FINAL REPORT to the PATENTED MEDICINES PRICES REVIEW BOARD
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THE DEFINITION OF MAKING AND MARKETING COSTS FOR PURPOSES OF SECTION 85(2) OF THE PATENT ACT

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1. Objective

The purpose of this study is to assist the Patented Medicines Prices Review Board in developing criteria which will enable it to define the "making" and "marketing" costs of patented medicines for purposes of Section 85(2) of the Patent Act.

2. Plan of the Paper

Section 3 of the paper covers the relevant sections of the Patent Act and briefly summarizes the maximum non-excessive price guidelines. Section 4 summarizes the guidance that can be drawn from past decisions of the Board. Section 5 discusses the implications of the economics of regulation for cost-based drug price regulation. Sections 6 and 7 provide background on cost and pricing concepts. Section 8 examines the role that certain types of costs might play in drug price determination. Section 9 discusses the implications of the study for the role that cost evidence might play in drug price regulation and the type of evidence that could be involved. Section 10 contains some brief conclusions. Readers in a hurry might wish to focus on sections 4, 5, 8 and 9 of the paper.

3. Background

Section 85 of the *Patent Act* sets out the factors that the Board is to consider in determining, under Section 83, whether a medicine is being or has been sold at an excessive price in any market in Canada. Subsection 85(1) lays out the mandatory factors the Board shall consider, 85(2) provides additional factors the Board may consider if it is unable to make a determination based on 85(1) and 85(3) clarifies what research costs the Board shall not consider.

Section 85 reads as follows:

85. (1) In determining under section 83 whether a medicine is being or has been sold at an excessive price in any market in Canada, the Board shall take into consideration the following factors, to the extent that information on the factors is available to the Board:

(*a*) the prices at which the medicine has been sold in the relevant market;

(*b*) the prices at which other medicines in the same therapeutic class have been sold in the relevant market;

(*c*) the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;

(*d*) changes in the Consumer Price Index; and

(*e*) such other factors as may be specified in any regulations made for the purposes of this subsection.

(2) Where, after taking into consideration the factors referred to in subsection (1), the Board is unable to determine whether the medicine is being or has been sold in any market in Canada at an excessive price, the Board may take into consideration the following factors:

(*a*) the costs of making and marketing the medicine; and

b) such other factors as may be specified in any regulations made for the purposes of this subsection or as are, in the opinion of the Board, relevant in the circumstances.

(3) In determining under section 83 whether a medicine is being or has been sold in any market in Canada at an excessive price, the Board shall not take into consideration research costs other than the Canadian portion of the world costs related to the research that led to the invention pertaining to that medicine or to the development and commercialization of that invention, calculated in proportion to the ratio of sales by the patentee in Canada of that medicine to total world sales.

The Board's interpretation of what constitutes a non-excessive price under Section 85(1) is given in its non-excessive price guidelines.[1] There are three major tests. These are: the therapeutic class comparison test; the international price comparison test and; the Consumer Price Index (CPI) test. The first two tests are to determine whether the initial price of a new drug is excessive and the last is to determine whether increases in the price of an existing drug are excessive.

The therapeutic class comparison test compares the price of the DIN under review with the prices of DINs that are clinically equivalent and are sold in the same markets at prices that the Board considers not to be excessive. Comparable drug products are first selected and then their prices are compared against the drug product under review. The international price comparison test compares the average transaction price of the DIN under review with the publicly available ex-factory prices of the same medicine sold in France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States. Under the CPI test, the price of an existing drug product during the year under review will be presumed to be excessive if it exceeds the benchmark price of the DIN adjusted

[1] Patented Medicines Prices Review Board, "Compendium of Guidelines, Policies and Procedures" Chapter 1 – Excessive Price Guidelines http://www.pmprb-cepmb.gc.ca/english/view.asp?x=1034&mid=802

for the cumulative change in the Consumer Price Index (CPI) from the benchmark year to the year under review (CPI-adjusted price). In addition, one year price increases may not exceed 1.5 times the forecast change in the annual CPI. Also in periods of high inflation (over 10%), the limit will be five percentage points more than the forecast change in the annual CPI.

The Board has had no need to turn to Section 85(2) to determine whether a drug price is non-excessive. As a consequence, it remains to be determined how the costs of making and marketing a medicine might be taken into account. There are indications, however, that there may be a need for more formal criteria regarding how Section 85(2)(a) would be interpreted.

4. Guidance from Board decisions

In its Virazole decision in 1995, the Board stated the role cost considerations under Section 85(2) might play in future proceedings:

> However, for the benefit of patentees who are, or might in the future be, subject to the Board's jurisdiction, the Board would like to comment on the position of the Respondents that the price of Virazole could not possibly be said to be excessive if the costs of making and marketing the medicine exceeded the revenue from sales.
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> There would have to be compelling reasons for the Board to determine the MNE on the basis of a patentee's costs of making and marketing a medicine and it seems likely that the instances in which that analysis will be appropriate will be rare. However, it is not inconceivable that, where the criteria in subsection 85(2) were properly being considered by the Board, a patentee could present evidence which would satisfy the Board that the MNE for a medicine could be established by reference to the costs of making and marketing the medicine.
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> Nonetheless, even where the Board is instructed by the *Act* that it may consider such evidence, it is not axiomatic that in each case the costs of making and marketing the medicine will establish a floor for the MNE of the medicine. While each case would have to be considered on its merits, it seems probable that the Board would, pursuant to clause 85(2)(b), examine the broader context in which the situation arose before coming to a conclusion on the point. Also, it will always be for the Board itself, after consideration of the relevant evidence, to make its own determination on the identification, characterization and relevance of each element of costs alleged by a patentee to comprise part of the costs of making and marketing the medicine.
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> Finally, it should be noted that, given the potentially complex and contentious nature of the financial and accounting evidence on this issue, the Board expects that the determination of a MNE by reference to the costs of making and marketing the medicine would only be possible where the Board received clear and reliable evidence on the point.[2]

[2] Decision: PMPRB-95-D5/VIRAZOLE In The Matter Of the *Patent Act* R.S. 1985, c. P-4, as amended by R.S. 1985, c. 33 (3rd Supp.), and as further amended by S.C. 1993, c. 2 And In The Matter Of Canadian Patent Nos. 997,756, 1,028,264, 1,261,265, 1,297,057 and 1,297,058 And In The Matter Of ICN Canada Ltd. And ICN Pharmaceuticals Inc. (Respondents)
Hearing On The Merits Decision/Reasons PMPRB-95-D5/Virazole, pp.11-12.

In its *Copaxone* decision in February, 2008, the Board addressed the question of whether a price increase that is deemed excessive under the CPI guidelines (Section 85 (1)(d) could be justified by other factors the Board may take into account under Section 85(1). In this case, the drug remained the lowest priced in its therapeutic class even after a price increase deemed excessive under the CPI guidelines. The Board concluded that this was a relevant consideration in determining whether to allow a price increase in excess of the CPI guidelines:

> 40. The unique situation is that Copaxone, in both forms of delivery, has always been the lowest priced drug in its therapeutic class. When introduced, there was only one other drug in the class, Betaseron, and its price was found by the Board to be non-excessive when the Board approved a VCU, establishing the Betaseron price at a level approximately 25% higher than the introductory price of Copaxone. Later, three other drugs in the same therapeutic class came into the market – Avonex and two versions of Rebif – and all carry prices significantly higher than Copaxone. The only issue, therefore, is the permissible increase to the price of Copaxone in 2004, and whether it must be strictly limited in accordance with the terms of the current CPI Methodology in the Guidelines.
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> 45. The Board confirms its comments made above whereby it allocates the greatest weight to the CPI factor in paragraph 85(1)(d) in situations concerning increases in prices of existing medicines. The Board agrees however, that fact situations involving price increases similar to the circumstances of Copaxone in this matter cross a threshold where the CPI factor should not be the sole determinant of whether a price increase is excessive. In other words, the Board is prepared to recognize that the factors in paragraphs 85(1)(b) and (c) should apply to situations involving an increase in the price of a medicine that was and remains the lowest in a group of medicines of its therapeutic class in order to moderate the determination of excessiveness of price based on the Guidelines' CPI methodology.
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> 46. The Panel is prepared to adopt this interpretation of the Act because it is of the view that at some point the price of a medicine relative to that of the other medicines in its class, which are the measures referred to in paragraphs 85(1)(b) and (c), can be so low that it flies in the face of common sense to conclude that the medicine is excessively priced merely because the increase exceeds the CPI. The Panel recognizes that the determination of the point at which price differentials between medicines will impact on issues of price increases is not easy to formulate. In all the circumstances, the Panel considers that a reasonable threshold for the application of paragraphs 85(1)(b) and (c) factors is crossed in the situation presented by Copaxone, when after an increase in the price of a medicine it remains the lowest priced in a group of medicines in its therapeutic class. In these exceptional circumstances, the Panel is prepared to conclude that the patentee may increase the price of its medicine in an amount in excess of the Guidelines, subject to certain limitations described below.[3]

Although it appears to have found that Section 85(1) (b) and (c) factors warranted a price increase in excess of the CPI guidelines, the Board also invoked Section 85(2), finding that there had been a substantial improvement in the delivery mechanism for Copaxone and this had required substantial

[3] Decision: PMPRB-06-D2-COPAXONE in the matter of the Patent Act, R.S.C. 1985, c. P-4, as amended and in the matter of Teva Neuroscience G.P. – S.E.N.C., (the "Respondent") and the medicine "Copaxone"

expenditures in Canada to make and market it:

> 48. The Panel is cognizant that this is the first time that the Board is required to address excessive pricing issues based on paragraph 85(2)(a) factors and that the Guidelines provide no guidance on this issue. Paragraph 85(2)(a) refers to "the costs of making and marketing the medicine". Obviously costs are regularly incurred by patentees in the making and marketing of medicines. Thus, it is only in exceptional circumstances that the Board is prepared to consider costs of this nature under this provision. It must normally be something which demonstrates that the costs incurred in making or marketing the medicine are so exceptional or provide such an obvious benefit to users that the Board is entitled to rely on this provision. In addition, because the circumstances before the Panel concern whether an increase in the price of Copaxone above the CPI should be considered excessive, the Panel must normally be satisfied that these costs were incurred after the benchmark price of the medicine was established and that it is reasonable to take them into consideration in the matters of price increases in medicines.
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> 49. After due consideration, the Panel concludes that the only costs referred to in this matter that it is prepared to consider under paragraph 85(2)(a) are those in relation to the successive improvements in the delivery of the medicine made between 1997 and 2002. While there was no evidence showing that these delivery improvements affected the therapeutic value of the medicine, the Panel is satisfied that the "cost of making … the medicine" in paragraph 85(2)(a) is not limited to costs that improve the therapeutic value of the medicine. The Panel considers the improvements to have significantly benefited users of Copaxone, particularly for patients with MS whose personal coordination limitations make improvements in the delivery of their medicines of considerable importance to them. Paragraph 85(2)(a) includes reference to marketing costs which is indicative that a wide range of costs are to be considered under this provision and not just those related to the therapeutic value of medicines. The Board is also of the opinion that where benefit is demonstrated, it is appropriate to consider the costs incurred in making the delivery mechanisms and other necessary components of medicine as part of the costs of making a medicine, as those words are used in paragraph 85(2)(a).
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> 50. The Respondent did not provide any objective data on the costs incurred in making the improvements to the delivery mechanisms of Copaxone. Nor did it attempt to attribute these costs to Canada, as opposed to those incurred in other countries where its affiliates carry on business. Instead, it relies upon the obvious conclusions that such improvements in the delivery mechanisms involve very substantial investments in research and manufacturing and that it is reasonable to attribute a portion of those costs to Canada where the medicine is sold.
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> 52. While the Panel would have preferred to have more concrete evidence as to the precise expenditures incurred by the Respondent, for these purposes the Panel is satisfied that substantial costs were incurred which should properly be attributed to the Canadian operations of Teva. In the circumstances the improvement initiatives undertaken involved sufficient additional costs to Teva Canada to justify an increased price in the medicine that is not considered excessive.[4]

The Board took comfort in the observation that the price increase in Copaxone was in fact similar in magnitude to the cumulative increases in the CPI since

[4] Supra, n.3

Copaxone was introduced. That is, the patentee's price increase essentially kept it whole in real terms. It appears that but for the restriction on the banking of CPI increases, the patentee's price increase would not have been deemed excessive:

> 51. Because the increase in prices that Panel is considering herein are in the realm of the magnitude of CPI increases that Teva could have taken after 1997, but chose not to implement, there is less concern about the need to demonstrate a direct relationship between the costs incurred to improve the delivery mechanisms and the increase in the price of Copaxone. To some extent, it is generally recognized that yearly increases in prices up to the CPI are intended to reflect the increasing cost of medicines. Not having increased its price, there is no issue of the Respondent taking these costs twice.

The Board's *Copaxone* decision provides some guidance as to how it interprets section 85(2). To be considered relevant under section 85(2) the costs incurred in making or marketing the medicine must be exceptional or provide an obvious benefit to users. The benefits to users need not be therapeutic. They can involve improvements in the delivery mechanism of the medicine that make it more convenient for users. Where there is a demonstrable benefit, the Board is prepared to consider the cost of making this improvement (in this case, the cost of the syringe).

These costs must also have been incurred after the benchmark price of the medicine was established and the Board must further be satisfied that it is reasonable to take them into consideration in the matters of price increases in medicines. The costs involved must either be incurred by or be 'properly attributable" to the Canadian operations of the patentee.

The decision in *Copaxone* leaves open the following questions: (1) what constitutes an exceptional cost increase? (2) what costs should be considered in determining the cost of a product improvement? (3) what costs of a product improvement should be deemed reasonably attributable to Canada?

Some further guidance as to the role cost considerations (although not necessarily Section 85(2)) might play is provided by the *Prolastin* Voluntary Compliance Undertaking in 2004.[5] Prolastin is drug product derived from human plasma. It was introduced in Canada in 1991 and priced within the PMPRB guidelines until 2003 when its manufacturer (Bayer) announced a price increase in excess of 100 percent. Bayer argued that the price of blood plasma had risen markedly and the price of Prolastin had risen with it in the other countries in which it was sold:

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[5] Voluntary Compliance Undertaking Of Bayer Inc. To The Patented Medicine Prices Review Board (accepted July 9, 2004 (Prolastin)) http://www.pmprb-cepmb.gc.ca/english/View.asp?x=326&mp=126

> 3.2 By reason of a significant decrease in the global supply of blood plasma (from which Prolastin is derived), higher operating costs to comply with regulatory manufacturing standards, and escalating demand for Prolastin worldwide, Bayer cannot assure a continuing supply of Prolastin to Canadian patients unless it is sold at a price level that is reflective of its prices in other countries listed in the Regulations.

The application of the international price test under Section 85(1)(c) showed that after the increase, its price in Canada would below the international median. Although not required under the Guidelines, the Canadian price of Prolastin was also below the U.S. price. The Voluntary Compliance Undertaking effectively defined Bayer's announced price as the new benchmark price for Prolastin. In turn, Bayer committed to limit subsequent price increases to the lesser of the increase in the CPI and the change in the international median price. Bayer further agreed that if it was unable to do this, it would inform the Board in advance and provide a satisfactory written explanation.

The *Prolastin* Voluntary Compliance Agreement has the interesting feature that evidence of an increase in the cost of a major ingredient was used as a justification for re-weighting the Section 85(1) factors. In essence, the median international price test under Section 85(1) (c) took precedence over the CPI test under section 85(1)(d). Moreover, the international price comparison itself appeared to have been taken as further evidence that there had been significant cost increases.

5. Regulatory Concepts

Economists generally prefer competition, even very imperfect competition, to price regulation. In the present case, price regulation is mandated by legislation and the question at hand is how best to incorporate cost and cost change evidence in the regulatory process.

A point of emphasis in the economics of regulation is that much of the information required by the regulator is in the hands of the firms being regulated. This places the regulator at a severe informational disadvantage. This has led to a move away from forms of regulation (such as rate of return regulation) that rely heavily on internal cost data toward forms of regulation (such as price cap regulation) that focus on outcomes and rely on generally observable benchmarks. This newer form of regulation is called incentive regulation because it gives regulated firms an incentive to operate efficiently. The Board's non-excessive price guidelines have many characteristics in common with incentive regulation.

Rate of return regulation

Rate of return regulation allows the regulated firm to set its price or prices at a level that yields revenue that is sufficient to cover its costs plus a "fair" rate of

return. This is also called cost-plus regulation. Rate of return regulation was once widely used but has given way either to deregulation or to what is known as incentive regulation over the last 30 years.

A major problem with rate of return regulation is that it does not give the regulated entity any incentive to control its costs. This can result in "gold-plating," "rate-base-padding," and over-capitalization. Another problem with rate of return regulation is that it relies extensively on information that can only be provided by the firm(s) being regulated and this gives rise to issues of verification and interpretation. Further problems with rate of return regulation include lengthy and costly disputes over what a "fair" rate of return is and what costs should be included in the rate base.

Price cap regulation

Price cap regulation is a form of incentive regulation. Incentive regulation recognizes that the regulator has limited knowledge of the costs of the firms it is mandated to regulate and therefore has limited ability to engage in cost-based regulation. Under price cap regulation, the regulator sets a price ceiling which is allowed to increase annually at the rate of inflation (usually measured by the change in the CPI) minus a productivity growth factor. The price ceiling is usually defined for baskets of goods thereby allowing some prices within the basket to increase faster than the ceiling provided some increase more slowly.

Price cap regulation provides the regulated form with what economists call a high-powered incentive to reduce costs. If it is able to reduce its costs by more than the productivity growth factor, it keeps all the resulting increase in profits. If it allows its costs to increase by more than the productivity factor it suffers a commensurate decline in profits.

The problems with price cap regulation are, first, that it provides no guidance for setting the initial prices of the regulated products. This has not been a problem in many instances because price cap regulation has evolved out of a prior regulatory regime.

Second, firms subject to a price cap have an incentive to increase their profits by degrading product quality as well as by increasing productivity. Price cap regulation may have to be supplemented by service or product quality standards. An alternate approach to dealing with quality degradation is to employ a quality-corrected price index instead of the CPI. If quality is degraded the quality-adjusted price index increases less than the CPI. The advantage of using a quality-adjusted price index in place of the CPI is that this also provides an incentive for the regulated firm to make quality improvements. If quality is improved, the quality-adjusted price increase increases faster than the CPI. Note that quality-adjusted price indexes are based on observable and quantifiable

quality improvements (for example, computers that run faster) rather than on any additional costs incurred by the regulated firms involved.

Third, as is the case with all price ceilings, there is a risk of shortages or even the exit of suppliers from the market if the initial ceiling is set too low or if the productivity growth factor is set too high. In particular, firms subject to price cap regulation may experience increases in input costs that are greater than the annual rate of change in the CPI and that are beyond their control. In this case, the regulator might have to revisit the productivity growth factor to avoid shortages. This could involve a negative productivity growth factor, that is, allowing a price increase in excess of the rate of change in the CPI. In revisiting productivity factors, however, the regulator runs the risk of having price cap regulation degenerate into cost-plus regulation.

The PMPRB maximum non-excessive price guidelines

The PMPRB guidelines allow the prices of patented medicines to increase at the annual rate of inflation provided the price of the medicine involved does not become the highest in the seven country comparator group as a consequence. This criterion is essentially the same as price cap regulation with a zero productivity growth factor. It provides the patentee with a high-powered incentive to optimize production and distribution. The PMPRB guidelines also provide mechanisms for setting initial prices. A complementary regulatory regime under Health Canada as well as the incentive of the patentee to maintain the value of its reputation ensures product quality.

The CPI formula contains a further provision (inserted in 1994) limiting the allowable annual percentage increase in a DIN's price to the lesser of (a) the cumulative percentage change in CPI since the benchmark year to a maximum of three years back, and (b) 1.5 times the current year forecast change in CPI. Under this provision, any allowed price increase which is not taken within three years is lost. This regulatory design departs from normal price cap regulation and appears to entail some adverse incentive effects in that it induces patentees to increase prices as soon as they become eligible to do so. This increases both consumer costs (in present value terms) and the patentee's menu costs.

The PMPRB criteria for allowable price increases for patented medicines may have to address some of the issues that confront price cap regimes in other industries. In particular, certain costs may increase faster than the rate of increase in the CPI for a sustained period and these increases may be beyond the control of the patentee. Product functionality may also improve over time and these improvements the regulator will have to take these improvements into account.

Implications of the economics of regulation for MNE price guidelines

A reasonable interpretation of the conclusions of students and practitioners of economic regulation is that detailed cost-based regulation should be avoided if possible. In the present context this implies interpreting the section 85(1) factors so as to minimize the frequency with which it is necessary to appeal to section 85(2). Obviously, the Board has been successful in doing this in the past.

Refinement of Section 85(1)(d) criteria

Insofar as the price increase criteria are concerned, suggestions for the future include: (1) the use of price indexes other than the CPI to allow for the possibility that relevant costs in the pharmaceuticals industry may be changing at a different rate than the CPI; (2) use of quality-adjusted price indexes to reflect quality improvements; (3) use of positive or negative productivity growth factors to reflect the productivity experience of the pharmaceuticals industry and; (4) recognizing that notwithstanding restrictions on banking and annual rates of price increase, price changes that do not exceed cumulative CPI increases do no more than keep the firm involved whole in real terms.

Interpretation of Section 85(1)(b) and (c) criteria as they apply to price increases

In its *Copaxone* decision, the Board found that "… a reasonable threshold for the application of paragraphs 85(1)(b) and (c) factors is crossed in the situation presented by Copaxone, when after an increase in the price of a medicine it remains the lowest priced in a group of medicines in its therapeutic class." There is merit in attempting to define the circumstances under which a reasonable threshold for the application of Section 85(1)(b) and (c) criteria is crossed and under which 85(1)(b) and (c) considerations could outweigh CPI considerations. Among the factors on which this threshold would likely depend are the extent to which a proposed price increase exceeds the amount allowed under the CPI guidelines, the price of the drug concerned relative to the prices of other drugs in its therapeutic class and the price of the drug in Canada relative to its price in the comparator countries. This threshold may turn out to be such as to further reduce the number of occasions on which it is deemed necessary to appeal to Section 85(2). Indeed, one interpretation of its *Copaxone* decision is that the Board was not actually obliged to turn to Section 85(2) although it chose to do so.

In the *Prolastin* Voluntary Compliance Undertaking, evidence of a significant cost increase was major consideration but not under Section 85(2). Instead it triggered a re-weighting of Section 85(1) factors under which a price increase that was excessive under the CPI guidelines was deemed non-excessive by virtue of its compliance with the median international price guidelines. This approach has a great deal to commend it in that cost evidence was not used for purposes of price setting but rather to motivate a reconsideration of the relationship between the Section 85(1) factors.

Defining the circumstances under which costs are considered under Section 85(2)

If recourse to section 85(2) is necessary, it may be possible to limit the extent to which this involves detailed cost-based regulation. The teaching of the economics of regulation is that the features of incentive regulation should be preserved wherever possible and that the cost-plus regulation should be avoided wherever possible. This turns out to be easier to do in connection with regulating price changes of existing drugs than in connection with setting prices for new drugs.

With respect to price changes, consideration is limited to events that have occurred either since the drug concerned was introduced or since the last price change. Two types of events are likely to merit consideration. These are material quality improvements and exceptional cost increases. With respect to quality improvements, the Board may wish to focus on increased benefits derived by users of the drug in the use of the drug itself rather than ancillary social or economic benefits.[6] In assessing the magnitude of benefits to users, it would be preferable to rely on direct evidence of benefits to users rather than on costs incurred when evaluating claims of product improvement. The key here is to start with a defined product improvement and then to determine the expenditures that were necessary to develop and introduce it. The alternative of inferring the existence and magnitude of an improvement from expenditure claims is likely to distort the investment decisions of the firms involved as well as reducing their incentives to control their costs and is to be avoided if possible.

With respect to the cost increases the Board might consider, a way of avoiding detailed cost-based regulation is to define exceptional cost increases as those that: (1) are non-transitory; (2) are beyond the control of the regulated firm; (3) could not reasonably have been anticipated and; (4) are in excess of the rate of change in the CPI over the relevant time period. This leaves the question of the cost categories that might be deemed relevant for consideration under Section 85(2). This requires some background, presented below, on costs and pricing.

6. Cost Concepts

Discussions of cost-based price regulation usually distinguish among various types or categories of costs. Some are relevant to the determination of the economic cost of a product while others are not. Some types of costs are directly observable while others must be imputed and imputation methods may vary.

[6] A variety of terms appear to be used by specialists in this field to describe benefits to users. These benefits may be described as therapeutic, medical or clinical or in other terms. The key is that the benefits be derived in use. This could include an innovation that allows a drug to be taken at home rather than in hospital.

Opportunity cost

The opportunity cost of any action is the value of the best alternative foregone. In a properly functioning market the prices of goods and services reflect the opportunity cost of the resources (primary and intermediate inputs) required to produce them. When there are supply restrictions, opportunity cost may replace input costs as the relevant cost. When selling a fixed supply of a product, the cost of serving one customer is the revenue foregone by not serving another.[7]

The determination of the cost of equity capital is essentially an exercise in determining the opportunity cost of shareholders. What rate of return could shareholders expect on alternate investments with equivalent risk?

Sunk cost

Sunk costs are not avoidable, that is, they cannot be recovered if the firm involved leaves the market. The costs of assets that are specialized to a market are usually sunk, at least in part. By definition, the opportunity cost of a sunk asset is less than its acquisition cost.

Out of pocket costs

Out of pocket or cash costs are actual cash expenditures made to pay for inputs of various kinds that are acquired during a given period. This includes payment for materials acquired for immediate use as well as payments to purchase machinery, equipment or structures that may last many years. Cash costs appear on a source and application of funds statement.

Cash costs need not correspond closely with economic costs. A business may be a cash cow in the sense that its current cash income exceeds its current cash expenses but this may be a result of expenditures for relevant inputs (physical plant, R&D) being front-end loaded while revenues are back-end loaded. A cash cow may be uneconomic when viewed in retrospect.

Accounting costs

Accounting costs are costs that are deemed to accrue to a particular time period. Accounting costs can be calculated for purposes of financial reporting or for tax purposes. Accounting costs calculated for purposes of financial reporting are intended to provide management and investors with an accurate picture of their firm's profitability. There are many instances, however, in which opinions differ

[7] For example, in the case of electric power generators subject to environmental limitations on emissions, the cost of generating in hour X is the revenue foregone by not generating in hour Y. In the *Prolastin* case, the relevant cost to Bayer of selling in Canada was the revenue foregone by not selling the limited available quantities of this drug in other countries.

regarding the accounting procedures that most accurately reflect a firm's economic circumstances.

Accounting costs differ from cash costs in that accounting cost are accrued to the time period in which an input is used rather than the time period in which it was acquired. The obvious example of this distinction is capital equipment, the cost of which is depreciated over the life of the asset involved. This distinction is not universal. R&D and advertising expenditures which may yield a flow of profits to the firm over time are generally expensed rather than amortized on the grounds of conservatism (not overstating current profitability).

Short-run versus long-run costs

Economists distinguish three time horizon for purposes of cost and price determination. These time horizons are not specific periods of time. Rather they are determined by the options production or supply options open to the firm(s) involved. The shortest period is called the market period. In the market period, supply of the relevant product is fixed and prices are essentially demand determined. An example would be a localized market for an agricultural product after the harvest.

Beyond the market period is what economists call the short-run. The short-run is defined as a period over which some inputs are variable but some are not. In the short-run, supply can be varied but the options for doing so are limited. An example might be working overtime or adding an extra shift (implying a sequence of short-run responses). The costs of inputs that can be varied in the short-run are called variable costs. The costs of inputs that cannot be varied in the short-run are called fixed costs.

The long-run is defined as a time period over which all inputs can be varied. This is usually thought of as a period over which long-lived capital investment decisions are made. Conceptually, the long-run is a period over which all costs are variable, that is, there are no long-run fixed costs. As a practical matter, firms generally see some costs as inescapable given their continued existence and regard these as long-run fixed costs.

The investment decision

The general approach to determining whether a given investment is economic is to compare the stream of revenue it is expected to yield over time with the stream of cash costs that is expected to be incurred. This is also called the discounted cash flow (DCF) approach. It has three basic elements. These are the discount factor, the revenue stream and the cost stream. Under the DCF approach, a project is economic if its discounted revenue stream exceeds it discounted cost stream, that is, if it has a positive net present value (NPV).

Forecasting the revenue stream requires estimates of the price of the product(s) concerned and the demand for them over the product life cycle. This requires, in turn, market intelligence on the gap or niche in the market that the product(s) concerned will fill, the willingness of potential customers to pay and the speed with which either imitators will enter the market or the product concerned will be superseded by superior products. In some cases there will be a range of possible revenue forecasts depending on the circumstances that are assumed.

The discount factor reflects the time value of money. Ten dollars today is worth more than the promise of ten dollars ten years from now. Discounting makes projects with quicker pay-offs more attractive (other things being equal) and makes projects with large front-end costs less attractive. The discount factor employed in DCF analysis depends on the cost of capital for the firm involved.[8] This depends, in turn, on the rate of return the firm must promise in order to induce lenders and equity investors to finance the project involved. In essence, the discount factor reflects the opportunity cost of investors, that is, the rate of return they could earn on alternate investments of equivalent risk.

The stream of cash costs includes initial expenditures for any R&D, structures, machinery or equipment that is required as well as for production, marketing and related costs that are incurred over time. If an initial investment in R&D or facilities is required, the cost stream is said to be front-end loaded.

An alternative to the discounted cash flow approach is to find the internal rate of return on a proposed investment and compare it with the firm's hurdle rate. The hurdle rate is the firm's required rate of return on its investments. The internal rate of return is the rate of return at which the present discounted value of the revenue stream is just equal to the present discounted value of the cost stream of the investment project under consideration.

Cost functions

Cost functions show the relationship between the volume or amount of an activity conducted during a given period of time and the cost incurred as a result. Cost functions typically show the relationship between output produced during a given period of time and some measure of cost incurred during the same time period. Economists distinguish between short-run and long-run cost functions and between single product and multi-product cost functions.

Short-run cost functions distinguish between fixed and variable costs. Fixed costs are costs of inputs that cannot be varied over the time period in question. These include the amortization and depreciation of investments in R&D, structures, machinery and equipment. Economists annualize the cost of capital assets by treating them as if they were rented for the year (or the period

[8] In the simplest case, if the cost of capital is r, than the discount factor is 1/(1+r).

involved). This is known as the implicit rental price of capital.[9]

Single product cost concepts

Fixed Cost

Fixed costs do not vary with the volume of production, output or activity during a given time period. Fixed costs are not avoidable if the firm involved remains in business. To the extent that they are not also sunk, fixed costs are avoidable if the firm involved leaves the market. Fixed costs are sometimes called overhead costs although overhead costs may vary with output if the changes in output are large enough. Fixed costs include charges for depreciating or amortizing expenditures for R&D, structures, machinery and equipment that yield services (revenues) over several time periods.

Average fixed cost

Average fixed cost is defined as fixed cost divided by output per period. It is also called unit fixed cost. If output has more than one physical dimension there will be more than one way to measure average fixed cost.

Variable Cost

Variable costs are costs that vary with the volume of production per period of time. They may vary more or less than proportionately with production volume (or with the level of the activity concerned). They may vary continuously (small changes in output result in changes in cost) or variation may be subject to discontinuities (step functions). Some costs are called semi-variable, being fixed over a range of production volumes and changing discretely after a certain production volume threshold is reached.

The relationship between variable cost and output depends on how output is defined. Even in the simplest examples the definition of output may not be unique. That is, there may be a variety of cost drivers. For example, in the transportation industry, some costs may vary with the number of passengers, some with the number of miles traveled and some with the number of passenger miles.

Variable costs are sometimes called direct costs in that they vary directly (although not necessarily proportionately) with output (or with the level of the activity concerned). Major categories of direct costs are direct labor cost and direct materials cost.

[9] In the simplest case, if a firm must promise its investors an annual rate of return r, its implicit annual rental cost of an asset that was purchased for $P and that decays in value at an annual rate of d is P(r+d).

Average variable cost

Average variable cost is equal to total variable cost incurred during a given period divided by the quantity of output produced during that period. This is also known as unit variable cost. In order to calculate a meaningful unit variable cost, it is necessary to determine what constitutes a unit of output. Unit variable cost is said to be constant when it does not vary with the volume of output produced during a given time period. Constant unit variable costs may still change over time if input prices change or if production methods change. Unit variable cost is frequently disaggregated into unit labor cost and unit materials cost.

Contribution margin

The contribution margin is the excess of revenue over variable cost. This is revenue available to contribute toward the coverage of fixed costs. As long as revenue exceeds variable cost the loss-minimizing strategy is to continue production.

Shutdown point

The shutdown point occurs when revenue is less than variable cost or the price of the product is less than its average variable cost. At this point, the contribution margin is negative and the loss-minimizing strategy is to cease production.

Total Cost

Total cost is the sum of fixed and variable costs. It is essentially the cost of doing business during a given period. Total costs include the cost of all inputs used in production including the annualized cost of both tangible and intangible assets (the implicit rental price of capital).

Investments are made in the expectation that revenues will be sufficient on average to cover total costs. If expectations are disappointed and revenues fail to cover total costs, a variety of responses is possible. In the simplest case in which fixed costs are not sunk, the best response is to exit the market. If fixed costs are partially sunk and revenues cover avoidable cost, the best response is to remain in the market but not to reinvest in it.

Average total cost

Average total cost is the total cost incurred during a given period divided by the quantity of output produced during the same period. It is also called unit cost. As defined by economists, it includes a rate of return on investment is just equal to the opportunity cost of lenders and equity investors. The expectation of suppliers in a market is that the price they receive for their product will be sufficient to cover its average total cost. If it is less, investors are said to incur economic

losses. If it is greater, investors are said to earn economic profits or supra-normal rates of return.

Economic or supra-normal profits

Economic or supra-normal profits are said to exist when the rate of return on investment consistently exceeds the rate of return that would be realized on alternative investments with equivalent risk. In this case the assets of the firm are earning more than their opportunity cost and the owners of these assets (proprietors or shareholders) are said to be earning rents. The relevant rate of return is for the firm as a whole over time. The rate of return on a particular product at a particular point in time does not give an accurate indication of whether the assets of the firm are earning more or less than their opportunity cost.

Marginal cost

Marginal cost is the change in total cost (and in variable cost) that results from a one unit change in output. This presupposes a definition of a unit of output. Marginal cost may be constant or it may vary with output. This depends on whether cost changes proportionately with output. If marginal cost is constant it is equal to unit variable cost. Constant marginal costs may still change over time if input prices change or if production methods change.

Marginal cost can be measured in either the short-run or the long-run. Short-run marginal cost is the change in cost resulting from a small change in output when some inputs cannot be varied. Long-run marginal cost is the change in cost resulting from a small change in output when all inputs can be varied. It is the cost of additional production when all inputs can be chosen optimally.[10]

Marginal cost is central to the economic analysis of business pricing behavior. It is much more difficult to measure than unit variable cost because it is the change in cost associated with a small change in output, holding all other influences on cost constant. Unit variable cost is often used as a proxy for marginal cost. It is a good proxy if cost varies proportionately with output.

Long-run average cost

The long-run average cost function or planning curve shows the relationship between unit or average cost and the planned scale of output per period. It is also called the scale curve. It shows the relationship between unit cost and the

[10] Telecommunications regulators have developed a closely related cost concept for regulatory purposes. TELRIC (total element long-run incremental cost) is the basis on which the Federal Communications Commission (FCC) sets access prices for CLECs (competing local exchange carriers) in the U.S.

planned rate of output per period when all inputs can be varied optimally.

Multi-product cost concepts

Joint and common costs

Joint and common costs are costs that cannot be attributed to any product, product line or line of business. Corporate overhead is an example of common cost although joint and common costs can exist at the plant level or within functional areas. For example, a sales force may promote and solicit orders for a broad range of products and its cost may not be attributable to any one product or set of products.

Joint products

Joint products are produced together. In some cases they are produced in fixed proportions (for example, cuts of beef). Pricing of products produced in fixed proportions is essentially demand-driven. In other cases (petroleum refining, for example), proportions can be varied somewhat. In these cases the cost of one product (gasoline, for example) is the revenue that could have been derived from the other distillates (fuel oil, jet fuel, for example.

Product specific fixed costs

Product-specific fixed costs are attributable to a particular product, product line, or production run. They must be incurred if the product concerned is to be offered but they do not vary with the output of it. In a manufacturing context these costs are sometimes called start-up costs or changeover costs.

Product specific variable costs

Product-specific variable costs vary with the quantity of a specific product produced during a given time period. These costs may vary either proportionately or more or less than proportionately with the quantity produced.

Average incremental cost

Average incremental cost is the sum of product-specific fixed and variable costs incurred during a given time period all divided by the output of the product concerned over the same time period. If product-specific fixed cost is positive, average incremental cost will depend on the output of the product concerned.

Incremental versus avoidable cost

Incremental cost is forward looking. It is the additional cost that is incurred when

a product line is added. Avoidable cost is the cost that is saved when a product line is dropped. Avoidable cost is less than incremental cost if some product-specific fixed costs are sunk.

Product-specific entry/exit rule

A for-profit firm would enter production of a product or product line only if it expects the revenue that it derives from the product concerned to exceed its product-specific fixed and variable costs and therefore to make some contribution toward covering joint and common costs. Viewed in terms of pricing, looking forward, there must be an expectation that the price of a product will exceed its average incremental cost in order to warrant production. A for-profit firm would cease production of a product or product line if its price were to fall below its average avoidable cost.

Cross-subsidization

A product line is cross-subsidized (looking forward) if it the revenue derived from it is less than its product-specific fixed and variable cost. A cross-subsidized product line makes no contribution toward the recovery of joint and common costs. If a product line is cross-subsidized the subsidy must come from other product lines. A product line is said to be the source of a cross-subsidy if the revenue derived from it exceeds its standalone cost. The standalone cost of a product is the cost of producing that product by itself, that is, as a single product firm.

Cross-subsidization is essentially a regulatory phenomenon. It is an off-budget means of providing service to high cost customers (in rural areas, for example) on the same terms as to low cost customers. Under normal circumstances, a for-profit firm will not willingly engage in cross-subsidization.[11]

Multi-market costs

A multi-product firm likely sells each of its products in a number of geographic markets. This implies that in addition to product-specific costs there may be geographic market-specific fixed and variable costs. Geographic market-specific fixed costs could include local set-up costs, the costs of complying with local regulatory requirements such as product standards and labeling requirements.

Geographic market-specific fixed costs may not be attributable to any one product or product line. An example might be local “head office” costs. From the perspective of the geographic market involved, these are joint and common

[11] Promotional (introductory) pricing or loss-leadering may appear to involve cross-subsidization but in these cases the revenue deficiency involved is made up either over time as sales increase or from additional revenues on complementary products. Thus, viewed from a broader perspective there is no cross-subsidization.

(overhead) costs.

Product/geographic market-specific entry exit rule

A for-profit firm with an existing presence in a given geographic market would offer an existing product or product line in that geographic market only if it expects the revenue that it expects to derive from the product concerned in the geographic market concerned exceeds the fixed and variable costs specific to of offering the product concerned in the geographic market concerned and therefore makes some contribution toward covering joint and common costs in that geographic market. Viewed in terms of pricing, looking forward, there must be an expectation that the price of a product will exceed its local average incremental cost in order to warrant introducing it locally. A for-profit firm would cease offering a product or product line locally if its price were to fall below its local average avoidable cost.

Geographic market-specific entry/exit rule

A for-profit firm will enter a new geographic market with an existing set of products or product lines only if it expects the revenue that it expects to derive from the products concerned in the geographic market concerned exceeds the fixed and variable costs specific to of offering these products in this geographic market by an amount that is sufficient to cover the joint and common costs of operating in that geographic market. A for-profit firm would abandon a geographic market if it could no longer cover its local avoidable joint and common costs.

7. Pricing concepts

Looking forward, costs are incurred by for-profit entities in the expectation that revenues will ultimately be sufficient to cover them. This does not mean that all costs influence pricing decisions in the same way. There are many theories of pricing. Some claim to represent “reality.” It is more likely that reality differs from industry to industry and even from firm to firm within an industry.

Price setters versus price takers

Price setters choose the most profitable price for their product subject to competitive considerations and the willingness of potential customers to pay. Price takers have no discretion over the price of their product. Their only decision is how much to offer to the market at that price. Firms in textbook competitive markets are price takers. In practice, price takers tend to be suppliers of commodity products. Producers of pharmaceuticals are likely to be price setters.

Marginal cost pricing

Marginal cost pricing occurs under textbook perfect competition. It is also the ideal from an economic planner's perspective in that (absent other distortions) marginal cost prices signal the cost to the economy of serving one more customer. If average cost exceeds marginal cost, however, marginal cost pricing results in negative profits which must be covered from some other source.

Profit maximization with imperfect competition

Imperfect competition includes the general range of likely cases. At one end there is large numbers competition with differentiated products. At the other end is monopoly. In the middle there is small numbers competition (oligopoly) with either homogeneous or differentiated products. In all cases but one, price exceeds marginal cost.

Single product pricing

A textbook profit-maximizing firm in an imperfectly competitive market sets the price of a given product as a mark-up on marginal cost. The mark-up factor depends on the elasticity of demand for the product and on the competitive conditions in the market for it. The elasticity of demand for the product depends, in turn, on the price responsiveness of the product's customers and potential customers. The less price-responsive are customers and potential customers, the higher is the profit-maximizing mark-up factor.

Fixed costs do not enter directly into the profit-maximizing pricing decision. The profit-maximizing firm is comparing projected revenues and costs at various prices and fixed costs do not affect these comparisons. Fixed costs do enter the pricing decision indirectly. Going forward, if the profit-maximizing price is not sufficient to cover average fixed cost plus average variable cost, the product would not be offered. Ex ante, the price of a product is equal to or greater than the sum of its average fixed and average variable cost. Of course, expectations may be disappointed and revenues may turn out to be insufficient to cover all fixed and variable costs. In that event, the loss-minimizing strategy would be to continue to offer the product involved as long as the revenues derived from it are sufficient to cover its avoidable fixed and variable costs.

Economic theory predicts that a change in the marginal cost of a product changes its profit-maximizing price. The simplest case is one in which marginal cost does not vary with the volume of production. In this case marginal cost and average variable cost are equal and any change in either must be due to a change in the prices of the variable inputs or a change in production methods. An increase in marginal cost under these circumstances increases the profit-maximizing price. In most cases, the increase in price is less than proportionate

to the increase in marginal cost.[12] The extent to which a given percentage increase in marginal cost is passed on depends on the characteristics of the demand for the product involved.[13] Changes in fixed costs are not passed on and the amount of any change in marginal cost that is passed on does not depend on the magnitude of fixed costs.

Multi-market pricing

Multi-product pricing involves setting profit-maximizing prices in different product and geographic markets. A single product firm can be a multi-market firm if it sells in several geographic markets. Geographic markets can be national, sub-national or even local. An essential feature of a geographic market is that it is distinguishable from a pricing perspective, that is, price differences between the area concerned and other areas will not simply be arbitraged away. Depending on demand and cost conditions, profit-maximizing prices may differ for each product in each geographic market.

The profit-maximizing multi-product firm sets the price of each product in each geographic market as a mark-up on the marginal cost of that product in that market. The mark-up factor depends on the elasticity of demand for the product concerned and on competitive conditions in the geographic market concerned. The elasticity of demand depends, in turn, on the price responsiveness of customers and potential customers of the product concerned in the geographic market concerned.[14] The price responsiveness of customers may vary across geographic markets due to differences in tastes, incomes and competitive conditions among other factors.

Neither product-specific nor geographic market-specific fixed costs enter the profit-maximizing decision directly. This is because this decision involves comparing the profitability of various price points and fixed costs are, by definition, the same at each price point.

Profit-maximizing prices change in a multi-market context if the local marginal cost of the product concerned changes or if local demand conditions change and this changes the local mark-up factor.

<u>Differential pricing</u>

[12] The reason for this is that demand becomes more price responsive (elastic) at higher prices and the profit-maximizing mark-up factor falls. Although there are exceptions (iso-elastic demand) an imperfectly competitive firm is generally not able to pass on the full increase in its marginal cost to its customers.

[13] For example, if the demand schedule is linear half the increase in marginal cost would be passed on.

[14] Multi-product mark-up factors also depend on whether the products the firm is selling are related in demand. For example, the mark-up factors for two products that are substitutes will be higher than if they were independent in demand. The reverse would be true if the two products were complements.

Differential pricing is also known as price discrimination or value of service pricing. In the simplest terms it is pricing a product according to the willingness of customers to pay for it. This can involve setting a mark-up factor on the basis of the elasticity of demand in the market concerned as described above. The basic requirement for this form of differential pricing is an ability to separate customers according to their willingness to pay.[15] Other forms of differential pricing include two-part prices (a membership fee plus a usage fee) and various forms of volume or loyalty discounts. Differential pricing can also be unsystematic, granting varying discounts off list prices to attract or hold a footloose customer.

Bundled pricing

Multi-product firms often bundle several of their products for sale as a package. If products are sold only as a package this is called pure bundling. If they are sold separately and also bundled with other products, this is called mixed bundling. In the case of mixed bundling, the bundle is sold at a price that is less than the sum of the prices of its components. This can reflect the efficiencies of bundling but it can also be a means of separating customers according to their willingness to pay for each of the components of the bundle.

Bundling is ubiquitous and often passes unnoticed. (for example, most consumer durables are sold assembled (implying that parts and their assembly are bundled). Bundling generally occurs for technological or logistical reasons but it can also be a means of differential pricing (price discrimination). Under restricted circumstances bundling can also be a means of extending market power from one product to another.

Rule of thumb pricing

Given the difficulties in measuring marginal cost and in estimating the elasticity of demand, firms are likely to employ rules of thumb involving either a mark-up on unit variable cost or full-cost pricing. Mark-up pricing could involve standard mark-ups but it would be surprising if mark-ups did not vary according to the firm's perception of what the market will bear. With rule of thumb mark-up pricing, a given percentage increase in unit variable cost would result in the same percentage increase in price. Changes in fixed cost would not influence the pricing decision directly although they may influence target mark-ups over time.

Full cost pricing usually involves the calculation of standardized or normalized average total cost at a given volume or level of capacity utilization. Price is then set equal to standardized unit cost. In this case fixed and variable costs have the

[15] For example, airlines offer discounts for advance booking. This assumes that customers booking less than a week in advance have the highest willingness to pay.

same influence on the price of the product. Prices cover all costs unless production or sales volume falls short of standardized volume. In this case overhead is said to be under-absorbed. A variant of full-cost pricing is target rate of return pricing. A firm practicing target rate of return pricing would set prices so as to cover standardized unit cost as well as yielding a target level of profitability.

Full cost pricing constitutes the extreme end of the spectrum in terms of pricing strategies in that it ignores demand side considerations. More precisely, it assumes that demand is inelastic. It predicts, for example, that a firm faced with declining sales volume will increase its prices in order to cover its overhead and meet its rate of return target. Viewed from a demand-side perspective, however, declining sales may imply that the prices of the products concerned are already too high.

Life cycle pricing

Textbook profit maximization implies a period to period relationship between the marginal cost of a product and its price. Especially in the case of durable goods it may make more sense to price a product on the basis of its life cycle costs, that is, on its average (discounted) cost over its life cycle. Life cycle costs incorporate the effect of the learning curve on unit costs over time.[16] Life cycle pricing also allows recognition of demonstration and network effects among users that can increase sales over time. Products priced on a life cycle basis might be re-priced only if there are material changes in circumstances.

Menu costs

Menu costs are the costs of changing prices and other terms of sale. This can be more than just the costs of changing price lists and promotional literature. Frequent price changes may also confuse consumers and blur brand identity. Buyers of durable goods (or longer term service contracts) will want an assurance that prices will not be cut drastically soon after they have made their purchase. For any or all of these reasons, it may not be profitable from a longer term perspective to change prices as and when marginal or unit variable cost changes. Prices changes may be confined to situations in which unit cost changes are deemed to be significant and permanent.

Transfer pricing

Transfer prices are prices assigned to intermediate goods transferred within a vertically integrated or multi-market firm. They are used for three general purposes. First they are used for purposes of providing internal incentives, creating “profit centers” for purposes of evaluating the performance of functional

[16] For example commercial aircraft may be priced on the basis of what their unit cost would be after a given number, say, 250, have been produced. This becomes the break-even point.

areas and lines of business within the firm. Second, they are necessary for financial reporting purposes if there are corporate entities within the enterprise that have outside minority shareholders. Third, they are necessary for tax purposes when transfers are made across international boundaries.

Transfer prices used for tax and financial reporting purposes are supposed to mimic arm's-length prices, that is, prices that would be negotiated between independent buyers and sellers. This can be difficult in some cases because one of the reasons multi-market firms exist is to transfer intermediate inputs that are not readily transferred on an arm's-length basis.

National governments are concerned that transfer prices will be used to transfer profits from high tax to low tax jurisdiction. For this reason, the tax authorities monitor transfer prices closely.

Multi-market pricing and the coverage of joint and common costs

Joint costs can exist in any functional area of a multi-market business. By definition, they are not attributable to any one product. While there are various means of allocating these costs to individual products, they are essentially arbitrary.[17] This should not be taken to imply that it does not matter how joint costs are allocated. Accountants are taught that bad allocation rules can result in a "death spiral" which leads to the abandonment of product lines that were in fact contributing to the recovery of joint costs.

The appropriate allocation rule is to base contributions on the respective contribution margins of each product involved. This is likely to involve apparently disproportionate contributions from high demand products in the ascendancy of their respective life cycles and from geographic markets with a relatively high willingness to pay.

The profit-maximizing multi-market firm sets prices in each product and geographic market so as to maximize its contribution margin. If the sum of these contribution margins is not sufficient to cover joint and common costs then retrenchment of some kind would be required. The essential point here is that market based prices essentially solve the cost allocation problem. There is not much fretting about whether to allocate the costs of poultry processing to chicken wings or to drumsticks.

This is not much comfort to a cost-based regulator. The cost-based regulator wants to reverse the process, allocating joint costs to individual product and

[17] Research in accounting practice has explored a variety of theoretical approaches to the cost allocation problem. For an approach that is highly technical but has endured see: Alvin Roth and Robert Verrecchia, "The Shapley Value as Applied to Cost Allocation: A Reinterpretation" Journal of Accounting Research 17, (1979) pp.295-303.

geographic markets so as to build up a "cost-based" price for each market. The problem for cost-based price regulation in a multi-market context is then one of choosing among essentially arbitrary cost allocation rules.

Ramsey pricing

Ramsey pricing is a central concept in the economic theory of regulation. Ramsey pricing is a methods of allocating joint and common costs among markets so as to yield what is known as a second-best optimum. In an (economist's) ideal world, prices equal marginal costs. If there are fixed costs (or, more generally, increasing returns to scale), however, marginal cost is less than average cost so that marginal cost pricing would result in losses for the firms concerned. Ramsey prices are second best optimal, first, because they depart from marginal cost prices by just enough to cover fixed cost and no more and second, because the departure from marginal cost in each market is such as to minimize the distortion of consumption and production decisions. In essence, the Ramsey mark-up on marginal cost in the markets in which demand is least sensitive to price (markets with the lowest elasticities of demand).[18]
Ramsey prices allocate joint costs across markets according to willingness to pay and this is the best that can be done from an economic efficiency perspective in a world in which there are fixed costs to be covered. Regulators often have other objectives and this leads them to allocate fixed costs across markets using political criteria.[19]

Access pricing

Access prices are prices that are charged by vertically integrated firms to non-integrated downstream rivals for access to their upstream production facilities. These facilities are sometimes called essential or bottleneck facilities. Essential facilities are often defined as facilities that are necessary to compete in the market concerned but that are not economically feasible to replicate. Whether facilities are, in fact, essential is often disputed. Access pricing disputes are common in deregulated network industries. Industry regulators may be obliged to set access prices. Regulatory access prices are generally based on the incremental cost of access plus a contribution toward recovery of the fixed costs of the facilities involved. The determination of this contribution is problematic. The regulator's dilemma is that if the access price is set too high, downstream competition will be discouraged. If it is too low, facilities-based entry will be discouraged. Two methods of setting access prices are the efficient components

[18] The pattern of Ramsey prices across markets is the same as that of a profit-maximizing firm but Ramsey prices are lower because they are only marked up enough to cover joint fixed costs.
[19] For example, for years the CRTC set long distance telephone rates at a considerable mark-up on incremental cost while residential telephone rates were set at or below cost. This was the opposite of what would have occurred under Ramsey pricing (demand for local phone service was highly inelastic) and was probably due to a political concern with the affordability of local telephone service.

pricing rule (ECPR) and Ramsey pricing. The access price under ECPR is the marginal cost of access plus the contribution margin foregone as a result of granting access.

Implications of pricing rules for price regulation

There is no one size fits all view of price determination. While costs are incurred with the expectation that they will be covered, they can impact the pricing decision in a variety of ways. At one end of the spectrum is full cost pricing which implies that the price of a product is based on the sum of its unit fixed and variable costs. Unit fixed costs would include product-specific fixed cost plus a pro rata allocation of joint and common costs all expressed on a per unit basis at some assumed standard activity (volume) level.

At or near the other end of the spectrum is some form of pricing based on a mark-up on unit variable cost. The mark-up depends on market conditions and these may vary over the product life cycle as well as across products and across geographic markets. If expectations are realized, the mark-up is sufficient to cover all product-specific fixed costs as well as to contribute to the coverage of common costs.

The mark-up view of price determination properly recognizes that there is not a unique set of rules for setting contribution margins. To say that contribution margins depend on market circumstances does not help the regulator whose decisions essentially determine market circumstances. In this regard, average or full cost pricing may be more helpful given that the resulting unit costs can be viewed as assigning a prorate share of the fixed cost burden to each customer.

8. Types of drug costs and their role in drug pricing decisions

In this section, the role played by different types of drug costs in decisions regarding both initial prices and subsequent price changes is considered. The types of drug costs examined include: (1) ingredient costs; (2) wage and salary costs; (3) building and equipment costs; (4) regulatory compliance costs and; (5) indirect corporate overhead costs.

Drug ingredient costs

Ingredient costs are directly variable costs that are normally reflected over time in the price of the product concerned regardless of where they happen to have been incurred. This is especially true of ingredients that account for a large fraction of the value of a product.[20]

[20] For example, gasoline prices track crude oil prices (plus a refining margin) closely.

Drug ingredient costs would normally be reflected in both the initial price at which a drug is offered on the market. Changes in the prices of ingredients should also be reflected in the prices of the drugs involved over time. To the extent that drugs are priced according to competitive considerations and willingness to pay in unregulated situations, ingredient costs may play a minor role in determining the initial price of a drug. Similarly, if the cost of ingredients constitutes a small fraction of the initial price of a drug, drug prices may not track ingredient prices closely in situations where they are unconstrained by regulation.

Viewed from a regulatory perspective, there would be concerns about whether ingredients prices are arm's-length prices and if they are, whether an ability to pass along increases in the cost of ingredients would dull the incentive of the firm involved to shop the market and negotiate aggressively with its suppliers. It may also be the case that ingredients price increases in excess of the rate of inflation were anticipated and some allowance for this was built into the initial price of the drug concerned.

Royalty costs

Royalties that must be paid for the right to produce or sell a drug are obviously specific to that drug. Per unit royalties can be treated as directly variable costs and an increase in them increases unit variable cost. In an unregulated environment, unit variable cost increases would be passed on although not necessarily in full.

Sales royalties are slightly different in that the royalty payment depends on the price at which the drug concerned is sold. While an increase in the sales royalty rate cannot be interpreted simply as an increase in unit variable cost, it does have the effect of increasing the price a for-profit entity would charge in an unregulated environment. Again, there would not necessarily be a full pass-on of the increase in royalty costs.

From a regulatory perspective royalty payments pose several problems. First, they may not involve arm's-length transactions and would therefore not qualify as being beyond the control of the firm involved. Second, even arm's-length licensing transactions may pose regulatory problems. For example, firms in a cross-licensing arrangement may raise their respective royalty rates and seek price increases on this basis.

Third, a royalty payment is for the right to serve the Canadian market. This differs from payments for ingredients or labor. If the price of fine chemicals goes up salaries of biochemists goes up, firms have no choice but to pay. If a licensor raises royalty fees, the Canadian licensee may see no choice but to pay, but the compensation to the licensor for the right to serve the Canadian market is ultimately for the Board to determine.

Salary and benefit costs

Labor costs can be categorized as either direct or indirect. Hourly rated employees are more likely to be direct labor while salaried employees are more likely to be indirect. Direct labor varies with output (or throughput) and it may be attributable to individual products thus allowing for the calculation of the unit labor cost of the products involved. Unit direct labor cost would normally be reflected in the price of the product concerned regardless of where it happens to be incurred.

Indirect labor costs do not vary directly with output, throughput or the volume of the activity concerned although they do vary if the changes in the level of activity are large enough. They involve a variety of supervisory and support functions at various stages of production. They may be allocated arbitrarily to individual products and thus reflected in the prices of these products or they may be covered disproportionately by the product(s) with the largest contribution margin(s). If these costs are specific to a geographic market they must ultimately be covered from the contribution margins earned in that market. If they are not, the functions involved would have to be reorganized or downsized and if that is insufficient, the geographic market involved might ultimately have to be abandoned.

Building and equipment costs

Building and equipment costs may be specific to a product and a geographic market, specific to a product but not a geographic market, specific to a geographic market but not a product or common across products and geographic markets.[21]

A product would be offered in a geographic market in the expectation that building and equipment costs that are specific to the product and the geographic market concerned would be covered by the contribution margin derived from that product in that geographic market. These costs would a component of the floor price below which the product concerned would not be offered in the geographic market involved. The cost of these structures or equipment could also enter a decision to change prices if they are rented and rental rates increase faster than the rate of inflation or if they are owned by the firm involved but could readily be rented to others.

With respect to building and equipment costs that are specific to a drug but not a geographic market (drug-specific common costs), the decision to develop the drug and bring it to market would be made in the expectation that the contribution margins in the geographic markets in which this drug would be sold would

[21] More permutations are possible. These costs could be common across some geographic markets and some product markets.

exceed geographic market-specific fixed costs by enough to cover these common building and equipment costs.

With respect to building and equipment costs that are specific to a geographic market but not a drug (market-specific common costs), the decision invest in the facilities and equipment involved would be made in the expectation that the contribution margins on the drugs offered in that geographic market would exceed their respective product and market-specific fixed costs by enough to cover these to market-specific common costs.

With respect to building and equipment costs that are common across products and geographic markets, the ongoing operation of the firm involved is contingent on these costs being covered by contribution margins available after product-specific and market-specific fixed costs have been covered.

Regulatory and compliance costs

Regulatory and compliance costs are likely to be specific to a country and to a product. In other words they are product and geographic market-specific fixed costs. In addition, they are front-end loaded. The decision to offer a product in a given geographic market would be made in the expectation that the discounted value of the revenues derived from that market over the life cycle of the product involved will be sufficient to cover these costs. For this reason, these costs would be relevant in the determination of the initial price at which the drug would be offered in the geographic market concerned. More precisely, these costs would constitute part of the floor price below which it would not be economic to offer the product concerned in the geographic market concerned. They would not normally be relevant to a decision to increase prices unless local regulators imposed new requirements.

There may be regulatory and compliance costs that are specific to the product concerned but not specific to any geographic market (for example, the costs of complying with regulatory standards in product development or manufacture). That is, they are common costs from a geographic market perspective. The decision to bring a drug to market would be made in the expectation that the revenues from the geographic markets in which this drug is sold would exceed geographic market-specific costs by enough to cover these common regulatory and compliance costs.

Corporate overhead costs

Corporate overhead costs can include both local head office costs and international head office costs. Local head office costs are not likely to be attributable to individual drugs. That is, they are common costs as far as drug products are concerned but are specific to the geographic market concerned (market-specific common costs). The decision operate a local head office would

be made in the expectation that the contribution margins on the drugs offered in that geographic market would exceed their respective product and market-specific fixed costs by enough to cover local head office and other local common costs. Failure to cover these costs would presumably lead to a reduction in local head office activity, perhaps by consolidating some of the functions with those provided by head offices in other geographic markets or by the international head office.

International corporate overhead costs are likely not attributable to either individual drug products or to individual geographic markets. That is, they are common across products and geographic markets. The ongoing operation of the firm involved is contingent on these costs being covered by contribution margins available after product-specific and market-specific fixed costs have been covered. Failure to cover these costs results initially in reduced returns to equity investors but would presumably ultimately lead to a reduction in the activities involved and even a reorganization of some kind, possibly including a merger or divestitures.

9. Possible considerations for cost-based drug price regulation

The first consideration is that cost-based regulation should be a last resort. The Board has been successful in doing this in the past and it appears that in one recent instance in which cost-based criteria were considered, this could easily have been avoided. The need to rely on cost evidence might also be reduced by refining or augmenting the decision criteria under section 85 (1). Possible refinements include: (1) the use of price indexes other than the CPI to allow for the possibility that relevant costs in the pharmaceuticals industry may be changing at a different rate than the CPI; (2) use of quality-adjusted price indexes to reflect quality improvements; (3) use of positive or negative productivity growth factors to reflect the productivity experience of the pharmaceuticals industry; (4) recognizing that notwithstanding restrictions on both banking and annual price increases in the guidelines, price increases that do not exceed the cumulative increase in the CPI do no more than keep the firm concerned whole in real terms and; (5) delineating circumstances, if any, under which the price of the drug concerned relative to the prices of other drugs in its therapeutic class in Canada and the price of the drug in Canada relative to its price in the comparator countries is low enough to outweigh an increase in price in excess of what is allowed under the current CPI guidelines.

There are good reasons for setting a high threshold at which it is deemed necessary to turn to cost-based regulation. First, to the extent that it is anticipated by the firms involved, it is likely to distort their investment and other business decisions and to reduce their incentive to control their costs.

The second reason for setting a high threshold at which to turn to cost-based price regulation is that the regulatory process is likely to be complex, costly and

non-transparent. Any excursion into cost-based regulation must recognize the severe information asymmetry problem faced by a would-be regulator. Virtually all the relevant cost information lies in the hands of the firms being regulated. This information is proprietary and commercially sensitive as well as being costly to produce in the detail required and perhaps even more costly to verify.[22] Indeed, given the dynamic nature of the industry and the importance of intangible assets in it, cost accounts may be open to a variety of interpretations and verification itself may be problematic. This implies that any regulatory proceedings involved would require high level, industry-specific cost accounting expertise and would be largely in camera and subject to limited (or severely edited) reporting. It is difficult to imagine any firm voluntarily incurring these costs except to avoid an extremely unfavorable decision under the Section 85(1) criteria. This implies a further asymmetry in that it would likely be more costly to prove that the maximum non-excessive price should be lower than would be allowed under either the initial price or price change guidelines than it would be to prove that the maximum non-excessive price should be higher.

The cost, complexity and potential inconclusiveness of cost-based regulatory proceedings raises the issue of cost effectiveness. While this may or may not be a concern to the regulator, it is apparent that drugs for which there is a relatively small Canadian market might not be able to bear the cost of a cost-based regulatory proceeding.[23] Assessment of likely cost-effectiveness of cost-based price regulation should distinguish between the application of the price change guidelines and the application of the initial price guidelines. Proceedings regarding changes in the prices of existing drugs have a better chance of being cost-effective.

The use of cost-based evidence in the application of the price change guidelines can be focused in a variety of ways. The initial price has already been determined and attention can confined to events that have occurred since the drug concerned was introduced. Attention can be further confined to events that would warrant a real price increase, that is, a price increase in excess of the cumulative increase in the CPI since the last price increase or since the initial price was set.[24] Within this set of events, two categories might be distinguished.

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[22] There is no history of standardized cost reporting in this industry. It could take years to square the regulatory costing framework with the way the firms involved keep their accounts. Moreover, the pharmaceuticals industry is a dynamic industry in which intangible assets play a very large role. The value of these assets may change drastically from year to year depending on market developments.

[23] From a global cost-benefit perspective, there are costs but no benefit. Real resources are used to adjudicate the magnitude of a transfer of surplus. From a strictly Canadian benefit-cost perspective, it looks better. Some Canadian resources are used to adjudicate the magnitude of a transfer from Canadian consumers to (largely) foreign shareholders. From a restricted cost-effectiveness perspective, one possibility is to compare the private and public cost of the proceeding with the gain (reduced drug expenditures) to Canadian consumers or taxpayers.

[24] A strong argument can be made for avoiding recourse to cost-based regulation in cases where the price increase involved does not exceed the cumulative increase in the CPI but is

These are: (1) product improvements deemed by the Board to have been of significant benefit to users and (2) relevant cost changes that could not reasonably have been anticipated and are beyond the control of the firm involved.

With respect to product improvements, these should be improvements with which there is a record of user experience and user benefits that the Board can assess. To the extent possible, cost-based assessments of the value of an improvement should be avoided.[25] There is also a case to be made for focusing on benefits to users in the use of the drug itself. This would avoid involving the Board in assessing the worth of ancillary economic or social benefit packages.

With respect to cost changes, there is a case for focusing on changes that could not reasonably have been anticipated and thus built into the initial offer price and that a diligent firm could not have avoided by timely procurement or shopping around. The obvious example of a cost change of this nature is the cost of responding to additional regulatory requirements imposed after a drug has been introduced. Evidence based on actual or equivalent arm's-length transactions would be preferred changes in transfer prices. It may also be possible to agree on a hierarchy of costs according to their relevance to a proposed price change. The most relevant costs would be those that are directly attributable to the product involved. These include directly variable costs (wherever incurred) and Product and Canada-specific fixed costs. The cost hierarchy is discussed further below.

Cost-based regulation of initial prices poses the ultimate challenge. It is difficult to focus or to simplify because all cost categories are potentially relevant and allocations of common costs are arbitrary. Much depends on the regulator's objective. Some of the issues involved are discussed below.

Cost hierarchy

One way of limiting the ambit of cost-based regulation is to limit the types of costs that will be considered in any proceeding under Section 85(2). In this regard, there is a reasonable case for establishing a hierarchy of cost categories based on relevance to the pricing decision in a particular market. In order of relevance to the price of a given drug in a given geographic market these cost categories are: (1) directly variable costs; (2) product and geographic market-specific fixed costs; (3) geographic market-specific common costs; (4) product-specific common costs and; (5) organizational common costs.

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nevertheless deemed excessive due to restrictions on either banking of allowed CPI changes or on the magnitude of any annual increase.

[25] In the first instance it is preferable to attempt to quantify user benefits in the form of time saved, inconvenience avoided or reduced discomfort. This type of evidence is common in tort litigation. Failing this, cost evidence could be used but there would be merit in imposing a cost-sharing rule of some kind.

At the top of the hierarchy is directly variable cost. This cost can be attributed to a particular drug and it varies directly with the quantity of it produced and brought to market. Directly variable cost can also be expressed as a unit or average variable cost. The unit variable cost of serving a market must be covered by the selling price in that market and prices are often set as a mark-up on unit variable cost. The unit variable cost of serving the Canadian market can, and likely does include directly variable costs incurred in other countries.[26] Notwithstanding its central conceptual role in the pricing decision, unit variable cost is likely to account for a relatively small fraction of the price of most drugs and it may not play a large role in regulatory proceedings regarding either initial prices or price changes.

Next in the hierarchy are product and geographic market-specific fixed costs. These costs are attributable to a specific drug and to a specific geographic market such as Canada. An example of this type of costs would be the cost of complying with Canadian regulatory requirements or labeling or standards requirements that are unique to Canada. Looking forward, the drug concerned would be introduced in Canada in the expectation that the price at which it would be sold yield a contribution margin that is sufficient at least, to cover these costs. Given that these costs are probably largely sunk, failure to cover them would not likely result in the withdrawal of the drug from the market.[27] It would, however, influence future decisions about what drugs to offer in Canada or perhaps when to offer them. It would also influence decisions about the nature of the firm's future operations in Canada given that the drug concerned would not have made any contribution to covering the common costs of operating in Canada.

Next in the hierarchy would be costs that are not attributable to a specific drug but are attributable to the Canadian market. These are Canada-specific common costs. The likelihood is that for the larger firms, the majority of costs incurred in Canada are of this nature. That is a significant fraction of packaging, warehousing, distribution and marketing costs are unlikely to be attributable to individual drugs. The expectation going forward would be that the contribution margins on the drugs offered in Canada would exceed their respective product and market-specific fixed costs by enough to cover these to market-specific common costs. To the extent that these costs are sunk, failure to cover them would affect only decisions regarding future expenditures in Canada. To the extent that these costs are not sunk, they may be reduced either by reducing some of the activities involved or by consolidating them with operations in other

[26] The "Canadian share" of these variable costs is simply the unit cost multiplied by the number of units sold in Canada. Formally:

$$CDN.SHARE = vQ(q_C/Q) = vq_C$$

where v=unit variable cost, Q is worldwide sales (in units) and q_C is Canadian sales.

[27] If they are not sunk, they might be reducible if they have a discretionary element (advertising costs might be an example). If they are not sunk and can be reduced only by exiting the market, then the drug might be withdrawn.

countries.

Next in the hierarchy would be fixed costs that are attributable to a specific drug but not to a specific geographic market (drug-specific common costs). These costs, which include attributable drug development costs, would have been incurred in the expectation that the contribution margins the drug concerned would yield in the geographic markets in which it is sold would exceed its geographic market-specific fixed costs by enough to cover these common costs. This begs the question of how these costs should be distributed across geographic markets. In an unregulated environment, these costs would be covered where and when market conditions (willingness to pay, competitive conditions) allowed it. In a regulated environment, the allocation of these costs is essentially political. Regulatory objectives may be to avoid making any contribution to the coverage of these costs or to contribute some "fair share." Fair share calculations are frequently based on the portion of aggregate sales (either in physical units or in value) accounted for by the national market concerned.[28]

Last in the hierarchy are costs that are not attributable to a drug product or to a geographic market. These organizational common costs include international headquarters costs as well as non-attributable R&D costs.[29] The ongoing operation of the firm involved is contingent on these costs being covered by contribution margins available after product-specific and market-specific fixed costs have been covered. In an unregulated environment, these costs would be covered by contribution margins from the drug products and geographic markets that would bear it. In a regulated environment, the allocation of these costs is essentially political and the discussion above applies.

10. Conclusions

This study approaches the question of what constitutes making and marketing costs indirectly. It attempts to specify the limited circumstances under which cost evidence might be considered. In the case of the determination of whether a price increase is excessive, it is suggested that these circumstances be limited to instances in which there has been a demonstrable, medically-related product improvement and to instances in which there have been increases in ongoing costs that were not anticipated and are beyond the control of the firm involved.

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[28] The "Canadian share" of the total cost of developing a drug and bringing it to market is the fully absorbed world-wide average cost per unit multiplied by the number of units sold in Canada. Formally:

$$CDN.SHARE = TC(q_C / Q) = ACq_C$$

where TC is (worldwide) total product-specific cost, Q is worldwide sales (in units) and q_C is Canadian sales and AC fully absorbed product-specific average cost.

[29] Common costs would also include R&D costs that were incurred in connection with drugs that were either technical or economic failures or economic underachievers.

The suggestions made in this paper regarding the role cost evidence might play in decisions regarding excessive price increases can be viewed as an elaboration of the Board's existing jurisprudence. It is not clear that there would be anything to be gained by embodying this in formal guidelines. Indeed, there is much to lose. The existing guidelines have the virtue of relative clarity, transparency and predictability. Attempts to codify possible regulatory responses to isolated and idiosyncratic instances in which reliance on cost data is unavoidable risks compromising these virtues.

The cases in which it is deemed necessary to make use of cost data in setting initial prices would be much more challenging. Depending on the objectives of the regulator, there may be merit in using unit costs based on full cost pricing (at least at the product level) as a benchmark.

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