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Globalization, trade deals and drugs:

Heads the industry wins, tails Canada loses

By Joel Lexchin, M.D.

The recent panic over a possible terrorist attack with anthrax has brought the issue of drug patents and trade agreements to public attention in a dramatic way. As Health Canada scrambled to assemble a stock of the antibiotic ciprofloxacin in case of an emergency it became clear that past actions of the Canadian government have come home to haunt it. At one point it looked like the government would have to violate its own patent law in order to ensure that it could get an adequate amount of ciprofloxacin. The law that it was willing to break was one that it had passed as a condition of the North American Free Trade Agreement (NAFTA) and the Trade Related aspects of Intellectual Property Rights (TRIPS) agreement and one that it affirmed after a review in 1997.

This paper explores the relationship between trade agreements and drug patents in Canada and then goes on to show how trade agreements in specific and globalization in general have impacted on pharmaceutical issues.

Introduction

For the past couple of decades one of the buzz words throughout the world has been globalization. Globalization "is not just some economic fad, and some passing trend. Today, it is an overarching international system, with its own rules and logic, shaping the domestic politics and foreign relations of virtually every country."[1] Globalization has gone hand-in-hand with trade liberalization and right in the middle has been the pharmaceutical industry.

In the international arena the media have been full of stories connecting the industry with trade agreements: the suit against the South African government launched by 39 multinational pharmaceutical companies over intellectual property provisions in that country's laws that were alleged to have violated trade agreements; the restrictions on importing and using generic drugs in developing countries that kept prices for HIV/AIDS drugs at the same level as those in North America. Here in Canada, there have been intense debates since the mid1980s over Canadian patent laws as they apply to pharmaceuticals and their impact on drug prices.

In fact, the pharmaceutical industry has been leading the drive for more stringent intellectual property rights and pushing the trade agenda of countries like the United States. As Table 1 shows, and as will be discussed below, in Canada all three—the pharmaceutical industry, intellectual property rights and trade agreements—have been intimately linked.

During the 1960s a series of three reports all pointed out that drug prices in Canada were among the highest in the world and all three reports identified patent protection as one of the major reasons for this situation.[2 3 4] The decision of the Liberal government was to extend compulsory licensing and allow companies to receive a license to import a drug into Canada. A compulsory license is essentially a permit which effectively negates a patent. Theoretically, the company owning the patent on a drug would be a monopoly seller until the patent expired. However, if other companies apply for, and are granted, a compulsory license against a drug, they can

Table 1: Trade Agreements and Changes to Canadian Patent Law

Trade Agreement	Date entered into force	Parties	Accompanying change in Canadian patent law	Date law took effect	Main features
Free Trade Agreement (FTA)	1987	Canada, United States	Bill C-22	1987	New drugs exempt from compulsory licensing for 7 years; exemption extended to 10 years if active ingredient manufactured in Canada
North American Free Trade Agreement (NAFTA)	1994	Canada, United States, Mexico	Bill C-91	1993	Compulsory licensing abolished (retroactive to Dec. 1991); patent life changed from 17 years from date patent granted to 20 years from date patent filed for (retroactive to Oct. 1, 1989)
Trade Related aspects of Intellectual Property Rights (TRIPS)*	1995	Worldwide			

*TRIPS was part of the package that created the World Trade Organization (WTO). There are four other agreements within the WTO that impact on health: General Agreement on Tariffs and Trade (GATT), General Agreement on Trade in Services (GATS), Agreement on Technical Barriers to Trade (TBT) and agreement on the application of Sanitary and PhytoSanitary measures (SPS).

then market their own version of that drug before the patent has expired. The compulsory aspect means that the company owning the patent cannot block the license from being granted.

For obvious reasons compulsory licensing was vigorously opposed by the multinational pharmaceutical industry, but without any important allies, either within the country or externally that opposition never produced any results. Starting in the early 1980s that situation changed significantly. At that time the United States had a large trade imbalance. One of the factors that was seized on as a significant contributor to this problem was lost sales due to "piracy" in the entertainment and pharmaceutical industries. Piracy here means that countries with "weak" intellectual property rights were copying American goods and selling them at prices that undercut those being offered by American companies.

In 1981 U.S. President Ronald Reagan appointed Ed Pratt to head the United States' top private sector trade advisory panel. Pratt was also president of Pfizer Inc., an American multinational drug company, and with his help the issue of intellectual property rights and patent protection for pharmaceuticals became the top priority of the U.S. trade agenda.[5]

As a result, Canadian policies around patent protection and compulsory licensing became a major issue in U.S.-Canada relations. When Reagan met with Prime Minister Brian Mulroney at the "Shamrock Summit" in Quebec City in March 1985 one of the key items discussed was drug patents. In October of that year the annual report of the U.S. Trade Representative on trade irritants with U.S. trade partners listed Canada's drug legislation as one of the irritants. The chief U.S. Trade Representative Clayton Yeutter rebuked the Con-

servatives for failing to make the long awaited changes in Canada's drug patent laws. George Bush, U.S. vice-president at the time, publicly complained about the delay in the changes when he visited Ottawa in June 1986.[6]

At the same time that patent protection moved to the fore of U.S. interests, the Conservatives fixated on a policy of free trade with the U.S. The Conservatives continually and vigorously denied that there was any connection between the free trade agreement and changes in compulsory licensing,[7] [8] but the facts make their denials hard to credit. Bill Merkin, the U.S. deputy chief negotiator in the free trade talks, said: "Ottawa didn't want it [intellectual property] to be in the free trade negotiations. They didn't want to *appear* to be negotiating that away as part of the free trade agreement. Whatever changes they were going to make, they wanted them to be *viewed* as, quote, 'in Canada's interest.' . . . It was a high priority issue for us. We were not above flagging the importance of resolving the issue [to the Canadian negotiators] for the success of the overall negotiations" (Emphasis in original).

The Americans gave conclusive evidence of the linkage between the two issues the day after the successful conclusion of the Free Trade Agreement (FTA). A U.S. summary of the agreement said the accord contained a clause "to make progress toward establishing adequate and effective protection of pharmaceuticals in Canada by liberalizing compulsory licensing provisions."[9] It was only after Conservative politicians demanded the removal of that section that it was dropped from the final text of the agreement.

In return for free trade with the Americans the Conservatives produced Bill C-22 and eventually passed it in December 1987. The essence of the bill was that it gave companies introducing new drugs a minimum of seven years of protection from compulsory licensing. One senior official in the U.S. Administration said that "We want better than that [bill] in a free-trade agreement," while to another senior official it was "barely acceptable." The U.S. Pharmaceutical Manufacturers Association (PMA) was willing to support the bill, but said that the U.S. industry "would like to see a similar level of protection as in Western Europe and the U.S. . . . Canada's out of synch."[10]

Canadian patent laws changed once again in the early 1990s. This time the fight was over Bill C-91 which abolished compulsory licensing and gave the multinational companies 20 years of patent protection for their products. In this case instead of the FTA it was the Canadian eagerness to sign the NAFTA and GATT agreement that coincided with the interests of the drug industry. Although there is an argument that compulsory licensing would have been theoretically possible under these agreements[11] the Canadian government used them as the grounds for completely eliminating compulsory licensing.

Ed Pratt, the Pfizer chairman, systematically went about putting intellectual property rights onto the GATT agenda. He first formed alliances with the U.S. motion picture and computer industries and helped form the "Intellectual Property Rights Committee" (IPC) which consisted of 13 major U.S. corporations. Then with the encouragement of Clayton Yeutter, Pratt sought allies in Europe and Japan and eventually won over the two major umbrella industrial organizations—UNICE (the Union of Industries of the European Community) in Europe and Keidanren in Japan.[12] What made the GATT and NAFTA ideal candidates for enforcement from the IPC's point of view was their jurisdiction over trade. Implicit in the choice of enforcement through the GATT is the threat of "cross retaliation", that is, the withdrawal of market access for exports of goods from countries that did not enforce a standard of intellectual property rights sought by the IPC.

Having laid out the background behind the Canadian experience with trade agreements, intellectual property rights and pharmaceuticals the next part of this paper will

examine the effects that these changes have had in four areas:

- prescription costs and overall spending on drugs,
- the prospects for a national pharmacare program,
- Canada's reaction to problems in the developing world
- the economic consequences for Canada.

Trade agreements are only one aspect of globalization. Another defining characteristic is the desire to be "globally competitive." This ambition is not just confined to the private sector but also extends to services offered by the public sector, in this case the Therapeutic Products Directorate (TPD), the agency charged with managing Canada's drug approval process. This push has lead to significant changes in the TPD and an analysis of those changes will be the subject of the penultimate section of this paper.

Finally, I will conclude by looking at ongoing issues and what is likely to happen over the next several years.

Prescription costs and overall spending on drugs

The Patented Medicine Prices Review Board (PMPRB) was established in the wake of Bill C-22 to protect consumer interests with powers to limit the introductory prices for new patented drugs and prevent prices for existing patented drugs from rising by more than the rate of inflation. Within this context the PMPRB has been a success. Its 2000 report demonstrates that between 1988 to 2000 the rate of inflation for the price of patented medications has risen by just 0.8% per year; when Canadian prices are compared to the average of those in seven other countries (France, Germany, Italy, Sweden, Switzerland, the United Kingdom, United States) the ratio has dropped from 1.23 in 1987 to just 0.92 in 2000.[13] However, these figures hide a basic failure in the ability of the PMPRB to protect consumers from high prices when it comes to the price they pay for a prescription.

The average price per prescription (excluding the dispensing fee) in Ontario has gone from $24.58 in 1993 to $27.74 in 1997, an annual rise of 3.1% compared to an increase in the Consumers Price Index of 1.4%. Over half of the rise in prescription costs is due to the introduction of new drugs, specifically new (since 1987) patented medications. Prices for prescriptions containing new patented medications rose at a rate of 20.9% per annum between 1993-97 compared to 6.6% for prices for prescriptions of existing patented drugs (patented prior to 1987) and 4.1% for unpatented drugs.[14] (See Table 2) Physicians have been substituting these newer, more expensive drugs for older, less costly ones leading to the rise in the cost of the average prescrip-

Table 2: Increase in Prescription Prices 1993-1997*

Year	Cost per prescription ($)		
	New patented drugs	Existing patented drugs	Unpatented drugs
1993	36.03	49.43	17.12
1994	39.98	52.45	17.94
1995	46.76	56.83	18.28
1996	61.18	59.15	18.83
1997	76.88	63.70	20.10
Average annual increase 1993-1997	20.9%	6.6%	4.1%

*Includes manufacturer and wholesale distribution costs; excludes dispensing fee.
Source: Green Shield Canada

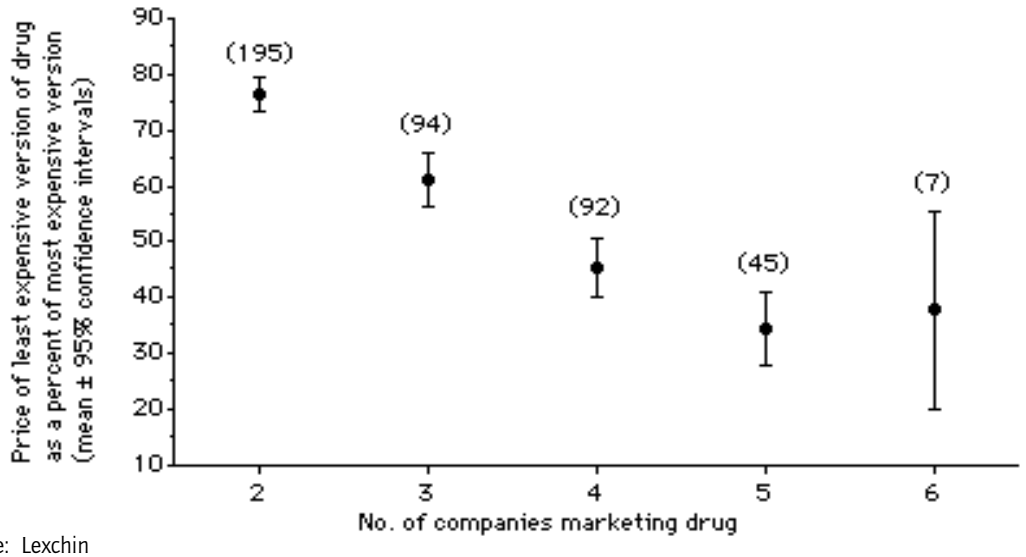
tion, despite the absence of any good evidence that the vast majority of these new medications have any significant therapeutic advantages.[15] For evidence of this increasing use of newer, more expensive drugs consider that between 1995 and 2000 sales of patented drugs as a proportion of total sales went from 43.9% to 63.0%.

The prescribing of newer more expensive drugs in place of older, less expensive, but not necessarily less effective, ones was not something that started in 1987. The practice was well entrenched when Canada had compulsory licensing. What is different is that after Bill C-91, the prolonged delay in the introduction of generic competitors for these new patented medications. Prior to 1987 generics were coming on the market within five to seven years after the appearance of the originator product. The first generic would typically be priced about 25% lower than the brand name product and when there were three or four generics then the price differential would be 50%.[16] (Figure 1) In the absence of compulsory licensing the originator product typically is in a monopoly situation for about 12-13 years. (The first 7 to 8 years of patent life are used up in clinical trials and the drug approval process.) Not only has Bill C-91 delayed the entry of generic products by about seven years but also by the time they appear sales of the brand name drug are usually starting to decline and therefore savings that result from the substitution of generic for brand name products is less.

This delay in the entry of generics has contributed to the continual climb in overall spending on drugs. Between 1975 and 1987, drugs went from taking up 9.0% of the total health care dollar to 10.1% for a change of 0.09% annually; in comparison the change between 1988 and 1996 was from 10.5% to 12.5% for a rise of 0.25% per year.[17] Per capita spending on drugs has also seen dramatic increases since the 1988 going from $138 to almost $370 in 2000, a rise of over 150%.

It seems an inescapable conclusion that the interests of Canadian consumers in getting prescriptions at a reasonable price and controlling drug spending have been sacrificed for the sake of trade agreements.

Figure 1: Relationship between number of companies marketing a drug and price spread between the least and most expensive versions of a drug
(number of drug preparations in brackets)



Source: Lexchin

The prospects for a national pharmacare program

Drug costs now account for over 15% of total health care spending. The percent growth in drug spending between 1985 and 1998 was more than twice as high as for overall health expenditure.[18] Controlling drug expenditures will be a multistep process involving ensuring rational prescribing but a key feature in any system will need to be a national public pharmacare program. The current mix of public and private drug coverage leaves about 12% of Canadians without any coverage at all and many people undercovered. For instance, the average family in British Columbia has to spend $600 out-of-pocket every year before seeing any benefits from the provincial drug plan; seniors in Saskatchewan with an average drug consumption pattern have to pay $450 out-of-pocket per year compared to just $40 in Ontario. Lexchin has calculated that a first-dollar coverage public plan could cut overall prescription drug costs by over $650 million per year while providing coverage to the entire population.[19]

Existing trade agreements may make a national public pharmacare plan impossible. Chapter 11 of NAFTA deals explicitly with investment (rather than trade) and most importantly includes a mechanism for dealing with "investor-state" disputes. These are disputes between corporations and governments and foreign corporations are allowed to sue governments directly whenever they think their "rights" have been violated by a particular government measure. Key to the investor-state provision is NAFTA's extremely broad definition of "expropriation."[20] Therefore, there is a distinct possibility that if foreign companies, such as Liberty Mutual, that sell drug insurance in Canada are no longer allowed to do so they could sue the Canadian government. Canada has already lost a NAFTA challenge launched after it tried to bar the use of the toxic gasoline additive MMT.[21]

Faced with the prospects of being sued the government may decide to opt for a mixed private-public plan or no extension to what already exists. While a private-public plan would increase coverage it is distinctly inferior to an all public plan, in terms of the potential for cost control.

The GATS agreement also has provisions that might deter the government from going ahead with pharmacare. In his book on Canada and GATS, Sanger points out that under the financial services subsector of the GATS agreement the government has committed to, among other things, expanding market access for private health insurance and treating foreign insurance companies the same as domestically owned ones. Moreover, Sanger notes, negotiators "bound" Canada's commitments in this sector, meaning all future government measures affecting health insurance services must be GATS-consistent. Health services, such as the cost of hospitalization and doctors' services, which were fully publicly provided in 1994 (the year that health services were first listed in Canada's GATS schedule) would probably be protected from any challenges. Insurance for all other health services—i.e., those covered only or partially by commercial health insurance in 1994—such as drug insurance, would be considered included in the listing for health insurance in Canada's schedule. Sanger believes that any move to extend Medicare to cover drugs could conceivably face a GATS challenge on the grounds that the expansion of Medicare is an extension of the public health insurance monopoly to a service covered by Canada's specific commitments . Although GATS does not allow private corporations to sue the government, Canada could be forced to compensate WTO members before implementing any expansion.

Whether or not NAFTA and GATS could actually stop a pharmacare plan is unknown, but the theoretical possibility might be enough to stop federal or provincial govern-

ments from even trying to bring forth such a measure.

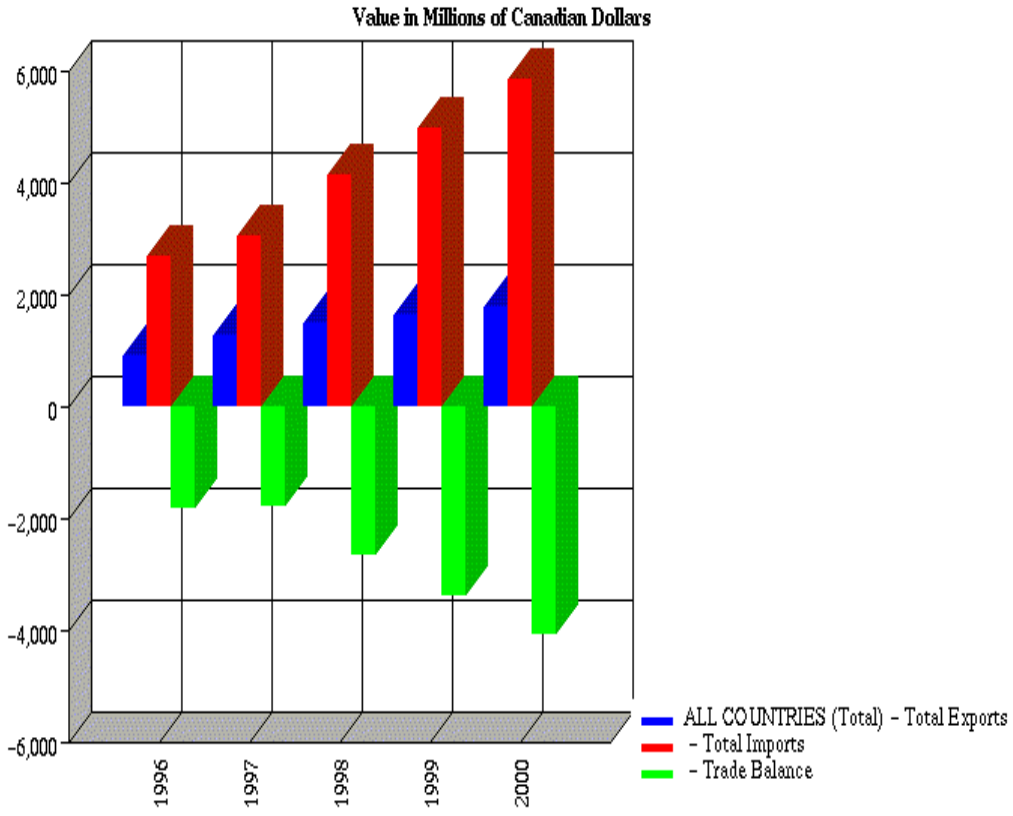
Canada and the developing world

Having signed and ratified the International Covenant on Economic, Social and Cultural Rights, Canada has committed itself to recognizing "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health." According to the United Nations Committee on Economic, Social and Cultural Rights the Covenant means that the obligations of states are extended to their international relations in addition to their domestic policies: "States parties should ensure that the right to health is given due attention in international agreements. . ."

When it comes to access to HIV/AIDS drugs in developing countries Canada is violating its international commitments. Until very recently multinational drug companies were selling their HIV/AIDS drugs in Sub-Saharan Africa for virtually the same price as they charged in North America. The cost of "triple therapy" was about US $12,000 per year in countries were the entire expenditure on health was $5-$10 per year. Companies from India, where TRIPS will not come into force until 2005, are able to make generic AIDS "cocktails" and sell them for just US $350 per year but the multinationals used their monopoly patent rights, rights that were enforced under TRIPS, to stop countries from importing these low cost generic products.

In the face of this situation, in June 2001, Canada, along with the United States backed away from an European initiative to give poor countries better access to inexpensive AIDS drugs. A spokesman for Pierre Pettigrew, Min-

Figure 2: Trade deficit in pharmaceuticals 1996-2000



Source: Trade Data Online

ister for International Trade, justified the Canadian position with the claim that "the TRIPS agreement at this time provides sufficient flexibility in the AIDS crisis."[22]

Time has not softened the Canadian position. On September 19, the WTO TRIPS Council held its second Special Discussion on TRIPS and access to medicines. At that meeting a group of developing countries put forth a draft text for a Ministerial Declaration on TRIPS and Public Health, which the developing countries want to see endorsed by ministers at the forthcoming Doha Ministerial Conference in November 2001. Among other things included in the draft was a statement that "nothing in the TRIPS Agreement shall prevent Members from taking measures to protect public health." The developing country paper would also have the WTO Members agree to "refrain from imposing or threatening to impose sanctions or ... granting incentives or other benefits ... which could curtail the ability of developing and least-developed country Members to avail themselves of every possible policy option to protect and promote public health."

A coalition, lead by the United States and Switzerland, with the backing of a number of other countries including Canada countered with its own paper that implicitly rejected the developing countries' call for a separate Ministerial Declaration on TRIPS and public health, and sought to restrict the discussion and/or any declaration to only medicines for pandemics such as HIV/AIDS.[23] In supporting the U.S. position, the Canadian government is clearly putting its commitment to trade agreements ahead of its commitment to health in the developing world.

Economic consequences

1. Trade

From 1983 to 1987 the Canadian deficit in the trade of pharmaceuticals grew from $366 million to $491 million. After Canada became a party to the Free Trade Agreement in 1987 the trade deficit went from $624 million to $1464 million in 1993. By 1996, Canada had the second largest trade deficit out of the 29 countries in the Organization for Economic Cooperation and Development[24] and since NAFTA (1994) and GATS (1995) the deficit has gone from $1612 million in 1994 to $4059 million in 2000.[25] [26] Figure 2 gives a dramatic presentation of what has happened to the trade deficit in the last five years.

Dramatic as these figures are, they do not give a true picture of how much Canada has come to depend on imports to supply our pharmaceutical needs. Table 3 shows the import penetration of the Canadian domestic market for the three time periods 1983-87, 1988-1993, 1994-2000. Most imports are fine chemicals that form the active ingredients in the medications that we use. Therefore, coincident with the implementation of the trade agreements and the change in the Canadian

Table 3: Import Penetration of Domestic Market

Year	Imports as a percent of domestic market	Percent annual change
1983	18.0	0.55
1987	20.2	
1988	23.9	2.1
1993	34.4	
1994	39.2	6.1
2000	75.5	

Calculated from data in Industry Canada and Trade Data Online.

patent laws, there has been a failure to develop a fine chemical industry and pharmaceutical manufacturing has taken on more of an assembly line nature whereby ingredients are combined into their final form.

2. Employment

Increases in employment are often cited by the multinational industry as one benefit of liberalizing the Canadian patent laws. According to figures in the latest publication from Canada's Research-Based Pharmaceutical Companies, Rx&D, the multinational association, employment by member companies went from 14,521 in 1987 to 20,990 in 1999.[27] However, in this regard, the multinational subsidiaries are not doing any better than the generic industry. Up-to-date figures for the generic industry are not available but from 1990-1995, employment in this sector rose from 1531 to 3631 for an annual increase of just over 27%.[28] In the same time period, the number of people employed in the multinational sector went up by 1971, [29] less than the increase for the generic companies and on an annual basis the rate of rise in employment was just 2.5%.

3. Spending on research and development

As with employment figures, the multinational sector uses changes in research and development (R&D) spending to trumpet the value of longer patent life. The graph in the 2000-2001 annual report from Rx&D shows that in 1987 only $106 million was being spent in this area compared to $944 million by 1999. While this growth does seem impressive it also hides the fact that in recent years spending on R&D as a percent of total sales has been declining. R&D to sales for Rx&D member companies hit a peak of 12.9% in 1997 but had fallen off to 10.6% in 2000.

While there have been some positive economic changes since Canada entered into the various trade agreements there have also been some decidedly negative ones. Our exports have grown but our trade deficit has grown even faster; employment is up but it is also up in the generic industry and spending on R&D, relative to total sales, is on the decline after climbing for the first decade after Bill C-22 and the Free Trade Agreement.

The Canadian regulatory environment

Drug regulatory agencies around the world are all striving to be "globally competitive" in order to attract pharmaceutical investment into their countries. Globally competitive translates into rapid approval of drugs and Canada's actions are entirely compatible with that objective. In January 2000, the Therapeutic Products Directorate (then the Therapeutic Products Programme), the branch of Health Canada that approves new drugs, floated a proposal that would have seen Phase I human investigational drug trials (trials on healthy people) approved in as little as 48 hours. (The final decision was to have a 30 day review period.) Dann Michols, director of the TPP said that the changes would make Canada more competitive in the global market for drug research[30] a point repeated in the regulatory impact statement that accompanied the proposed changes.[31]

For similar competitive reasons Canada has also been taking part in the International Conference on Harmonization (ICH). The ICH is a process that has been underway since 1990 to harmonize the regulatory requirements for drug approval in the world's major markets. The main players are the industry associations from the U.S, European Union and Japan along with the regulatory agencies in these countries. Representatives from the World Health Organization, the European Free Trade Area and Canada have "observer" status at ICH meetings. The ICH is primarily an industry driven exercise aiming to get new drugs onto the market more rapidly. This outcome could potentially be beneficial to the public by freeing up resources for innovative

Table 4: Evaluation of New Drugs in France, 1981-2000*

Category	Number of drugs	Percent of total
Major therapeutic innovation in an area where previously no treatment was available	7	0.31
Product is an important therapeutic innovation but has certain limitations	67	2.96
Product has some value but does not fundamentally change the present therapeutic situation	192	8.51
Product has minimal additional value and should not change prescribing habits except in rare circumstances	397	17.59
Product may be a new molecule but is superfluous because it does not add to the clinical possibilities offered by previous products available. In most cases it concerns a "me-too" product	1427	63.23
Product without evident benefit but with potential or real disadvantages	58	2.57
Editors postpone their judgements until better data and a more thorough evaluation of the drug is available	109	4.83
Total	2257	100

*The total corresponds to new preparations or indications presented by drug companies to French doctors. It excludes over-the-counter products and range extensions (new dose, strength, new form or presentations).
Source: Prescrire International[33]

drug discovery but thus far this does not appear to have been the case. John Abraham and Tim Reed at the University of Sussex have studied the ICH in detail and in their view within the ICH process the main knowledge flow has been from industry to regulators with industry tending to set the agenda. There has been no participation by consumer/patient organizations, academics, health care professionals or the generic drug industry. Therefore, the sources of expertise framing innovations around which kinds of tests are necessary before registering a new drug have been narrowly based. Furthermore, Abraham and Reed note that a further consequence of the lack of challenge to an industrial agenda within ICH is that the commitment to product innovation in the public interest has been weak. Industry is inclined to translate the savings in R&D resulting from reduced drug test-

ing requirements into the development of more "me-too" drugs which are not innovative at all.[32]

Besides the issue around innovation, more rapid drug approvals also raise questions of safety. La revue Prescrire, a French drug bulletin, has been evaluating new medications in France for almost 20 years and recently published a compilation of its assessments which are summarized in Table 4. Out of over 2200 drugs fewer than 75 were major innovations. There are differences between Canada and France but those differences are not significant enough to affect the numbers in any meaningful way.

Approving new drugs quickly has the potential to lead to serious safety issues. The proposed new "expedited" system would have offloaded the responsibility for basic scientific review of phase I trials from the TPD, the agency charged with and funded by the public purse to regulate the industry, to the volunteer Research Ethics Boards at the university level. This move would have been an inappropriate delegation of function. There were serious questions about whether or not the Research Ethics Boards in Canadian hospitals had the expertise and resources to be able to approve and monitor the volume of trials that would have resulted from such a change.

The General Accounting Office in the United States conducted a study on postapproval risks for drugs approved by the FDA between 1976-85. Out of 198 drugs for which data were available, 102 had serious postapproval risks that could lead to hospitalization, increases in the length of hospitalization, severe or permanent disability or death. Among drugs approved in fewer than four years, those that had serious postapproval risks had generally been approved in a shorter time than those without such risks.[34] According to a survey of FDA reviewers conducted in the fall of 1998, 12 reviewers identified 25 new drugs in the previous three years that they felt had been approved too quickly.[35]

When regulatory agencies become globally competitive the multinational pharmaceutical industry benefits but the benefits to anyone else are hard to find.

The present

The impact of the TRIPS agreement is still being felt in Canada. Two separate challenges were launched against Canada in the WTO in recent years. The European Union complained about a provision in the Canadian patent law that allowed generic drug companies to begin testing, manufacturing and stockpiling drugs for sale before patents expired. When Canada changed from a 17 to a 20 year patent term for drugs approved after Oct. 1, 1989, the change was not made retroactive. The United States charged that there a group of about 30 drugs which were patented before Oct. 1989 should receive an additional 3 years of patent life. (The complaint by the U.S. did not just cover drugs but patents on all products that were granted before Oct. 1989 and that were still valid.)

Canada lost the case filed by the U.S.[36] and the WTO also ruled that generic companies could not stockpile drugs for sale before the patent expired.[37] As a result of these decisions, in mid 2001 Canadian patent laws were amended once more with the passage of Bill S-17. The extension of the patent term on the 30 drugs is expected to add an estimated $40 million to Canada's prescription drug costs according to the Canadian Drug Manufacturers Association the lobbying arm of the generic industry.[38] Prohibiting generic companies from stockpiling drugs until the patent expires will delay the marketing of generic products for months.

Despite the changes that Canada has made to its patent laws in the wake of the FTA, NAFTA, TRIPS and the recent WTO rulings, the multinational pharmaceutical industry is

still not satisfied with the results. In February 2000, PhRMA, the Pharmaceutical Manufacturers Association of America, recommended that the U.S. government place Canada on that country's "Special 301" Priority Watch List, a list that is used to pressure countries to modify their trade-related practices.[39] PhRMA's list of problems included Canada's failure to extend patent protection to the pre Oct. 1989 drugs and allowing generic companies to stockpile medications. PhRMA also accused Canada of violating the section of the TRIPS agreement dealing with registration data (data submitted to show that a drug is safe and effective). To gain marketing approval, generic companies typically demonstrate that their product is bioequivalent to a patented product (that is, that the generic is chemically similar and works the same in the human body) and then rely on the patented product's safety data to earn approval. In many instances, if a generic company cannot use the already-generated registration data, it will not introduce a generic version of the patented product; and if it regenerates the safety data, consumers suffer from delay in introducing the generic version.

Canada currently allows generic companies to use registration data generated by multinational companies when the generics file for the approval of their copies. Based on PhRMA's reading of Article 39.3 Canada does not offer enough protection for the registration data. PhRMA also views Canada's action in this regard as "a major negative precedent for less developed countries (LDCs)." As had been the case in the past, when it comes to Canada and drug patent issues, PhRMA found a receptive ear in the U.S. administration and in April 2001 the U.S. placed Canada on its Special 301 list citing as one reason Canada's lack of drug data protection.[40]

The future

The multinational industry is still calling for further concessions from Canada. One of the key industry goals is "patent term restoration." The multinationals want Canada to emulate the U.S., the EU and Japan and extend the length of patent protection to make up for the time that drugs spend in the regulatory approval process. The Free Trade Area for the Americas (FTAA) negotiations may be where the industry will achieve its objective. The draft of the FTAA chapter on intellectual property rights is primarily in brackets, meaning that terms have not been agreed on. This makes it impossible to say precisely what is "in" the FTAA, because a single provision may be followed by an alternative that directly contravenes it. However, among the proposals that appear in the U.S. summary FTAA proposals are ones that would grant patent term restoration and apply much more specific rules about the use of registration data.[41]

Conclusion

Globalization in general and trade agreements in particular have had a definite effect on pharmaceutical issues in Canada. In fact, the intimate involvement of the pharmaceutical industry in shaping the trade deals that Canada has been party to, ensured that there would be significant changes. While a few of those changes, such as increased research spending, could arguably be favourable to the country as a whole, the main beneficiary has been the industry itself. The cost of a prescription has risen dramatically as a result of the long delay before generic equivalents appear on the market. Provisions in NAFTA and GATS may make it economically impossible for Canada to go ahead with a pharmacare plan. Canada's commitment to the restrictive intellectual property rights clauses in the TRIPS agreement has meant that it is willing to support measures that deny people in developing countries access to essential medications at affordable prices. Since Canada entered into trade agreements our balance of trade in pharmaceuticals has plummeted and

imports now make up over 75% of the value of our pharmaceutical market. There has been some increase in employment in the multinational sector of the industry but the generic branch has grown even faster both in relative and absolute terms. Although investment in research and development increased after the FTA with the U.S., in the past few years it has slowed down relative to sales. The Therapeutic Products Directorate wants to be globally competitive in order to attract more drug company investment and as a result is willing to sacrifice safety. The erosion of Canada's ability to control its own pharmaceutical policy continues to be eroded as the recent passage of Bill S-17 in response to decisions at the WTO demonstrates. The negotiations around the FTAA may lead to even further deterioration in Canada's position vis-à-vis drug costs.

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Canadian Centre for Policy Alternatives
Suite 410-75 Albert Street, Ottawa, ON K1P 5E7
tel: 613-563-1341 fax: 613-233-1458
email: ccpa@policyalternatives.ca web site: www.policyalternatives.ca

CAW 567 OTTAWA