The link between publicly funded health care and compulsory licensing

Aidan Hollis

Is there any justification for compulsory licensing of pharmaceuticals and other medical services in the developed world? Compulsory licensing involves breaking a patent right in order to change the terms of bargaining between a buyer and a seller. If a government, as buyer, and a patent holder, as seller, are unable to reach an agreement about the price of a product, the government may override the patent and "license" another firm to sell the product. The threat of such licensing alone strengthens the bargaining position of the government, leading to a lower price. I argue that compulsory licensing is essential in Canada in some cases in which the bargaining power of the state-funded medicare system has been enfeebled by the requirement to provide "medically necessary" patented treatments.

An example of such a situation is testing for the *BRCA1* and *BRCA2* genes. Under a 1999 appeal ruling, the Ontario Health Insurance Plan is required to provide such testing as an "essential and timely medical service."[1] Myriad Genetics, which holds a patent over such testing, is therefore in a position to charge any fee it wishes, because the government is constrained to purchase the service as being medically necessary. The combination of medical necessity and the patent right open up the possibility of unlimited exploitation of monopoly power, which, I argue, can only be effectively combatted through the use or threat of compulsory licensing.

Compulsory licensing was actively used in Canada in the past but has been little used recently, although the Patent Act and Canada's international trading commitments (including the North American Free Trade Agreement) allow for it. Such licensing is limited in the Patent Act to cases in which governments have attempted unsuccessfully to obtain a licence on reasonable commercial terms and, if the compulsory licence is granted, the licensee is required to "adequately" remunerate the patent holder.

The standard justification for patents

The standard analysis of patents focuses on the trade-off between economic efficiency and the incentives for innovation. Because a patent confers a temporary monopoly, the patent holder will set prices above cost to maximize profits, thus creating an efficiency cost known to economists as "deadweight loss." The deadweight loss is the value lost to society by the fact that some individuals who value the product more than its marginal cost of production (but less than the monopoly price) do not buy the product. If the product were supplied by a perfectly competitive industry, then prices would be driven down to the cost of production, thus eliminating deadweight loss.

The government enables this inefficiency, because in the absence of a patent monopoly no firm would have an incentive to develop new products: other firms could copy the product, and competition would drive prices down to the level at which there would be no reward for innovation. The patent is thus an imperfect, but effective, instrument for promoting the development of new products.

The deadweight loss is not the only effect of high prices: they also create a financial transfer from buyers to the monopolist. In most economic analyses, this transfer is of little concern, because in itself it does not imply any reduction in aggregate welfare — just a shifting of wealth from buyers to sellers. In addition, there is normally a limit to the size of the transfer created by a monopoly: the firm's willingness to raise the price is constrained by the reduction in sales this entails.

Why public health care is different

In a public health care system such as Canada's, the state is the largest buyer of some products. This creates a situation akin to a "bilateral monopoly," in which there is a single seller and a single buyer who will negotiate over price. The presence of a bilateral monopoly suggests that prices will in general be somewhere between the competitive price and the monopoly price — the buyer will typically be able to negotiate with the seller to obtain a mutually satisfactory price.[2] Thus, by taking aggressive measures such as reference-based pricing (in which the formulary limits the price at which a product can be sold to conform with other possible treatments), the provincial health authorities can potentially reduce prices from the monopoly level. This may, however, not be true in the case of certain "medically necessary" health care services and pharmaceuticals, which the provinces are constrained by their mandate to provide.

The Canada Health Act requires public insurance of "medically necessary" hospital and physician services. There is thus a legal entitlement to certain health care services that has been enforced through the courts in some cases. The courts have interpreted medical necessity to be whatever the physician recommends and have stated that "considerations of cost-containment" are irrelevant.[3,4]

In defining medical necessity, one might weigh risk and

convenience — but not price. This implies that the demand for a medically necessary treatment is independent of price. Although in a bilateral monopoly position, a province is thus unable to exercise any bargaining power, because the courts constrain it to purchase a service. An example of this situation is provided by the drug Herceptin, which in 1999 was priced at $2700 for a month's treatment. The seller, Genentech, provides the product for free to indigent and uninsured patients in the United States (financed, perhaps, by profits on sales to those who do pay). But in Canada, because all patients are insured, the provinces must pay for the drug for all patients who qualify medically.[5] As a result, in Canada, despite the considerably lower average income per capita than in the United States, no patients obtain the drug for free. As noted in a letter from the medical director of Hoffmann-La Roche, which distributes Herceptin in Canada, it is not the responsibility of the pharmaceutical industry to make up for "deficiencies" in provincial funding.[6]

Since demand is independent of price, it appears that higher prices will not increase deadweight loss, because the same amount of the product or service will be consumed regardless of the price. This does not mean that there is no efficiency cost created by high prices. High prices require more funding, which in turn require higher taxes, which themselves create a deadweight loss. Indeed, it is likely that the deadweight losses created *indirectly* through the tax system will be much larger than those that would be created *directly* by charging the monopoly price. It is estimated that the tax system creates deadweight losses that are about 30% as large as the amount raised.[7] The tax-related deadweight losses will thus be very substantial if the seller is able to charge a very high price because the buyer lacks bargaining power.

The fundamental problem here is in the combination of patent rights — which confer the ability to choose price — and the application of medical necessity — which forces governments to purchase products regardless of the price. Either one by itself is reasonable, but together they grant potentially unlimited profits to patent holders, unlimited costs to taxpayers and disproportionate efficiency costs. The ability to charge excessive prices is little constrained by the Patented Medicines Prices Review Board, which is limited to reviewing the prices of pharmaceuticals only in order to ensure that their price is consistent with the prices of other medicines in the same therapeutic class, and with prices of the same product in other countries, without any consideration of therapeutic benefit.

Provincial governments, in these circumstances, must use their rights of compulsory licensing. Section 19 of the Patent Act allows provinces to apply to the Commissioner of Patents for a compulsory licence if they have been unsuccessful in negotiating an agreed licence with the patent holder. The threat of compulsory licensing shifts the power over price from the patent holder to the government. If the government is reasonable, it will set the price so as to leave the monopolist with the same profits as it would have obtained had there never been government involvement or the concept of "medical necessity." This will protect the incentive to innovate, without allowing firms to abuse patent rights.

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Dr. Hollis is with the Department of Economics, University of Calgary, Calgary, Alta.

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Correspondence to: *Dr. Aidan Hollis, Department of Economics, University of Calgary, 2500 University Dr. NW, Calgary AB T2N 1N4; fax 403 282 5262; ahollis@ucalgary.ca*