Incentives for valued innovation in the pharmaceutical sector:
Issues for consideration by domestic and international policy makers

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November 2006
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Report prepared for Health Canada

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Draft Dated:
21 November 2006
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- Policy relevant
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Funding and Support

This report was supported by a research contract from Health Canada. Steve Morgan is supported in part through a Canadian Institutes of Health Research “New Investigator Award” and through a Michael Smith Foundation for Health Research “Scholar Award.”

CHSPR receives core funding from the BC Ministry of Health, and ongoing support from the University of British Columbia and the UBC College of Health Disciplines. This enables the Centre to focus on research that has a direct role in informing policy and health reform.

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Main Point Summary

- Investment in research and development in and of itself does not indicate the efficient production of innovations of value to society.

Innovation, patents and incentives

- Because innovation requires production of a valuable economic good (new and useful information) that can easily be copied and used by others, a truly “free market” provides limited private sector incentives to innovate. Patents therefore create deliberate, time-limited competition barriers in order to create private sector incentives for innovation. To promote efficiency, patents reward research productivity rather than compensate research costs; they do so through the potential to earn profits on patent-protected goods and services.

- When the market for patented goods and services exhibits effective competition and efficient demand, patents reward inventions in proportion to their social value and thereby stimulate true innovation. Competition among technologies will result in improved welfare and productivity in terms of price per unit of performance over time.

Pharmaceutical market imperfections

- An unregulated pharmaceutical sector would not be characterized by efficient consumer demand or effective competition among firms, due to a number of factors.

- Inefficient consumer demand in the sector results from: the difficulty of determining the comparative effectiveness of pharmaceuticals; the extraordinarily high willingness-to-pay exhibited by patients (or society) for lifesaving or life-extending treatments; and, the fact that due to coverage plans or insurance, patients and physicians seldom bear the full cost of drugs.

- Potential barriers to competition in the sector include the costs of bringing an innovation to market and a number of other fixed costs associated with entry.

Market dynamics due to market imperfections

- The lack of price sensitivity among prescribers and patients, combined with the difficulties of determining the comparative effectiveness of products, gives manufacturers incentive to “invent around” existing patents and market similar products. Firms selling imitative, patented drugs do not compete in terms of performance.

Measuring valued pharmaceutical innovation

- There has long been interest in the development of indicators of overall innovation in the pharmaceutical sector; however, measures adopted in the past have been acknowledged to be incomplete unsatisfactory: these include number of patents filed, drug prices and revenues, and research and development expenditure.

- Because the pharmaceutical market does not function like an ordinary, competitive marketplace, previously adopted measures of overall innovation have failed to recognize the therapeutic significance of new products, or the importance of competition among products based on performance.

- When developing measures of valued innovation—and the policies aimed at promoting innovation—it is important to recognise that the unique features of the pharmaceutical sector necessitate ongoing monitoring and policy intervention to ensure efficient demand and ongoing competition.
Executive Summary

Governments, charitable organizations and drug manufacturers spend vast sums on pharmaceutical research and development each year. We place high hopes on this investment, given the close connection between innovations in drug treatments and the fundamental health and wellbeing of populations. Yet, investment in research and development in and of itself does not indicate the efficient production of innovations of value to society. Only a fraction of the thousands of new drugs brought to market in recent years represent “substantial” improvements over existing health technologies. This high level of imitation, rather than innovation, reflects an undesirable market dynamic that results from unique features of the pharmaceutical sector. These unique features necessitate policy intervention to ensure efficiency in the use of pharmaceuticals today, and optimal incentives for truly valued pharmaceutical innovations tomorrow.

Innovation, patents, and incentives

Innovation requires the production of information that is both novel and useful. Although essential to economic development, information is an economic good with a number of characteristics that distinguish it from ordinary commodities. These include the “sunk cost” of research required to produce new information and the fact that, once discovered, information is a “public good” that can be reproduced and used by many people at little or no cost. Because of these characteristics, firms would have little or no incentive to produce innovations in a truly free market.

Governments provide valuable, direct public funding for research and invention through a variety of means (e.g., universities, research institutes, grants, competitions). There are, however, many additional advantages to engaging the private sector in the innovation process. If policy interventions can be devised in a manner that creates a viable and competitive marketplace for innovation, it may be possible to achieve forms of productivity and efficiency that are similar to those achieved in markets for conventional commodities. Specifically, policies designed to engage the private sector in research and development would seek to achieve the best possible use of resources in the research enterprise and in the end markets for innovative goods and services.

Optimal use of resources in the research enterprise requires efficiency in the selection of projects to undertake, and in the research process itself. Efficiency in the process requires that sought after innovations be researched and developed in a manner that is cost effective. Redundant and duplicative research steps should be avoided. Efficiency in the selection of projects to undertake requires investment in only those projects that are expected to generate societal benefits that outweigh the cost of the research and development process. When, given the current state of knowledge, it is expected that the additional societal benefits created by an innovation would be smaller than the societal cost of achieving it, such an innovation should not be sought after.

Optimal use of resources in markets for goods and services that may be sold by patent-holding firms—just like optimality in any market—requires competitive supply and demand that results in consumption that is efficient from a societal perspective (“efficient demand”). Optimal end-market use of patented goods and services (just like optimality in markets for conventional products) requires competitive supply and demand that results in consumption that is efficient from a societal perspective (efficient demand). Pursuing these goals in innovative markets will be subject to the basic limitations on competition that are necessary to promote investment in innovation in the first place. Unless firms that invest in research and development are able to limit competition when they produce an innovation, other firms could copy an innovation and price the end product or service at a level that makes it difficult (or impossible) for innovators to recover their sunk research costs. The creation of some form of barrier to competition is therefore necessary to create a marketplace in which the private sector will innovate.
Patents create deliberate, time-limited competition barriers in order to provide private sector incentives for innovation. Patents reward research investment through profits earned on products that use the patented technology. If a firm anticipates that goods or services based on a potential innovation will generate sufficient profits to justify research costs, incentive exists to engage in the research necessary to produce that innovation. If equivalent or better goods or services are already available at equal or lower cost, and if consumer demand would be directed toward those options, there is little incentive to invest in the necessary research. Given the connection between consumer demand, profits and incentives for innovation, the optimality of patents as a mechanism for promoting desired innovation hinges significantly on the optimality of the marketplaces to which patents apply. If there are market imperfections with respect to the efficiency of consumer demand or the level of firm competition in end markets, patents may not allocate research efforts efficiently from a societal perspective. If market imperfections exist—either in the form of inefficient consumer demand or low levels of competition among firms—patents may not allocate or reward research efforts efficiently from a societal perspective.

**Pharmaceutical market imperfections**

There are many ways in which the pharmaceutical sector is a distinct unique economic market. Owing to the nature of pharmaceuticals and their use in pursuit of improved health, the organization and activities of both consumers of pharmaceuticals (demand side) and producers of pharmaceuticals (supply side) fail to meet classical economic assumptions about well-functioning markets.

Pharmaceuticals are not ordinary consumer goods. They are potent inputs into the production or maintenance of the health of individuals and populations. Given the cost, inconvenience and potential risks associated with their use, pharmaceuticals derive their societal value from the established impacts they have on patient health. However, it is difficult for patients or prescribers to determine these impacts with certainty. A patient who feels better or worse after using a therapy cannot know with certainty whether nature, placebo or drug was responsible. As a result of the specialized knowledge and skills required to make informed drug choices, and the inherent risk involved in making uninformed choices, the legal requirement of a physician’s prescription (in most countries) is imposed to ensure that a suitably trained expert acts as an agent in diagnosing the need for treatment and selecting treatment options. Moreover, mechanisms for third party payment of pharmaceutical costs have evolved around the world to promote access to medicines and to reduce both the risks and inequities of financial burdens associated with ill health. Owing to such coverage—and to the ways in which physicians are paid for their prescribing services—patients and prescribers seldom bear the full cost of drugs. As a result, the demand side of the pharmaceutical sector is characterised by a number of market imperfections that make a truly “free market” a potentially inefficient one.

On the supply side, research costs are not the only expenses in bringing new pharmaceutical products to market. Manufacturing requires significant fixed costs in specialized equipment and highly trained personnel. Also, as with initial research needed to discover new ideas, licensing requires that firms invest in research to show that their products meet government standards for safety, efficacy, purity and manufacturing quality. Unlike initial research costs, however, the sunk costs of product licensing do not create a public good. A license to sell a product is based on information about a given manufacturer’s production processes and standards. Even if the ideas behind a product and production process are publicly available (e.g., any patents on them have expired), market entry still requires investment in fixed licensing costs to prove that the application of those ideas by a particular firm is producing the desired end product. All these costs create potential barriers to competition.
Market dynamics due to market imperfections

The combined effects of the imperfections on the demand and supply sides of the market for pharmaceuticals create an environment with unique forms of competition. In particular, the lack of price sensitivity among prescribers and patients, combined with the difficulty for prescribers and patients to determine the comparative effectiveness of products, gives manufacturers incentive to “invent around” existing patents and market similar products. Firms selling imitative, patented drugs compete not in terms of price per unit of performance, but through intense promotion of minor differences among products.

Manufacturers of patented “me-too” drugs within established therapeutic categories invest more in marketing efforts to distinguish their products from their competitors’ than they invest in the development of the “me-too” drug or in research that would generate valuable scientific evidence of comparative benefits. Marketing that creates unsubstantiated product differentiation is of questionable value to society.

Even if pharmaceutical promotions were strictly informative, the marketplace for disseminating information through advertising may have problems similar to the market for developing innovative through research. Advertising expenditures are “sunk costs” that create a form of “public good” in truly competitive markets. The only drug manufacturers that possess market power necessary to recoup advertising expenditures are those selling brand-name products protected by patents. The resulting concentration of advertising on new, patented drugs, to the exclusion of off-patent medicines that may be as effective and cheaper, creates a market distortion: it draws attention only to those products for which there are barriers to competition.

Measuring valued pharmaceutical innovation

There are a number of strong rationales for measuring innovation in the pharmaceutical sector. Firms and countries may wish to provide evidence of research productivity in order to justify (to shareholders or taxpayers) the expenses involved. The measures that have historically been used to gauge innovation in this sector have, however, been compromises. It is relatively straightforward to collect and report activity related to the process of innovation, measures of the property rights conferred on inventions, and indicators of the rewards of innovation (prices and revenues for end products). It is harder to measure the societal value of inventions, and therefore, to gauge the true value of innovation in this sector.

Because the pharmaceutical market does not function like an ordinary, competitive marketplace, previously adopted measures of overall innovation fail to recognize the therapeutic significance of new products, or the importance of competition in terms of price per unit of therapeutic value. When developing measures of valued innovation—and the policies aimed at promoting innovation—it is important to recognize that the unique features of the pharmaceutical sector necessitate ongoing monitoring and policy intervention to ensure efficient demand and ongoing competition.
1 Introduction

Governments, charitable organizations and drug manufacturers spend vast sums on pharmaceutical research and development each year. We place high hopes on this investment, given the close connection between innovations in drug treatments and the fundamental health and wellbeing of populations. Yet, investment in research and development in and of itself does not necessarily produce valued innovations. Only a fraction of the thousands of new drugs brought to market in recent years represent “substantial improvements” over existing health technologies [1-4]. Many of the world’s current top-selling drugs are new, patented and relatively high-priced modifications of drugs first brought to market in the 1980s or earlier. Newer drugs that treat serious and life-threatening conditions, such as cancer, are increasingly being brought to market at prices many times higher than average annual incomes, even in the world’s wealthy countries. Yet such treatments are rarely “miracle drugs” that dramatically improve upon patient outcomes that are obtained using available treatment options. Overall, despite the ostensible scientific basis of both demand and supply in the pharmaceutical sector, the sector is characterized by greater competition in product marketing than in price per unit of scientifically established performance.

Promoting innovation in virtually any sector of the economy presents a paradox. Firms competing in a “free market” have little or no incentive to innovate because innovations are easily copied once revealed. Unregulated competition would therefore dissuade firms from investing in the research necessary to bring innovations to market. Thus, contrary to conventional wisdom regarding the functioning of markets, innovation policy deliberately introduces barriers to competition in an attempt to provide incentives for innovation that would not otherwise exist. Promoting innovation that is valued by society requires that incentives created through policy are “fit for purpose” in the markets to which they apply.

Among the most important interventions used to stimulate private sector innovation is the granting of intellectual property rights by way of patents. Patents are applied across sectors on relatively uniform terms. They create an incentive to invent by way of the potential to earn profits on patent-protected goods or services. The extent to which this produces socially optimal incentives for valued innovation depends on the characteristics of the market in question. If the profits that a firm can earn from a patent are closely connected to the societal value of the new patent-protected good or service, and if sellers engage in genuine competition over price and quality, then patents alone may generate significant welfare gains without further policy interventions.
Business and consumer electronics provide vivid examples. For example, a Toshiba Satellite laptop costing US$3,500 and weighing 7.75 pounds in 1995 had a processing speed of 0.075 GHz, 0.5 GB of hard drive storage and a 10.5-inch screen. In 2005, a Toshiba Satellite laptop costing US$1,000 and weighing 6.5 pounds had a processing speed of 1.5 GHz, 60 GB of hard drive storage and a 15.4-inch screen. In just ten years, Toshiba was offering a machine that was lighter, had a larger screen, 20 times the processing speed and 120 times more storage for less than one-third the price. Similarly, the Apple iPod MP3 player was first launched in 2001 at a price of US$399 offering five GB of storage. Within five years, Apple was offering an 80 GB iPod for US$399—16 times the storage capacity for the same price, at the same size. Despite the fact that the technologies involved are protected by a variety of patents, the incentives created in markets for products like laptops and MP3 players have resulted in the availability of newer and better products at prices that reflect steadily falling cost per unit of performance.

In other sectors of the economy, the market value of a patent and the societal value of the invention may not equate, due to characteristics of the market itself. The market reward from patents may be too high, too low or allocated inappropriately within a given sector, depending on the nature of supply and demand for the related goods or services. This can result in suboptimal rewards for innovation if patents are relied upon without further policy interventions.

The pharmaceutical sector is unquestionably one example where, owing to the unique nature of both the supply and demand of medicines, the use of patents alone may over-reward some inventions while under-rewarding others. Valued innovation may not be achieved efficiently (if at all) without interventions to better align the market and social value of inventions. Even Bill Gates, one of the world’s fiercest protectors of patented intellectual property rights in information technology, has explicitly recognized that incentives created by market-based innovation policy might fail in the health care sector: the Bill & Melinda Gates Foundation requires that the researchers who accept funding for HIV/AIDS vaccine research must share findings and work toward global access for research innovations[5].

This paper provides a brief review of the economics of information and patents and an explanation of how several characteristics of the pharmaceutical market may produce suboptimal incentives for innovation. We discuss how certain pharmaceutical pricing and reimbursement policies (taken by both state and private actors) may not only be necessary for efficient pharmaceutical purchases, but may also help ensure that patents provide appropriate economic incentives for future innovation. We conclude with an examination of methods by which innovation is measured and
argue that the unique characteristics of the pharmaceutical industry may justify changes in both how we measure innovation and how we reward it.

2 Innovation and the economics of information

- Innovation is the application of new information in ways that have an impact on economic or social activity.
- Production of new information involves many “sunk costs” that, once committed to research and development, cannot be recovered for other uses.
- Information has unique characteristics that make it a form of a “public good”—like clean air or national security—that is often universally available once produced.
- Paradoxically, the public good nature of information limits free market incentives for investing sunk costs in its production.

To “invent” is to produce something previously unknown through ingenuity or imagination; to “innovate” is to apply new ideas in ways that impact economic or social activity. To innovate therefore requires the production of information that is both novel and useful. Although essential to economic development, information is an economic good with a number of characteristics that distinguish it from ordinary commodities. These include the “sunk cost” of research required to produce new information, which once discovered is a “public good” that can be reproduced and used by many people at little or no cost. Because of these characteristics, firms will have little or no incentive to produce innovations in a perfectly competitive marketplace.

2.1 Research and development requires investment of “sunk costs”

The production of novel and useful information involves the costs of basic research required to generate ideas and the applied research required to determine their value in particular applications. These costs are generally unpredictable. Research costs may be small if researchers are lucky enough to quickly make a discovery and verify its usefulness. But in many instances, searches are lengthy and fruitless, or tests prove that a novel discovery does not have value. Research projects may have to be abandoned if they hit such dead-ends. Because research activities are highly labour intensive, most of the resources (the time and energy of research teams) involved cannot be recouped. These are referred to as “sunk costs” because such resources cannot be recovered for other uses once they are committed to the research process.

In addition, the research production process is one in which there are relatively few gains from the “partial production” of information. Although research tasks may improve the analytic skills
and knowledge of researchers, the research process is not productive unless new information is discovered. It is worth noting, however, that research results needn't necessarily be limited to finding the sought after information; it is often the case that unanticipated discoveries are made.

2.2 Information as a “public good”

Discoveries resulting from research processes are a form of “public good” due to two properties. First, information differs from physical commodities in that it is not diminished as people consume it: an idea can be used by one person or many people at virtually the same cost and without altering the amount available to each user. This property, referred to as being non-rival in consumption, means that individuals do not need to compete over the use of an idea once it has been produced. This implies that, once an innovation has been made, it is not economically efficient, from a societal perspective, for the new information to be kept secret. It would be better to promote broad publicity of ideas and information so that valuable resources are not used to unnecessarily repeat research processes that have already led to particular discoveries.

The second characteristic of a public good is that it is difficult to exclude people from using it once it has been produced. With ordinary goods and services, it is generally possible to provide the good or service only to specific users (e.g., paying customers). In contrast, it is difficult to prevent anyone from obtaining a piece of information once it is made public. While firms may be able to stop individuals from possessing a good or service based on an invention, it is much more difficult to exclude others from taking the ideas behind a good or service they have observed or purchased. Reverse engineering may be required to determine the ideas behind a new product, but those ideas do not have to be re-invented. This property, referred to as non-excludability, implies that it would be difficult for innovators to prevent competing firms from copying their innovations once they are made public.

2.3 Sunk costs + public good = policy paradox

The fact that innovation requires firms to invest sunk costs in the production of a public good (information) creates a policy paradox. The non-rivalry of information implies that it is most economically efficient for ideas to be widely used once discovered. The non-excludability of information readily enables this goal. However, non-excludability also implies that firms will have little or no incentive to innovate in a free market, where competitors could easily copy the new good or service and bring prices down to marginal cost—the point where firms are just covering the cost of producing and distributing the good or service. While such competition is a hallmark of market
efficiency for goods and services, it would dissuade firms from investing in the research necessary to bring innovations to market in the first place. This would be undesirable if both consumers and producers could be made better off by appropriately rewarding valued innovation.

3 Patents and incentives for innovation

- Patents create deliberate, time-limited barriers to competition in order to provide incentives to efficiently produce new innovations.
- Patents are “forward-looking” instruments in that they reward research productivity rather than compensate research costs.

Governments provide direct public funding for research and invention through a variety of means (e.g., universities, research institutes, grants, competitions). Such investments are critical to the overall innovation process—particularly in health care\(^{12,13}\). There are, however, many additional advantages to engaging the private sector in the innovation process. If policy interventions can be devised in a manner that creates a viable and competitive marketplace for innovation, it may be possible to achieve forms of productivity and efficiency that are similar to those achieved in markets for conventional commodities. Specifically, policies to engage the private sector in research and development would seek to achieve the best possible use of resources in the research enterprise and in the end markets for innovative goods and services.

Optimal use of resources in the research enterprise requires efficiency in the research process itself and in the selection of research projects to undertake. Process efficiency requires that sought after innovations be researched and developed in a manner that is cost effective. Redundant and duplicative research steps should be avoided. Efficiency in the selection of projects requires investment in only those projects that are expected to generate societal benefits that outweigh the cost of research and development. When, given the current state of knowledge, it is expected that the additional societal benefits derived from an innovation would be smaller than the societal cost of achieving it, such an innovation should not be sought. The project may eventually become viable as changes in knowledge illuminate less costly routes to discovery or illustrate benefits previously not considered; but the project should only be undertaken when it can reasonably be expected that the benefits will outweigh the costs.

Optimal use of resources in markets for goods and services that may be sold by patent-holding firms—just like optimality in any market—requires competitive supply and demand that results in consumption that is efficient from a societal perspective (what we will call “efficient demand”). Pursuing these goals in innovative markets will be subject to the basic limitations on
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competition that are necessary to promote investment in innovation in the first place. Unless firms that invest in research and development are able to limit competition when they produce an innovation, other firms could copy an innovation and price the end product or service at a level that makes it difficult (or impossible) for innovators to recover their sunk research costs. The creation of some form of barrier to competition is therefore necessary to create a marketplace in which the private sector will produce innovations.[10,11] Policy must aim to ensure that markets behave as competitively and efficiently as possible, subject to the competition barriers that are intentionally created for the purpose of stimulating innovation.

3.1 Patents create intentional barriers to competition

Patents are a policy mechanism through which firms are offered protection from competition if they produce an invention. A patent grants time-limited intellectual property rights that allow the patent holder to legally exclude others from the use of an invention for a specified period of time. In exchange for this monopoly, the invention must be published in the patent. Patents thereby aim to stimulate innovation, while ensuring that new ideas are made public.

The monopolies created by patents can have undesirable consequences in terms of the efficiency and equity of markets for goods and services and in terms of the efficiency of knowledge production and technological advancement. If a patent protecting monopoly over the use of an idea was to last forever, for example, consumers would always face inflated costs for related products; and other firms would never be able to use the idea to further advance science and technology, which would stifle technological progress[14-17]. Therefore, there are limitations on the length of a patent and on what can be patented. Patent terms are limited to 20 years from the date of filing the patent application under the World Trade Organization’s Agreement on Trade-Related Aspects of Intellectual Property Rights. After the patent term has expired, competitors are free to apply the invention for their own uses. Competitors may reproduce and compete with the original good or service, or they may apply the original invention to create new innovations. Patents are granted only on inventions that (1) have never before been made public; (2) advance existing knowledge in ways that would not be obvious to anyone familiar with the subject area; and (3) are of some utility to society. These requirements—that patented information be novel, non-obvious and useful—mean that patentable inventions must hold at least some promise of being a true innovation: new ideas that have the potential to impact economic or social activity.
3.2 Patents are “forward-looking” policy instruments

Patents are “forward-looking” policy instruments in that they reward the product of research and development, not the research process itself. The value of obtaining a patent is equal to the profit that the patent holder can expect to obtain from the goods and services that will be protected by it. It is against these potential profits that firms must weigh decisions concerning research efforts. The patent system provides little incentive for firms to produce inventions without the promise of profit.

A “backward-looking” policy that offered reimbursement of costs accumulated during the research process would not provide incentives to conduct research efficiently. If firms knew that the size of an award was determined by the amount of research expense, they would have an incentive to increase, rather than control, the costs of research. A backward-looking reimbursement of research expenses would also fail to provide incentives for efficiency in the selection of research projects of promising societal value. All research, no matter what it produced, would be rewarded.

In providing forward-looking incentives, patents promote efficiency in the research enterprise. Firms will not waste research expenditure on unnecessary steps or processes because the profits generated by the invention are not a function of the processes that generated the invention. As with the profitability of any economic commodity, the potential profitability of an invention is maximized if it is produced as efficiently as possible.

The separation of research costs from patent rewards also helps to prioritize the selection of research objectives. Firms will only invest in those projects for which the cost of research is less than or equal to the expected value of the reward conferred by a patent. While there is no guarantee that a patent will recoup its fixed costs, if the end markets for goods and services are characterized by competitive supply and efficient demand, profits earned will reflect the societal value placed on the discovery. At the outset of a research project, firms are making a calculated but risky investment: firms that take such risks will sometimes lose. On the other hand, the market for goods and services based on the patented product may generate much more profit than anticipated. Firms that make risky investments sometimes win.

4 Market valuation, patents, and creative destruction

- Patents reward research through the profits that a firm may earn selling goods and services based on a patented invention; these profits, in turn, are related to consumers’ willingness to pay for the patent-protected goods and services.
• Consumers’ willingness to pay for goods and services reflect the societal value of a good or service when a number of economic assumptions are met.

• Competition after patent expiry significantly increases the societal value created by an invention; and competition among new and old technologies results in improved welfare and productivity in terms of price per unit of performance over time.

Patents reward research investment through profits earned on products that use the patented technology. If a firm anticipates that goods or services based on a potential innovation will generate sufficient profits to justify research costs, there is an incentive to engage in the research necessary to produce that innovation. If equivalent or better goods or services are already available at equal or lower cost, and if consumer demand would be directed toward those options, then there would be little incentive to invest in the necessary research. Given the connection between consumer demand, profits and incentives for innovation, the optimality of patents as a mechanism for promoting desired innovation hinges significantly on the optimality of the marketplaces to which patents apply. If market imperfections exist—either in the form of inefficient consumer demand or barriers to competition among firms—patents may not allocate or reward research efforts efficiently from a societal perspective.

4.1 Profits from a patented invention depend on consumer “willingness-to-pay”

During the life of a patent, the patent holder is free to choose a price for goods or services based on a patented invention that will maximize profits subject to market demand and production costs.

The demand for a given product is the amount of the product that buyers would select at different prices; or, conversely, the price that consumers would be willing to pay for each unit of the product if the market was restricted to various levels of supply. It is typically assumed that consumers are well informed and rationally pursue the maximum welfare they can achieve subject to the constraints established by their budgets and the prices they face for all available goods and services. Under these circumstances, their willingness to pay for a given product will reflect the value they place on that product, taking into consideration all available alternative uses of their money. When added up across individuals, the market demand can be plotted on a graph with the quantity of units sold along the horizontal axis and price per unit sold on the vertical axis. As illustrated in Figure 1, demand is typically downward sloping because some people will typically have higher “willingness-to-pay” for a product than others and because individual buyers of a product will typically be willing to pay less per unit of a large quantity than they will pay per unit of a small quantity.
The cost curve illustrated in Figure 1 shows the marginal cost of producing each unit of the product. For simplicity, marginal cost is drawn as a straight, horizontal line to depict the notion that the cost of producing each unit of the item is about constant. Economies of scale in production imply that the typically marginal cost of producing a good tends to fall as the quantity produced increases. The marginal cost curve does not illustrate fixed production costs; and, importantly, it does not illustrate the sunk costs of research and development needed to bring the product to market in the first instance.

The producer will choose a monopoly price ($P^m$) that maximizes its profits, which are revenues from units sold at that price ($Q^m$) minus the marginal production cost of those units ($C$). The monopolist will always choose a price that exceeds marginal production costs. As illustrated in Figure 2, total profit from sales of the end product or service is equal to the difference between the monopoly price and marginal production costs multiplied by the amount sold at the monopoly price.

The profit of a patent holder will be larger if consumers’ willingness-to-pay is higher. It is in this sense that the incentives for research created by patents are proportionate to consumers’
willingness-to-pay for the end product. Profit is not all that is produced through the sale of goods and services based on the patented technology. When a producer charges a constant price, there are individuals who purchase the product at a cost that is less than what they would have been willing to pay. This difference represents a “consumer surplus” that is produced through the transaction. It is not actually a financial transfer (like profit); but it is an indication of extra value (for consumers) created by the availability of the product.

4.2 Consumers’ willingness-to-pay and the societal value of transactions

If consumers’ willingness-to-pay for the product is an accurate reflection of the societal value of its consumption, then the profits generated for the producer during the life of the patent will be proportionate to (and represent a significant share of) the total societal value of the innovation. Under such circumstances, firms would have the greatest incentive to search for innovations of the greatest expected societal value. The patent system would thereby efficiently allocate research efforts: firms would invest in research projects for which the expected societal benefits of the innovation furthest exceed the expected cost of producing the innovation.

However, there are a number of assumptions that must be met before the demand curve can be accepted as a gauge of the societal value of consumption. Required assumptions include the following:

1. Consumer preferences are the best measure of their welfare;
2. A consumer’s consumption has no impact on the wellbeing of others;
3. Associations between willingness-to-pay and income or other circumstances are socially acceptable;
4. Consumers are fully informed about the impact of a good on their wellbeing; and
5. Consumers bear the full cost of all purchases.

These assumptions must be satisfied if unmanaged market demand is to reflect societal value. Consumer behaviour in many markets will indeed satisfy these conditions. Consider the example of Apple iPod MP3 players referred to earlier. In such an “ideal” consumer market, it is not unreasonable to assume that (1) consumers are in the best position to appraise the value of an MP3 player to their wellbeing; (2) purchasing an MP3 player has little or no impact on the wellbeing of others; (3) any association between consumers’ willingness-to-pay for MP3 players and their income or circumstances are probably acceptable; (4) consumers can easily become well informed about the relative performance of different MP3 players on the market; and (5) those purchasing MP3 players bear the full costs of their purchases. It can be concluded that the market demand created by consumers’ willingness-to-pay for MP3 players reflects the societal value placed on them.
If one or more of the five conditions listed above is violated in the market for a good or service, there is no guarantee that demand will reflect societal value. In such “imperfect” consumer markets, patented products might earn profits that exceed the societal value of the innovation, inducing excessive research and development, or earn profits that are less than the societal value of the innovation, inducing sub-optimal research and development. Policy interventions might improve the pricing and/or allocation of goods and services in markets that violate the assumptions above; in doing so, policy may improve efficiency of the current market while better aligning incentives for future innovation.

4.3 Competition after patent expiry maximizes the societal benefit from innovation

Monopolies are inefficient and potentially inequitable relative to the welfare gains from perfect competition. This is one of the reasons why patents are granted for finite periods. After a patent expires, competing firms are legally permitted to enter the end markets previously protected by patent, compete, and potentially drive prices down. Under perfectly competitive circumstances, the only price that can be charged by any firm is equal to the marginal cost of bringing the product to market. Such pricing is the hallmark of competitive market efficiency—depicted as $P^c = C$ in Figure 3. When competition drives prices down in this way, consumer welfare is significantly enhanced.

![Figure 3: Competitive, price, quantity and consumer surplus after patent expiry](image)

This gain in social welfare results because the patent-holding monopolist will charge a price exceeding the cost of production. In setting this price, the monopoly excludes some consumers from purchasing the end product even though they value the product at a willingness-to-pay that exceeds the cost of producing it. While it would technically have been more efficient to require the monopolist to charge a competitive price during the life of the patent, doing so would have eliminated the market value of discovering the patented invention. Again, this paradox is why patents grant firms a legally protected monopoly for a finite period.
Perfect competition, as illustrated in Figure 3, drives profit toward zero. This does not mean that firms will disappear; it just implies that no extraordinary profits will be earned in the production of the particular good or service after the relevant patent expires. Competition ensures only a competitive rate of return to the firms in the market (and such a return is implicitly part of the curve depicting marginal cost of production).

It is possible that the price of a product may not fall to competitive levels following the expiry of relevant patents. Such a “market failure” may occur if, in addition to patents, other barriers to competition exist. This could result from high costs of entry into the market, such as the construction of costly manufacturing facilities or requirements to conduct expensive regulatory testing prior to entry. Regardless of what creates a barrier to competition, failure of a market to act competitively following the expiry of relevant patents may justify regulatory intervention. The goal of regulatory intervention would not only be to improve welfare in that particular market; it would also be to improve competition among related technologies.

4.4 “Creative destruction”: competition among related technologies

Ongoing productivity gains in an economy (characteristic of macroeconomic growth) require that successive generations of technology provide increased performance from a given level of inputs (e.g., given amounts of labour and capital). For economies to realize the full value of innovation and its potential to improve economic productivity, it is necessary that markets behave competitively after a patent expires. As discussed above, competition after patent expiry will drive prices down in the end markets and thereby remove the temporary inefficiency created by the monopoly power of the patent-holding firm.

Competition is also important insofar as it creates appropriate incentives for value-added innovation over time. Competition is needed within the end markets specific to innovations for which patents have expired and among related patented and non-patented technologies. If the demand side of the market is efficient—characterised by informed, rational, welfare-maximizing consumers who consider the full costs and benefits of available options—a patent-holding firm is restricted to pricing its patented product in accordance to its value relative to all other products, new and old, patented and non-patented. The “threat” that consumers could adopt other technologies, ensures that the incentives for innovation (expected profits from a future patented innovation) are proportional to the value added relative to existing technologies. When those existing technologies are competitively supplied, the incentives ensure that rewards are related to the value added over and above the efficient use of existing technologies.
Competition among generations of technologies can give rise to a phenomenon known as creative destruction, a term originated by Joseph Schumpeter in 1947\cite{18}. Creative destruction (or Schumpeterian competition) occurs when technologies are sufficiently innovative that they entirely replace old ones—the technological equivalent of survival of the fittest in Darwinian evolution. For example, a new, more efficient production process (word-processing) may drive old technology (typewriting) out of the marketplace, subject to the time required for technology to be adopted. Similarly, a new product may be so superior to an old one that the old product no longer has a market—one can no longer buy a five GB iPod now that Apple and its competitors offer 80GB MP3 players.

![Figure 4: Ongoing performance improvement due to competition among new and old technologies](image)

In an efficiently functioning, innovative market, consumers become better off over time as innovations both compete with, and build upon, each other (Figure 4). Such highly innovative markets will be characterized by constant change and productivity growth in terms of falling prices per unit of performance.

5 Market imperfections on the demand side of the pharmaceutical sector

- Pharmaceuticals derive their societal value from the effects they have on patient health, relative to the effects that could be obtained with treatment alternatives; yet, it is extraordinarily difficult for consumers to determine this value.
- Because specialized knowledge and skills are required for the diagnosis of need, the selection of products, and the monitoring of impacts, both product regulations and legally required agency relationships exist.
- Significant vulnerability associated with the needs for certain treatments can make patients’ willingness-to-pay extraordinarily high.
Neither patients nor their prescribing physicians bear the full cost of drugs consumed due to drug coverage offered to encourage access to needed treatments.

The optimality of patents as a mechanism for promoting desired innovation hinges significantly on the optimality of the marketplace to which patents apply. Markets that satisfy classical economic assumptions about competition among firms and the efficiency of consumer behaviour will function efficiently both in the static market for end products and in the dynamic market for innovation. Examples of such markets include the business and consumer electronics industries, where reasonably well-informed consumers aim to maximize their wellbeing by weighing the costs and benefits of available alternatives, and where producers compete with a variety of rapidly changing technologies to provide the best value in terms of price per unit of performance.

The pharmaceutical sector is not like ordinary economic markets. Owing to the nature of pharmaceuticals and their use in the pursuit of improved patient health within the health care system, both consumers (demand side) and industry (supply side) fail to meet classical economic assumptions about consumer behaviour and firm competition.

Unmanaged consumer demand for a good or service will reflect the societal value of that good or service if a number of assumptions are met. In the following sections, we delineate ways in which consumer behaviour in health care deviates from the assumptions necessary for this to occur. Each unmet assumption represents a source of market imperfection that moves the pharmaceutical sector away from the idealized model of a competitive and efficient marketplace toward one in which at least some level of policy intervention is required for demand to reflect the societal value of a given innovation.

5.1 The societal value of pharmaceuticals is based on their health impacts

Economic assumption #1: Consumer preferences are the best measure of their welfare.

As with health care more generally, it must be acknowledged that pharmaceuticals are not consumption goods in the classic sense. Drugs are potent inputs into the delivery of health care aimed at restoring or maintaining health. Pharmaceuticals themselves are of no intrinsic universal value to consumers or society. They are of value only insofar as they effectively treat a given medical condition, and only to the extent that the treated patient suffers from the condition that the drug is indicated for. Thus, while patient preferences over the possible effects of pharmaceuticals
are relevant considerations in determining their value, preferences that are not based on the actual effect of those medicines cannot generally be considered an appropriate gauge of societal value.

This particular feature of pharmaceuticals is important insofar as it relates to the persuasive effects of advertising and other forms of product branding. Despite the scientific nature of the value of innovation in the industry, pharmaceutical manufacturers have long invested substantial sums in marketing activities that have relatively little to do with scientific communications\[19-43\]. This includes gifts provided to doctors, which research suggests affects prescribing behaviour\[25\]. More recent examples are the use of celebrity endorsements in advertising targeted directly at consumers\[44\]. It may be the case that such practices are necessary to help doctors and patients remember information. However, the resulting demand for products may not necessarily be in the best interests of patients or society because such advertisements may create brand loyalties that are not based on the actual effects of the products. In apparent recognition of this characteristic of the pharmaceutical market, most nations endeavour to regulate pharmaceutical marketing activities and place limits on the audiences that may be targeted by them.

### 5.2 Pharmaceutical use may affect the wellbeing of others

Economic assumption #2: A consumer’s consumption has no impact on the wellbeing of others.

For the most part, pharmaceutical consumption is a private matter with respect to both the use of a product and its effects. However, there are examples of pharmaceutical consumption that can affect the welfare of others. Examples include cases where the consumption of a medicine has a technical impact on the health of others or their risk of illness: e.g., the positive effects that one’s vaccination has on reducing others’ risk of infection, or the negative effects that overuse of antibiotics can have on others. There are also altruistic externalities in health care: e.g., citizens care that other members of their society receive treatment, in part because we care about those who are suffering, and in part we care about the cost to the economy (in terms of health care and lost economic productivity) that results from avoidable illness.

The fact that consumption of health care can affect the wellbeing of others is one of the motivations for the public provision of health care or health insurance. Public provision enables access to care that might not otherwise be available to all under a “free market”. Pharmaceutical coverage is a policy intervention that is designed, at least in part, to ensure access to medicines that might help both the individual and society at large.
5.3 Income and vulnerability can inequitably affect willingness-to-pay

Economic assumption #3: Associations between willingness-to-pay and income or other circumstances are socially acceptable.

The relationship between willingness-to-pay and ability-to-pay in health care has been acknowledged as a source of distortion in the allocation of health care resources for many years\(^{45}\). Although access to health care is considered a common good in many societies, it is often allocated inequitably: wealthier (or better insured) individuals may receive more care than less wealthy (or uninsured) people with equivalent needs\(^{46-49}\). As a result of differential ability-to-pay for treatment, the use of market valuation as a reward for innovation will tend to focus research investment on those markets where recipients of care will have the greatest income, insurance coverage, or both. This is most readily observed in the vast amounts of money available for the health care of citizens in wealthy, developed countries, which attract a disproportionate share of research investment relative to the share of global disease burden they bear\(^{50-52}\). As summarized by a recent World Health Organization report, intellectual property rights “...can do little to stimulate innovation in the absence of a profitable market for the products of innovation, a situation which can clearly apply in the case of products principally for use in developing country markets.”\(^{12}\)

Within markets of a given income (high or low), the relationship between patient vulnerability and willingness-to-pay can also be sufficient to generate societal concerns. If a drug is needed to treat a serious medical condition, the patient may not defer purchase with the hope that competition will eventually drive prices down. This creates the potential for extraordinarily inelastic demand—the kind of market that might be described as “captive”. In such markets, a monopolist may charge a very high price without necessarily losing many sales. This challenge involves both ethics and economics, because health care markets with inelastic demand often result from the “money or life” tradeoffs inherent in purchasing decisions. To reduce this possibility, policy interventions may be required to set reasonable limits on prices charged for treatments that aim to improve or prolong the health of vulnerable patients.

5.4 Consumers may have difficulty knowing the impact of pharmaceuticals

Economic assumption #4: Consumers are fully informed about the impact of a good on their wellbeing.

Significant knowledge, skill and experience are required to diagnose the need for pharmaceuticals and to select a treatment that will produce the greatest benefit for a given person and a given condition. Any course of treatment will also involve an element of uncertainty. Very few,
if any, drugs produce desired results 100 percent of the time, and all drugs involve some degree of risk from side effects, adverse events and inappropriate use.

A person who feels better or worse after drug consumption cannot know with certainty whether nature, placebo or the drug itself was responsible for their change in health status. This characteristic of pharmaceuticals makes them “credence goods” in economic terms—those for which the value to the consumer is difficult or impossible for the consumer to ascertain. To know, with reasonable scientific certainty, whether a drug is comparatively safe and effective requires that thousands of patients be randomly assigned to receive various treatments, typically under circumstances where both patients and providers are unaware of which treatment is being administered to which patient. Even if the results of such trials are available to consumers, understanding and keeping abreast of scientific literature requires considerable knowledge and dedication.

As a result of the specialized knowledge and skills required for informed drug choices, and the inherent risk involved in making uninformed choices, both government regulation of products and a legally required agency relationship have arisen in the pharmaceutical sector. Regulations aim to ensure basic safety and efficacy of drugs available on the market. The legal requirement of a physician’s prescription (in most countries) is imposed to ensure that a suitably trained expert acts as an agent for the patient in diagnosing the need for treatment and selecting among treatment options. These interventions are intended to correct for the fact that consumers will find it difficult to assess both their need for pharmaceuticals and the impact of pharmaceuticals taken.

5.5 Those selecting pharmaceuticals seldom pay full prices

Economic assumption #5: Consumers bear the full cost of all purchases.

Many patients lack a financial incentive to carefully consider price when making drug purchases because public or private insurance covers part or all of the cost. When people do not bear the full price of a good or service, they tend to consume more of it than would be considered economically efficient—this phenomenon is known as “moral hazard” in economics. In health care, the moral hazard caused by insurance will not necessarily induce demand for care. Because of the inherent risks, inconvenience and discomfort, treatment will not be demanded by people who are not sick. Moral hazard in health care does, however, imply that insured individuals will not be sensitive to differences in the cost of alternative approaches to dealing with their medical conditions. Similarly, physicians seldom have an incentive to carefully consider price when making prescribing
decisions because they bear none of the cost of the drugs they prescribe. Indeed, research surveys have consistently shown that relatively few prescribers have adequate knowledge of the relative cost of commonly prescribed drugs\textsuperscript{[53-56]}. The lack of price sensitivity among prescribers and patients can result in inefficient product selection. If neither the patient nor the prescriber is affected by the relative cost of alternatives, neither has an incentive to choose the lower cost option among alternatives that produce equivalent health outcomes. Indeed, research on the determinants of drug expenditures over the past decade reflect this, illustrating that expenditure trends are driven not only by increased use of medicines but by increased use of newer, more expensive alternatives in the place of older, less costly ones offering similar health benefits\textsuperscript{[57-61]}. The use of interventions such as reference pricing or tiered formularies are mechanisms that endeavour to encourage patients to consider the relative cost of drugs; similarly, physician incentives and physician fund-holding (wherein physicians are responsible for managing drug budgets) are policies that aim to make doctors more price conscious.

5.6 Summary of demand side market failures

It is clear that pharmaceuticals are unlike ordinary commodities in many ways. The societal value of pharmaceuticals is based on the extent to which patients value the actual (scientifically established) health impacts of drugs, but not on patients’ or prescribers’ loyalty to particular brands. Pharmaceutical use may affect the health of others; and the wellbeing of others may also be affected if a patient’s needs are not met. The connection between income and willingness-to-pay for medicines creates global inequities in the pharmaceutical sector (under-rewarding innovations that might improve the lives of the world’s poor); while patient vulnerability can lead to extraordinarily high prices. Consumers may have difficulty determining their needs for pharmaceuticals and the actual impact of drugs consumed. Finally, owing in part to policy initiatives aimed at improving access to medicines, those selecting pharmaceuticals seldom pay full prices. Because of these market imperfections on the demand side of the pharmaceutical sector, an unregulated demand for pharmaceuticals will not reflect the societal value of consumption. This may result in inefficient allocations (prices and consumption) in the pharmaceutical market and, as a result, inefficient incentives for future pharmaceutical innovations.

Given these market imperfections and the special role played by health technologies, replicating conventional “free market” competition is not likely to be the optimal policy objective. Rather, policy interventions should aim for what economists refer to as the “second best”—the best possible policy given that a free market will be sub-optimal\textsuperscript{[62]}. A variety of interventions in the
pharmaceutical marketplace may be justified in this effort. The provision of pharmaceutical coverage, the regulation of safety and effectiveness, the requirement for physicians’ prescriptions, and the use of incentives in coverage policy all aim to address market imperfections. Determining whether the best possible outcome is being achieved requires policy evaluation and consideration.

6 Imperfections on the supply side of the pharmaceutical sector

- In addition to the costs of bringing an innovation to market, there are a number of other fixed costs associated with entry into the pharmaceutical industry that create potential barriers to competition after a patent expires.

- Barriers to entry that increase the price of non-patented products also have the effect of increasing the price of patented products.

The economic and social gains from innovation are greatest when industries act competitively, subject to the limitations created by patents. Effective competition occurs when firms compete in terms of price and value to consumers. Manufacturers of older, non-patented technologies compete to the point where prices reflect the cost of production. Manufacturers of new products compete in terms of value for money relative to those older, competitively priced technologies. Such competition within and among producers of different technologies generates the greatest societal value in end markets and results in improved productivity over time (falling price per unit of performance). Effective competition may not occur in all markets due to the characteristics of the outputs, technologies, or market size for certain goods or services.

Research costs are not the only expenses in bringing new pharmaceutical products to market. Product manufacturing requires significant fixed costs in specialized equipment and highly trained personnel. These capital costs (human and physical) are a fixed investment necessary to begin a production process. Also, as with the research needed to discover new ideas, product licensing requires that firms invest in information-generating research to show that their products meet government standards for safety, efficacy, purity and manufacturing quality. This is a sunk cost of market entry. Unlike research costs, however, the sunk costs of product licensing do not create a public good. A license to sell a product is based on information about a given manufacturer’s production processes and standards. Even if the ideas behind a product and production process are publicly available (e.g., any patents on them have expired), entry into the market still requires investment in fixed licensing costs to prove that the application of those ideas by a particular firm is producing the desired end product.
These fixed costs of specialized capacity and licensing processes are a cost of entry required not only for those entering the market with a new innovation, but also for would-be competition that might enter markets after patent expiry. They create barriers to competition: would-be competitors are not simply free to enter any given drug market in order to compete and drive prices down, as is required for perfect competition to be realized. Thus, even after a patent expires, the costs of entry into a market imply that competition will not be perfect: without policy intervention, pricing will generally exceed marginal cost of production. Pricing in markets with fixed costs of entry will be “monopolistic,” maintained by the competition among a limited number of firms in a given market and by the threat of market entry by further competition. Depending on how large the costs of market entry are relative to the size of market to be served (which will be unique to the country and product type), unregulated pricing may be excessive. That is, barriers to entry may provide extraordinary profits (those above the rate of return expected in a competitive marketplace).

Therefore, even if the demand side of the pharmaceutical sector exhibited ideal consumer behaviour (e.g., fully-informed, welfare-maximizing, and cost-conscious), the potential for imperfect competition in the pharmaceutical sector due to entry barriers might itself be grounds for policy intervention. The objective would be to mimic perfectly competitive pricing in off-patent markets and therefore ensure that the prices charged by patent-holding firms are relative to competitively priced alternatives—including non-patented technologies. Patented firms will still achieve monopoly prices, but these will be relative to prices of non-patented technologies that are kept at (or close to) perfectly competitive prices. This would improve efficiency in the end market for pharmaceutical products itself. It can also help to improve incentives for innovation.

### 7 The result of supply side and demand side market imperfections

- Due to imperfections on both the demand side and supply side, the pharmaceutical industry is characterized by limited price competition within and among patented and non-patented technologies.

- The lack of price sensitivity among prescribers and patients, combined with the difficulty for prescribers and patients to determine the comparative effectiveness of products, gives manufacturers incentives to “invent around” existing patents and market similar products.

- Firms selling imitative, patented drugs compete not in terms of price per unit of performance, but through intense product promotion.

The combined effects of imperfections on the demand and supply sides of the market for pharmaceuticals create an environment with unique forms of competition. For over a half century, it
has been acknowledged that competition in the pricing of pharmaceutical products is limited, whereas competition in the advertising and promotion of products is extensive\textsuperscript{[19,20,63,64]}. 

### 7.1 Limited price competition among patented and non-patented technologies

Because prescribing physicians seldom have an incentive to consider price, and insured patients are similarly insensitive to price differences between products, manufacturers of brand-name pharmaceuticals do not compete on price with generic drug manufacturers. Economic research has shown that manufacturers of patented, brand-name drugs will choose not to reduce their prices upon expiry of their patents, even though generic manufacturers will offer copies of the drug at a discount\textsuperscript{[65-70]}. While generic manufacturers in many markets (such as Canada’s) seldom price at a level indicative of perfect competition—that is, they do not bid prices down to the cost of production—the discounts offered by generic manufactures would still be sufficient to change consumption patterns in an ordinary market. After all, generics are typically priced 30 percent or more below their brand-name counterparts, and they are government-certified to be equivalent to brand-name drugs.

In the pharmaceutical sector, however, there are segments of “brand loyal” consumers who will continue to purchase a brand even when it is priced considerably higher than generics. Their loyalty stems from either their lack of price sensitivity or from their belief in that particular brand. If the former is the cause, the loyalty is “spurious” (simply a matter of convenience and habit) and reflects an economic inefficiency owing to price insensitivity. If beliefs about brand superiority cause loyalty, then the resulting demand reflects a real preference—albeit one based on beliefs that are not substantiated scientifically. Indeed, manufacturers of brand-name drugs often sell higher priced versions of their once patent-protected products to this market segment while also selling cheaper generic versions of the same drug (known as pseudo-generics). In this way, brand-name firms earn revenues from two segments of the off-patent market, neither of which is perfectly competitive.

The effect of off-patent brand-name drugs maintaining premium prices after patent expiry is important because it is enabled by the same product loyalties and price insensitivity that allow patent-holding brands to avoid price competition with off-patent generics. To the extent that manufacturers of brand-name patented products price their products to be competitive with any products, they typically do so only in comparison with the monopoly price of other brands. This lack of price competition in the pharmaceutical market significantly reduces the productivity gains that could be achieved through effective competition among different technologies. It also creates an
incentive for imitative research and development that would not be rewarded in a properly functioning market.

7.2 Rewards for “invent around” existing patents

The lack of price competition among firms selling comparable drugs creates an incentive for firms to “invent around” existing patents. Based on the science that led to the breakthrough product patented by the first inventor in a drug category, competitors develop a substitute product that is distinct enough to warrant a new patent but fundamentally similar to the original. These imitative rather than innovative products are often referred to as “me-too” drugs.

There is considerable evidence that imitative inventions dominate the pharmaceutical marketplace. While spending on research and development is increasing steadily and the rate of US pharmaceutical patents is growing faster than overall US patent activity, most new drug applications to the US Food and Drug Administration (FDA) are for reformulations of existing drugs. The National Institute for Health Care Management (NIHCM) Foundation in the US reviewed FDA statistics on new drug approvals from 1989 to 2000 and stratified them along an innovation spectrum based on the FDA’s own categories of therapeutic potential. This system classifies according to novelty and potential health impact. The three categories of novelty, from highest to lowest, include (1) new molecular entities; (2) incrementally modified drugs; and (3) other drugs (identical to previous drugs). There are two categories of potential health impact: (1) priority reviews for drugs with significant potential for clinical improvement; and (2) standard reviews for other drugs. Over the 12-year period studied, a minority of the drug approvals (35 percent) were for new molecular entities, fewer than half of which (15 percent) were considered to be priority reviews. The largest group by far in the analysis was standard reviews of incrementally modified drugs: me-too drugs with little or no therapeutic advantage over existing therapies and low novelty. Of all the new drugs approved by the FDA from 1989 to 2000, 77 percent were classified by the FDA as offering little or no therapeutic gain.

The situation is similar in other countries. The Patented Medicine Prices Review Board (PMPRB) of Canada also appraises the therapeutic novelty of every patented medicine in Canada to distinguish breakthrough drugs from other medicines for the purpose of monitoring drug prices. Of the 1,147 patented drugs brought to the Canadian market from 1990 to 2003, 68 (5.9 percent) met PMPRB regulatory criteria for being a breakthrough: “…the first drug to treat effectively a particular illness or which provides a substantial improvement over existing drug products.” Prescrire—an agency that produces the drug bulletins La Review Prescrire and Prescrire International—classifies
medicines based on therapeutic value. Of 3,335 drugs reviewed from 1981 to 2005, Prescrire classified 312 (less than 10 percent) as drugs that offered therapeutic advantages over alternatives; Prescrire classified only seven drugs (less than one percent) as major therapeutic advances\[^{[4]}\].

Sales figures also indicate that the rewards from this incremental innovation are greater than would be expected under competitive market conditions. Among the world’s 31 “blockbuster” drugs (with annual sales of US$1 billion or more) between 1992 and 2001, 23 were me-too drugs\[^{[73]}\]. In a study by the NICHM Foundation, standard (non-priority) drugs that were classified as incremental innovations contributed more than any other category (36 percent) to increased spending on new drugs from 1995 to 2000. A full two-thirds (67 percent) of the US$44 billion increase came from standard-rated medicines with low potential for significant clinical improvement over existing technologies\[^{[2]}\].

Canadian researchers conducted similar work using the regulatory classifications of the PMPRB to track spending on drugs with varying levels of therapeutic value over the period from 1996 to 2002\[^{[3]}\]. They found that me-too drugs—which did not offer substantial improvements over drugs existing on the market prior to 1990—accounted for 44 percent of drug utilisation and 63 percent of expenditures by 2003. The average cost-per-day of therapy of these me-too drugs was four times higher than generic versions of comparable medicines. In total, 80 percent of the increase in drug expenditure between 1996 and 2003 was driven by the use of new, patented drug products that did not offer “substantial improvements” over less expensive alternatives available prior to 1990.

Firms often assert that earnings from imitative me-too products are needed so that they can afford to invest in research that might lead to truly innovative breakthrough drugs. This, however, is contrary to economic theory. Profit maximization requires that investment decisions concerning research be based solely on the expected return of such an investment, relative to the return from alternate uses of the funds. The ability to earn monopoly profits from relatively low-risk and low-cost imitative research reduces the incentive for innovation because funding and scarce research inputs (expert personnel) are drawn away from potentially riskier but more socially valuable research toward truly innovative drugs.

Thus, to the extent that the profitability of imitative “me-too” research strategies is a result of market imperfections on the supply and/or demand sides of this sector, the earnings from imitative me-too products create societal inefficiencies. However commercially valuable imitative research may be, there is a societal opportunity-cost to research designed to invent around discoveries that have already been made. Scientists trying to discover a substitute invention for an
existing product cannot simultaneously be working on other, truly innovative research efforts. Given
the opportunity, society would carefully weigh the costs and benefits of applying limited scientific
resources to imitative research that, even if successful, would not generate significant new
knowledge. Society might, however, wish to encourage such imitation if it generated effective
competition between new and old technologies that yields steady productivity gains and improved
consumer (and thereby societal) welfare created by way of reduced cost per unit of performance.

7.3 Limited price competition creates incentive for competition in marketing

The fact that pharmaceuticals are credence goods (it is difficult for consumers to determine
their impact on their health status) and the lack of price sensitivity of both prescribers and patients
creates a form of market competition where firms focus more on marketing and attempts at product
differentiation than on price per unit of quality. This has been noted by inquiries into the
pharmaceutical industry dating to the 1950s and 1960s[19-21,63,74]. Canada’s 1985 Commission of
Inquiry on the Pharmaceutical Industry reported that the average proportion of sales going to
promotional activities was approximately 21 percent, whereas the ratio of research and development
to sales was 4.5 percent[74]. The American consumer organization, Families USA, recently compiled
data from Securities and Exchange Commission filings for the seven largest US drug manufacturers
and found that spending on marketing, advertising and administration accounts for 32 percent of
revenues, while spending on research and development accounts for approximately 14 percent of
revenues[75]. Even if half of the US “marketing, advertising, and administration” costs went toward
administration, it would remain safe to say that major firms spend more on marketing than on
research and development.

The major “innovations”—the application of new ideas in a way that has an impact on
economic or social activity—created through competition in marketing are innovations in just that:
marketing. By definition, the average me-too drug is not itself a major innovation. Similar to average
entrants into the markets for portable MP3 players or laptop computers, the average me-too drug
entrant is roughly comparable to existing competitors. What distinguishes a pharmaceutical me-too
from a consumer electronics me-too is that the market conditions for the latter force firms to
compete in terms of a quantifiable price per unit of performance (e.g., processor speed, storage
capacity, size, battery life) and the fact that the societal value of brand preferences per se is less
questionable in consumer markets than in health care.

Indeed, while manufacturers of consumer electronics do brand their products, the level of
innovation in their marketing efforts pales in comparison to the innovation in pharmaceutical
marketing. Pharmaceutical marketing innovations take advantage of several characteristics of pharmaceuticals and the pharmaceutical sector. First, given the fact that pharmaceuticals are credence goods, differences between products will be difficult to prove or disprove. It is similarly difficult to prove or to disprove claims made or implied through promotional activities. Second, physicians, who play an important role as agents for patients, have little time to evaluate all available evidence. As the volume of “information” about competing pharmaceutical products increases to the point where it might be overwhelming (or, at least, very costly for an individual to process), personal relationships and trust between the firm and the prescribing professional have increasingly become a mechanism for simplifying communications about the basic value of products. Third, physicians have a professional ethic compelling them to provide the best possible care for each individual patient, which means that advantages, however minor, justify costs, however large. This also means that offering similar performance at a lower price will not be a major selling point. Finally, patients who have similar (if not greater) challenges adequately evaluating information about drug options, also prefer that they receive the best possible care, and are often insensitive to price if their drug purchases are insured. All of these factors imply that designing communication strategies that build trust and loyalty toward the brand would result in marketing innovations (ideas that impact on economic and social activity). It also implies a strategy of challenging and competing with authorities that might otherwise become trusted sources of information—such as national drug review agencies.

The “innovative” marketing that occurs in the pharmaceutical sector is unquestionably of commercial value to the sponsors—otherwise drug manufacturers would not invest in it. Whether these marketing activities are of social value depends almost exclusively on the extent to which they are strictly informative with regards to actual advantages and disadvantages of alternative therapeutic products, and to the extent that they provide that information in a more efficient manner than alternative mechanisms for informing the prescribing process.

A large body of research evidence suggests that the marketing activities of drug manufacturers impart questionable information content while creating feelings of loyalty, brand-preference, or the need for reciprocity (to return favour for gifts and other incentives provided to prescribers, in particular). It would therefore appear that a great deal of the “innovation” in drug advertising is non-scientific differentiation of products that might otherwise be comparable in terms of established impact on patient health.

Moreover, even if pharmaceutical promotions were strictly informative, the marketplace for information through advertising may encounter problems similar to the market for product
innovation. Advertising expenditures are “sunk costs” in the production of information about particular products. Manufacturers will have little or no incentive to invest in advertising to the extent that the information created by an advertisement generates demand that can be “stolen” by competitors. The drug manufacturers that can (at least partially) exclude their competitors from serving advertising-induced demand, and thereby hope to recoup advertising expenditures, are those selling brand-name products protected by patents. For, if a manufacturer advertises a particular brand-name version of an off-patent drug, generics and other competitors could steal some (or all) of the advertising-induced market demand. The same result would occur if a firm advertised an off-patent generic drug.

Evidence of the fact that firms selling older, off-patent drugs have only a fraction of the patent holding firm’s incentive to engage in advertising is found in the advertising expenditure data. For example, between 1998 and 2005, the 10 most heavily promoted prescription drugs (in terms of annual expenditure on direct-to-consumer advertising) were patented brand-name drugs\(^8\)\(^{0-84}\).

The concentration of advertising on new, patented drugs, to the exclusion of off-patent medicines that may be as effective and cheaper, creates a market distortion: it draws attention only to those products for which there are barriers to competition. Nicholas Kaldor once summarized the social utility of advertising as a mechanism for disseminating information as follows:

As a means of supplying information, it may be argued that advertising is largely biased and deficient. Quite apart from the making of deliberately faked claims about products which legislation and professional etiquette have never yet succeeded in suppressing, the information supplied in advertisements is generally biased, in that it concentrates on particular features to the exclusion of others; makes no mention of alternative sources of supply; and it attempts to influence the behaviour of the consumer, not so much by enabling him to plan more intelligently through giving more information, but by forcing a small amount of information through its sheer prominence to the foreground of consciousness \(^{85}\)\ p.5.

While Kaldor’s assertions might overstate the problems caused by advertising in markets where firms act competitively and where consumers have both the incentive and ability to evaluate all available options\(^{86-90}\), his assessment of the societal value of advertising can reasonably apply to the pharmaceutical market\(^{79}\).

8 Measuring valued innovation in the pharmaceutical market

- There has long been interest in the development of indicators of overall innovation in the pharmaceutical sector; however, measures adopted in the past (including number of patents
filed, frequency of patent citation, and research and development expenditure) have been compromises.

- Because the pharmaceutical market does not function like an ordinary, competitive marketplace, the measures of overall innovation used in the past may be inappropriate indicators of actual performance of the sector, both at the national and international levels.
- Traditional measures of overall innovation fail to recognize the therapeutic significance of new products, or the importance of competition among innovation in terms of price per unit of therapeutic value.
- At a national level, traditional measures fail to reflect the fact that innovations first patented or marketed in one country may be supported by other nations through scientific contributions in the research process and sales of the end product.

There are a number of reasons for measuring innovation in the pharmaceutical sector. Firms and countries may wish to provide evidence of research productivity in order to justify (to shareholders or taxpayers) the expenses involved. The measures that have historically been used as a gauge of innovation in this sector have, however, been compromises. It is relatively straightforward to collect and report activity related to the process of innovation, measures of the property rights conferred on inventions, and indicators of the reward to invention (prices and revenues for end products). It is harder to measure the societal value of inventions and, therefore, to gauge the true value of innovation in this sector.

8.1 Previous measures of overall innovation in the pharmaceutical sector

Attempts to measure the value of pharmaceutical innovation at a national level date as far back as the industry inquiries of the 1950s and 1960s. Similarly, international reports on innovation date from the 1960s. In 1969, an OECD report articulated the difficulty of measuring national outputs of pharmaceutical innovation. The criteria used to identify “significant” innovations by countries participating in that study were usually “a compromise between a commercial and a technological concept of drug innovation: for example, the drugs with the highest sales volume were first selected; certain of those which had no great medical significance were then deleted, and some others which were medically important, or likely to become important, were added in spite of low sales figures.” In 1973, the Pharmaceuticals Working Party of the Economic Development Committee for Chemicals of the British National Economic Development Council studied approaches to measuring innovation, and included such matrices as: number of new chemical entities marketed, their market performance, assessment of therapeutic significance, assessment of chemical novelty, and market share within a therapeutic group. More recent discussions have focussed on measuring innovation by way of patents and patent citation indexes—on the assumption that the
more frequently a patent is cited in other patent applications, the more scientifically important it is\[93\].

For pragmatic purposes, the measures of innovation that are most often employed are those that are most easily calculated. These include process measures of pharmaceutical innovation: the number of scientists employed in a region, public funding of research, and the amount of private expenditure on research and development. Process measures of pharmaceutical innovation are “backward-looking” measures that provide information about investment in innovation, but not necessarily information about innovative productivity. Intermediate indicators of productivity are also easily measured and therefore applied in research and policy evaluation (e.g., the numbers of patents filed or the numbers of products marketed in a given country). These measures come closer to being “forward-looking” in the sense that they count research outputs, rather than inputs. They do not, however, indicate the value of the research outputs. The final, common measure of innovation used is one that attempts to gauge the value of innovations. Specifically, it is common to use either the prices or sales of patented drug products as a measure of their value of innovation or, in some uses, as a measure of the extent to which countries reward innovation. However, as outlined above, prices and the profits earned by patent holding firms only reflect the societal value of the products sold if the marketplace is characterised by effective competition and efficient demand. The pharmaceutical market exhibits neither. Therefore, the price of a product, or consumer willingness-to-pay, cannot be taken as a measure of innovation. Some patented products may be priced well above their true societal value while others may be priced well below. Other measures of the societal value of innovation in the pharmaceutical sector are, as a result, needed so that pricing and rewards can be gauged against such valuations.

8.2 Developing measures for the pharmaceutical industry

The tension between medical significance and market value as indicators of innovation observed by the OECD in 1969 persists to this day. As the OECD noted in 1969, there is a need for conceptualizing the societal value of innovation (as opposed to the incentives for, or commercial results of, invention) in the pharmaceutical sector because simply counting inventions (e.g., new patented drugs) would “…fail to distinguish between major innovations and trivial variations.”\[91\] Given the unique nature of pharmaceuticals as inputs into health care, measuring and quantifying the innovative value of a pharmaceutical entity should be done by an assessment along two vectors: novelty and health impact (or health value added). Thus, pharmaceutical innovations may be classified as incremental, substantive or radical based on their degree of technical novelty, and the
additional value they offer, either over existing technologies, or through improving market performance:

![Diagram](image)

**Figure 5: Classifying pharmaceutical innovations**

Novelty: Of the two dimensions of innovation, novelty is the easier to measure. Pharmaceutical novelty may be measured in terms of molecular structure, biologic target, pharmacologic action, or therapeutic application⁹²,⁹⁴. The range of novelty begins with drug products such as generics or other copies of an existing drug with the same active ingredients, formulations, and indications for use. These products are low on novelty. Slightly more novel drugs may be ones with similar therapeutic action as existing drugs but differences in active ingredients or dosage form: me-too drugs. New pharmaceutical technology *per se* may also involve the new application of previously existing drugs. New uses of old medicines represent moderate novelty. Finally, pharmaceuticals may involve entirely new molecules with never-before pharmacologic action and therapeutic objectives. These first-in-class drugs represent the highest level of novelty.

Value-added: The value added by a new pharmaceutical is, in many ways, more difficult to measure and conceptualize. This is, in part, because a product that is totally new (e.g., a new molecular entity with a novel mechanism of action for the treatment of a previously untreated condition) may have little or even negative value in terms of health impact. Indeed, many promising new entities are winnowed away in the research and development process because their effects on patient health turn out to be of minimal benefit, or worse. At the other end of the spectrum, generic drugs introduced to off-patent markets may offer important value by fostering competition where previously none existed. Their worth is the value of immediate competition and related efficiencies in end markets and in providing incentive that future innovations must add value relative to competitively supplied existing technologies. Through these two extreme examples, it can be seen

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that the value-added of new pharmaceuticals lies in the ratio of incremental health impact to incremental costs.

8.3 Aggregate measures of the impact of innovation

An increasing number of studies have been done to determine the aggregate impact of pharmaceutical innovation on population health and on health care systems\(^{95-109}\). Most look for relationships between expenditure on pharmaceuticals and population health status at a national or regional level\(^{97,102-105,109,110}\). Due to the limited scope of data available, it is difficult to separate the contributions of health and pharmaceutical care from the contributions of social, educational and economic policy that, though unmeasured, also contribute to the health status of a population\(^{110}\). A few studies have looked for correlations between trends in aggregate measures of health status and pharmaceutical availability, some using patient-specific data from the United States\(^{96,98-100}\). While these studies are improvements upon national-level analyses, many of those published to date suffer from methodological and conceptual weaknesses\(^{111}\), and at least one has been replicated and shown to be invalid due to poor study design\(^{106}\).

While studies of the aggregate impact of pharmaceuticals seek to answer a critically important question—do societies receive value for their pharmaceutical expenditure—the research to date is not of sufficient quality to justify its use in comparative analyses of the level, value and support of innovation. Moreover, aggregate analyses provide information that may be true on average, yet false in a majority of situations. To assess the value of innovations—and the appropriateness of pricing and reimbursement policies—requires that evaluation occur on a product-by-product basis. This will ensure that incentives are consistently aligned with relative value by product and the related therapeutic sub-market.

8.4 Attribution of scientific contributions and financial incentives

When used to measure national innovation in the pharmaceutical sector, indicators such as patents applied for or granted, product launches or research expenditure fail to recognize that the scientific research enterprise that leads to innovation in the pharmaceutical sector is a global one. Basic and applied knowledge in biology, chemistry, pharmacology, genetics and other fields is pursued by researchers working in the private and public sector around the world. As a public good, information discovered through research can be quickly shared around the world and built upon by a variety of teams—sometimes working within a given company, often working across the private and public sectors and in different industries. For example, scientists in Australia might use public
funding to conduct research that results in the discovery of information about a given biologic target for therapeutic intervention; in a private-public partnership, scientists at a Japanese institute of technology might use the Australian invention to synthesize pharmaceutical agents that would be candidates for targeting the biologic mechanism; clinicians working in Switzerland, France and Germany might test the candidates through a variety of clinical trials on behalf of a foreign private firm; finally the firm, based in the United Kingdom, might market launch the resulting innovation in the United States while having filed patents internationally.

When measuring and comparing innovation across countries, it is therefore important to recognize that support for pharmaceutical innovations in terms of scientific contributions and profits earned come from markets around the world. A country with a small domestic pharmaceutical industry may still provide appropriate support for innovation by paying for medicines in proportion to societal value. Similarly, a country with a significant domestic pharmaceutical industry may impede valued innovation in the sector through pricing and reimbursement systems that over-reward imitation and under-reward innovation.

9 Conclusion: promoting valued innovation in the pharmaceutical market

- Given imperfections in the supply and demand sides of the pharmaceutical market, free markets will not allocate resources efficiently nor provide incentives for valued innovation.
- Increased use of evidence-based and efficiency-minded coverage regimes by public and private third-party payers may improve the efficiency of the market for pharmaceutical products and thereby better align the incentives for innovation created by patents.
- Measures of pharmaceutical innovation, and the support thereof, should reflect the unique characteristics of the pharmaceutical industry.

“Free markets” will generate sub-optimal private sector investment in innovation because innovations are a form of public good. Patents can be an effective mechanism for generating private sector incentives for innovation in well-functioning marketplaces. However, due to a number of distinct features of the sector, an unregulated pharmaceutical market would not be characterized by the efficient consumer demand and effective competition among firms required for optimal societal outcomes from private sector investment in innovation. In particular, the sectors’ pattern of competitive focus on marketing activities rather than on price per unit of performance has prompted a significant share of imitative research and development and kept prices relatively high. This dynamic comes at the societal opportunity-cost of reduced incentive for, and investment in, true innovations that would be of greatest societal value.
It is possible that emerging trends in drug coverage policy—by both private and public purchasers—may correct some of the market failures in the sector. Mechanisms for third-party payment of pharmaceutical costs have evolved around the world to promote access to medicines and to reduce both the risks and inequities of financial burdens associated with ill health. While these drug plans are partially responsible for the lack of price sensitivity on the demand side of the pharmaceutical market, the buying power achieved through these third-party purchasers may be used to promote other efficiencies. Specifically, the purchasing power of drug plans can be used to force firms to price competitively even if there are barriers to entry in the pharmaceutical market. Through the use of policies such as volume discounts, preferred listings and tendering, the private insurance industry (particularly in the US) and public drug plans around the world have been able to secure more competitive prices than would be the case in a “free market” for pharmaceuticals.

However, exercising buying power to lower prices is not sufficient to improve efficiency of this market—particularly with respect for the incentive for innovation. Utilization is an important dimension of pharmaceutical markets and rewards to innovation. Coverage policies that ensure access to medicines for patients also provide manufacturers with access to markets. For firms that offer valued innovation (e.g., by way of substantial improvements in outcomes or reduction in costs), the ability to be “listed” on a formulary of a large purchasing group affords considerable, secure rewards. Such rewards to listing involve not just the price of the product listed but also the volume of sales to populations covered by a drug-purchasing agent.

The societal optimality of rewards granted through coverage policy requires consideration of the comparative cost-effectiveness to available alternatives—including competitively priced off-patent options. When constructed in a rigorous, transparent and accountable fashion, evidence-based coverage policies can promote fairness and efficiency in pharmaceutical utilization\[112-115\]. Moreover, by reflecting the comparative societal value placed on competing products, such evidence-based coverage design can emulate the competitive supply and efficient demand of a well-functioning market. A description of how coverage policy can promotes competition and valued innovation is provided in Appendix A.

As early as 1969, the OECD articulated the tension between medical significance and market value as metrics of a product’s significance\[91\]. For valued innovation to be provided with appropriate incentive, firms must expect that the profitability of a would-be discovery will be in proportion to its value to society relative to available alternatives. It is therefore critically important that both policies and comparative studies reflect the fact that unique features of this sector will necessitate ongoing monitoring and policy intervention to ensure that demand is efficient and firms are competitive.
Given the market imperfections inherent in the pharmaceutical sector, it will not suffice to organize and monitor pharmaceutical markets as if they were competitive markets for ordinary commodities—that is, measuring dollars spent on drugs or on research and development will not illuminate the national or cross-national policies that truly support valued innovation. When devising measures of valued innovation and national support for it, policy makers should consider whether a country’s system of drug pricing and reimbursement encourages efficiency in demand and competition in supply. Through evidence-based coverage policies—and thereby evidence-based systems of market access and reward—private sector incentives can be focused on the development of truly valued “breakthroughs” and on the enhancement of welfare through meaningful competition in terms of price per unit of performance.
References


Appendix: A rubric for purchasing efficiency

Using evidence of health and economic impacts in coverage policy can improve both the efficiency in the end market for pharmaceuticals and incentives for future innovation. A rubric for efficiency-minded drug coverage decisions can be delineated by dividing drug products according to their expected impacts on health outcomes and costs, relative to an appropriate clinical comparator\[^{112}\]. As illustrated in Figure 6, a product may be more effective, less effective, or as effective as a relevant comparator. It may offer these outcomes at higher cost, equal cost, or lower cost than the comparator. Decisions regarding the coverage of a product therefore depend on where it lies, relative to its comparators.

![Figure 6: Efficiency-minded drug coverage decision-making rubric](image)

It would be technically inefficient to cover products producing equivalent or worse health outcomes at higher cost than available alternatives. In contrast, a product that produces equal or better health outcomes at lower cost than available alternatives would be an efficient choice. Products that produce better health outcomes but cost more than alternatives, involve trade-offs and, therefore, must be deliberated. Some such products will be covered, others will not. These decisions depend on the local proprieties regarding the tradeoffs they necessitate due to the additional resources required to fund them.

Failure to consider the “opportunity cost” of resources needed to fund better-but-more-expensive drugs may result in allocative inefficiency\[^{116-118}\]. Indeed, failure to consider such tradeoffs is arguably the most important effect of the non-standard incentives of prescribing physicians and

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insured patients. It is, therefore, important for coverage policy to generate a transparent, consistent, and fair process for determining which products in this region will be covered\textsuperscript{[113-115]}. 

It also follows that failure to cover some such technologies does not imply that a region or drug plan does not support innovation. Health priorities of the local context may imply that some “breakthrough” drugs are not paid for in some regions. For example, if the treatment of a given rare disorder is not viable in a given region, related drugs may not be covered. Similarly, breakthrough treatments for birth control or erectile dysfunction treatments might not be paid for by a particular private insurance plan whose beneficiaries determine that such drugs are the private responsibility of members.

Finally, firms that produce a “me-too” product that offers some advantages for some patients have choices in markets governed by efficiency-minded coverage policy. They may secure a high price for the share of the market for which the product is actually of value. In which case, the drug will be listed as a “2\textsuperscript{nd}, 3\textsuperscript{rd}, or 4\textsuperscript{th}-line” therapy to be used only by patients known to benefit from the particular drug (typically after lower cost alternatives have been tried and failed). Or the firm can price competitively with the existing technologies and, through negotiation with the purchasing agent, secure a significant volume of sales (e.g., an exclusive 1\textsuperscript{st}-line listing) due to its advantages for selected population groups. Either way, the firm’s reward (through high price/low volume; or low price / high volume) should equate to the value of the drug (relative to comparators) for the particular population that might benefit from it. This reward should not be of a scale that would indicate significant value for the entire population of potential users—unless, of course, the drug was of significant value for the entire population of potential users (in which case it would not be a “me-too” product).

When conducted in a rigorous and transparent fashion, evidence-based coverage policy can also be used to help inform patients and prescribers. As mentioned above, through innovative marketing strategies, firms can change the burden of proof if they can establish a belief of benefit among consumers (patients and/or their physicians): if the perceptions of advantage are engrained deeply enough, patients and/or their physicians will demand scientific evidence disproving this perception, rather than requiring scientific evidence to supporting the advantage. Transparent and evidence-based drug coverage policy can help to place burden of proof of comparative advantages back on those making such claims\textsuperscript{[78]}.

By instituting an evidence-based coverage policies as described, policy makers help the pharmaceutical market to achieve the predictions of Schumpeter’s competition by better aligning incentives for innovation to with the relative value added in comparison with existing, competitively
supplied alternatives. Over time, real productivity improvements will be achieved as new and old technologies compete. Innovators that produce equivalent outcomes at lower cost or better outcomes at a favourable price per unit of performance will be rewarded.

Figure 7: Schumpeterian competition using efficiency-minded pharmaceutical coverage

Figure 7 illustrates how appropriate pricing and reimbursement policy can mimic the ideal outcomes of a competitive, innovative market. This illustration depicts competition in terms of cost per unit of consumption against the performance per case treated. For the pharmaceutical context, the unit of consumption will be the case treated. The outcome per case treated could be either the inverse of the number needed to treat (NNT) in order to achieve one desired clinical outcome (e.g., to avoid one stroke) or the expected number of quality adjusted life years (QALYs) gained per patient treated.

The first-generation of product in a given therapeutic group might come to market with modest performance and yet command a high price due to the fact that there are no alternatives for consumers. This is suitable provided that the price reflects the societal value of the outcome level. Following expiry of the patent on the initial technology, or through the invention of highly similar technologies during the life of the first-generation patent, competitors will bid the cost per case treated down. This reduces the price per unit of performance (increase real productivity), even though the output per case treated has not changed.

A second-generation of treatment alternative might then come to market with a slightly improved performance and a slightly higher cost. Note, however, that this generation of technology is priced to be slightly (though acceptably) more expensive than the competitively supplied versions of the first-generation technology. Rational, informed purchasers would not accept the second-generation technology if it were priced relative to the initial, monopolistically supplied version of the
first-generation technology; they would be better off using the lower cost versions of the older technology because the second-generation product is not a radical innovation over the first.

The third-generation technology illustrated in the figure offers a dramatic improvement over the first and second-generation technologies. Priced to compete with the second-generation technology, this generation of technology might be “radical” in Schumpeterian terms insofar as it could gain a monopoly over the entire market. To do so, it would have to price competitively with the second-generation technology that, in turn, was priced competitively with the competitively-supplied first-generation technology. This is the nature of creative destruction. The new technology obtains significant market size (sells to the entire market), but its price is kept in check with the older technology options.

A fourth-generation technology may enter to coincide with the third-generation, and eventually become competitively supplied with new entrants into the market that are identical or very similar. Finally, a fifth-generation technology might, once again, revolutionize the market with an improvement in performance so great that it might capture the entire market at a price that is higher per case treated than competitively-supplied versions of the fourth-generation technology. The purchasing agent might agree to the price terms and reward the firm with exclusive market share until patent expiry. Eventually, then, competition will enter the market for this fifth-generation technology and drive prices down.

The example just described would apply to many highly innovative, highly research intensive industries such as those that produce automobiles, computers, cell phones, and consumer electronics. It might, however, appear foreign to those who study the pharmaceutical market given that this sector’s characterised by many market imperfections that makes it less competitive than would be ideal for steady productivity improvement. Latter generations of pharmaceuticals typically price as though there were no prior comparators.