

Patent Act

job creation, and the continued protection of the Canadian consumer.

The proposed amendments have five principal objectives: to transform Canada's pharmaceutical sector into a world-class industry led by an unprecedented increase in investment and jobs in pharmaceutical research and development; to ensure drug prices remain reasonable throughout the creation of an independent price review board; to guarantee that the pharmaceutical industry's commitments for research and development are met; to maintain opportunities for growth in the Canadian generic industry; and finally to harmonize Canada's intellectual property laws with those of other western industrialized nations.

The protection of the consumer is an important part of this Bill. It is ensured in four different ways: a continued presence of existing generic drugs; a transitional payment to provincial drug plans; the provision for further generic competition; and the drug prices review board. This board will work in close cooperation with the provinces because of their particular interest in drug prices.

Provincial Governments will have the right to make representations directly to the board if they suspect an abuse in drug pricing. In cases of excessive prices, the board will have the authority to remove periods of protection. Not only will the board be monitoring the prices of all patented drugs, it will also have the power to review the performance of the innovative pharmaceutical industry through annual reports on research and development activities. This, together with a Cabinet review after four years and a full parliamentary review in the tenth year, will ensure that the commitments of the innovator sector to increase research and development in Canada are fulfilled.

Changes to the Patent Act to encourage investment in research and development in the pharmaceutical industry in Canada have long been sought by numerous scientific, medical, pharmacological, and research groups. The Government has received a firm commitment from the innovative drug sector to double the R and D to sales ratio from the pre-policy level. This represents a move from 4.9 per cent to 8 per cent in 1990, then to 10 per cent in 1995. That level is enjoyed by most other industrial countries. This amounts to a total of \$1.4 billion in incremental research and development outlays above and beyond the normal expected growth.

The increase in research and development activities generated by Bill C-22 will result in the creation of about 3,000 scientific and research-related jobs in the innovative sector. This means that Canadian university graduates will have an excellent opportunity for employment here in Canada and that we will continue to benefit from their technological and scientific expertise. The new policy provides for research and development investment by the innovative sector by ensuring compensation for the risks associated with the research and development of new health-care products.

Bill C-22 will also provide for continued opportunities for the generic companies to grow and prosper. First, it is important to remember that all generic drugs that have a compulsory licence and have received a notice of compliance from the Department of Health and Welfare are unaffected by this policy, and will continue to be available. Furthermore, there are new opportunities for fine chemical manufacturing by generic companies. All existing brand name drugs now on the market are available immediately to a generic firm if it manufactures the fine chemical ingredients in Canada instead of simply importing the chemicals, thereby creating additional jobs.

To allow for the immediate manufacture of a product in Canada by generic firms, all existing licences to import that have been granted to generic companies will automatically be extended to a licence to manufacture. One should also remember that the generic firms are not entirely dependent on products covered by compulsory licences to import.

The sale of drugs via compulsory licence, on average, amounts to less than 50 per cent of the revenues of generic firms. Therefore, the existence of a flourishing generic industry does not, and should not, depend upon compulsory licencing. Nevertheless, seven years after the first notice of compliance, or NOC, is granted for a new drug, a generic company will be able to manufacture the chemicals in Canada and sell the drugs in direct competition with the innovative company.

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Opportunities for generic firms also exist through the sanctions available to the drug prices review board. If excessive pricing has been determined, the board could remove the period of patent protection to allow for generic competition.

In the case of the innovative sector, the law will include a Cabinet review of research and development commitments of the industry after four years. If the industry has not met its commitments, the Government will either reduce or remove the period of protection.

Consumer protection is ensured through generic competition of drugs now on the market, and in the future through a transitional payment to provincial drug plans by the drug prices review board. Canada's patent law will also be harmonized with the rest of the world resulting in increased investment, not only in the pharmaceutical industry but in other industries as well.

By promoting new investment, Canada will enter the same league as Japan, Italy and the United States in terms of R and D expenditures as a proportion of sales. The Canadian pharmaceutical sector will become a world class innovative industry led by a significant increase in investment and jobs and in research and development. In short, Bill C-22 will bring positive economic benefits to Canada while protecting Canadian consumers.