patented drugs

- If Canada chooses to use all 13 countries as comparators to cap prices, ex-factory prices of patented drugs would be reduced by 15% (savings of \$1.95 bn).
- Total Business Expenditures in R&D in the Canadian pharmaceutical sector is \$1.3 bn. Tax subsidies for R&D accounts for 59% of that total. Net business expenditures in R&D was thus \$533 M.
- Canadians accept to pay \$1.95 bn more for brand name drugs, as compared to using all 13 comparators, and in return they obtain \$533 M in R&D expenditures.

What about the engagement of respecting the 10% R&D to sales ratio?

- This ratio has not been respected since 2001. It is now 7.5% and is still decreasing (Merck and Pfizer recently announced important slashing in R&D).
- Drug companies claim that this engagement does not have to be respected anymore:

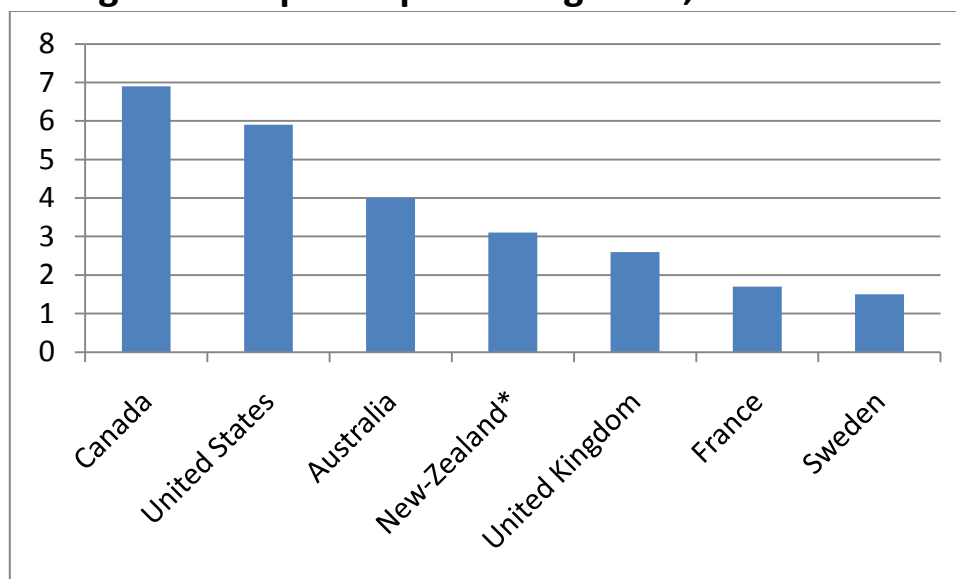
«Le 10%, on fait tout ce qu'on peut pour y arriver. Mais ce que je vous dis, c'est qu'à l'époque, il y avait des règles d'accès aux médicaments. Ces règles-là ne sont plus les mêmes. Donc ça se joue des deux côtés. Il faut regarder l'ensemble», a répondu M. Lévesque, qui ne considère pas que cet engagement était ferme de toute façon.

«Ce n'est pas un engagement dur, c'était une aspiration à atteindre (aspirational)».

- Paul Lévesque, Président de Pfizer Canada, cité dans La Presse, 8 décembre 2010

Incapacity to Contain Drug Costs in Canada

Real annual growth in prescription drug costs, from 2001 to 2007 (%)



*: Average based on available data from 2004 to 2007.

Sources : OECD Health Data 2009; OECD Main Economic Indicators; NHS Information Centre 2009

Potential Impact of the European Position for CETA on the Canadian Pharmaceutical Sector

(based on Hollis and Grootendorst 2011)

If Canada accepts the European position, CETA will have no impact on European Pharmaceutical Policy, but will have major impact on Canadian Pharmaceutical Policy:

- Extended Patent Term: up to 5 years patent extension to recoup time for marketing approval, + 6 months if paediatric clinical trials.
- Data Exclusivity: from 8 to 10 years, including for non-innovative drugs, which will provide more financial incentive to develop me-too drugs.
- Patent Linkages and Right of Appeal: applies only to Canada; will delay by 6 to 18 months the entry of Generics.

Based on the analysis of 15 drugs for which the first generic NOC was granted in 2010, we can estimate that the additional delay before the introduction of generics would be 1264 days, or 3.46 years. Using the most conservative assumptions it can be estimated that **the new regulations would induce an additional yearly cost of \$2.8 bn.**

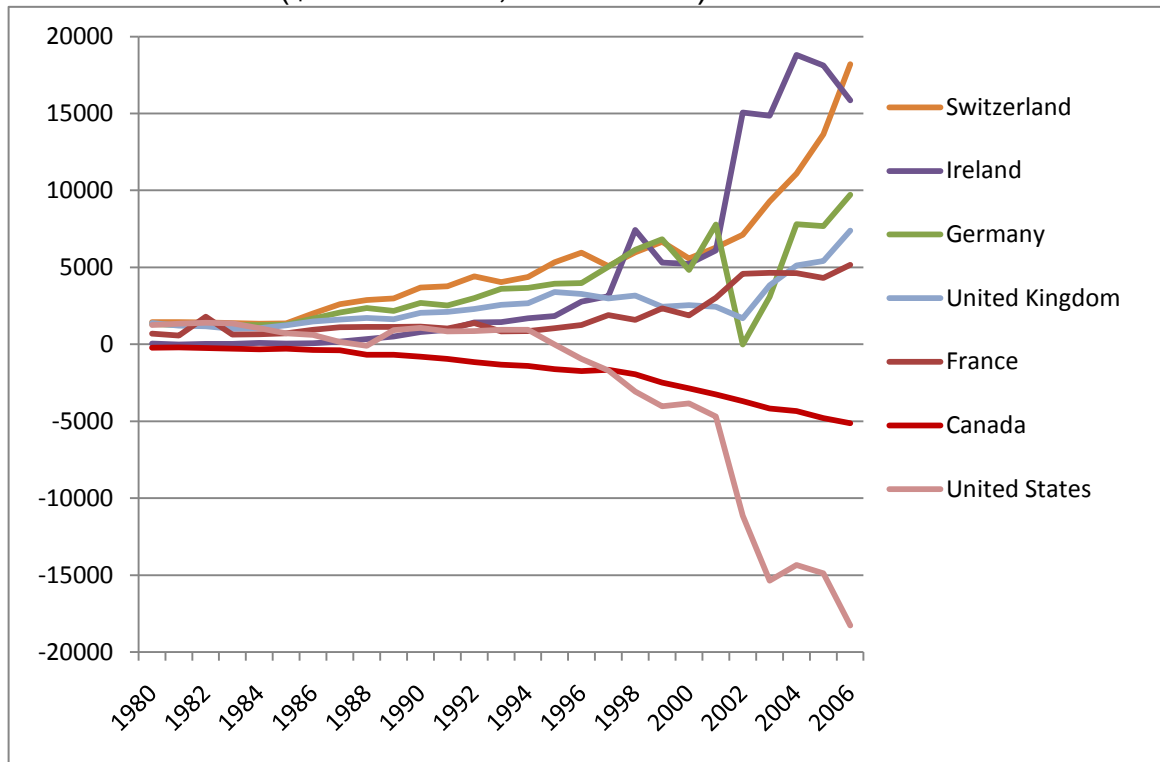
Assuming that the pharmaceutical companies would continue to devote 7.5% of their sales to R&D, **total incremental R&D would be \$345 M** (without taking into account tax subsidy).

Increased costs might be compensated by provinces by reducing access to new drugs. The problem is that with the arrival of biologics and expensive cancer drugs, improving access should be a priority.

But maybe it's time to start looking at what's being done in the United States. Due to the lack of new drugs produced by private pharmaceutical companies, which spend twice as much on promotion as on R&D, the Obama administration announced in January 2011 that it is creating a Government research center to develop medicines. The idea is to have a major research lab that's not organized as a promotional campaign to increase sales, like most major drug companies have. Paying directly for public pharmaceutical R&D might still be the best way to produce innovative drugs while reducing the cost burden for all Canadians.

Trade Balance in Pharmaceuticals for Canada, United States and selected countries of the European Union

(\$US Millions; 1980-2006) Source: OECD Health Data



Major European countries have a positive trade balance in pharmaceuticals, while Canada and the United States have a trade deficit. Note that in 2001, the production of pharmaceuticals massively moved to Ireland because of major tax incentives in this country.

While the United States is the world's first producer of pharmaceutical products, they also have the most expensive prices, which is causing their trade deficit (drugs are bought at a high price in the United States and sold at a low price abroad). Canada is the world's third most expensive country for patented drugs. These drugs are usually 15% to 20% cheaper in Europe. In 2009, Canada imported \$5.3 bn in pharmaceutical products from the EU and exported \$1.3 bn to the EU. The trade deficit with Europe is 4\$ bn

Any increase in patent protection, artificially increasing the cost of patented drugs in Canada, will further increase the Canadian trade deficit.

Many European countries have relatively lower prices and better access to medicines thanks to universal coverage. They also are the most successful producers and exporters, and they have a more important R&D to sales ratio. Extending patent protection based on the European demands will not allow Canada to achieve the same results. It will increase costs and reduce access, and existing evidences show that it is unlikely that it will reduce the trade deficit and increase its R&D-to-sales ratio over 7.5%.

BIBLIOGRAPHY

- Canadian Generic Pharmaceutical Association (CGPA). *The Real Story behind Big Pharma's R&D spending in Canada*. Montréal: CGPA, 2008.
- Canadian Institute for Health Information. *Dépenses en médicaments au Canada, de 1985 à 2009*. Ottawa : ICIS, 2010.
- COWEN and Co. *Therapeutic Categories Outlook*. March 2008.
- EFPIA. *The Pharmaceutical Industry in Figures; 2009 Update*. Bruxelles: EFPIA, 2009.
- Gagnon, Marc-André. *The Economic Case for Universal Pharmacare*. Canadian Centre for Policy Alternatives. 2010. (available at pharmacarenow.ca)
- Gagnon, Marc-André. *The Nature of Capital in the Knowledge-Based Economy; The Case of the Global Pharmaceutical Industry*. Doctoral Dissertation in Political Science: York University. May 2009.
- Gagnon, Marc-André and Joel Lexchin, "The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States", *PLoS Medicine*, vol. 5, #1, January 2008: pp.1-6.
- GROOTENDORST, P. and A. HOLLIS. *The Canada-European Union Comprehensive Economic Trade Agreement; An Economic Impact Assessment of Proposed Pharmaceutical Intellectual Property Provisions*. Report for CGPA. February 2011.
- S. Morgan, M.-A. Gagnon, M. Law, C. Cunningham et J. Kohler. *Pharmaceutical industry employment in Canada: Levels, trends, and issues for consideration*. Pharmaceutical Policy Research Collaboration. 2010. (available at www.pharmaceuticalpolicy.ca)
- Morgan, Steve, Colette Raymond, Dawn Mooney et Daniel Martin. *The Canadian Rx Atlas* (2nd edition). Vancouver: Centre for Health Services and Policy Research, 2008.
- OCDE. *Pharmaceutical Pricing Policies in a Global Market*. Paris: OCDE, 2008.
- Paris, Valérie et Élisabeth Docteur. *Pharmaceutical Pricing and Reimbursement Policies in Canada*. OCDE Working Paper. Paris: OCDE, 2006.
- PMPRB. *Rapport du CEPMB sur les prix des médicaments non brevetés distribués sous ordonnance : Tendances des prix pratiqués au Canada et dans les pays de comparaison*. Ottawa : CEPMB, 2006.
- PMPRB. *Rapport annuel 2009*. Ottawa : CEPMB, 2010.
- Prescrire. "L'année 2009 du médicament: Trop peu de progrès pour soigner et trop de régressions". *Prescrire* 30 #316 (February 2010): 136-142.
- PriceWaterhouseCoopers. *Les entreprises de RX&D; Pour une économie canadienne plus saine et plus forte*. PWC, 2005.
- Silversides, Ann. « Ontario's law curbing the cost of generic drugs spark changes ». *CMAJ*. 181 (3-4), August 4 2009a: E43-E45.
- Statistics Canada. *Survey of Intellectual Property Commercialization in the Higher Education Sector, 2006 and 2005*. October 2008.
- Statistics Canada. *Estimates of Total Spending on Research and Development in the Health Field in Canada, 1997 to 2008*. Ottawa: Minister of Industry, March 2009.