

of the patent for a company to assemble the required data package for registration. Because of its volume, the evaluation of the data may take from one to three years. Once the data is evaluated and accepted, registration most often occurs in years 3 to 6 of the patent period. Thus, the actual market protection available to a product is not the entire 17-year patent period but is most often 11 to 14 years after the product comes on the market.

From 1980 through to June 1, 1987, this period of patent life was effectively extended in perpetuity by a registration policy authorized under the regulations of the *Pest Control Products Act* called Product Specific Registration 80 (PSR 80). Many witnesses singled out PSR 80 as being responsible for the lack of competition in the farm chemical market place and therefore the high cost of farm chemicals.

Before 1980, to obtain registration, data owned by one company could be used to support another's products, i.e. all data were used in common for all registrants. There was no protection of data generated to achieve registration, or, in other words, no data ownership. But, in the late 1970s, concerns arose about micro-contaminants in the active ingredients that form the basis of farm chemicals. The perceived solution was for registration to require that the source of the active ingredient in each formulated product be known and that each active ingredient from each source have its own supporting data base. At the same time, there was pressure from the agricultural chemical industry to recognize data ownership, while Agriculture Canada wanted updated data bases which would confirm the safety of older active ingredients. The department hoped that, if it provided data protection, companies would be willing to carry out additional testing.

Accordingly, Agriculture Canada issued Memorandum R-219 on September 8, 1980. It required that: (1) any new product be supported by its own new data base; and (2) provided unlimited data protection. Before long, however, the department realized that the policy had more disadvantages than advantages. These were expressed by Dr. Jean Hollebome, Acting Director, Planning and Priorities Division, Pesticides Directorate:

For a start, it promoted monopolies. Once a manufacturer was on the market, he would stay there, and it was very difficult for new sources to get onto the market. Secondly, it did not provide any incentives for these manufacturers or companies on the market to update their data packages. Since they were protected in perpetuity, there was no incentive to provide modern studies. That bothered us considerably, because the keystone of our Act is the determination of safety.

That is the situation that exists with pesticide registration today, that unless a new source of registered active ingredient is prepared to supply a data package to support his source of active ingredient or may obtain (access to data supporting) a registered source from another company. . . he has no access into the market, and we will not register his product. What we would like to do is change it (this policy). Everyone, including ourselves, industry, and growers, realizes it has to be changed (Issue 6:7, 28-1-87).

The effect of PSR 80 on farmers has been significant. With the high cost of producing the full data package required for registration under the policy, only a large corporation which originates a product and which has patent protection has been able to afford to register chemicals in Canada. The extension of right of data ownership in perpetuity under PSR 80, by effectively extending a company's patent rights, made it difficult and expensive for producers of generic products to get their products to market. PSR 80 has therefore been accused of hampering the growth of an agricultural chemical industry in Canada.

Farmers believe that as a result of this situation they have had to pay excessively high costs for a few products. The Manitoba-North Dakota Zero Tillage Farmers' Association told the Committee that, ". . . the cost to produce that data is simply passed on to the farmer through higher prices in