



Interview with Shang Ming, Director General of the Anti-Monopoly Bureau Under the Ministry of Commerce of the People's Republic of China

Editor **Fei Deng** and **Yizhe Zhang** interview **DG Shang Ming** of China's MOFCOM regarding the recent trends and developments in China's merger review process and MOFCOM's plans for the future.

Patents, Antitrust, and the High Cost of Health Care

Thomas Cotter discusses the comparative role of patents, antitrust, regulations, and other factors contributing to the high cost of health care in the U.S., using a recent series of articles in *The New York Times* as a point of departure.

Patents, Monopoly Pricing, and Antitrust in Health Care Markets

Roger Blair and **Christine Piette Durrance** analyze ways to address the rising cost of health care goods and services in the U.S. They consider whether antitrust remedies could be pursued to reduce perceived monopoly pricing in certain health care markets.

The 2015 Amendments to the Federal Rules of Civil Procedure: The Path to Meaningful Containment of Discovery Costs in Antitrust Litigation?

Edward Cavanagh reviews the proposed 2015 Amendments to the Federal Rules of Civil Procedure and studies their potential effects on the problem of escalating discovery costs in antitrust litigation following *Twombly* and *Iqbal*.

Supreme Court of Canada Allows Indirect Purchaser Class Actions for Antitrust Claims

John Bodrug, **Adam Fanaki**, and **Chantelle Spagnola** review a recent trilogy of decisions by the Supreme Court of Canada allowing indirect purchaser class actions for antitrust claims and compare the results to the U.S. law on class certification.

Interview with Shang Ming, Director General of the Anti-Monopoly Bureau Under the Ministry of Commerce of the People's Republic of China

Editors' Note: This is the third interview with Director General Shang by The Antitrust Source.* We once again follow up with DG Shang regarding the recent developments in China's merger review process and MOFCOM's plans for the future. We thank DG Shang for sharing his views with us, and SUN Miao and other officials from MOFCOM for facilitating this interview.

This interview was conducted in writing for The Antitrust Source by Fei Deng and Yizhe Zhang on March 7, 2014.

THE ANTITRUST SOURCE: MOFCOM recently issued the *Interim Rules of the Criteria for Simple Cases of Concentrations of Undertakings*.¹ Compared to the review of the regular case, how does the review of a simple concentration differ with respect to the review time, procedure, and the information the parties are required to provide?



DIRECTOR GENERAL SHANG MING: On February 11, 2014, MOFCOM issued an announcement regarding the implementation of *Interim Rules on the Criteria for Simple Cases of Concentrations of Undertakings* (Criteria Rules on Simple Cases). The Criteria Rules on Simple Cases lay out clear quantitative and qualitative criteria under which a case will qualify as a simple case as well as exceptional circumstances under which the criteria will not apply.² Right now, we are working on the relevant procedural rules for such cases, including how to apply for simple case status, the materials to be provided, the review procedures and time frames, etc. We will issue these procedural rules when appropriate.

* Interview with Shang Ming, Director General of the Anti-Monopoly Bureau Under the Ministry of Commerce of the People's Republic of China, ANTITRUST SOURCE, Feb. 2009, <http://www.abanet.org/antitrust/at-source/09/02/Feb09-ShangIntrvw2-26f.pdf>; Interview with Shang Ming, Director General of the Anti-Monopoly Bureau Under the Ministry of Commerce of the People's Republic of China, ANTITRUST SOURCE, Feb. 2011, http://www.americanbar.org/content/dam/aba/migrated/2011_build/antitrust_law/feb11_shangintrvw2_23f.authcheckdam.pdf.

¹ See <http://fldj.mofcom.gov.cn/article/ztxx/201402/20140200487001.shtml> (in Chinese).

² *Id.*; see also <http://www.jonesday.com/antitrust-alert--china-moves-towards-an-expedited-review-for-mergers-but-leaves-details-unclear-02-24-2014/>. The Rules specify the following criteria under which a concentration would be treated as a "simple" case: (1) a horizontal merger where the combined share of all parties is less than 15% in each relevant market; (2) a vertical merger where the parties' market shares do not exceed 25% in either the upstream or downstream market; (3) a conglomerate merger where the market share of each party in each market involved does not exceed 25%; (4) a joint venture established outside of China that has no activities in China; or (5) an acquisition of a foreign company that has no activities in China. The Rules provide that a case will not be treated as "simple" if (1) the concentration involves a joint venture previously controlled by two or more parties that post-concentration will be controlled by one of the parties and the joint venture competes with the controlling party in the same relevant market; (2) the relevant markets are difficult to define; or (3) MOFCOM believes that the concentration may result in adverse effects to market entry, technology development, consumers, other undertakings or the national economy. The Rules also provide that MOFCOM will revoke the "simple" case status if it finds out that the notifying party concealed material information or provided false or misleading information, if third parties provide evidence showing the existence of competitive concerns, or if significant changes occur with respect to the concentration or in the relevant markets.

ANTITRUST SOURCE: Recently, the information disclosed by MOFCOM's conditional approval announcements of concentrations has been more comprehensive and, as exemplified by the announcement regarding the acquisition of Life Technologies by Thermo Fisher Scientific, has included the results of economic analysis. Does this reflect that MOFCOM is utilizing more applied economic analysis tools in its reviews?

DG SHANG MING: The importance of economic analysis in the review of concentrations has been widely recognized. The application of economic theories and models not only provides the Bureau with new tools to obtain evidence, but also enhances the scientific credibility of the review. MOFCOM has always highly valued the application of economic theories and analytical methods and has built a specialized economist team. MOFCOM will selectively apply economic analysis tools in the review process based on the actual circumstances. For those significant and complicated cases, MOFCOM may also engage outside economists to facilitate the analysis when necessary.

ANTITRUST SOURCE: The *Provisions on the Imposition of Restrictive Conditions on Concentrations of Undertakings (Draft for Public Comment)* were published for comment in March 2013. When do you expect to issue the final Provisions? Could you give us some insight on what factors MOFCOM will take into account when making decisions to impose restrictive conditions and how these factors are considered? How does MOFCOM evaluate the efficiency defenses that the notifying parties make?

DG SHANG MING: In March 2013, *Provisions on the Imposition of Restrictive Conditions on Concentrations of Undertakings (Provisions)* were released on MOFCOM's website, soliciting public comment. We reviewed and compiled a large number of opinions and suggestions provided by the public during the process, and further revised the draft. Currently, the main body of the Provisions has been finalized, and the Provisions are under MOFCOM's internal legislative procedure. We are aiming to issue the final Provisions within this year.

Regarding the factors considered and practices adopted when deciding whether to impose restrictive conditions, MOFCOM will notify and explain to the notifying parties within a reasonable period of time, should MOFCOM, during the review process, find any adverse impact the concentration may have on competition. Within the prescribed period of time, the notifying parties then shall submit proposals on restrictive conditions that would be sufficient to eliminate the adverse effect on competition. Of course, the parties are welcome to voluntarily submit proposals on restrictive conditions before MOFCOM raises any concerns. If the notifying parties have proposed restrictive conditions within the prescribed time period, MOFCOM will discuss them with the parties, evaluate the effectiveness, feasibility and timeliness of the proposals, and inform the parties of the evaluation results. If the parties have not proposed restrictive conditions, or if the proposed restrictive conditions fail to sufficiently mitigate the adverse effect on competition, then MOFCOM will prohibit the transaction.

In considering relevant factors, MOFCOM focuses on whether the restrictive conditions to be imposed can mitigate the adverse effect on competition. The factors considered may come from various perspectives, including efficiency, whether a bankrupt company is involved, the balance of the public interest, etc.

ANTITRUST SOURCE: It would appear from the published decisions that MOFCOM is more inclined to impose behavioral remedies rather than structural remedies in horizontal merger cases. Do you agree with this conclusion?

DG SHANG MING: MOFCOM has no general preferences over the type of remedy, but rather we determine the type of remedy according to the specific nature of each case and the necessity of addressing competition issues. There are plenty of examples where the remedies imposed by MOFCOM are purely structural, or a combination of structural and behavioral. In order to decide the remedies to impose, the primary consideration is the specific circumstances of the case, including the extent to which the transaction negatively impacts competition, the appropriateness and the feasibility of the remedies, as well as the difficulty in monitoring the implementation of such remedies. It is not appropriate to conclude that MOFCOM has a general preference for a particular type of remedy based only on a few individual cases.

ANTITRUST SOURCE: One of the major disadvantages of behavioral remedies is that continuous monitoring may require substantial human resources and costs. Given MOFCOM's limited staffing, how can MOFCOM ensure effective monitoring of behavioral remedy implementations?

DG SHANG MING: Compared with structural measures, monitoring of behavioral remedies is more difficult and more resource-consuming for regulatory authorities. As for the monitoring of a hold-separate commitment, we require the parties to engage a monitoring trustee to be responsible for monitoring the remedy implementation. On one hand, we require the monitoring trustee to fulfill their duties and to do their job with due diligence. On the other hand, we may require the parties to submit implementation reports on a regular or ad hoc basis.

ANTITRUST SOURCE: In practice, how does MOFCOM supervise the trustee to ensure that it does not abuse its mandate by expanding the scope of its duties?

DG SHANG MING: MOFCOM will require the notifying parties to propose several trustee candidates and will evaluate them. An important consideration is whether the monitoring plan the trustee proposes is clear and feasible. When the monitoring trustee is appointed, MOFCOM will further evaluate the monitoring plan and set clear boundaries on the rights and obligations of the appointed monitoring trustee. The notifying parties must provide the monitoring trustee with all necessary support. The notifying parties may report to MOFCOM if they disagree with the monitoring trustee's conduct.

ANTITRUST SOURCE: What new rules or guidelines does MOFCOM plan to promulgate in the near future? Also, as indicated by some media outlets, the National People's Congress (NPC) is contemplating amending the Antimonopoly Law. What role will MOFCOM have in this process?

DG SHANG MING: In 2014, MOFCOM will focus its work on issuing the abovementioned *Provisions on the Imposition of Restrictive Conditions on Concentrations of Undertakings* and guidance for the notification of simple cases. In the meantime, based on experience gained over the past five years, MOFCOM is considering amending the *Notification Measures of the Concentration of Undertakings* and the *Review Measures of the Concentration of Undertakings*.

With regard to the amendment of the Antimonopoly Law, the provisions of the Antimonopoly Law are general in nature. Over the past five years of enforcement, MOFCOM has promulgated a series of supplementary rules to make the law more enforceable. However, for some important issues such as the definition of control, as an enforcement agency we have no power to interpret them; they are subject to authoritative interpretation by the upper legislative bodies. Therefore, it

is a primary task in the mid- and long-term to amend the Antimonopoly Law so as to provide a clearer basis for its enforcement. MOFCOM will actively cooperate with the legislative bodies to facilitate this process.

ANTITRUST SOURCE: MOFCOM has recently issued warnings and fines where merging parties failed to notify a concentration with MOFCOM. Could you offer some more details about these cases and how MOFCOM learned about these suspected notification failures?

DG SHANG MING: The information of suspected unnotified cases mainly comes from two sources: one is third-party whistle-blowing, and the other is clues MOFCOM discovers during its reviews of other concentrations.

With regard to suspected unnotified cases, during the investigation MOFCOM will take into account the nature, extent, and duration of the failure to notify, as well as whether the concentration has or may have the effect of eliminating or restricting competition. Where, after investigation, the concentration is verified to be a concentration that was not duly notified, MOFCOM may impose a fine of up to RMB500,000 on the undertakings and can additionally require the investigated parties to take measures to restore competition to the state that existed before the concentration. Depending on the specific circumstances, such measures may include terminating implementation of the concentration, disposing the parties' shares or assets within a specified time limit, selling their businesses within a specified time limit, and other necessary measures.

Up to now, MOFCOM has investigated and punished 11 unnotified cases, and the main penalties imposed have been warnings and fines.

ANTITRUST SOURCE: Over the past five years, MOFCOM has made a number of efforts to increase the transparency of its enforcement work, including the timely release of the announcements regarding conditional approvals and prohibitions, as well as the quarterly release of the statistics for unconditional approvals. What other measures will MOFCOM take to further increase its enforcement transparency?

DG SHANG MING: MOFCOM has always paid great attention to the transparency of its antimonopoly enforcement. At the enforcement level, in addition to the disclosure of cases prohibited and conditionally approved in accordance with the law, it can be observed that, over the past five years, the content of the published decision has been transformed from simple to comprehensive, with an increasing amount of information provided over time. Since October 2013, MOFCOM has started to disclose basic information on all unconditionally approved cases. These data are currently disclosed on a quarterly basis. At the legislative level, over the last five years, MOFCOM has promulgated a series of supplementary rules to provide clear guidance to the notifying parties and to increase the transparency of enforcement. In the future, MOFCOM will continue to issue relevant rules and further steadily increase the transparency of enforcement.

ANTITRUST SOURCE: Looking back over the past five years since MOFCOM's formation, what have you learned, what might you have done differently, and what are your future goals for the Bureau?

DG SHANG MING: As a witness to the entire process from the drafting to the enforcement of the Antimonopoly Law, I am delighted to see that MOFCOM has made positive progress on many aspects since the promulgation of the Antimonopoly Law five years ago. Personally, I think our

greatest achievement is that competition policy and the notion of competition has stepped up from unheard-of to front-and-center in the everyday life of Chinese society, and its important role in economic development has been widely recognized. In some of the significant government documents recently released, terms such as “fair competition” and “antimonopoly” were repeatedly mentioned, which is significant historical progress. Moreover, as individuals and as a team, we who make competition policies and enforce the law have grown rapidly. In respect of antitrust review of concentrations, China has become one of the most important jurisdictions in the world in a short time. Specifically, over the past five years we have made positive progress in the following aspects:

(1) We have built a professional enforcement team. We have established a scientific work process and trained a young and professional enforcement team through the adoption of internal rules, training and building of talent and capabilities, and gradual improvement in the structure of our internal organization.

(2) We have gradually improved the legal system regarding merger review. In the past five years, on average we issued two sets of supplementary rules per year and have established a multilayer system of rules, consisting of, from top to bottom, State Council regulations, AMC guidelines, MOFCOM ministerial rules, and guidance of the Antimonopoly Bureau of MOFCOM.

(3) We have duly carried out our enforcement work. From 2008 to the end of February 2014, MOFCOM has completed the review of 775 concentrations, among which 753 cases were unconditionally approved, 21 were conditionally approved, and 1 was prohibited. Through enforcement work, we have maintained the effectiveness of market competition and protected consumer welfare.

(4) We have promoted competition culture. MOFCOM has organized and carried out many kinds of competition training activities to enhance the legal awareness of antimonopoly law among various levels of government authorities, enterprises, and the general public, and has fostered the formation of the Chinese competition culture.

(5) We have engaged in full international cooperation. MOFCOM has established cooperation mechanisms with the competition enforcement agencies in major jurisdictions and has also established good cooperative relationships with international organizations such as OECD, APEC, and UNCTAD.

Of course, we are fully aware that we only have several years of enforcement experience, and there is still a lot to be further improved. The new administration of the Chinese government has offered a grand blueprint for China's future reform. I believe that the Antimonopoly Law will play an increasingly important role in China's in-depth reform and the wider opening-up. Specifically, MOFCOM's future work priorities include:

(1) To continue issuing supplementary rules. MOFCOM will keep summarizing the accumulated enforcement experience and will continue to promulgate supplementary rules to meet the needs of enforcement.

(2) To enhance law enforcement. MOFCOM will summarize the experience accumulated in concentration reviews, further enhance the review quality and efficiency, more strictly investigate and punish unnotified cases, and strengthen the awareness of the need for compliance in the whole society through strict enforcement of the law.

(3) To promote a culture of competition. The enforcement of the Antimonopoly Law requires support, understanding, and cooperation from all sectors of the society, and requires a good legal environment, where not only the enforcement agencies are required to responsibly perform their duties, but also undertakings are required to voluntarily abide by the law. MOFCOM will actively promote a culture of competition through its enforcement, innovated training activities, etc.

(4) To further deepen international cooperation. MOFCOM will continue to deepen the cooperation with the antimonopoly authorities in other major jurisdictions, further enhance case cooperation, and continue to contribute to maintaining the structure of market competition around the world. ●

Patents, Antitrust, and the High Cost of Health Care

Thomas F. Cotter

The recent series of articles in *The New York Times* by Elisabeth Rosenthal on the high cost of health care in the United States paints a picture of a highly dysfunctional system.¹ To be sure, the quality of health care available to those who can afford or otherwise have access to it is extremely high. Americans today have a higher life expectancy than at any time in the past; advances in diagnostics, including genetic screening, enable better preventive care and personalized medicine; many diseases and conditions that would have killed people just a few decades ago are now curable; and while others (like AIDS) remain for now incurable, many affected patients are able to live long, productive lives with the assistance of newer and better therapeutics.

And yet the negatives are all too apparent as well. Costs not only continue to increase, but often are enormously higher than what patients and insurers in other developed countries pay. At the same time, these higher costs do not translate into a longer life expectancy at birth than is enjoyed by residents of Canada, Japan, and much of Europe.² Indeed, except for the absence of any redeeming humor, the manner in which drugs and health care services in this country are priced can sometimes seem like something dreamed up by a Kafka or an Ionesco: as described by Rosenthal, “products can simply disappear and prices for vital medicines can fluctuate far more than they do for a carton of milk.”³ The obvious questions are why costs are so high, and what can be done about them? Is patent law the principal culprit, or is it a lack of antitrust oversight, or something else? What sort of reforms might make the system better?

This article discusses the comparative role of patents, antitrust, and other bodies of law in contributing to the high cost of health care as documented in the Rosenthal series. Patents have cer-

¹ See Elisabeth Rosenthal, *Patients’ Costs Skyrocket; Specialists’ Incomes Soar*, N.Y. TIMES, Jan. 19, 2014, at A1, available at http://www.nytimes.com/2014/01/19/health/patients-costs-skyrocket-specialists-incomes-soar.html?hpw&rref=us&_r=0 [hereinafter Rosenthal, *Payment Reform*]; Elisabeth Rosenthal, *As Hospital Prices Soar, A Stitch Tops \$500*, N.Y. TIMES, Dec. 3, 2013, at A1, available at http://www.nytimes.com/2013/12/03/health/as-hospital-costs-soar-single-stitch-tops-500.html?_r=0 [hereinafter Rosenthal, *Stitch*]; Elisabeth Rosenthal, *The Soaring Cost of a Simple Breath*, N.Y. TIMES, Oct. 13, 2013, at A1, available at <http://www.nytimes.com/2013/10/13/us/the-soaring-cost-of-a-simple-breath.html> [hereinafter Rosenthal, *Breath*]; Elisabeth Rosenthal, *In Need of a New Hip, But Priced Out of the U.S.*, N.Y. TIMES (Aug. 3, 2013), http://www.nytimes.com/2013/08/04/health/for-medical-tourists-simple-math.html?hp&_r=2& [hereinafter Rosenthal, *Hip*]; Elisabeth Rosenthal, *American Way of Birth: Costliest in the World*, N.Y. TIMES (June 30, 2013), <http://www.nytimes.com/2013/07/01/health/american-way-of-birth-costliest-in-the-world.html?pagewanted=all>; Elisabeth Rosenthal, *The \$2.7 Trillion Medical Bill*, N.Y. TIMES (June 1, 2013), <http://www.nytimes.com/2013/06/02/health/colonoscopies-explain-why-us-leads-the-world-in-health-expenditures.html>; see also Elisabeth Rosenthal, *Health Care’s Road to Ruin*, N.Y. TIMES, Dec. 22, 2013, at SR1, available at <http://www.nytimes.com/2013/12/22/sunday-review/health-cares-road-to-ruin.html?ref=elisabethrosenthal> [hereinafter Rosenthal, *Road to Ruin*] (referring to aspects of the current system as “Kafkaesque”); Elisabeth Rosenthal, *Good Deals on Pills? It’s Anyone’s Guess*, N.Y. TIMES (Nov. 9, 2013), <http://www.nytimes.com/2013/11/10/sunday-review/good-deals-on-pills-its-anyones-guess.html>. Equally damning is Steven Brill’s article *Bitter Pill: Why Medical Bills Are Killing Us*, TIME, Mar. 4, 2013, at 16, available at <http://content.time.com/time/magazine/article/0,9171,2136864,00.html>.

² See Aaron Carroll, *Chart: Life Expectancy at Birth and Health Care Spending Per Capita*, THE INCIDENTAL ECONOMIST BLOG (Nov. 21, 2013, 12:15 PM), <http://theincidentaleconomist.com/wordpress/chart-life-expectancy-at-birth-and-health-care-spending-per-capita/>.

³ Rosenthal, *Breath*, *supra* note 1, at A1.

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tainly played a part in raising health care costs, although that effect is offset to some degree by substantial countervailing benefits. More troubling has been a two-decades-long failure of antitrust law to prevent anticompetitive hospital mergers and other welfare-reducing practices, though in recent years the courts and agencies have begun to correct some of the worst abuses. Arguably more significant than the failures of either of these two bodies of law, however, are the many ways in which hospitals, drug companies, and other health-related industries often have been able to capture Congress and other entities that supposedly regulate their behavior.

Patents

One obvious potential source of high health care costs is the patent system. Patents, after all, are intended to induce invention by conferring monopoly rights. So, when drug companies, medical device manufacturers, and others in the health care industry obtain patents that confer market power, it should not come as a big surprise when they charge prices that exceed marginal cost. Up to a point, this ability to set price above marginal cost is a good thing because it encourages private actors to invest in creating and disclosing drugs, devices, and other inventions from which the public ultimately benefits. The whole point of the patent bargain is that the public gains something in return for conferring those monopoly rights.

At the same time, there is no universal consensus on just how much of an incentive is necessary to induce the invention of new drugs and other health care innovations. The most widely cited study, conducted by DiMasi, Hansen, and Grabowski, concluded that the average cost of developing a new drug up to the point of marketing approval was \$802 million in 2000 dollars, while a subsequent time-adjusted estimate by DiMasi and Grabowski pegged it at \$1.3 billion in 2005 dollars.⁴ By contrast, a 2011 study by Light and Warburton critiqued DiMasi et al.'s research and concluded that the median cost of developing a new drug was as little as \$43 million in 2000 dollars.⁵ DiMasi and his coauthors have vigorously defended their work, however, and their responses to the critiques leveled by Light and Warburton appear convincing.⁶ For example, DiMasi et al.'s inclusion, as a cost of drug development, of the opportunity cost of capital calculated using the average rate of return in the drug industry over the relevant time period seems reasonable from an economic standpoint. DiMasi et al. also clearly indicate their cost estimates as pre-tax costs and provide a reasoned explanation for why the appropriate focus of drug cost estimates should be on self-originated new molecular entities as opposed to all new drug applications.⁷ In addition, the DiMasi et al. estimates are consistent with two studies published by FTC economists Christopher Adams and Van Brantner, who estimated drug company R&D costs on the basis of

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⁴ See Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 166 (2003); Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 MGMT. DECISION ECON. 469, 476–77 (2007).

⁵ See Donald W. Light & Rebecca Warburton, *Demythologizing the High Costs of Pharmaceutical Research*, 6 BIOSOCIETIES 34, 46 (Mar. 2011).

⁶ See Letter from Kenneth I. Kaitin, Dir. & Research Professor, Tufts Ctr. for the Study of Drug Dev., to Supporters and Friends (Mar. 2011), available at http://csdd.tufts.edu/news/complete_story/internal_news (containing Dr. DiMasi's response to Light and Warburton's article); Joseph A. DiMasi et al., *Reply: Extraordinary Claims Require Extraordinary Evidence*, 24 J. HEALTH ECON. 1034 (2005) [hereinafter DiMasi et al., *Extraordinary*]; Joseph A. DiMasi et al., *Reply: Setting the Record Straight on Setting the Record Straight: Response to the Light and Warburton Rejoinder*, 24 J. HEALTH ECON. 1049 (2005).

⁷ See DiMasi et al., *supra* note 4, at 163–64, 173; DiMasi et al., *Extraordinary*, *supra* note 6, at 1035, 1038–40, 1041–42.

publicly available information.⁸ Finally, although there are some economists who argue that *all* patents generate more costs than benefits and should be abolished,⁹ my sense is that most patent scholars and innovation economists who have studied the matter agree that patents do serve an important public purpose by encouraging companies to incur the risks and costs of developing new drugs. Put another way, if any industry needs patent protection, it is the drug industry. Thus, while it may be burdensome (or worse) to pay a monopoly price in exchange for a life-saving drug, it's better than not having the drug developed at all, if that would be the consequence of patent abolition.

Of course, to state that patents may encourage research and development of new drugs does not mean that patents are the only, or even the best, policy tool for achieving this result. According to some economists, for example, prizes might work better than patents under some circumstances.¹⁰ Moreover, the full panoply of health-related inventions includes not only drugs but also other subject matter, such as medical devices and diagnostic methods, for which to my knowledge there are no published studies analogous to those conducted by DiMasi and others, estimating average or median R&D costs. And even if patents are necessary to stimulate the invention of drugs and other health-related subject matter, this does not necessarily mean that the optimal policy is, always and everywhere, to permit patent owners to charge whatever the market will bear. Public utility monopolies are regulated, after all; and in theory there is no obvious reason why monopolies based on patents could not be too, as they are in countries that regulate drug prices.¹¹ Finally, even if we reject price controls as too radical an idea, perhaps there are some reforms that would better align the social costs and benefits of patents for drugs and other health-related subject matter.

Identifying just what those reforms might be, however, is far from easy. One possibility would be to introduce a tougher nonobviousness standard to weed out patents that offer few improvements over the prior art but enable their owners to charge above-market prices. Critics sometimes charge, for example, that drug companies devote inordinate effort in developing “me-too” drugs that offer only marginal improvements over competitors’ products.¹²

In addition, companies sometimes engage in the practice known as “evergreening” or “product hopping,” whereby they obtain a series of patents all relating to the same drug, with the later

⁸ See Christopher Paul Adams & Van Vu Brantner, *Spending on New Drug Development*, 19 HEALTH ECON. 130, 131–32 (Feb. 2010); Christopher P. Adams & Van V. Brantner, *Estimating the Cost of New Drug Development: Is It Really \$802 Million?*, 25 HEALTH AFF. 420, 420 (2006).

⁹ See MICHELE BOLDRIN & DAVID K. LEVINE, AGAINST INTELLECTUAL MONOPOLY 68–96, 243–44 (2008); Michele Boldrin & David K. Levine, *The Case Against Patents*, 27 J. ECON. PERSP. 3, 4 (2013).

¹⁰ For discussion and citation to the relevant literature, see Michael Abramowicz, *Perfecting Patent Prizes*, 56 VAND. L. REV. 115 (2003). For a recent critique of prizes, see Benjamin N. Roin, *Intellectual Property Versus Prizes: Reframing the Debate*, 81 U. CHI. L. REV. (forthcoming 2014), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2337825.

¹¹ Compulsory licensing of patented subject matter is constrained in various ways by article 31 of the TRIPs Agreement. See Agreement on Trade-Related Aspects of Intellectual Property Rights, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPs Agreement]. And to my knowledge developed countries today rarely if ever require the compulsory licensing of drugs. They do sometimes impose price controls, though, and apparently this practice is viewed as compatible with TRIPs. See Thomas F. Cotter, *Market Fundamentalism and the TRIPs Agreement*, 22 CARDOZO ARTS & ENT. L.J. 307, 328 n.97 (2004).

¹² See, e.g., MERRILL GOOZNER, THE \$800 MILLION PILL: THE TRUTH BEHIND THE COST OF NEW DRUGS 241–42 (2004). But see Contra Joseph A. DiMasi & Laura B. Faden, *Competitiveness in Follow-On Drug R&D: A Race or Imitation?*, 10 NATURE REV. DRUG DISCOVERY 23 (Jan. 2011) (arguing that most me-too drugs are the result of patent races, not imitation); Henry I. Miller, *Critics of ‘Me-Too Drugs’ Need to Take a Chill Pill*, WALL ST. J. (Jan. 1, 2014, 5:13 PM), <http://online.wsj.com/news/articles/SB10001424052702303293604579256263038269796>.

patents claiming merely minor variations in dosage or packaging. The effect can be that generic competition is deterred and delayed, as explained more fully below.¹³ As Ben Roin points out, however, even if one concedes that these practices on balance reduce social welfare, adopting a tougher nonobviousness standard might not be an appropriate response.¹⁴ The problem is that nonobviousness is evaluated as of the date of invention (or, for applications filed on or after March 16, 2013, as of the date of filing),¹⁵ and this date typically occurs years before any clinical tests have established that the drug is safe and effective, let alone whether it will be a modest success or a significant breakthrough. Nonobviousness, in other words, is only loosely tied to any concept of social value; and while this might seem like a defect of the patent system generally, it is hardly obvious (no pun intended) how patent examiners could predict the social value of an invention far in advance of any clinical studies. Requiring that examination be deferred until after the completion of clinical studies also seems unworkable, not only because it would require significant changes to the patent statute's definition of "prior art," but also because, as Roin notes, drug companies are reluctant to go forward with clinical testing until they have a patent in hand.¹⁶

It is also worth noting that various patent doctrines eliminate or reduce patent owners' ability to extract supracompetitive profits under certain circumstances. For example, a diagnostic or therapeutic method that in substance is nothing more than a recitation of a naturally occurring correlation (for example, between the presence of an elevated level of a metabolite in the blood and the need to increase the dosage of a prescribed medication) is considered a patent-ineligible law of nature; and the Supreme Court recently held that human genes are patent-ineligible products of nature.¹⁷ In addition, Section 287(c) of the Patent Act prevents an owner from enforcing a patent claiming a medical or surgical procedure against a medical practitioner. The doctrine of double patenting prevents a drug company from patenting an obvious variation over its own previously patented drug,¹⁸ and the inherency doctrine precludes patenting a metabolite that is produced in the body upon ingestion of a prior art drug.¹⁹ And while the practice of permitting patent owners to file continuations—separate applications for variations derived from an initial "parent" application—is largely unknown outside the United States, and in the past may have contributed

¹³ See Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 TEX. L. REV. 685, 687 (2009) ("The pharmaceutical industry has witnessed this behavior for years, as branded drug companies have used exclusionary tactics to stay one step ahead of generic entry. In one species of this behavior—called 'product hopping'—the branded company makes repeated changes in a drug's formulation to prevent generic substitution, rather than to improve the efficacy of the drug product.").

¹⁴ See Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 536–39 (2009).

¹⁵ For applications filed prior to March 16, 2013, the applicable text reads "A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a) (2006). For applications filed on or after March 16, 2013, nonobviousness is evaluated as of the date of filing. See 35 U.S.C. § 103 (2012) ("A patent . . . may not be obtained . . . if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.").

¹⁶ See Roin, *supra* note 14, at 545.

¹⁷ See *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2111 (2013); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293–94 (2012).

¹⁸ See, e.g., *Sun Pharm. Indus. v. Eli Lilly & Co.*, 611 F.3d 1381, 1384–85 (Fed. Cir. 2010).

¹⁹ See *Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373, 1379 (Fed. Cir. 2003) ("In general, a limitation or the entire invention is inherent and in the public domain if it is the 'natural result flowing from' the explicit disclosure of the prior art.").

to evergreening, amendments passed ten years ago have reined in drugmakers' ability to use continuations to ward off generic competition.²⁰

To sum up, patents surely contribute to the high cost of health care. At the same time, they also (most likely) serve a valid public purpose. To the extent patents drive prices higher than they need to be to stimulate invention, some reforms to patent law may be desirable or other regulatory responses may be appropriate. But it's far from clear that patent doctrine itself requires a major overhaul.

Antitrust

A less defensible cause of high health care costs is the insufficient level of effective antitrust enforcement in health care markets. Three examples are provided below.

[I]t's far from clear that patent doctrine . . . requires a major overhaul.

First, the market for health care related services has become remarkably more concentrated over the past two decades. Hospital consolidation took off in the early 1990s. Since that time there have been over 1000 hospital mergers or acquisitions in the United States, including over 500 between 2007 and 2012.²¹ Concentration within health care markets, not surprisingly, has steadily risen. According to Capps and Dranove, the average metropolitan statistical area HHI in the market for hospital ownership as of 2009 was "roughly 4700," well above the level (2500) the enforcement agencies consider highly concentrated.²² The agencies themselves lost six consecutive cases against hospital mergers between 1993 and 1995, and did not block a single one for over a decade.²³ In a 2004 article, Thomas Greaney argued that courts permitting these mergers (and other practices Greaney believes were questionable) were applying theory divorced from facts by assuming away pre-existing market imperfections in defining geographic and product markets.²⁴

The empirical evidence appears to be consistent with Greaney's critique. In the 2006 report cited above, Vogt and Town stated that the "great weight of the literature" to date showed that hospital consolidation "raised prices by at least five percent and likely by significantly more."²⁵ A 2011 update by Gaynor and Town reported, on the basis of empirical studies published since 2006, that increases in hospital market concentration had led to increases in the price of hospital care; that hospital mergers in concentrated markets had generally led to significant price increases ("most

²⁰ See Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U. L. REV. 63, 81–83 (2004).

²¹ See WILLIAM B. VOGT & ROBERT TOWN, HOW HAS HOSPITAL CONSOLIDATION AFFECTED THE PRICE AND QUALITY OF HOSPITAL CARE? 1 (2006), available at http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2006/rwjf12056/subassets/rwjf12056_1 ("By the mid-1990s, hospital merger and acquisition activity was nine times its level at the start of the decade."); Kate Pickert, *Fewer Hospitals May Lead to Higher Prices*, TIME (July 23, 2013), <http://swampland.time.com/2013/07/23/fewer-hospitals-may-lead-to-higher-prices/> (citing data provided by Professor Martin Gaynor and from the American Hospital Association); see also Avik S.A. Roy, Senior Fellow, Manhattan Inst. for Policy Research, Presentation at the MAHP Annual Conference: Hospital Consolidation: The Biggest Driver of Health Care Costs that (Almost) Nobody Talks About 9, 12 (Nov. 19, 2011), available at <http://www.mahp.com/unify-files/MAHP%20Avik%20Roy.pdf>.

²² See Cory Capps & David Dranove, *Market Concentration of Hospitals*, AHIP COVERAGE 2 (June 2011), available at <http://www.ahipcoverage.com/wp-content/uploads/2011/06/ACOs-Cory-Capps-Hospital-Market-Consolidation-Final.pdf>.

²³ See Cory Capps, *Federal Health Plan Merger Enforcement Is Consistent and Robust* 36 (2009), available at <http://www.bateswhite.com/media/pnc/7/media.227.pdf> (America's Health Insurance Plans' public comment submitted to the Department of Justice and the Federal Trade Commission on the Horizontal Merger Guidelines Review Project); Mark E. Rust, *From HCQIA to ACA: The 180° Arc of Provider Antitrust Concerns In Healthcare Over 25 Years*, 33 J. LEGAL MED. 21, 29–30 (2012).

²⁴ See Thomas L. Greaney, *Chicago's Procrustean Bed: Applying Antitrust Law in Health Care*, 71 ANTITRUST L.J. 857, 858–59 (2004) ("Chicago [School]'s tendency to brush over market imperfections in health care often causes tribunals to miss important features of health care markets and misjudge the impact of antitrust claims.")

²⁵ VOGT & TOWN, *supra* note 21, at 4.

exceeding 20 percent”); and that for certain procedures, concentration reduced quality while competition had the opposite effect.²⁶

Since the early 2000s, however, the tide has started to turn. In 2004, the FTC filed a complaint against the then-consummated merger involving Evanston Northwestern. The Administrative Law Judge and the Commission both found the merger to be anticompetitive, and the matter terminated with a conduct remedy under which the two previously separate entities must negotiate prices separately.²⁷ In 2008, the FTC opposed a proposed acquisition by Inova Health System Foundation Inc. of Prince William Health Systems, which the merging partners ultimately abandoned.²⁸ In 2012 the FTC ordered the divestiture by ProMedica Health System, Inc. of St. Luke’s Hospital in Lucas, Ohio,²⁹ and in 2013, following a favorable Supreme Court remand, entered into a consent agreement for a conduct remedy with two health care providers in north Georgia.³⁰

It is probably too late to undo some other consummated anticompetitive mergers, however; and some commentators have expressed concern that the Federal Trade Commission/Department of Justice Statement Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program³¹—a keystone of the Affordable Care Act—could encourage consolidation that will result in clinical providers acquiring or exercising greater market power.³²

Second, until recently, “reverse payment” or “pay-for-delay” settlements of pharmaceutical patent litigation between brand-name and generic drugmakers were all but per se legal in some circuits. This was despite the FTC’s estimate that such agreements “on average prohibit[ed]

[U]ntil recently,

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or “pay-for-delay”

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some circuits.

²⁶ See MARTIN GAYNOR & ROBERT TOWN, THE IMPACT OF HOSPITAL CONSOLIDATION—UPDATE 2 (June 2012), available at http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2012/rwjf73261. For example, one of the more recent studies Gaynor and Town review, Deborah Haas-Wilson and Christopher Garmon’s *Hospital Mergers and Competitive Effects: Two Retrospective Analyses*, 18 INT’L J. ECON. BUS. 17, 27–30 (2011), concludes that a 2000 merger of two suburban Chicago entities, Evanston Northwestern Healthcare Corporation and Highland Park Hospital, allowed the merged entity to charge significantly higher prices than would have been possible absent the merger. Haas-Wilson and Garmon further conclude that the merger did not result in the merged entity accepting significantly more complicated cases or improving quality, either of which could provide an alternative explanation for the increase in price. They also report that another merger occurring at about the same time in Waukegan, Illinois, did not exhibit these price effects. *Id.* at 28–29.

²⁷ See Case Summary, Fed. Trade Comm’n, Evanston Northwestern Healthcare Corporation and ENH Medical Group, Inc. (Apr. 28, 2008), available at <http://www.ftc.gov/enforcement/cases-proceedings/0110234/evanston-northwestern-healthcare-corporation-enh-medical-group>.

²⁸ See Press Release, Fed. Trade Comm’n, FTC Approves Order Dismissing Administrative Complaint Against Inova Health System Foundation and Prince William Health System, Inc. (June 17, 2008), available at <http://www.ftc.gov/news-events/press-releases/2008/06/ftc-approves-order-dismissing-administrative-complaint-against>.

²⁹ See Case Summary, Fed. Trade Comm’n, In the Matter of ProMedica Health System, Inc., a Corporation (June 25, 2012), available at <http://www.ftc.gov/enforcement/cases-and-proceedings/cases/2012/06/matter-promedica-health-system-inc-corporation>.

³⁰ See Case Summary, Fed. Trade Comm’n, In the Matter of Phoebe Putney Health System, Inc., Phoebe Putney Memorial Hospital, Inc., Phoebe North, Inc., HCA Inc., Palmyra Park Hospital, Inc., and Hospital Authority of Albany-Dougherty County (Aug. 22, 2013), available at <http://www.ftc.gov/enforcement/cases-and-proceedings/cases/2013/08/matter-phoebe-putney-health-system-inc-phoebe-putney>. For further discussion of the role of antitrust in policing health care mergers, see Roger Feldman, *Antitrust Policy in Health Care*, in INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMIES, THE HEALTH CARE IMPERATIVE: LOWERING COSTS AND IMPROVING OUTCOMES: WORKSHOP SERIES SUMMARY 314–19 (Pierre L. Yong et al. eds., 2010) (arguing, *inter alia*, that “healthcare mergers may be too numerous for antitrust to be a meaningful strategy,” and recommending that “[t]he Hart-Scott-Rodino financial triggers for healthcare mergers . . . be lowered” and that “state agencies should pursue local mergers”).

³¹ Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, 76 Fed. Reg. 67,026 (Oct. 28, 2011).

³² See J. Thomas Rosch, Comm’r, Fed. Trade Comm’n, Remarks at the ABA Section of Antitrust Law Fall Forum, Accountable Care Organizations: What Exactly Are We Getting? (Nov. 17, 2011), available at http://www.ftc.gov/sites/default/files/documents/public_statements/accountable-care-organizations-what-exactly-are-we-getting/111117fallforumspeech.pdf. For a more sanguine view, see Rosenthal, *Road to Ruin*, *supra* note 1, at SR6.

generic entry for nearly 17 months longer than agreements without payments” and “cost American consumers \$3.5 billion per year.”³³ To be sure, *some* payments from brand-name to generic drug-makers arguably should be permitted, given the peculiar framework of the Hatch-Waxman Act (which, among other things, permits the patentee to sue before the generic firm has begun marketing any products). Nevertheless, elementary economics suggests that when the consideration flowing from brand-name to generic exceeds the latter’s expected profit from marketing a generic drug, the most reasonable inference is that the brand-name is simply paying its competitor to exit the market.³⁴ Fortunately, the Supreme Court appears to have reined in the use of pay-for-delay settlements in its 2013 decision in *FTC v. Actavis, Inc.*,³⁵ although the precise framework for evaluating such settlements under the Sherman Act still remains to be worked out.

Third, antitrust courts arguably could play a greater role than they traditionally have in scrutinizing product hopping, along the lines suggested in *Abbott Laboratories v. Teva Pharmaceuticals USA, Inc.* (though of course this would depend on parties bringing the appropriate claims).³⁶ In the *Abbott* case, Abbott filed a series of New Drug Applications (NDAs) for different formulations of the same drug (TriCor), and after each was approved changed the code for the old version in the National Drug Data File to read “Obsolete.” This did not prevent generic firms from selling generic versions of the old formulations for which they had obtained FDA approval, but it did limit the marketability of the generic versions because the code change prevented pharmacists from substituting the generic for the new brand-name formulation.³⁷ The court rejected Abbott’s argument that its conduct was per se legal, concluding instead that the generic firms had stated a claim under the rule of reason.³⁸ As discussed by Lemley (who represented one of the generic firms) and

³³ FEDERAL TRADE COMMISSION, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 2 (2010), available at <http://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf>.

³⁴ See, e.g., HERBERT HOVENKAMP ET AL., IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 15.3a1, 15.38 n.147, 15.41–15.42 (2d ed. 2010).

³⁵ 133 S. Ct. 2223, 2237 (2013) (“In sum, a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects; one who makes such a payment may be unable to explain and to justify it; such a firm or individual may well possess market power derived from the patent; a court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent . . .”).

³⁶ 432 F. Supp. 2d 408 (D. Del. 2006).

³⁷ See *id.* at 415 (“Pharmacists may dispense the generic equivalent for a branded drug when the branded drug is prescribed by a physician. Such substitution is allowed, however, only if the generic drug has been ‘AB-rated’ by the FDA, which means not only that the generic drug is bioequivalent to the branded drug, but also that the generic has the same form, dosage, and strength. Therefore, an approved generic drug that is not AB-rated against a currently available branded drug, because, for example, the drugs have different formulations or dosages, may not be substituted for the branded drug and may only be sold, if at all, as a separately branded, rather than generic, drug.”); *id.* at 416 (“After the NDA for the tablet formulation was approved, Defendants stopped selling TriCor capsules and also bought back the existing supplies of those capsules from pharmacies. In addition, Defendants changed the code for TriCor capsules in the National Drug Data File (‘NDDF’) to ‘obsolete.’ The NDDF is a private database that provides information about FDA-approved drugs. Changing the code to ‘obsolete’ removed the TriCor capsule drug formulation from the NDDF, which prevented pharmacies from filling TriCor prescriptions with a generic capsule formulation.”).

³⁸ *Id.* at 422.

Dogan, however, the *Teva* court's approach contrasts with the more deferential approach of some other courts in cases involving firms that are subject to pervasive regulation.³⁹

On balance, it's fair to say that antitrust has not always been aggressive enough in responding to anticompetitive practices that have contributed to the high cost of health care. On the other hand, antitrust's role is limited. It does not (and should not) condemn high prices that result merely from the possession of substantial market share; and, except in certain discrete circumstances like those presented in *Abbott Labs*, it generally does not (and probably should not) prevent firms from exploiting otherwise lawful opportunities. Whether some of those opportunities should exist at all, however, is another matter.

Regulation and Other Obstacles

Of possibly greater significance, however, is a regulatory system that is subject to capture . . .

I argued above that both patents and lenient antitrust enforcement have contributed to some extent to the high cost of health care in the United States (though patents at least contribute something in return). Of possibly greater significance, however, is a regulatory system that is subject to capture, in combination with other obstacles the effect of which is to render fundamental reform extremely difficult. According to the Center for Responsive Politics, the health industry spent \$359,164,761 on federal government lobbying in 2013; in the preceding five years, the annual sum approached or exceeded \$500 million.⁴⁰ Lobbying, of course, has long qualified as protected First Amendment activity, but the *Citizens United* decision⁴¹ promises to expand corporations' ability to influence elections all the more.

Space constraints prevent me from exploring these points in depth, but as described in Rosenthal's series and other sources, a list of causative factors might include the following.

- **Protecting Incumbent Hospitals from Competition.** Certificate-of-need (CON) laws in force in 36 states and the District of Columbia arguably work to the advantage of incumbent hospitals by imposing barriers to entry in the construction of new facilities.⁴²

³⁹ See Dogan & Lemley, *supra* note 13, at 712–14. *But see* *Walgreen Co. v. AstraZeneca Pharm. L.P.*, 534 F. Supp. 2d 146 (D.D.C. 2008) (dismissing a complaint alleging that a drug company violated § 2 by marketing a new drug that allegedly was no better than an old drug, where the new drug and generic substitutes for it remained available in the market). A fourth possible antitrust response, suggested to me by Professor Bill Page, might be to challenge some of the contractual provisions imposed by device manufacturers as described in Rosenthal, *Hip*, *supra* note 1, though of course whether any of them are sufficiently exclusionary in nature to raise antitrust problems would depend on the facts. See also C. Scott Hemphill & Tim Wu, *Parallel Exclusion*, 122 YALE L.J. 1182, 1246–48 (2013) (discussing antitrust claims against surgical instrument makers' allegedly exclusionary practices and arguing that *Standard Oil Co. v. United States*, 337 U.S. 293 (1949), permits liability based on “cumulative foreclosure,” i.e., the aggregate effect of vertical restraints even in the absence of horizontal collusion among manufacturers).

⁴⁰ See Center for Responsive Politics, *Influence & Lobbying: Health*, OPENSECRETS.ORG, <http://www.opensecrets.org/lobby/indus.php?id=H&year=2013> (last visited Jan. 11, 2014).

⁴¹ *Citizens United v. FEC*, 558 U.S. 310 (2010).

⁴² See U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, *IMPROVING HEALTH CARE: A DOSE OF COMPETITION 22* (2004), available at <http://www.ftc.gov/sites/default/files/documents/reports/improving-health-care-dose-competition-report-federal-trade-commission-and-department-justice/040723healthcarerpt.pdf> (“The Agencies believe that, on balance, CON programs are not successful in containing health care costs, and that they pose serious anticompetitive risks that usually outweigh their purported economic benefits.”). For more recent work, see, e.g., Traci L. Eichmann & Rexford E. Santerre, *Do Hospital Chief Executive Officers Extract Rents from Certificate of Need Laws?*, 37 J. HEALTH CARE FIN. 1, 2, 12 (2011) (stating that “the verdict is still out” on whether CON laws influence health care spending, but that the literature consistently has found that they do reduce the number of hospitals and hospital beds; and presenting preliminary evidence that CON laws increase hospital CEO pay, “function as barriers to entry and . . . raise the overall cost of health care”); TRACY YEE ET AL., *HEALTH CARE CERTIFICATE-OF-NEED LAWS: POLICY OR POLITICS? 2* (2011) (although the evidence of the effect of CONs on health care costs has been inconclusive, the process of obtaining a CON “often takes several years,” and CONs “tend to be heavily influenced by political relationships”).

- **Protecting Incumbent Drug and Device Makers from Competition.** Even after the Hatch-Waxman Act, FDA rules make it more difficult, in comparison with practices in other countries, for firms to demonstrate that their products are as safe and effective as approved drugs and devices.⁴³ In addition, the FDA does not take into account matters such as cost effectiveness, access, and affordability when considering whether to approve a new drug or device, in the manner that national health services elsewhere routinely do.⁴⁴ On the other hand, firms can obtain exclusive marketing rights for conducting clinical studies on old (pre-FDA) drugs that had never before been tested for safety and efficacy. The result has been to take products such as the anti-gout drug colchicine, which has been in use since the 6th century A.D., out of the public domain.⁴⁵
- **Lack of Transparency.** Only recently has the federal government made available hospital chargemasters (price lists) for common inpatient and outpatient services and published regulations requiring the disclosure of pharmaceutical company payments to physicians.⁴⁶ Even so, as Steven Brill points out in his *Time* article, “Pharmaceutical and medical device companies routinely insert clauses in their sales contracts prohibiting hospitals from sharing information about what they pay and the discounts they receive.”⁴⁷ According to the Government Accountability Office, this lack of transparency “raises questions about whether hospitals are achieving the best prices possible.”⁴⁸ Rosenthal notes that gag clauses also sometimes prevent employers from knowing what rates insurers have negotiated on their behalf.⁴⁹ This lack of transparency makes competition on the basis of price more difficult than it otherwise would be.
- **Bargaining Power and Transaction Costs.** Contrary to practice in much of the rest of the world, drug and device makers, as well as health care providers in the United States, are generally free to charge whatever the market will bear for their products. For example, Congress has specifically forbidden Medicare from negotiating favorable prices for prescription drugs in

⁴³ See Rosenthal, *Breath*, *supra* note 1, at A1 (citing sources).

⁴⁴ See, e.g., Steven Grossman, *FDA Should Consider Cost in Some Decisions*, THE HEALTH CARE BLOG (Oct. 5, 2011), <http://thehealthcareblog.com/blog/2011/10/05/fda-should-consider-cost-in-some-decisions/> (arguing that “FDA . . . plays a role (however unintentionally) in exacerbating the crisis in affordable cancer care,” and that it “may need to find ways to favor less effective or riskier products only because they can be made available at a market-driven price”); Rosenthal, *Breath*, *supra* note 1, at A1 (“[E]xperts say, a significant problem is that none of the agencies that determine whether medicines come to market in the United States are required to consider patient access, affordability or need.”).

⁴⁵ See Ryan M. Mott, *Colchicine, Guaiifenesin, and the Constitutionality of FDA Market Exclusivity for Approval Pioneers*, SELECTED WORKS (Mar. 19, 2012), http://works.bepress.com/ryan_mott/1/; Jonathan D. Rockoff, *An Old Gout Drug Gets New Life and a New Price*, *Riling Patients*, WALL ST. J. (Apr. 12, 2010), <http://online.wsj.com/news/articles/SB10001424052748703630404575053303739829726>.

⁴⁶ See Ctrs. for Medicare & Medicaid Servs., *Medicare Provider Charge Data*, CMS.GOV, <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/> (last visited Jan. 07, 2014) (making available the chargemasters of more than 3000 U.S. hospitals for the 100 most common inpatient and 30 common outpatient services); Medicare, Medicaid, Children’s Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests, 78 Fed. Reg. 9458 (Feb. 8, 2013) (to be codified at 42 C.F.R. pt. 402, 403) (requiring affected groups to report their data by March 31, 2014).

⁴⁷ Brill, *supra* note 1, at 34.

⁴⁸ U.S. GOV’T ACCOUNTABILITY OFFICE, REPORT TO THE CHAIRMAN, COMMITTEE ON FINANCE, U.S. SENATE: MEDICARE: LACK OF PRICE TRANSPARENCY MAY HAMPER HOSPITALS’ ABILITY TO BE PRUDENT PURCHASERS OF IMPLANTABLE MEDICAL DEVICES 29 (2012), available at <http://www.gao.gov/assets/590/587688.pdf>.

⁴⁹ Rosenthal, *Stitch*, *supra* note 1, at A1.

[I]t's hard not to speculate that regulatory problems generate the most significant, and unnecessary, costs of the U.S. health care system, far in excess of the net costs generated by patents or by weak antitrust enforcement . . .

the manner of national health services elsewhere.⁵⁰ Medicare *does* decide how much to reimburse physicians for various services, and private insurance companies often follow Medicare's lead in this regard. Critics contend, however, that a number of factors create perverse incentives for physicians to structure treatment in ways that inflate prices. These include the formula by which reimbursement rates are set, the specialist-dominant nature of the committee that advises Medicare on these rates, and the fact that many physician services in the United States are delivered on a fee-for-service basis.⁵¹ Finally, the absence of a single-payer system (coupled with the transparency problems noted above) generates high transaction costs.⁵²

- **Rulings on Commercial Speech.** In the nearly 40 years since the Supreme Court first extended First Amendment protection to commercial speech, the Court has applied commercial speech doctrine to hold unconstitutional a Vermont law that attempted to constrain health care costs by restricting the sale to pharmaceutical companies of "pharmacy records that reveal the prescribing practices of individual doctors,"⁵³ as well as a federal law that prohibited certain ads by compounding pharmacies.⁵⁴ In addition, FDA regulations and commercial speech doctrine permit drug companies to engage in direct-to-consumer advertising, a practice that is absent from almost every other country.⁵⁵

At the end of the day, it's hard not to speculate that regulatory problems generate the most significant, and unnecessary, costs of the U.S. health care system, far in excess of the net costs generated by patents or by weak antitrust enforcement, and that some form of universal, single payer health care along the lines of what is found in Canada, Europe, and elsewhere would be an improvement over our current high-cost system. But despite the fact that universal care has been championed over the years by such luminaries as (Republican) President Theodore Roosevelt⁵⁶

⁵⁰ See 42 U.S.C. § 1395l(t)(14)(A)(iii) (2012) ("The amount of payment under this subsection for a specified covered outpatient drug . . . that is furnished as part of a covered OPD service . . . shall be equal . . . to the average acquisition cost for the drug for that year . . . as determined by the Secretary taking into account the hospital acquisition cost survey data . . . or if hospital acquisition cost data are not available, the average price for the drug . . . as calculated and adjusted by the Secretary as necessary for purposes of this paragraph."); § 1395w-111(i) ("the Secretary . . . (1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and (2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs").

⁵¹ See Rosenthal, *Skyrocket*, *supra* note 1, at A18–19; REPORT OF THE NATIONAL COMMITTEE ON PHYSICIAN PAYMENT REFORM 7–8, 11–12, 15–16, 18–19 (Mar. 2013), available at http://physicianpaymentcommission.org/wp-content/uploads/2013/03/physician_payment_report.pdf [hereinafter PAYMENT REFORM].

⁵² For discussion, see, for example, Nancy Folbre, *The Single-Payer Alternative*, N.Y. TIMES: ECONOMIX (Nov. 25, 2013), <http://economix.blogs.nytimes.com/2013/11/25/the-single-payer-alternative>.

⁵³ See *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011).

⁵⁴ See *Thompson v. Western States Med. Center*, 535 U.S. 357 (2002).

⁵⁵ See 21 C.F.R. § 202.1 (regulations relating to prescription drug advertising); U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: CONSUMER-DIRECTED BROADCAST ADVERTISEMENTS (Aug. 1999, updated Apr. 18, 2002), available at <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125039.htm>. For views on the legality of restrictions on drug advertising, see Symposium, *Commercial Speech and Public Health*, 21 HEALTH MATRIX 1, 7–189 (2011). According to the World Health Organization, the only other country in the world that permits direct-to-consumer drug advertising is New Zealand. See Gary Humphreys, *Direct-to-Consumer Advertising Under Fire*, 87 BULL. WORLD HEALTH ORG. 576, 576 (2009).

On the other hand, one reform often championed by the political right—tort reform—actually does not appear to have had a significant impact on reducing health care costs in Texas. See Myungho Paik et al., *Will Tort Reform Bend the Cost Curve? Evidence from Texas*, 9 J. EMPIRICAL LEG. STUD. 173 (2012).

⁵⁶ See Alexander Lane, *Obama Invokes Republican Icons on Health Care*, POLITIFACT.COM (Mar. 5, 2009, 6:39 PM), <http://www.politifact.com/truth-o-meter/statements/2009/mar/05/barack-obama/Obama-goes-back-to-his-Republican-roots-on-health-/> (substantiating the claim that Roosevelt championed a national health care program).

and the (emphatically nonsocialist) economist Friedrich von Hayek,⁵⁷ polls indicate that large numbers of Americans still view the rather mild version of universal care that is embodied in the Affordable Care Act in unfavorable terms.⁵⁸ And to be fair, universal health care is hardly perfect: the litany of its unintended consequences, including sometimes long waits for services and spartan facilities, is well-documented too. Perhaps innovation would suffer as well if Americans were not so willing to fund it by paying higher prices for drugs, devices, and other health-related products and service—though this hardly suggests a rationale for approving protectionist policies that have nothing to do with innovation. And maybe there is some better alternative to both our current system and the single-payer model, though for now I remain somewhat skeptical.⁵⁹

In any event, and for better or worse, over the course of more than a century, we have collectively chosen a different model for the provision of health care than has much of the developed world. If we are unwilling to change, we must accept the bitter with the sweet. As Pogo would say, we have met the enemy, and he is us. ●

⁵⁷ See F.A. HAYEK, *THE ROAD TO SERFDOM* 120–21 (1944):

Where, as in the case of sickness and accident, neither the desire to avoid such calamities nor the efforts to overcome their consequences are as a rule weakened by the provision of assistance—where, in short, we deal with genuinely insurable risks—the case for the state’s helping to organize a comprehensive system of social insurance is very strong. There are many points of detail where those wishing to preserve the competitive system and those wishing to supersede it by something different will disagree on the details of such schemes; and it is possible under the name of social insurance to introduce measures which tend to make competition more or less ineffective. But there is no incompatibility in principle between the state’s providing greater security in this way and the preservation of individual freedom.

⁵⁸ See, e.g., *CNN Poll: Support for Obamacare Slightly Edges Up* (Mar. 11, 2014) (reporting 57% opposed, though only 39% “because it is too liberal”), <http://politicalticker.blogs.cnn.com/2014/03/11/cnn-poll-support-for-obamacare-edges-up/>.

⁵⁹ For details on such alternative approach, see JAY BHATTACHARYA ET AL., *BEST OF BOTH WORLDS: UNITING UNIVERSAL COVERAGE AND PERSONAL CHOICE IN HEALTH CARE* 33 (2013), available at http://www.aei.org/files/2013/08/06/-best-of-both-worlds-uniting-universal-coverage-and-personal-choice-in-health-care_081610171236.pdf (proposing a move away from reliance on group plans in favor of portable, long-term individual policies, coupled with a subsidy for the poor to buy such policies); John H. Cochrane, *What to Do When ObamaCare Unravels*, *WALL ST. J.* (Dec. 25, 2013, 3:51 PM), <http://online.wsj.com/news/articles/SB10001424052702304866904579265932490593594> (similar).

Patents, Monopoly Pricing, and Antitrust in Health Care Markets

Roger D. Blair and Christine Piette Durrance

Health care costs in the United States have risen sharply over time, and relative to other nations, the U.S. spends considerably more money on health care. In 2010, the U.S. spent a total of \$2.6 trillion on health care, which translates into approximately \$8,400 for every man, woman, and child.¹ The share of GDP devoted to health care has increased steadily from 13.8 percent in 2000 to 17.9 percent in 2010.² Much of this increase can be attributed to rising prices. While the overall consumer price index (CPI)³ increased by 35 percent between 2000 and 2013, medical care (the combination of medical care commodities and medical care services) rose by 63 percent.⁴ More specifically, the cost of prescription drugs rose by 55 percent, the cost of hospital services rose by 129 percent, and the cost of physician services rose by 45 percent during this period.⁵

A recent series of articles in *The New York Times* described the rising cost of health care in the U.S. in several specific dimensions, including colonoscopies,⁶ birth,⁷ joint replacements,⁸ and prescription medications for the treatment of asthma.⁹ This series of articles raised issues of affordability in health care, especially among individuals with pre-existing conditions or without the benefits of health insurance. This series also highlighted the dramatic differences in the costs of health care goods and services in the U.S. relative to other developed countries.

Rising costs of health care goods and services have triggered questions about the existence of monopoly pricing and concerns over high markups in these markets. In this article, we examine the availability of modest public policy responses to curb the dramatic increase in costs. We

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¹ THE HENRY J. KAISER FOUND., HEALTH CARE COSTS: A PRIMER 1 (May 2012), available at <http://kaiserfamilyfoundation.files.wordpress.com/2013/01/7670-03.pdf>.

² *Id.* at 4.

³ The CPI is defined by the Bureau of Labor Statistics as “a measure of the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services.” *Consumer Price Index: Frequently Asked Questions*, BUREAU LAB. STATISTICS, http://www.bls.gov/cpi/cpifaq.htm#Question_1.

⁴ The annual CPI index was valued at 172.20 in 2000 and 232.96 in 2013, indicating that the percentage change in the index between 2000 and 2013 is equal to $(232.96 - 172.20) / 172.20 = 0.35$ or 35%. *Inflation and Price, Customized Tables*, BUREAU LAB. STATISTICS, <http://www.bls.gov/data/> (data on file with author).

⁵ *Id.*

⁶ Elisabeth Rosenthal, *The \$2.7 Trillion Medical Bill*, N.Y. TIMES, June 2, 2013, available at <http://www.nytimes.com/2013/06/02/health/colonoscopies-explain-why-us-leads-the-world-in-health-expenditures.html>.

⁷ Elisabeth Rosenthal, *American Way of Birth; Costliest in the World*, N.Y. TIMES, July 1, 2013, available at http://www.nytimes.com/2013/07/01/health/american-way-of-birth-costliest-in-the-world.html?pagewanted=all&_r=0.

⁸ Elisabeth Rosenthal, *In Need of New Hip, but Priced Out of the U.S.*, N.Y. TIMES, Aug. 3, 2013, available at <http://www.nytimes.com/2013/08/04/health/for-medical-tourists-simple-math.html>. [hereinafter Rosenthal, *New Hip*].

⁹ Elisabeth Rosenthal, *The Soaring Cost of a Simple Breath*, N.Y. TIMES, Oct. 12, 2013, available at http://www.nytimes.com/2013/10/13/us/the-soaring-cost-of-a-simple-breath.html?_r=0 [hereinafter Rosenthal, *Soaring Cost*].

do not consider efforts to revamp the entire health care system through government regulation or even nationalization. Instead, we consider whether intellectual property laws should be modified to reduce the length of exclusivity, change the criteria for granting a patent, or limit the firm's ability to set price above the competitive level. We also examine whether antitrust remedies should be pursued to reduce perceived monopoly pricing in certain markets.

Perceived Problems

The difference in patient cost in the U.S. versus abroad is striking; the U.S. cost is over 5 times the cost in Brussels, and includes less in the total package of goods and services. At least part of the reason for this glaring disparity is the cost of the medical device.

In the series on rising health care costs in the U.S., two of the four recent articles in *The New York Times* specifically tackle the rising costs of medical products and procedures. The author, Elisabeth Rosenthal, questioned the role of potential market power and intellectual property in the pricing of pharmaceuticals for asthma medications and for hip replacement. In the article, *In Need of a New Hip, but Priced Out of the U.S.*, the author described the experience of a patient who did not have insurance coverage for a necessary hip replacement because of a pre-existing condition. Instead of paying for the expensive procedure in the U.S., the patient went abroad and paid a fraction of the cost of the procedure in the U.S. The cost in the U.S. for the hip replacement (inclusive of the hip implant and the hospital charges) was estimated to be at least \$78,000.¹⁰ The patient's cost in Brussels was only \$13,660, which included the implant, physician fees, operating room charges, crutches, medicine, five days in the hospital, a week in rehab, and the airfare. The difference in patient cost in the U.S. versus abroad is striking; the U.S. cost is over 5 times the cost in Brussels, and includes less in the total package of goods and services.¹¹ At least part of the reason for this glaring disparity is the cost of the medical device.¹²

Rosenthal reported that the five largest joint implant manufacturers were referred to as a cartel by some economists. The suggestion of a cartel implies coordinated activity among the firms, in an attempt to keep prices above where they would otherwise be without the coordinated activity. In particular, three of the five largest manufacturers are located in the town of Warsaw, Indiana, a small town with a local population of 14,000. Rosenthal expressed concern that the relationship between physicians and medical device manufacturers is potentially problematic.¹³ Additionally, there is some concern about the granting of new patents for minor modifications of implants. Implant companies, however, claim that pricing reflects the "increasing complexity of the joint replacement business, including more advanced materials, new regulatory requirements, and the logistics of providing a now huge array of devices."¹⁴ Critics of the U.S. health care system, however, blame the absence of regulation and genuine competition in the market for these high prices.

In another article in this series, *The Soaring Cost of a Simple Breath*, there are concerns about the pricing of prescription medications, specifically for the treatment of asthma. According to the

¹⁰ The markup in the hip implant market is considerable. The product costs approximately \$350 to manufacture, is sold to hospitals for between \$4,500 to \$7,500, and the list price offered to the consumer in the article was \$13,000. Rosenthal, *New Hip*, *supra* note 8.

¹¹ This price difference is likely due to the regulation of permissible prices in Brussels.

¹² Interestingly, a recent study found that orthopedists at leading medical institutions were wrong about the cost of common implant devices 81 percent of the time, where wrong indicated a response that was more than 20 percent off from the true cost (Kanu Okike et al., *Survey Finds Few Orthopedic Surgeons Know the Costs of the Devices They Implant*, 33 HEALTH AFF. 103–09; John Tozi, *How Much Do Medical Devices Cost? Doctors Have No Idea*, BLOOMBERG BUSINESSWEEK, Jan. 23, 2014, available at <http://www.businessweek.com/articles/2014-01-10/how-much-do-medical-devices-cost-doctors-have-no-idea>).

¹³ The DOJ has investigated violations of anti-kickback laws. For example, in 2007, joint makers settled with the Justice Department after being accused of paying kickbacks to surgeons who used their medical devices. See Rosenthal, *New Hip*, *supra* note 8.

¹⁴ *Id.*

article, asthma affects over 40 million individuals in the U.S. and has an annual cost of approximately \$56 billion. The affordability of medications like albuterol is important because such medications reduce costly hospitalizations and the likelihood of death. Ten years ago, albuterol inhalers cost around \$15, but today cost between \$50 and \$100 in the U.S. Other medications like the Pulmicort steroid inhaler cost \$175 in the U.S., but are available for approximately \$20 in Britain. Asthma medications have received new patents mainly because the delivery systems have changed, not because the underlying medications themselves have changed. This practice may prevent generics from being able to penetrate the market for asthma drugs.¹⁵ Similar experiences have occurred with respect to oral contraceptives, insulin, and colchicine (the treatment for gout).¹⁶

Part of the question raised by the Rosenthal article is whether the new pharmaceutical patents firms receive are warranted. Are the new products truly innovative and result in improved health outcomes for the consumer? If so, then the exclusivity that is granted is the reward for developing an innovative product. Or are the innovations small modifications to existing patents designed to extend market power, with no meaningful changes in patient outcomes? If so, then is this deserving of a patent and the potential for exclusivity that goes with it? The U.S. Patent and Trademark Office's charge is to grant patents on the basis of novelty, usefulness, and non-obviousness, and offer the potential for exclusivity for a limited period of time. The FDA's charge is to grant approvals based on safety and efficacy.

Two main issues arise in the discussion of rising health care costs with respect to medical products and procedures: first, the role of intellectual property laws and the patent system, and second, the issue of perceived monopoly pricing that intellectual property laws allow and the role that antitrust can play. In this article, we address these issues in turn, as well as explore some other potential contributing factors.

Pharmaceutical Firms, Patents, and the Incentive to Invest

Pharmaceutical firms spend enormous sums on research and development (R&D) in an effort to invent a new (or improved) drug. Whether those investments are profitable depends on several factors: whether a new molecular entity is successfully discovered; the time and resources that will be necessary to win FDA approval; competition—albeit imperfect—from other pharmaceuticals; marketing success; and the length of the effective patent protection.

The risks associated with such investments are large.¹⁷ First, the R&D effort may not bear fruit. Second, the FDA may withhold approval if the potential side effects appear to be undesirable and significant. Third, a new drug may not supplant existing drugs in the market. Fourth, a new drug's success may be undermined by other new drugs introduced by rival pharmaceutical producers. Fifth, and finally, calls for price regulation may be heeded.

For an investment in a pharmaceutical R&D project to make economic sense, it must have a reasonable expectation of profits. Since there are many uncertainties, it is necessary for the expected revenues to exceed the expected costs. Complicating the analysis is the fact the costs

¹⁵ It is not completely obvious why new patents on the delivery system prevent the entry of generics for the underlying medications. It would seem that a generic version coupled with an unpatented delivery system could be profitable, but physicians may not prescribe it.

¹⁶ Rosenthal, *Soaring Cost*, *supra* note 9.

¹⁷ In fact, only 2% of potential drugs are brought to market, and only 20% of newly approved drugs are profitable. *Should Patents on Pharmaceuticals Be Extended to Encourage Innovation?*, WALL ST. J., Jan. 23, 2012, <http://online.wsj.com/news/articles/SB10001424052970204542404577156993191655000> [hereinafter *Should Patents Be Extended*].

and revenues are incurred at different points in time. Thus, we examine the expected net present value of the investment over its lifetime.

For a pharmaceutical project, there are two general types of costs that are incurred before any revenues can be realized. First, of course, are the costs incurred in the R&D process. We can denote these expected costs as I_t where the subscript represents the year in which the cost is incurred. Assuming that a new molecular entity has been discovered, the firm will apply for a patent and begin the testing required by the FDA. These expected costs will be identified as C_t . This process usually involves several stages including pre-trials, clinical trials (Phase 1, 2, and 3), FDA approval, and marketing. Both the pre-discovery and post-discovery costs must be incurred before any revenues are realized. Once sales begin, the firm will experience expected profits (or perhaps losses) for the remaining life of the patent. For simplicity, we assume that the profits on the production and distribution will be positive. We also assume that profits (Π_t) do not survive the expiration of the patent.¹⁸ We can write the expected net present value as follows, where Σ denotes the summation operator, i represents the discount rate, and t indicates time:

$$NPV = -\sum_{t=1}^{T_1} I_t/(1+i)^t - \sum_{t=T_1+1}^{T_2} C_t/(1+i)^t + \sum_{t=T_2+1}^{T_1+20} \Pi_t/(1+i)^t.$$

In this formulation, T_1 is number of years needed to invent the new molecular entity and $T_2 - T_1$ is the number of years spent on the patent application and FDA approval process. The remaining patent life is $20 - (T_2 - T_1)$ years. In our formulation, we assume that all costs are incurred at the end of the year and similarly all profits are assumed to be received at the end of the year. It is important to recognize that all these variables are subject to considerable uncertainty.

A Numerical Example

The significance of the delay in realizing the operating profit can be seen with a simple numerical example. Assume that the capitalized cost of bringing a new drug to market is \$1.3 billion, and the process to do so takes 14 years.¹⁹ Assume further that only 10 years remain on the life of the patent. If the value of the investment necessary to generate profits is \$1.3 billion, then the firm must earn annual profits of over \$211 million per year to break even.²⁰ Earning profit, however, is not guaranteed; in fact, only about 20 percent of pharmaceutical developments brought to market earn positive profits.²¹ This implies that expected markups after initial investment periods must be high to generate enough profit for the firms to undertake the initial investment, or the investment will not be profitable, and therefore would not be undertaken. This explains, in part, why prices of some prescription drugs appear to have supracompetitive prices or a substantial mark up over cost during the period of exclusivity.²²

¹⁸ The net present value calculation is sufficiently general to account for changing profitability each year which may result from changing adoption rates of the new drug and competition in the market.

¹⁹ *Should Patents Be Extended*, *supra* note 17.

²⁰ *Id.*

²¹ *Id.*

²² This analysis can be extended to include a company with multiple product lines where some R&D investment will result in marketable innovations while other R&D investments do not. In this more general case, the profits of successful R&D projects would have to offset the costs associated with unsuccessful R&D projects.

Profit Maximization

If a pharmaceutical firm has a patent on a drug, it may charge any price that it sees fit to charge. Nothing in the intellectual property or antitrust laws constrains the unilateral pricing freedom of the patentee. This often leads to extremely high markups over production costs. The reason for this result is the low elasticity of demand at the point where profits are maximized.

A monopolist maximizes profit by producing where marginal revenue equals marginal cost. It can be shown that²³

$$MR = P (1 - (1/\eta))$$

where MR is marginal revenue, P is price, and η is the price elasticity of demand. Now, suppose that $P = \$500$ and $MC = \$10$. Then we would have an elasticity of demand equal to 1.02.²⁴

For this to be the case, the demand curve must be extremely steep, which usually means that there are few—if any—reasonable substitutes.²⁵

There are several reasons why the elasticity of demand tends to be low for prescription drugs. First, the consumption of prescription drugs is often essential for health reasons and not discretionary in the usual sense, because they are needed for good health and to alleviate pain and suffering. Second, the patient ordinarily is not the one who chooses the prescription drug. Instead, the physician makes the choice and may be unaware of the relative pricing of medications to treat a specific condition.²⁶ Moreover, there may be few, if any, substitutes for the drug in question. Even in cases where there are substitutes, the consumer cannot switch medications without a new prescription from the physician. Third, the prevalence of health insurance coverage blunts the incentives of physicians and patients alike to fully investigate their options. When these conditions hold, it is quite possible to observe very high markups over production costs.

Issues Involving Medical Devices

With respect to medical devices (e.g., joint replacements), there are questions about the role of antitrust policy as well as intellectual property law. In this section, we explore whether antitrust law can play a role in affecting the prices of medical products as well as whether intellectual property laws could or should be modified in response.

Antitrust enforcement of Sections 1 and 2 of the Sherman Act would govern the conduct of firms that either were colluding with one another in an effort to raise prices or were attempting to monopolize a market. But to employ antitrust remedies there must be an antitrust violation. The exclusivity granted by patents and the high markups that may result are not unlawful. There is no suggestion that firms in this market are unilaterally attempting to monopolize the market for medical devices. There is, however, the possibility of collusion among the manufacturers located in close proximity, as in the small town of Warsaw, Indiana.

²³ For a firm with market power, marginal revenue is $P + Q (dP/dQ) = P (1 + (Q/P)(dP/dQ))$. Since the price elasticity of demand is $\eta = -(P/Q)(dQ/dP)$, marginal revenue is $MR = P (1 - (1/\eta))$.

²⁴ Solving the equation: $\$500 (1 - 1/\eta) = \10 yields $\eta = 1.02$.

²⁵ The lower the value of elasticity of demand, the greater the optimal markup. For example, if $\eta = 1.05$, then the markup will be over 20 times the marginal cost.

²⁶ In fact, pharmaceutical companies spend considerable money sending representatives to educate physicians on the merits of newer, and often more expensive, formulations. In some cases, this marketing may promote pharmaceutical drugs that are more expensive, but not more effective than existing pharmaceutical drugs.

²⁷ Rosenthal, *New Hip*, *supra* note 8.

In the example given in the Rosenthal article,²⁷ there is no evidence of overt collusion by the manufacturers. Rosenthal even points out that individuals working for competing companies in Warsaw avoid discussing competitively sensitive topics. While there appears to be no evidence of an actual conspiracy or cartel, it is possible that the companies are tacitly colluding.²⁸ This alone, however, is not a violation of the Sherman Act.

Medical device markets may appear to have pricing that looks like monopoly pricing. If so, and if this is perceived as undesirable, then one may argue that the appropriate remedy would be to regulate prices. But it is unclear which prices would be regulated, how would the prices be regulated, and who would do the regulating. If a regulatory agency were to decide that the pricing of medical devices is “too high,” what pricing would be appropriate? The experience in the U.S. of price regulation has not been encouraging.²⁹

Medical device markets may appear to have pricing that looks like monopoly pricing.

The high prices of medical devices may also be perceived as a function of the problems of intellectual property law and the patent law covering the devices. One could argue that the current patent system and lengths of exclusivity should be modified. First, consider modifications to new medical device applications. A modification of the length of exclusivity would reduce the length of time that monopoly pricing is in effect. But it would also reduce the incentive of firms to invest in the first place. Second, consider patent applications that represent simple modifications of previous inventions but are granted new patents. In this situation, the merits for receiving a patent would change.³⁰ In both these situations, lower prices could be achieved, but perhaps at the expense of fewer products.³¹

Markup Under Monopoly

The artificial knee and hip industry is dominated by five major suppliers. Together, they account for 60 percent of all implant devices used in the U.S.³² This level of concentration is apt to result in noncompetitive pricing, but is not apt to explain how prices are more than 10 to 20 times the production costs. Even if the five largest firms were acting collusively, the Lerner Index of monopoly³³ would be:

$$\lambda = \frac{S}{(\eta + E_f(1 - S))},$$

where S is the market share of the colluding firms, η is the price elasticity of demand, and E_f is the elasticity of supply of the remaining suppliers.

²⁸ For a discussion of tacit collusion, see ROGER D. BLAIR & DAVID L. KASERMAN, *ANTITRUST ECONOMICS* 227 (2d ed. 2009).

²⁹ W. KIP VISCUSI, JOHN M. VERNON, JOSEPH E. HARRINGTON, JR., *ECONOMICS OF REGULATION AND ANTITRUST* 555–87 (4th ed. 2005). Moreover, comparisons of prices in the U.S. with prices in other markets, such as Canada or the EU, may not be instructive. Currently, a manufacturer can earn substantial operating profits in the U.S. and much lower profits in markets with price controls. If those substantial profits were unavailable, however, the incentive to invest would be dampened, and would therefore jeopardize the future availability of new medications.

³⁰ In a recent *Wall Street Journal* article, Els Torrele argued for a benefits test requirement, i.e., a test showing that the new development has a therapeutic benefit over the existing treatment. *Should Patents Be Extended*, *supra* note 17.

³¹ Both of these policy proposals are risky because they may tradeoff increased consumer welfare now for lower consumer welfare later. It is difficult to measure consumer welfare now, and even harder to measure consumer welfare in the future with respect to products that have not been discovered.

³² Rosenthal, *New Hip*, *supra* note 8.

³³ Abba Lerner, *The Concept of Monopoly and the Measurement of Monopoly Power*, 1 *REV. ECON. STUD.* 157 (1934); William M. Landes & Richard A. Posner, *Market Power in Antitrust Cases*, 94 *HARV. L. REV.* 937 (1981).

In this case, the Lerner Index would be:

$$\lambda = \frac{0.6}{(\eta + E_f(0.4))}.$$

For λ to equal ten, the values set by η and E_f would have to be extremely low.

Alternative View of Market Structure

In the case of the artificial knee and hip industry, the observed pricing may be explained by a more realistic view of the industry and its structure. Rosenthal observed: “Though the five companies make similar models, each cultivates intense brand loyalty through financial ties to surgeons and the use of a different tool kit and operating system for the installation of its products; orthopedists typically stay with the system they learned on.”³⁴ This means that the competition among the five major implant producers does not take place in the usual way. The producers compete to be the device and surgical method of choice. Orthopedic surgeons then receive ongoing financial and professional support from the preferred implant supplier. In effect, each producer enjoys a monopoly over the supply of devices to their surgeons. In that event, the Lerner Index is then:

$$\lambda = 1/\eta.$$

If the elasticity of demand is 1.05 at the *optimal* profit-maximizing output, price will be 20 times the marginal cost. Contributing to this possibility is the fact that the patient’s choice of a surgeon also determines the choice of the medical device.

Conclusion

Health care costs have been increasing at staggering rates. In the absence of overt collusion or unlawful attempts to monopolize health care markets, there appears to be no antitrust remedy. In some cases, we might consider changes to our patent system. Such changes, however, are risky because they may lead to reduced product availability. Regulation, which is the norm in many—if not all—developed countries, poses other risks of reduced incentives. Thus, the problem of soaring health care costs is very real, but an ideal solution is unlikely to be found via U.S. antitrust enforcement or simple modifications to the existing intellectual property regime. ●

³⁴ Rosenthal, *New Hip*, *supra* note 8. The alleged financial ties between device manufacturers and surgeons may well be problematic. The DOJ has investigated and settled with various pharmaceutical and medical device makers for paying kickbacks to physicians. For example, joint makers settled after a DOJ investigation of kickback payments to surgeons. Barnaby J. Feder, *Artificial-Joint Makers Settle Kickback Case*, N.Y. TIMES, Sept. 28, 2007, available at http://www.nytimes.com/2007/09/28/business/28devices.html?_r=1&.

The 2015 Amendments to the Federal Rules of Civil Procedure: The Path to Meaningful Containment of Discovery Costs in Antitrust Litigation?

Edward D. Cavanagh

The Advisory Committee on Federal Civil Rules has proposed a package of amendments designed to streamline pretrial discovery, promote hands on litigation management by the courts and encourage cooperation among the parties and the courts in the conduct of the pretrial phase of a case. The timing of the proposed amendments—on track for adoption in 2015—is significant in that the new rules represent the first comprehensive change in discovery practice since the Supreme Court's decisions in *Bell Atlantic Corp.*¹ *Twombly* and *Ashcroft v. Iqbal*.²

It would be a mistake, however, to describe the proposals as the Advisory Committee's response to *Twombly* and *Iqbal*. The new rules are not only silent on pleading standards but also deal with a range pretrial issues that have long concerned federal practitioners and judges. Yet, at the same time, it would be naive to conclude that the Advisory Committee did not have *Twombly* and *Iqbal* in mind during the rulemaking effort.

The proposed rules reflect the Advisory Committee's continued belief that discovery is manageable and that costs can be effectively controlled through a combination of discovery limitations, cooperative discovery planning, active judicial supervision and early confrontation and resolution of discovery issues. This, of course, is counter to the holding in *Twombly*, wherein the Court concluded that discovery costs were beyond the practical ability of courts to control and that the best way to address the problem of runaway discovery costs was to dismiss implausible cases at the outset of litigation.³

The proposed rules should be of special interest to antitrust litigants. Although the proposed additional limitations on the number and length of depositions as well as the number of interrogatories will probably have little impact in antitrust cases, the emphasis on (1) confining discovery to that which is proportional to the needs of the case; (2) active judicial management; (3) cooperative discovery planning; and (4) prompt resolution of discovery disputes, especially those involving electronic discovery, does offer a path to meaningful containment of discovery costs in antitrust litigation. This approach can succeed, however, only if the courts in antitrust cases embrace their

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¹ 550 U.S. 544 (2007).

² 556 U.S. 662 (2009).

³ *Twombly*, 550 U.S. at 559 ("Probably, then, it is only by taking care to require allegations that reach the level suggesting conspiracy that we can hope to avoid the potentially enormous expense of discovery in cases with no 'reasonably founded hope that the [discovery] process will reveal relevant evidence' to support a § 1 claim.").

managerial obligations by actively supervising discovery and antitrust litigants cooperate with the court and with each other in planning discovery, especially electronic discovery, and in resolving discovery disputes.

Twombly

In its 2007 decision in *Bell Atlantic Corp. v. Twombly*, the Supreme Court redefined notice pleading and raised the bar for complaints challenged on the grounds that they fail to state a claim upon which relief can be granted.⁴ The Court acknowledged that Rule 8(a)(2), which requires that a pleading set forth a “[s]hort and plain statement of the claim showing that the pleader is entitled to relief,”⁵ embodies a simplified pleading regimen commonly described as notice pleading.⁶ At the same time, however, the Court eschewed the notion that the “Federal Rules had somehow dispensed with the pleading of facts altogether.”⁷

A complaint must provide notice of the claim and the grounds upon which it depends. Although Rule 8(a)(2) does not require detailed factual allegations, it “contemplate[s] the statement of circumstances, occurrences and events in support of the claim presented.”⁸ The Rule does not authorize the “bare averment that [the pleader] wants relief and is entitled to it.”⁹ Conclusory allegations, labels, and formulaic recitation of the elements of a cause of action “will not do.”¹⁰ Factual allegations must be enough to raise the right to relief above the speculative level. The complaint must provide sufficient factual matter to suggest “plausible grounds to infer [illegality].”¹¹ That is, the complaint must allege “enough fact to raise a reasonable expectation that discovery will reveal evidence of illegal [conduct].”¹²

The rationale for the *Twombly* holding was inextricably intertwined with two substantive issues in modern day antitrust litigation: the high cost of pretrial discovery and concerns about false positives. The Court cautioned trial judges to keep in mind that “proceeding to antitrust discovery can be expensive.”¹³ The Court found that judicial efforts to control discovery costs through careful case management had been at best modest and that only by weeding out infirm cases at the motion to dismiss stage can high discovery costs truly be avoided.¹⁴ As Judge Richard Posner has noted, *Twombly* “is designed to spare the defendant the expense of responding to bulky, burdensome antitrust discovery unless the complaint provides enough information to enable an infer-

⁴ FED. R. CIV. P. 12(b)(6).

⁵ FED. R. CIV. P. 8(a)(2).

⁶ *Twombly*, 550 U.S. at 555 n.3.

⁷ *Id.* (citations omitted).

⁸ *Id.* (citations omitted).

⁹ *Id.* (citations omitted).

¹⁰ *Id.* at 555.

¹¹ *Id.* at 556.

¹² *Id.* The Court specifically disavowed its prior, famous formulation in *Conley v. Gibson*, 355 U.S. 41, 45–46 (1957), that “a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim” At the same time, the Court reaffirmed the *Conley* mandate that a complaint provide “fair notice” of the claim and “the grounds upon which it rests.” *Id.* at 47.

¹³ *Twombly*, 550 U.S. at 558.

¹⁴ *Id.* at 559.

The rationale for the

Twombly holding was

inextricably intertwined

with two substantive

issues in modern day

antitrust litigation: the

high cost of pretrial

discovery and concerns

about false positives.

ence that the suit has sufficient merit to warrant putting the defendant to the burden of responding at least to a limited discovery demand.”¹⁵

In addition, the *Twombly* court was concerned about the problems of false positives that can arise where a plaintiff bases a Sherman Act Section One claim on parallel conduct alone. Although parallel conduct may be consistent with conspiracy, it is “just as much in line with a wide swath of rational and competitive business strategy, unilaterally prompted by common perceptions of the market.”¹⁶ Accordingly, there is a risk that competitive practices by firms may be wrongly condemned as collusive. As Richard Epstein observed in a passage cited by the Court with approval:

If subjected to an antitrust ordeal, these firms—even if they prevail after expensive litigation—will be punished for doing exactly what the law wants to encourage. No amount of private entry, moreover, will be able to mitigate the damages that the legal system can cause by allowing litigation to disrupt the operation of a competitive market. Accordingly, there is very good reason to be careful of any lax system of pleading or proof that invites a high rate of false positives.¹⁷

Not surprisingly, the response to Twombly was decidedly mixed.

The Response to *Twombly*

Not surprisingly, the response to *Twombly* was decidedly mixed. *Twombly* had staunch support from the defense bar. Proponents of *Twombly* agreed with the Supreme Court that early dismissal of infirm claims was the key to reining in skyrocketing discovery costs and further that the new pleading standards would help to level the litigation playing field as between plaintiffs and defendants.¹⁸

On the other hand, the decision faced an avalanche of criticism from the academic community as well as from the plaintiffs’ bar. Critics of *Twombly* emphasized three points: (1) that the Court in *Twombly* had, in effect, rewritten Rule 8 of the Federal Rules of Civil Procedure and thereby usurped the role of the Advisory Committee on Civil Rules in the rulemaking process;¹⁹ (2) that it was a mistake to address discovery problems by altering pleading standards rather than by confronting discovery issues head-on;²⁰ and (3) that *Twombly*’s heightened pleading standards put plaintiffs at a distinct disadvantage, particularly in those instances where information relevant to the claims and defenses in a case was exclusively in the hands of defendants.²¹

Twombly opponents sought relief from Congress and from the Advisory Committee on Federal Civil Rules.²² Efforts to address *Twombly* through legislation quickly fizzled. The response of the

¹⁵ *In re Text Messaging Antitrust Litig.*, 630 F.3d 622, 625 (7th Cir. 2010).

¹⁶ *Id.* at 554.

¹⁷ Richard A. Epstein, AEI-Brooking Joint Center for Regulatory Studies, *Motions to Dismiss Antitrust Cases: Separating Fact from Fantasy* 3–4 (2006), available at <https://www.competitionpolicyinternational.com/file/view/4655>.

¹⁸ Victor E. Schwartz & Christopher E. Appel, *Rational Pleading in the Modern World of Civil Litigation: The Lessons and Public Policy Benefits of Twombly and Iqbal*, 33 HARV. J. L. & PUB. POL’Y 1107, 1109 (“Although the contours of *Twombly* and *Iqbal* may not yet be fully understood, the Supreme Court’s purpose in developing a more careful judicial review of pleadings was clear; more thorough review is necessary to protect against frivolous and purely speculative lawsuits.”).

¹⁹ Paul D. Carrington, *Politics and Civil Procedure Rulemaking: Reflections on Experience*, 60 DUKE L.J. 597, 621, 648, 656 (2010).

²⁰ Arthur R. Miller, *Simplified Pleading, Meaningful Days in Court and Trials on the Merits: Reflections on the Deformation of Federal Procedure*, 88 N.Y.U. L. REV. 286, 371 n.310 (“With *Twombly* and *Iqbal*, it is quite possible that the Court implicitly abandoned or compromised its devotion to the transsubstantive character of the Rules.”) (citation omitted).

²¹ Edward Cooper, *King Arthur Confronts Twlqy Pleading*, 90 OR. L. REV. 955, 986–87 (2012) (“A great part of the dismay engendered by the *Twombly* and *Iqbal* decisions arises from concerns about ‘information asymmetry.’”).

²² See, e.g., Notice Pleading Restoration Act of 2010, S. 4054, 111 Cong. (2010); Open Access to Courts Act of 2009, H.R. 4115, 111 Cong. 1st Sess. (2009); S. 1504, 111 Cong. (2009).

Simply put, the parade of horrors feared by critics of *Twombly* has not come to pass. Consequently, the Advisory Committee has chosen to address neither Rule 8(a)(2) nor *Twombly*'s construction of that rule at this time.

Advisory Committee to *Twombly* was measured. Before taking steps to undo *Twombly*, the Advisory Committee looked for evidence that *Twombly* had, in fact, had an adverse effect on federal civil litigation.²³ An empirical study conducted by the Federal Judicial Center in the wake of *Twombly* found that while the number of motions to dismiss filed post-*Twombly* had increased above pre-*Twombly* levels, there was not a statistically significant increase in the number of dismissals with prejudice,²⁴ except in financial instrument cases. In other words, there was no compelling empirical evidence that cases that would have survived motions to dismiss pre-*Twombly*, were now being dismissed by the courts as a result of the changes wrought by *Twombly*. Simply put, the parade of horrors feared by critics of *Twombly* has not come to pass. Consequently, the Advisory Committee has chosen to address neither Rule 8(a)(2) nor *Twombly*'s construction of that rule at this time.

Nor did the Advisory Committee address the problem of asymmetry of information at the complaint stage of the lawsuit. Notably, it did not adopt Arthur Miller's proposal to permit some discovery focused on what is necessary to meet the plausibility requirement prior to any motion to dismiss, in cases where the defendant is in sole possession of relevant information or where defendant's state of mind is in issue.²⁵ The need for such pre-motion discovery is less intense when private antitrust actions follow government enforcement proceedings but critically important when the allegations have not gone before grand juries.

On the other hand, the Advisory Committee, recognizing "the tension between pleading forms and emerging pleading standards,"²⁶ has proposed the abrogation of Federal Rule 84 and the elimination of the Official Forms of pleading. The Advisory Committee specifically noted that any attempt to create form pleadings for antitrust cases in the wake of *Twombly* "would be an imposing and precarious undertaking."²⁷ In any event, the Advisory Committee found that few, if any, lawyers actually consult the Official Forms when drafting pleadings.²⁸ In addition, the Advisory Committee took to heart the Supreme Court's concern with high discovery costs and in May 2010 sponsored a conference at Duke University School of Law "to explore the current costs of civil litigation, particularly discovery, and to discuss possible solutions."²⁹ In convening this conference, the Advisory Committee "hoped that the papers and discussion at the Conference will frame an agenda for possible amendments to the Federal Rules of Civil Procedure."³⁰ Participants at the Duke Conference stressed three main themes: (1) proportionality in discovery; (2) cooperation among lawyers; and (3) active judicial case management.³¹ For nearly three years following the

²³ See Cooper, *supra* note 21, at 969–72.

²⁴ *Id.*

²⁵ See Arthur R. Miller, *From Conley to Twombly to Iqbal: A Double Play on the Federal Rules of Civil Procedure*, 60 DUKE L.J. 1, 108–09 (2010) ("Discovery would focus solely on what is necessary to meet the plausibility requirement, assuming it is retained, especially in contexts involving a defendant's mental state or motivation, and situations involving a private or government defendant or third party in sole possession of critical information.").

²⁶ Report of the Advisory Committee on Civil Rules, May 8, 2013 [hereinafter Advisory Committee Report], available at <http://www.uscourts.gov/uscourts/RulesandPolicies/rules/Reports/cv05-2013.pdf> at 61.

²⁷ *Id.*

²⁸ *Id.*

²⁹ Purpose Statement, 2010 Conference on Civil Litigation, May 10–11, 2010, available at <http://www.uscourts.gov/RulesandPolicies/rules/archives/projects-rules-committees/2010-civil-litigation-conference.aspx>.

³⁰ *Id.*

³¹ Advisory Committee Report, *supra* note 26, at 4.

Duke Conference, the Advisory Committee studied various means of advancing these goals, and from this work emerged the “Duke Rules” package of amendments.

The Duke Rules

Proportionality. A fundamental goal of the proposed amendments is to promote responsible use of discovery by mandating that discovery be “proportional to the needs of the case considering the amount in controversy, the importance of the issues at stake in the action, the parties’ resources, the importance of the discovery in resolving the issues and whether the burden or expense of the proposed discovery outweighs its likely benefit.”³² The notion that discovery must be proportional to the needs of the case is not new. The proportionality concept, which currently resides in Rule 26(b)(2)(C)(iii), was adopted as part of the Federal Rules in 1983.³³ The proportionality standard means that discovery rights are subject to the inherent limitations of cost-benefit analyses. No longer could parties insist on a no-stone-unturned discovery program. Equally important, the rule directed that the trial courts must limit discovery where its costs outweigh its benefits.³⁴

Although as a general matter, the proportionality concept works well in federal civil litigation, there remains a significant subset of cases—including many antitrust cases—involving (1) complex facts; (2) high stakes and (3) contentious behavior by the parties and their attorneys, where the proportionality concept has not taken root, either because the parties cannot agree on discovery limitations or because the courts fail to impose them.³⁵ In other words, the problem is not with the concept of proportionality but rather with its implementation in reining in excessive discovery demands.

To underscore the core concept that discovery must be proportional to the needs of the case, the amended rule moves the newly articulated proportionality language to Rule 26(b)(1), which sets forth the scope of discovery.³⁶ The amended rule provides that a party may seek discovery of “any non-privileged matter that is relevant to any party’s claim or defense and *proportional* to the needs of the case.”³⁷ In addition to the limitations on discovery that result from the exercise of cost/benefit analyses, the proposed amendments reduce the presumptive limits on depositions from ten per side to five per side and on interrogatories from 25 to 15.³⁸ The presumptive length of any deposition would be reduced from 7 hours to 6 hours.³⁹ Moreover, the proposed amendments introduce a presumptive limit of 25 on requests for admissions promulgated pursuant to Rule 36 of the Federal Rule of Civil Procedure.⁴⁰

The proposed amendments also recognize that proportionality concerns may be implicated by the conduct of parties asked to respond to discovery requests as well as by those making the discovery requests. For example, in Rule 34 document productions, it is not unusual for responding

³² *Id.* at 10.

³³ *Id.* at 9.

³⁴ FED. R. CIV. P. 26(b)(2)(C)(iii).

³⁵ Advisory Committee Report, *supra* note 26, at 10.

³⁶ *Id.*

³⁷ *Id.* (emphasis added).

³⁸ *Id.* at 12–14.

³⁹ *Id.* at 12.

⁴⁰ *Id.* at 14–15.

parties to assert a laundry list of objections to a document request and then, at the same time, produce voluminous materials subject to these objections. In such cases, it is unclear whether any information has been in fact withheld. To address these concerns, proposed Rule 34(b)(2)(B) would mandate the objections to document requests be stated with specificity. Proposed Rule 34(b)(2)(C) directs that the responding party state whether it is actually withholding materials on the basis of any objection.⁴¹

Cooperation. A second major feature of the Duke Rules is the promotion of cooperation among litigants, their attorneys, and the court.⁴² Cooperation is essential to the successful conduct of antitrust litigation.⁴³ Antitrust cases typically involve myriads of documents, many of which are electronically stored, large numbers of party and non-party witnesses, experts, intensive discovery and numerous dispositive and non-dispositive motions. Without some agreement among the parties regarding protocols for the conduct of discovery—when and where witnesses will be produced, the timing and form of document production, and the manner for raising and resolving discovery disputes—antitrust litigation simply could not move forward. However, given the inherently adversarial nature of litigation, and especially the obligation of lawyers to zealously represent the interests of their clients, it is difficult to impose and administer a general duty that strikes a proper balance of cooperation and appropriate adversarial conduct.

Accordingly, the Advisory Committee takes an aspirational approach. It seeks to amend Rule 1 to provide that the Federal Rules “should be construed, administered, *and employed by the court and the parties* to secure the just, speedy and inexpensive determination of every action and proceeding.”⁴⁴ Although this provision is not likely to eliminate all overzealous adversarial behavior, it does serve to underscore the importance of cooperation on discovery for litigants and it supports the courts in their efforts to contain overuse, misuse or abuse of the discovery process.

Case Management. A third area of rule changes is designed to improve early and effective judicial case management by (1) accelerating the timeframe for serving the complaint and issuance of the scheduling order;⁴⁵ (2) directing that scheduling conference, where held, must be conducted in person or through simultaneous communication;⁴⁶ (3) increasing the subjects appropriate for the scheduling order to address so as to include (a) preservation of electronically stored documents; (b) agreements to prevent waiver of privilege or work product under Rule 502 of the Federal Rules of Evidence; and (c) pre-motion conferences where the court is asked to intervene in discovery matters;⁴⁷ (4) adding preservation of electronically stored information and agreements to protect against waiver of privilege or work product under Rule 502 of the Federal Rules of Evidence as two additional items to be considered by the discovery plan under Rule 26(f);⁴⁸ and

[I]t is difficult to impose and administer a general duty that strikes a proper balance of cooperation and appropriate adversarial conduct.

⁴¹ *Id.* at 15–16.

⁴² *Id.* at 16.

⁴³ See Advisory Committee Report, *supra* note 26, at 16 (“Reasonable cooperation among adversaries is vitally important to successful use of the resources provided by the Civil Rules. Participants at the Duke Conference regularly pointed to the costs imposed by hyperadversary behavior and wished for some rule that would enhance cooperation.”).

⁴⁴ *Id.* (new language shown by emphases).

⁴⁵ *Id.* at 17–18.

⁴⁶ *Id.* at 18–19.

⁴⁷ *Id.*

⁴⁸ *Id.*

(5) modifying the existing discovery timeline to permit filing of document requests under Rule 34 prior to the Rule 26(f) discovery conference.⁴⁹

Timing of Complaint and Scheduling Order. The Advisory Committee is of the view that early stages of litigation take too long, thereby adding to the cost of litigation.⁵⁰ Accordingly, the proposed amendments shorten the time in which to serve a complaint from 120 days to 60 days from the date of filing.⁵¹ The proposed amendments also provide that the time for issuance of a scheduling order, currently with 120 days after a defendant has been served or 90 days after a defendant has appeared, be reduced to 90 days and 60 days respectively.⁵²

Scheduling Conferences. The Advisory Committee is of the view that scheduling conferences are most effective if parties engage directly, via telephone or face to face, or through more sophisticated electronic means. Accordingly, the proposed amendments abrogate the current authorization to conduct scheduling conferences by mail.⁵³

Additional Topics for Scheduling Orders. The provisions which authorize scheduling orders to provide for preservation of electronically stored information and to include agreements to prevent waiver of privilege and work product are intended to remind litigants that these are useful topics to discuss and agree upon at the outset of litigation.⁵⁴ The Advisory Committee added the proposed rule authorizing pre-motion conferences on discovery issues in light of the experience of many judges who find that such conferences can resolve disputes informally without the need for formal briefs, thereby saving the litigants and the courts both time and money.⁵⁵ The question of whether to require such pre-motion conferences is left to the judge's discretion.

Content of Discovery Plans. In line with the above-discussed proposals affecting the content of scheduling orders under proposed Rule 16(b)(3), discovery plans may also include provisions for the preservation of electronically stored information and for court orders under Rule 502 of the Federal Rules of Evidence to prevent waiver of privilege and work product.⁵⁶

Accelerating the Timing of Document Requests. The relaxation of the discovery moratorium to permit promulgation of document demands prior to the entry of the discovery plan under Rule 26(f) is intended to aid focused discussion of those document demands during the discovery conference.⁵⁷ This procedure could not only assist early discovery planning but also would allow concrete disputes as to the scope of discovery to be brought before the court at the outset of the litigation. Discussion among the parties of at the discovery conference may result in changes in the discovery requests without judicial intervention.

Impact of the 2015 Discovery Rules on Antitrust Litigation

Analysis. The proposed discovery amendments are modest compared to the major discovery overhauls in 1983 and 1993. The amendments reflect the Advisory Committee's consistent view

⁴⁹ *Id.* at 21–22.

⁵⁰ *Id.* at 4.

⁵¹ *Id.* at 17, Proposed Rule 4(m).

⁵² *Id.* at 18–19, Proposed Rule 16(b)(2).

⁵³ *Id.* at 18, Proposed Rule 16(b)(1).

⁵⁴ *Id.* at 7, Proposed Rule 16(b)(3).

⁵⁵ *Id.* at 7–8, Proposed Rule 16(b)(3)(v).

⁵⁶ *Id.* at 19, Proposed Rule 16(b)(3).

⁵⁷ *Id.* at 8, Proposed Rule 26(d)(2).

that pretrial discovery is not only capable of judicial management but also must be managed by courts to contain costs and limit delays, even in cases as complex as antitrust matters. In this respect, the proposed new rules are at odds with the Supreme Court's observation in *Twombly* that trial courts cannot effectively manage discovery and that the best tool to control discovery costs is the dismissal of infirm antitrust cases at the outset.⁵⁸ In light of the view of the majority in *Twombly* that judicial management of discovery is a futile exercise, one might argue that the Advisory Committee's renewed emphasis on case management in the 2015 amendments will not gain traction among trial judges and attorneys and is doomed to failure. Surely, district courts will pay attention to *Twombly* and not lightly cast it aside. On the other hand, *Twombly* was not a model of clarity, particularly in its articulation of the plausible pleading standard. Nor was *Twombly* a unanimous decision; and individual justices have since expressed support for case management. For example, Justice Breyer, dissenting in *Iqbal* two years after *Twombly*, strongly supported managed discovery as an alternative to dismissal at the outset of the case.⁵⁹ Moreover, the composition of the Court has changed significantly since *Twombly* was decided and the majority view may have shifted. In short, *Twombly* has left lower courts with some leeway in assessing the sufficiency of complaints, including those alleging antitrust violations..

Even assuming that pretrial discovery is capable of judicial management, the question remains as to whether active judicial oversight of discovery is cost-effective. Critics have long maintained that managed discovery adds significantly to the costs of litigation while producing only marginal benefits.⁶⁰ Critics point specifically to a Federal Judicial Center (FJC) survey to support their view that "meet and confer" procedures required by Rule 26(f) do not facilitate discovery.⁶¹ Among other things, the FJC data show:

- 72% of counsel meet with their adversaries to plan discovery.
- Only 40% of those participating in a meet and confer discussed electronic discovery issues.
- Some 60% discussed preservation obligations.
- Only 9% of such meetings were face to face; 25% of such meetings were by e-mail or other correspondence.⁶²

Critics also argue that some judges ignore the Rule 26(f) agenda topics and thereby signal the parties that they have no interest in refereeing discovery disputes.⁶³ Consequently, "meet and confer" becomes a mere formality with the parties simply going through the motions.⁶⁴ In any event, critics say, attempts to confront a wide range of discovery issues at the outset of a case increases disputes instead of resolving them.⁶⁵

Proponents of judicial management counter this criticism as unfair, noting that pretrial meetings are only as productive as the parties want them to be; if the parties do not meet and confer in good

⁵⁸ See *Twombly*, 550 U.S. at 559.

⁵⁹ *Ashcroft v. Iqbal*, 556 U.S. 662, 700 (Breyer, J. dissenting) (A trial court "can structure discovery in ways that diminish the risk of imposing unwarranted burdens upon public officials. . . . Neither the briefs nor the Court's opinion provides convincing grounds for finding these alternative case management tools inadequate, either in general or in the case before us").

⁶⁰ See H. Christopher Boehning & Daniel J. Toal, *Are Meet, Confer Efforts Doing More Harm Than Good?*, N.Y.L.J., July 31, 2012.

⁶¹ See Fed. Jud. Center, *Early Stages of Litigation Attorney Survey*, available at [http://www.fjc.gov/public/pdf.nsf/lookup/leeeearly.pdf/\\$file/leeeearly.pdf](http://www.fjc.gov/public/pdf.nsf/lookup/leeeearly.pdf/$file/leeeearly.pdf).

⁶² Boehning & Toal, *supra* note 60.

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ *Id.*

faith and courts remain disengaged, failure is inevitable.⁶⁶ Case management can succeed only if the parties are willing to cooperate and the court becomes engaged in the enterprise.

Creation of a culture of cooperation among parties is a key feature of the pilot program for complex litigation introduced in the Southern District of New York in November 2011.⁶⁷ The pilot program is designed to reduce costs, particularly the costs of electronic discovery, expedite the pre-trial phase of the case, minimize motion practice and encourage settlement.⁶⁸ Among other things, the pilot program requires parties to meet to identify and resolve potential discovery disputes and to confer prior to the filing of dispositive motions in order to obviate the need to file formal motion papers.⁶⁹ The pilot program still awaits formal evaluation, but the Southern District reports anecdotal evidence that suggests the program is reducing litigation costs and expediting resolution of disputes.⁷⁰

The proportionality concept . . . has made it onto very few judicial radar screens.

Given the *sui generis* nature of antitrust litigation, the proposed rule changes lowering the presumptive limits on depositions and interrogatories, shortening the deposition day by one hour and introducing presumptive limits on requests for admissions are unlikely to have significant impact in antitrust cases. The same is true with respect to proposed adjustments in the timelines for pleadings and issuance of scheduling orders, as well as the requirement that scheduling conferences be fact to face and not by mail.

On the other hand, the new rules with respect to proportionality, early service of document requests and the emphasis on management techniques generally are likely to have a profound impact on antitrust litigation and offer real hope that discovery costs can be contained.

Proportionality. The proportionality concept, embedded in the Federal Rules for over 30 years, has made it onto very few judicial radar screens. This may be due, in part, to the fact that as initially articulated, the proportionality requirement was part of a party's certification that the discovery sought was proper rather than an overall limitation on the right to discovery. By repositioning the proportionality concept so it will now be in Rule 26(b)(1) itself the Advisory Committee the Advisory Committee is sending a clear message to the courts and litigants that pretrial discovery is subject to inherent limitations; indeed, that proportionality is a limit on the scope of discovery. Just as a party is not entitled to seek discovery of information that is irrelevant or privileged, it is not entitled to discovery that is not proportional to the needs of the case. The requirement for proportionality thus will vitiate once and for all the notion that discovery rights are without limits. Moreover, the proportionality limitation will force parties and the courts to confront questions of discovery cost containment at the outset of litigation and thereby lessen the likelihood that pretrial costs will spin out of control.

As discussed above, whether discovery is proportional to the needs of the case turns on the importance of the issues at stake, the parties' resources, the importance of the discovery sought to the resolution of the issues in the case and whether the costs of the discovery outweighs its benefits.⁷¹ Determining proportionality may be more difficult in some cases than in others, but weighing benefit against burden is something that federal judges do all the time in antitrust cases. The

⁶⁶ See Pete Brush, *NY Complex Litigation Pilot Looks Promising Despite Criticism*, LAW360 (Aug. 17, 2012).

⁶⁷ *Id.*

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ See *supra*, notes 32–41 and accompanying text.

Federal Rules “provide courts significant flexibility and discretion to assess the circumstances of the case and limit discovery accordingly to ensure that the scope and duration of discovery is reasonably proportional to the value of the requested information, the needs of the case, and the parties’ resources.”⁷²

The Advisory Committee has acknowledged that the proportionality limitation as it currently exists in the Federal Rules “cannot be said to have realized the hopes of its authors.”⁷³ Nor will the proposed revision if courts do not implement the concept so as to limit the scope of discovery.

Early Document Requests. The easing of the moratorium on discovery to permit early service of document requests so that these requests can be considered at the discovery scheduling conference may also have a significant impact on discovery in antitrust cases. This allows the parties to focus in a concrete manner at the scheduling conference, which may lead to modification of such requests and development of an expedited discovery program. At the very least, it would get the parties and the court communicating, focused on specific discovery issues, and, hopefully, cooperating, all of which promote efficient pretrial discovery.

One downside of early document discovery, however, is that it may foster strategic behavior by one or more parties in the form of overly broad discovery requests from the outset, which, in turn, could undermine any meaningful attempts to achieve real containment of pretrial costs. That kind of strategic behavior would eliminate any advantage of early document discovery. A second possible downside is that parties may be reluctant to show their hands on discovery earlier than they absolutely have to do so. Since serving discovery before the initial case management conference is voluntary, conceivably little, if any harm, will result from failure to do so. But that could be myopic if it, significant benefits may be achieved by invoking early document discovery and confronting issues of cost and scope head on.

Expansion of the Pretrial Conference Agenda. Permitting the scheduling order and discovery plan to (1) provide for the preservation of electronically stored information; and (2) include agreements reached to avoid waiver of privilege and work product under Rule 502 of the Federal Rules of Evidence also may have a salutary effect on antitrust litigation. Issues surrounding preservation of electronically stored information can generate costly satellite litigation. Early attention to electronically stored information preservation issues can obviate the need for motion practice later on and prevent potentially significant problems from festering. Similarly, addressing issues of waiver of privilege or work product protection at the outset of the case is likely to prove beneficial in antitrust matters. Antitrust litigation is document intensive. Where large volumes of documents are exchanged by the parties, issues of inadvertent production and waiver of privileged materials invariably arise, giving rise to extensive and costly motion practice. Rule 502 protective orders can minimize the need for each motion practice by setting the ground rules at the outset of the case.

Pre-motion Conferences of Discovery Issues. The new rule authorizing pre-motion conferences as a precondition to the filing of formal motion papers in discovery disputes can also prove beneficial in antitrust cases by focusing the court’s attention on the matters in dispute, thereby saving the parties from the costly and labor-intensive exercise of preparing detailed written papers. A major concern is that requiring a pre-motion conference creates more work for the moving parties by making them argue their motions twice, thereby adding to the costs of litigation and com-

⁷² See *In re Morgan Stanley Mortgage Pass-Through Litig.*, Master File No. 09 Civ. 2137 (LTS) (SN), 2013 WL 4838796 (S.D.N.Y. Sept. 11, 2013) (citing The Sedona Conference, *The Sedona Conference Commentary on Proportionality in Electronic Discovery*, 11 SEDONA CONF. J. 289, 294 (2010)).

⁷³ Advisory Committee Report, *supra* note 26, at 4.

pounding the problem of delay. The goal here, however, is not to burden litigants with yet another hoop to jump through to get to a judge. Rather, it is designed to permit prompt access to the court to air a discovery dispute without the costs and delays that are part of formal motion practice. The pre-motion conference can, and very often will, lead to prompt resolution of the discovery disputes. Similar approaches implemented via local rule have proven successful in getting prompt resolution of discovery disputes at minimum costs in various districts through local rule.⁷⁴

Next Steps. The 2015 proposed rules face further scrutiny by the Standing Committee on Civil Rules, the Judicial Conference, and the Supreme Court. Further tinkering may result, but the package that will likely emerge from the process will be very much like the one now on the table.

Conclusion

The 2015 rules contain no talismanic solution to the problem of escalating discovery costs in antitrust litigation. Upon their adoption, the 2015 rules will test whether discovery costs in antitrust cases can be effectively managed, as the Advisory Committee contends, or whether those costs are beyond the powers of federal courts to control, as *Twombly* has stated. These new rules can be fairly tested, however, only if the federal judges take seriously the goal of discovery cost containment and demonstrate a willingness to impose the proportionality concept and actively manage the pretrial phase of the case. ●

⁷⁴ See Edward D. Cavanagh, *Rulemaking, Litigation Culture and Reform in Federal Courts*, 35 AM. J. TRIAL ADV. 49, 84 (2011) (discussing experiences in the Eastern District of New York) (“Parties were more concerned about resolving discovery disputes so the case could move forward than with retaining the right to file formal and perhaps lengthy, motion papers.”).

Supreme Court of Canada Allows Indirect Purchaser Class Actions for Antitrust Claims

John Bodrug, Adam Fanaki and Chantelle Spagnola

On October 31, 2013, the Supreme Court of Canada (SCC) released three decisions that authorized indirect purchasers to bring antitrust class actions.¹ In doing so, the SCC chose not to follow the reasoning of the U.S. Supreme Court in its 1977 *Illinois Brick* decision.² The SCC also adopted a more lenient standard for proof of damages at certification than that of the U.S. Supreme Court in *Comcast*.³

Particularly for parties or counsel dealing with conduct that raises potential claims in both the United States and Canada, it is important to understand the factors that could potentially lead to certification of a claim in Canada that might not be certified in a U.S. federal court, and the implications of such a certification in Canada. Those factors include: the recent recognition by the SCC of indirect purchaser class actions; less rigorous scrutiny of the plaintiffs' proposed methodology for proof of loss on a class-wide basis at the certification stage; and the absence of a requirement to show predominance of common issues. In this article we examine the SCC's rationales for allowing indirect purchaser class actions and question whether many such actions will be workable in practice, particularly in light of the SCC's clear position that trial courts should strive to avoid double recovery.

In addition, the relatively less rigorous evaluation of the plaintiffs' methodology for proving loss on a class-wide basis at the certification stage in Canada appears to be driven largely by the absence of pre-certification discovery as of right. Nevertheless, the SCC raised the prospect of a court re-visiting an initial certification decision later in the proceedings (presumably after discovery), so that an initial class certification may prove to be not as definitive an event in Canada as in the United States. In any event, subsequent judicial interpretation and application of the SCC's recent trilogy of decisions, combined with actual experience with trials of certified indirect purchaser class actions, may well lead to further shifts in the approach to class certification in Canada.

Background

Private antitrust litigation, particularly class actions, have grown in importance in Canada over the last 15 years. Increasingly, Canadian antitrust class actions have been brought on behalf of "indirect purchasers," such as retailers and consumers, who are one or more steps removed from original suppliers in the chain of distribution and claim they were harmed when their suppliers, such

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¹ *Pro-Sys Consultants Ltd. v. Microsoft Corp.*, 2013 SCC 57 (Can.); *Sun-Rype Prods. Ltd. v. Archer Daniels Midland Co.*, 2013 SCC 58 (Can.); *Infineon Technologies AG v. Option consommateurs*, 2013 SCC 59 (Can.).

² *Ill. Brick Co. v. Ill.*, 431 U.S. 720 (1977).

³ *Comcast Corp. v. Behrend*, 569 U.S. 6 (2013).

as wholesalers or retailers, passed on prices that were artificially raised by anticompetitive conduct, and seek to recover damages or restitution.⁴

The *Microsoft* case, one of the three indirect purchaser cases recently decided by the SCC, illustrates such a claim: the proposed class was composed entirely of purchasers who indirectly acquired a license for a Microsoft operating system or application software, e.g., by purchasing a new computer pre-installed with Microsoft software. The plaintiffs alleged that Microsoft had engaged in anticompetitive conduct that resulted in overcharges which were passed through by computer manufacturers to end customers.

The causal connection between the alleged illegal conduct and the alleged damages or restitution in indirect purchaser cases is often fraught with evidentiary challenges, including how a court can determine the extent to which an initial price increase was passed along the supply chain and incorporated in a higher price paid by users of an end product. Some supply chains have numerous participants operating in distinct markets. At some points in the supply chain, it may be possible to pass on some or all of a particular price increase to the next purchaser, but at other points, some or all of the price increase may be absorbed by the distributor. This economic reality may make it difficult for courts to determine which participants along the supply chain have actually suffered a loss or damage as a result of the alleged conduct, and the amount of any price increase that was ultimately passed on through the distribution chain.

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Canadian Approach to Antitrust Class Actions

To certify an antitrust class action in Canada, plaintiffs must satisfy the same certification criteria applicable to other types of class proceedings. Although the test varies slightly from province to province, plaintiffs must generally establish that:

- the pleadings disclose a cause of action;
- there is an identifiable class of two or more persons;
- the claims of the class members raise common issues;
- a class proceeding is the preferable procedure for resolving the claims;⁵ and
- there is an appropriate representative plaintiff.

The primary difference between the Canadian and U.S. federal criteria for certification is that the Canadian certification test does not require plaintiffs to show that common issues will pre-dominate over individual issues.

Prior to the recent SCC decisions, Canadian lower courts applied differing standards for allowing indirect purchaser class actions, and differing evidentiary standards for certifying a class of

⁴ Such actions typically rely on tort and restitution claims, as well as Section 36 of the Competition Act, R.S.C. 1985, c. C-34 (Can.), which provides that any person who has suffered loss or damage as a result of conduct contrary to certain offences in the Competition Act may sue for and recover such losses or damages and certain costs.

⁵ In *Pro-Sys Consultants Ltd. v. Microsoft Corp.*, 2013 SCC 57, ¶¶ 111–112 (Can.), the SCC found common issues related to both the existence of the cause of action and the loss to the class members, such that there was a realistic prospect of establishing loss on a class-wide basis. The SCC found that resolving the common issues would significantly advance the action. This was a sufficient basis for the certification judge to determine that a class action was the preferable procedure.

indirect purchasers.⁶ In 2011 the judicial attitude moved in a decidedly defendant-friendly direction as a result of the British Columbia (B.C.) Court of Appeal's decisions in *Pro-Sys Consultants Ltd. v. Microsoft Corp.*⁷ and *Sun-Rype Products Ltd. v. Archer Daniels Midland Co.*⁸ In those two cases, the B.C. Court of Appeal refused to certify proposed class actions on behalf of indirect purchasers on the ground that indirect purchasers have no cause of action maintainable in law. These decisions brought Canadian law into line with U.S. federal law as reflected in the above-noted *Illinois Brick* decision, where indirect purchasers of concrete blocks brought a claim against the manufacturers of those concrete blocks for alleged antitrust violations. The U.S. Supreme Court found that, because there was no defense of "passing-on" to a claim for price-fixing brought by direct purchasers, indirect purchasers could not assert a claim for damages on the basis that an illegal overcharge had been passed on to them by direct purchasers. The Court emphasized the potential complexity involved in calculating damages that may have been "passed-on" by direct purchasers to those further down the distribution chain, as well as the potential for indirect purchaser claims to impair deterrence by diluting incentives to sue for damages. The decisions in *Sun-Rype* and *Microsoft* were appealed to the SCC and heard together, along with the *Option consommateurs* case, on October 17, 2012.

The Supreme Court of Canada's Recent Decisions

In the decisions released on October 31, 2013, the SCC took a more plaintiff-friendly tack. Contrary to the B.C. Court of Appeal decisions in *Microsoft* and *Sun-Rype*, and the established U.S. federal law as reflected in *Illinois Brick*, the SCC ruled that indirect purchasers are entitled to assert antitrust claims.

First, the SCC confirmed that, under Canadian law, it is not a defense to a claim by direct purchasers that these purchasers passed on any price increases to their customers and, accordingly, did not suffer any damages.⁹ Microsoft had argued that, if it could not defend a case on the basis that the direct purchasers passed on all of the alleged price increase, then it follows that indirect purchasers should not be entitled to rely on such passing-on to maintain a cause of action. Otherwise, defendants could face the impermissible prospect of double recovery (*i.e.*, defendants could be liable to direct purchasers for all of the overcharge they paid, but could also be liable to indirect purchasers for whatever amount of the overcharge may have been passed on).¹⁰

The SCC rejected each of Microsoft's arguments. The Court stated that trial judges are equipped to guard against the prospect of double or multiple recovery, such as by denying or modifying damages awards to avoid any overlapping recovery.¹¹ The SCC noted that a defendant can bring

⁶ Compare *Irving Paper Ltd. v. Atofina Chems. Inc.* (2009), 99 O.R. (3d) 358 (Can. Ont. Super. Ct. J.) with *Chadha v. Bayer Inc.* (2003), 63 O.R. 3d 22 (Can. Ont. C.A.). In *Chadha v. Bayer Inc.*, the Ontario Court of Appeal refused to certify a class of indirect purchasers. The Court's decision in this regard was based in large part on the plaintiffs' failure to put forth a methodology capable of establishing loss on a class-wide basis, an essential element of the cause of action. Contrast this approach with the decision of the Ontario Superior Court in *Irving Paper Limited v. Atofina Chemicals Inc.*, where Justice Rady certified a class comprising both direct and indirect purchasers. Commenting on the evidence put forth by the plaintiffs to establish loss on a class-wide basis, Justice Rady held that courts are ill-equipped at the certification stage to reconcile competing expert reports, and was of the view that a court need only be convinced that a methodology *may* exist for the calculation of damages, notwithstanding any expert evidence to the contrary.

⁷ *Pro-Sys Consultants Ltd. v. Microsoft Corp.*, 2011 BCCA 186 (Can.).

⁸ *Sun-Rype Prods. Ltd. v. Archer Daniels Midland Co.*, 2011 BCCA 187 (Can.).

⁹ *Pro-Sys Consultants Ltd. v. Microsoft Corp.*, 2013 SCC 57, ¶¶ 18–29 (Can.).

¹⁰ *Id.* ¶¶ 30–35.

¹¹ *Id.* ¶ 37.

evidence of a risk of double recovery to the trial judge and ask the trial judge to modify a damages award accordingly: “If the defendant is able to satisfy the judge that the risk [of double recovery] is beyond the court’s control, the judge retains the discretion to deny the claim.”¹² The SCC further noted that a trial judge may do the same when faced with parallel proceedings in multiple jurisdictions, where a judge “may deny the claim or modify the damage award in accordance with an award sought or granted in the other jurisdiction in order to prevent overlapping recovery.”¹³

While this principle seems clear in theory, it may in practice prove difficult for trial judges to guard against the prospect of double recovery. It may be challenging to determine the full scope of damages or claims for the various different classes of purchasers, particularly where the alleged cartel involves numerous different levels in a distribution chain, or involves distributors that operate across several different jurisdictions. Given the wide scope of jurisdiction over foreign defendants with no presence in Canada, as found by the SCC in the *Option consommateurs* case,¹⁴ and similarly wide or uncertain jurisdictional scope in the United States and elsewhere, it could take years for defendants to identify and quantify the full scope of damages for an alleged multi-national cartel agreement.

The SCC further dismissed Microsoft’s concerns about the complexity of tracing losses to indirect purchasers that are several levels removed from direct purchasers, pointing to Justice Brennan’s dissenting opinion in *Illinois Brick*. Justice Brennan noted that concerns regarding complexity can be raised in most antitrust cases and should not preclude indirect purchasers from having the opportunity to make their case.¹⁵

Microsoft pointed out that the majority in *Illinois Brick* concluded that antitrust laws would be more effectively enforced by concentrating the full recovery of the overcharge in the direct purchasers. Although direct purchasers have been active litigants in the antitrust area in Canada, the SCC rejected this argument, noting that in some cases the direct purchasers might not be inclined to sue their direct supplier for fear of jeopardizing their business relationship.¹⁶

The SCC also commented that “allowing indirect purchaser actions is consistent with the remediation objective of restitution law because it allows for compensating the parties who have actually suffered the harm rather than merely reserving these actions for direct purchasers who may have in fact passed on the overcharge.”¹⁷ However, in some class action claims, it is reasonably clear from the initial filing that actual purchasers are unlikely to receive any payment from an award to the class (e.g., because the purchases were very small or the sales are very difficult to trace) so that any resulting order is likely to be a *cy-près* award, often consisting of payments to charities. In such cases, it is difficult to see how the outcome of the class action would advance resti-

Given the wide scope of jurisdiction over foreign defendants with no presence in Canada . . . it could take years for defendants to identify and quantify the full scope of damages for an alleged multi-national cartel agreement.

¹² *Id.* ¶ 39.

¹³ *Id.* ¶ 40; *see also* Sun-Rype Prods. Ltd. v. Archer Daniels Midland Co., 2013 SCC 58, ¶ 21 (Can.).

¹⁴ *See* Infineon Technologies AG v. Option consommateurs, 2013 SCC 59 (Can.), where the SCC also dealt with an issue of jurisdiction particular to the Province of Québec. In that case, the certification judge dismissed the action on the basis that the Québec court had no jurisdiction over the defendants, noting that the defendants had no offices in Québec and did not operate in that Province. The Québec Court of Appeal reversed this decision on the basis that the contract by which the end user acquired the product from a retailer had been entered into in Québec, and, pursuant to Québec consumer protection legislation, this was a sufficient nexus to ground jurisdiction in the Québec courts, even though none of the defendants was party to a contract with an end user. The SCC adopted the Court of Appeal’s reasoning in its entirety.

¹⁵ Pro-Sys Consultants Ltd. v. Microsoft Corp., 2013 SCC 57, ¶ 44 (Can.).

¹⁶ *Id.* ¶¶ 46–57.

¹⁷ *Id.* ¶ 50.

tutionary objectives. In any event, where cy-près remedies are the only realistic option, domestic or foreign government prosecutions in respect of the challenged conduct that result in fines based on volume of commerce and calculated to ensure that the defendant does not profit from the crime would appear to achieve the same objective as intended by a cy-près award, such that a cy-près award could lead to the type of double or multiple counting that the SCC indicated should not occur.

Finally, the SCC noted that in this case the Canadian Competition Bureau was not pursuing any action against Microsoft. As a result, the SCC said that if the class action did not proceed, the objectives of deterrence and behavior modification would not be addressed at all.¹⁸ It is not clear how much weight is to be given to this factor. On the one hand, the Bureau may not be pursuing a case because the Commissioner of Competition, the head of the Bureau, believes that the case has no merit. Conversely, if the Bureau is pursuing a case or has obtained a conviction, it remains to be seen whether that would be a factor that weighs against certification, particularly if there is no realistic prospect for class members actually receiving any monetary compensation because only a cy-près remedy is feasible.

The SCC acknowledged that its approach in the three decisions of October 31, 2013 differs from that of the U.S. Supreme Court in *Illinois Brick*, but noted that (1) many U.S. state “repealer” statutes permit indirect purchaser claims,¹⁹ (2) there have been calls for legislative amendments to overturn *Illinois Brick* at the U.S. federal level, and (3) a significant body of U.S. academic authority supports repealing the decision in *Illinois Brick* to further the objectives of antitrust laws.²⁰

Some courts and commentators recognize that the *Illinois Brick* repealer statutes are inconsistent with the “no double recovery” policy articulated in *Illinois Brick*. For example, shortly after the enactment of some of these state repealer statutes, the Ninth Circuit held that state indirect purchaser claims conflicted with federal policy because they allowed for double recovery.²¹ However, in the 1989 decision in *California v. ARC America Corp.*,²² the U.S. Supreme Court refused to strike down state repealer statutes, notwithstanding the possibility that double recovery could result.²³ While the risk of double recovery remains in certain U.S. states, the repealer statutes may reflect the emphasis on deterrence in U.S. antitrust policy, which is exemplified by the availability of treble damages for antitrust offenses.

With respect to remoteness of damages, some state legislatures have created statutory short-cuts that essentially eliminate indirect purchasers’ need to prove the extent of their loss. For example, each of Kansas, South Carolina, Tennessee, Colorado, Wisconsin, and Indiana have “full consideration” statutes, which allow an indirect purchaser to recover its entire payment from the defendant once the purchaser can show that it suffered some effect from the anticompetitive con-

¹⁸ *Id.* ¶ 141.

¹⁹ See Michael A. Lindsay, *Overview of State RPM*, ANTITRUST SOURCE, www.antitrustsource.com (Supplementary Materials), which identifies 25 U.S. states that have statutes which permit recovery for indirect damages suffered as a result of the violation of state antitrust laws.

²⁰ *Pro-Sys Consultants Ltd. v. Microsoft Corp.*, 2013 SCC 57, ¶¶ 55, 59 (Can.).

²¹ See *In re Cement and Concrete Antitrust Litig.*, 817 F.2d 1435, 1445–46 (9th Cir. 1987).

²² 490 U.S. 93 (1989).

²³ *Id.* at 103–06.

duct in question.²⁴ The Canadian statutory cause of action does not go that far, and instead limits damages to actual losses suffered by indirect purchasers.²⁵

Required Methodology to Establish Loss and Damages

In its three recent decisions, the SCC acknowledged the importance of the gatekeeper function of the certification judge and reaffirmed “the importance of certification as a meaningful screening device.”²⁶ To satisfy the requirement that there be “some basis in fact” for concluding that damages can be proved on a class-wide basis, the SCC found that “some assurance is required that the questions are capable of resolution on a common basis” and expert evidence is normally used to satisfy this requirement.²⁷ The SCC held that expert evidence “must offer a realistic prospect of establishing loss on a class-wide basis so that, if the overcharge is eventually established at the trial of the common issues, there is a means by which to demonstrate that it is common to the class (i.e., that passing-on has occurred).”²⁸ To satisfy the court that there is a method by which impact can be proved on a class-wide basis, the plaintiffs must provide a “credible and plausible methodology.” “[This] methodology cannot be purely theoretical or hypothetical, but must be grounded in the facts of the particular case in question.”²⁹ The Court noted that “[e]vidence has a role to play,”³⁰ but not on a “balance of probabilities” standard. Rather, a court need not “resolve conflicting facts and evidence at the certification stage,” but must engage in more than a superficial analysis.³¹ The SCC declined to resolve conflicts between the experts at the certification stage, noting that the trial judge will have the benefit of the full record to resolve such conflicts.³²

Canadian courts have resisted the U.S. approach of a “robust analysis of the merits at the certification stage” . . .

The SCC found that it was not necessary or appropriate to subject the proposed methodology for calculating damages to rigorous scrutiny at the certification stage. Given that, unlike in the United States, plaintiffs are not entitled to pre-certification discovery as of right, the SCC considered that a defendant cannot insist on such scrutiny for certification.³³ In this regard, the SCC expressly noted that Canadian courts have resisted the U.S. approach of a “robust analysis of the merits at the certification stage,”³⁴ which may involve some weighing of the evidence and deeper assessment of the economic theory.

However, the SCC trilogy of cases does appear to establish a stricter standard for evaluating the plaintiffs’ proposed methodology for calculating damages at the certification stage than that found in some earlier Canadian decisions. In particular, the SCC’s standard would allow for

²⁴ KAN. STAT. ANN. §50-115; S.C. CODE ANN. § 39-3-30; TENN. CODE ANN. § 47-25-106; COLO. REV. STAT. § 6-4-121; WIS. STAT. ANN. § 133.14; IND. CODE ANN. § 24-1-1-5 (West).

²⁵ Competition Act, R.S.C. 1985, c. C-34, § 36 (Can.).

²⁶ Pro-Sys Consultants Ltd. v. Microsoft Corp., 2013 SCC 57, ¶ 103 (Can.).

²⁷ *Id.* ¶ 114. However, the SCC found that a lower standard applies in the province of Québec where the Civil Code requires only that plaintiffs present an arguable case and expert evidence is not normally provided at the certification stage. See Infineon Technologies AG v. Option consommateurs, 2013 SCC 59, ¶¶ 127–128 (Can.).

²⁸ Pro-Sys Consultants Ltd. v. Microsoft Corp., 2013 SCC 57, ¶ 118 (Can.).

²⁹ *Id.* ¶¶ 103–104.

³⁰ *Id.* ¶ 100.

³¹ *Id.* ¶ 102.

³² *Id.* ¶ 126.

³³ *Id.* ¶ 119.

³⁴ *Id.* ¶ 105.

greater scrutiny of the proposed methodology of calculating damages than that applied by the Ontario Superior Court in *Irving Paper*³⁵ insofar as it now appears to be necessary for the plaintiffs to establish that the proposed methodology accords with sound principles of economics. While, under the new SCC standard, a court may not be required to weigh all of the competing evidence advanced by the parties, it appears open to defendants to challenge conceptual flaws in the evidence put forward by the plaintiffs in support of certification, including evidence with respect to the ability to prove a class-wide impact from the challenged conduct. However, the extent to which Canadian certification courts will consider evidence put forth by defendants challenging the plaintiffs' satisfaction of such criteria remains to be seen.

Common Issues

The SCC confirmed a number of aspects of the need for plaintiffs to identify common issues. Unlike the standard in U.S. federal courts, the common issues need not predominate over issues affecting only individual members for the class to be certified by a Canadian court. To be "common," an issue must be necessary to the resolution of each class member's claim. The factual basis for the claims need not be identical, although the class members' claims must share a "substantial common ingredient." All class members must benefit from a successful prosecution of the action, although not necessarily to the same extent.³⁶

Respondents in the appeals before the SCC argued that including indirect purchasers in the same proceedings as direct purchasers created the potential for a conflict between the class members. The SCC noted, however, that "to the extent that there is conflict between the class members as to how the aggregate amount is to be distributed upon awarding of a settlement or upon a successful action, this is not a concern of the respondents and is not a basis for denying indirect purchasers the right to be included in the class action."³⁷ For example, the plaintiffs' expert in *Sun-Rype* provided evidence that the presence or absence of pass through should be ascertainable statistically at each industry/distribution level, based in part on information that was likely to become available in the discovery process relating to the industry, price/cost margins, industry concentration, and elasticity of demand at each level of distribution. He also suggested that class members at a distribution level with a very low profit margin are likely to pass through a relatively high percentage of a price increase.³⁸

The requirement that all class members must benefit from a successful prosecution would seem to imply that a class cannot include members who fully passed on a price increase and suffered no loss. However, courts have accepted that just because some class members may not ulti-

³⁵ See *Irving Paper Ltd. v. Atofina Chems. Inc.* (2009), 99 O.R. (3d) 358 (Can. Ont. Super. Ct. J.) (holding that it was not necessary or appropriate to subject the plaintiffs' proposed methodology to rigorous scrutiny, or even to decide whether it accords with sound principles of economics, as a condition to certification).

³⁶ *Pro-Sys Consultants Ltd. v. Microsoft Corp.*, 2013 SCC 57, ¶ 118 (Can.).

³⁷ *Sun-Rype Prods. Ltd. v. Archer Daniels Midland Co.*, 2013 SCC 58, ¶ 20 (Can.).

³⁸ Expert report of Dr. Jeffrey Leitzinger, Econ One Research, Inc., June 19, 2009, filed with the Supreme Court of British Columbia in the *Sun-Rype* case, ¶ 60.

mately be able to establish their claim on the merits, they are not barred from inclusion in the class at the certification stage.³⁹

The SCC recognized that there may well be a multitude of variables among the class that present a significant challenge at the merits stage, but for certification the plaintiffs need establish only common questions and that a class action is the preferable procedure.⁴⁰ The SCC found that if material differences emerge following certification, courts can deal with them when the time comes,⁴¹ including potentially by decertifying the class. The SCC indicated that a court's gatekeeper function extends past an initial decision to certify, observing that

the outcome of a certification application will not be predictive of the success of the action at the trial of the common issues. . . . After an action has been certified, additional information may come to light calling into question whether the requirements of s. 4(1) [of the B.C. Class Proceedings Act ("CPA")] continue to be met. It is for this reason that enshrined in the CPA is the power of the court to decertify the action if at any time it is found that the conditions for certification are no longer met (s. 10(1)).⁴²

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While there have been few decertification motions to date in Canada, lower courts could take the SCC's comments as an invitation to be more proactive in considering decertification in light of new facts emerging in discovery, for example.

Comparison to the U.S. Approach to Certification

The SCC decisions depart from the trend in U.S. federal courts of requiring a thorough and rigorous analysis at the class certification phase, including the weighing of conflicting expert testimony, to determine whether each of the requirements for certification in Rule 23 of the U.S. Federal Rules of Civil Procedure have been satisfied. In *Comcast Corp. v. Behrend*, the U.S. Supreme Court directed trial courts to conduct a rigorous analysis of the criteria for class certification before certifying an action, and expressly recognized that this analysis will frequently overlap with the merits of the plaintiffs' underlying claim because the certification criteria are enmeshed in the factual and legal issues comprising the plaintiffs' cause of action.⁴³

While the Canadian standard for certification is clearly more plaintiff-friendly than that in the United States, even under the SCC's approach in its recent trilogy, certification is not a fait accompli. Indeed, the facts of *Comcast* may well provide an example of a case that would still not be certified in Canada. In *Comcast*, the claim was brought on behalf of more than two million current and former Comcast cable subscribers. The plaintiffs alleged that a series of acquisitions "clustering" Comcast's operations within a geographic region had enabled Comcast to withhold local sports programming, reduce the level of "benchmark" competition on which cable customers compare prices, increase Comcast's bargaining power relative to content providers, and reduce the level of competition from adjoining cable companies that "overbuild" into areas in which Comcast

³⁹ See *Bywater v. Toronto Transit Comm'n*, [1998] O.J. No. 4913, ¶ 11 (Can. Ont. Gen. Div.). Note also that the SCC did find that a calculation of damages on an aggregate basis cannot be used to establish liability because the relevant provincial class action legislation was not intended to allow a group to prove a claim that no individual could. *Pro-Sys Consultants Ltd. v. Microsoft Corp.*, 2013 SCC 57, ¶¶ 131, 133 (Can.). This finding resolved a debate in the case law about whether plaintiffs were allowed to use provisions in provincial class proceedings legislation allowing damages to be calculated in the aggregate as a means to show loss on a class wide basis.

⁴⁰ *Pro-Sys Consultants Ltd. v. Microsoft Corp.*, 2013 SCC 57, ¶ 111 (Can.).

⁴¹ *Id.* ¶ 112 (citing *Western Canadian Shopping Centres Inc. v. Dutton*, 2001 SCC 46, ¶ 54 (Can.)).

⁴² *Pro-Sys Consultants Ltd. v. Microsoft Corp.*, 2013 SCC 57, ¶ 105 (Can.).

⁴³ *Comcast Corp. v. Behrend*, 569 U.S. 6 (2013).

operates as the incumbent cable provider. The district court had rejected all but the “overbuilding” theory of antitrust impact on Comcast subscribers and certified a class of subscribers seeking damages on only this theory of liability.

In reversing certification, the U.S. Supreme Court held that the plaintiffs’ regression model did not even attempt to measure damages attributable to only the “overbuilder” theory. Instead, the model compared actual prices in the relevant market to hypothetical prices that would have prevailed but for all of Comcast’s allegedly anticompetitive activities, without isolating the damages resulting from the one surviving theory of harm. As a result, the U.S. Supreme Court found that the model could not possibly establish that damages are susceptible to measurement across the entire class. As such, the plaintiffs’ model was not consistent with its liability claim.⁴⁴

It might be questioned whether the SCC would have upheld certification on the facts of *Comcast* under the less robust “some basis in fact” standard. In particular, it is not clear whether there was some basis in fact for finding that the questions at issue were capable of resolution on a common basis. The difficulty with the class in *Comcast* was conceptual and did not seem to require a weighing of the evidence put forward by the opposing party. In any event, the U.S. Supreme Court’s reasoning in *Comcast* did not require a more in-depth consideration of factual issues than that which was undertaken by the SCC in *Sun-Rype*, wherein certification was denied on the basis that the plaintiffs had not put forth evidence to establish that any potential class member could demonstrate that he or she had in fact purchased a product containing high-fructose corn syrup, which was the defining characteristic of the class.⁴⁵

Post-*Comcast* cases in the United States are also instructive in a comparison of the Canadian and U.S. approaches to class certification. The D.C. Circuit Court cited *Comcast* in deciding to vacate certification of a class action alleging a price fixing conspiracy among freight railroads because the defendants demonstrated defects in the plaintiffs’ regression and damages models presented as evidence that injury and overcharge were capable of common proof. In particular, the defendants argued that the plaintiffs’ models generated false positives and yielded similar results for both shippers who experienced rate increases and shippers subject to legacy contracts whose rates did not change during the alleged conspiracy period. The district court had certified the class on the basis that the plaintiffs’ models were “plausible,” but the court of appeals commented that a “hard look” at the soundness of statistical models was mandated as a result of the *Comcast* decision, and the case law was “far more accommodating to class certification” before the *Comcast* decision.⁴⁶

Also, in *In re High-Tech Employees Antitrust Litigation*, the Northern District of California cited *Comcast* and examined the expert evidence of both the plaintiffs and the defendants, including regression analyses and studies of common factors and compensation movements.⁴⁷ The plain-

⁴⁴ *Id.* at 6–11.

⁴⁵ In *Sun-Rype Products Ltd. v. Archer Daniels Midland Co.*, 2013 SCC 58, ¶ 20 (Can.), the SCC declined to certify the proposed class. With respect to the claims of indirect purchasers, the SCC found that the plaintiffs had failed to establish an identifiable class of at least two persons who suffered a loss. The proposed class consisted of consumers of products that contained high-fructose corn syrup (HFCS) who purchased those products between 1988 and 1995. However, the plaintiffs failed to put forth evidence demonstrating that it was possible for consumers to determine whether products they purchased contained HFCS rather than some other form of sweetener. The SCC noted that the labels on relevant products sold in Canada did not identify which type of sweetener was used, sugar being a significant alternative. In these circumstances, the plaintiffs had failed to establish some basis in fact that there was an identifiable class of two or more indirect purchasers who could prove that they actually suffered a loss.

⁴⁶ *In re Rail Freight Fuel Surcharge Antitrust Litig.*, 725 F.3d 244 (D.C. Cir. 2013).

⁴⁷ *In re High-Tech Employees Antitrust Litig.*, 289 F.R.D. 555 (N.D. Cal, San Jose Div. 2013).

tiffs alleged that a number of employers had violated Section 1 of the Sherman Act by agreeing not to solicit each other's employees and sought to certify a class comprised of all of the defendants' salaried employees. Following a detailed review of the expert reports, the court was satisfied that the plaintiffs had met the burden of demonstrating a plausible method for providing an estimate of damages.⁴⁸ However, the court had concerns about the capacity of the plaintiffs' evidence and proposed methodology to prove an impact on all class members.⁴⁹ Nevertheless, the court granted the plaintiffs leave to amend their pleadings to permit them to benefit from discovery that had occurred subsequent to the certification motion.⁵⁰ After a further hearing on a supplemental motion, the Court certified a narrower class of technical employees.⁵¹

It seems apparent from the foregoing that both the SCC and U.S. courts are influenced by the degree of discovery (if any) that has occurred prior to the date of the certification hearing and are wary of holding plaintiffs to a higher standard in the absence of discovery. If Canadian courts were to take up the SCC's above-noted comment that courts can appropriately revisit an initial certification decision at a later stage in the proceedings, the Canadian approach could move closer to the U.S. model. In other words, it may be open to Canadian courts in the future to treat the initial certification decision as an interim certification (which must pass the "some basis in fact" test and stand up to conceptual scrutiny), but also entertain more rigorous scrutiny on a post-discovery motion. It would be consistent with the principles of judicial economy and fairness to permit a further "gatekeeping" analysis after discovery rather than force defendants to expend significant time and costs, under the threat of potentially material or even crippling damage awards, and defend to trial a class action claim that is based on theories that do not meet a rigorous test comparable to that applied in *Comcast*.

[D]efendants may well

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Implications

While the Supreme Court's recent trilogy of cases has provided direction in some areas, such as the ability of indirect purchasers to assert claims in antitrust class actions, the decisions also leave other questions unresolved, such as the appropriate standards and methodologies for resolving the complex evidentiary issues inherent in indirect purchaser claims, exactly what level and type of assessment of a class and its claims is to take place at the certification stage, and what types of evidence defendants can introduce on these points. Future cases may also require Canadian courts to deal with the risk of multiple recovery by different indirect purchaser plaintiffs in different countries or at different levels of a distribution chain.

It is not clear how certification and trial judges will grapple with and resolve these complex issues, and whether courts will be prepared to decertify class actions at later stages of a proceeding, such as after discovery but before trial, on the basis of a more rigorous evaluation of the expert evidence such as that applied by U.S. courts following *Comcast*. In any event, defendants may well face certified class actions in Canada with respect to alleged cross-border cartels for which certification would not be available (or may have been denied) to indirect purchasers in the U.S. federal courts, because of either *Illinois Brick*, the more rigorous scrutiny engaged in by U.S. courts at the initial certification stage, or the absence of a need in Canada to demonstrate pre-

⁴⁸ *Id.* at 570.

⁴⁹ *Id.* at 582.

⁵⁰ *Id.* at 584.

⁵¹ *In re High-Tech Employees Antitrust Litig.*, 2013 U.S. D. LEXIS 15372 (N.D. Cal. San Jose Div. 2013).

dominance of the common issues. Although the full impact of the decisions on competition policy and class actions remains to be determined, these three SCC decisions will undoubtedly be a focal point of debate in future cases for years to come and experience with actual trials of indirect purchaser class actions could expose practical issues that could potentially persuade Canadian judges to limit damage claims, or even decertify class actions. In effect, the approach to class certification in Canada could potentially move closer to the U.S. federal approach. ●