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Patent-Backed Securitization for Innovation and Economic Growth in the Life Sciences: A Proposal for Incremental Securities Law Reform

Grace Sweeney*

I. THE BALANCE OF SECURITIES LAW BETWEEN CONSERVATISM AND INNOVATION

(a) Introduction

One hundred years ago, with the advent of the telephone, the courts grappled with the same perpetual challenge: the construction of a body of law capable of yielding to advances in technology.

Sophisticated legal constructs, in the form of provincial *Securities Acts* and their appointed Commissions, have since manifested in response to this challenge. Operating on the premise of efficient market theory, the modern body of law has chosen the vehicle of the prospectus¹ — containing “full, true, and plain disclosure”² of material facts relating to issued securities — to direct capital to promising enterprise. The surrounding securities legislation strives to regulate this capital flow in a manner that is efficient, while also inducing confidence in the market by preventing fraud.³

It is arguable that this legal system — enabling the investing of money based upon real and traditional property — made possible much of the development of industrial wealth in the 20th century.⁴ Historically, securities law has had empirical effects of increased capital at reduced cost,⁵ increased flexibility in the exercise of investment preference, reduced financial risk, and, ultimately, increased innovation.

Striking the correct balance between conservatism and innovation remains the challenge facing securities law today. As the landscape has changed, the chosen vehicle of the prospectus has been blamed for its effects. Speculation as to the va-

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¹ *Securities Act*, RSO 1990, c S5, s 53(1).

² *Ibid.* at s. 56(1).

³ *Ibid.* at s. 1.1.

⁴ Howard P Knopf, “Security Interests in Intellectual Property: An International Comparative Approach”, (2002) 7 *International Intellectual Law & Policy* 90-1, online: Heinonline <<http://heinonline.org>> [Security Interests].

⁵ Christian Leuz, “Capital-Market Effects of Securities Regulation”, (4 February 2011), online: Harvard Law School Forum on Corporate Governance and Financial Regulation <<http://blogs.law.harvard.edu/>>.

lidity of the theoretical premises of effective market theory, and the information service provided by the prospectus, is not the intention of this article. What this article seeks to accomplish, instead, is a topographical illustration of the larger landscape within which the prospectus operates. While skepticism of the extent of regulation may be warranted, another alternative is equally possible — the economic landscape has changed, and the chosen vehicle of the prospectus must adapt accordingly. The incremental reforms presented in this article, it is proposed, are appropriate to accomplish such a purpose.

(i) *The Vehicle of Securities Law: The Prospectus*

The prospectus, requiring issuers' continuous "full, true and plain disclosure of all material facts", acts as a medium between the securities issued and the investors.⁶

Under National Instrument 41-101's General Prospectus Requirements, the book value of a company — its hard financial, built, and manufactured capital — is captured in the form of the balance sheet, financial statements, and corporate and capital structure.⁷ Under section 8.6(1)(c), additional disclosure requirements for venture and IPO issuers mandate disclosure of intangible assets as material facts.⁸ The method of disclosure in the prospectus process is not similarly regulated, however, but left to the discretion of the issuer.

In the last century, this vehicle for disclosure, with its primary focus on tangible assets, served the twin goals of investor protection and efficient capital markets well. A tangible asset like hot steel was a prime player, weighing in at 2000 pounds and \$370 USD for a unit price of 0.20 USD per pound. Today, a 0.00068 lb. dose of Viagra costs \$8 USD — a comparative unit price of \$11,766.00 per pound.⁹

Milton Friedman's analogy, "I, Pencil", aptly captures the importance of intangible assets. Although the wood pencil is common, few know how to acquire the required inputs: the compressed graphite from South American mines, the wood from Eastern Red Cedar, the iron ore for the obligatory saw. Knowledge of how to make a pencil assumes primacy, relatively speaking, to mere possession of the tangible assets required for its assembly. In the same way, the intangible asset class — inclusive of intellectual property assets like patents, trade-marks, and copyrights — are a primary source of value. It is the intangible assets underlying a company — its established goodwill, patent monopolies, and brand value — which confer its *market value*.

⁶ See *Securities Act*, *supra* note 1. See also Ontario Securities Commission, *General Prospectus Requirements*, OSC NI 41-101 (8 August 2013) [NI 41-101].

⁷ Davies Ward Phillips & Vineberg, *Public Offerings in Canada* (21 August 2009), online at: Davies Ward Phillips & Vineberg <<http://www.dwpv.com>>.

⁸ NI 41-101, *supra* note 6 at s. 8.6(1)(c). If the issuer is a venture issuer or an IPO venture issuer that has not had significant revenue from operations in either of its last two financial years, disclose a breakdown of material components of (c) intangible assets arising from development; Companion Policy to National Instrument 41-101, *General Prospectus Requirements*.

⁹ Geoffrey Colvin, "We're Worth our Weight in Pentium Chips, But We're Producing A Lot More," *Fortune* (20 March 2000) online: CNN Money <<http://money.cnn.com>>.

Economic commodities have become increasingly weightless; value is concentrated, not in steel tractors, but ethereal streams of data, images, and symbols¹⁰ with little or no physical manifestations.¹¹ In 1982, while tangible assets comprised 62 percent of market value of the S&P 500,¹² traditional financial instruments were efficient and capable of investor protection. Today, between 50 and 84 percent of that value is locked up in intangible assets (See Appendix A).¹³ It is trite to say that the “efficient capital market” no longer gravitates, at least not primarily, on the axis of tangible asset exchange.¹⁴ In this respect, the accounting methods and disclosure contained in the prospectus may comprise only the tip of the iceberg of a company’s market value, and warrant consideration.

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- ¹⁰ Charles Goldfinger, *Intangible Economy and Financial Markets* (2000) 40 *Communications and Strategies* 59, online: [IDATE<http://www.idate.fr/fic/revue_telech/68/goldfing.pdf>](http://www.idate.fr/fic/revue_telech/68/goldfing.pdf) [“Intangible Economy”].
- ¹¹ Danny T Quah, *Increasingly Weightless Economies* (1997) 31:1 *Bank of England Quarterly* 49, online: [Bank of England <http://www.bankofengland.co.uk/publications/Documents/quarterlybulletin/qb970106.pdf>](http://www.bankofengland.co.uk/publications/Documents/quarterlybulletin/qb970106.pdf).
- ¹² The Conference Board, *Interim Report: Intangible Capital and the Valuation of Companies — A Comparison of German and U.S. Corporations* (Power Point Presentation), online: http://www.coinvest.org.uk/pub/CoInvest/COINVESTHulteninterim/HHJ_INTERIM_report_June25_2009_to_JONATHAN.pdf; Juergen H Daum, *Intangible Assets and Value Creation* (Toronto: John Wiley & Sons, 2002) [Intangible Assets]; Ocean Tomo Intellectual Capital Equity, *Intangible Asset Market Value*, online: <http://www.oceantomo.com/productsandservices/investments/intangible-market-value>. In more conservative estimates, intangible assets comprise 54 percent of total assets for American pharmaceutical firms. Using Juergen Daum’s, and intangible asset merchant bank Ocean Tomo’s, methodology, intangible assets comprise approximately 80 percent of market value. In this methodology, intangible book value is calculated by subtracting the tangible book value from the market capitalization of a given company or index. In practice, companies report tangible book value per share, number of shares outstanding, and market capitalization. Therefore, intangible book value can be calculated by subtracting the market capitalization from the tangible book value per share multiplied by the number of shares outstanding. It is expedient to do the calculation on a per share basis, and simply subtract the tangible book value per share from the market price. There are modest discrepancies between the two numbers due to differences in setting shares outstanding on a company-by-company basis. However, the discrepancy is rarely more than a few percentage points, which are within the error needed for most purposes.
- ¹³ Michael A Gollin, *Monetizing Intellectual Property to Improve Financial Performance IP Buzz* (November 2011), online: [Venable LLP <http://www.venable.com>](http://www.venable.com) [Monetizing Intellectual Property]; Daum, *Intangible Assets*, *supra* note 12.
- ¹⁴ Goldfinger, “Intangible Economy”, *supra* note 10.

(ii) *Purposes of the Securities Act: Investor Protection and Market Efficiency*

The mandates of the Securities Act, investor protection¹⁵ and fair and efficient capital markets, are accomplished through disclosure¹⁶ of all facts¹⁷ which can “reasonably be expected to have a significant effect on the market price or value of the securities”.¹⁸ Limiting disclosure to tangible assets omits up to 84 percent of corporate value. Investors, exercising reasonable reliance on the prospectus, are vulnerable to un-quantified risk exposure, introducing volatility into the markets. These are not the hallmarks of a “fair and efficient” capital market, but a precarious one.¹⁹ To the extent that the prospectus operates, primarily in the paradigm of tangible assets, the model falls prey to the law of diminishing returns in both of its stated purposes.

(iii) *Moving Forward — Models for Disclosure Relating to Intangible Assets*

The present set of questions will focus on whether an improved legal climate, offering broader and more appropriate recognition for the intangible asset class, would be useful to lenders, investors, and borrowers over the long term. While implications may be drawn for all intangible assets, life science patents, due to their robustness and extensive data, are examined here. The proposed reforms are relevant to market value, generally. However, the financial instrument of asset-backed securities, in which the patent is the asset underlying the security, provides a more functional sphere of analysis. Incremental reform of disclosure requirements, ensuring disclosure of all material facts relating to underlying assets, consistency, and a “level playing field” among issuers, can fulfill the purposes of investor protection and efficient capital markets.

(b) Overview

In this section, the historical balance struck by securities law between conservatism and innovation was considered in the context of a shifting economic landscape.

In Section II, the life sciences sector will be chosen to illustrate the current barriers impeding capital flow to high-value enterprise, resulting in decreased innovation and economic growth. These include the existence of “ever greening”, non-practicing entities, patent thickets, and onerous transaction costs on upstream patent holders with limited competency.

In Section III, the tool of intangible asset finance will be introduced as a means of harnessing the value of intellectual property assets, and leveraging them through securitization. This will be proposed as a method of constructing a bridge

¹⁵ *Ibid.*

¹⁶ *Securities Act, supra* note 1 at s. 53(1).

¹⁷ *Securities Act, supra* note 1 at s. 56(1).

¹⁸ *Securities Act, supra* note 1 at s. 1.1.

¹⁹ *Securities Act, supra* note 1 at s. 1.1.

between early-stage research at the bench, and clinical applications at the bedside. In Section IV, case studies of the instrument of patent-backed securities will be presented with regard to the life sciences sector. Financial instruments, including drug royalty securitization companies and mega funds, will be analyzed, and several benefits outlined, along with more long-term impacts on the economy and public health.

In Section V, quantitative, standardized, and empirically relevant indicia were selected as measures of underlying asset value in patent-backed securities. Twenty-two indicia will be identified for incremental reform of securities law, supplementing existing areas of the prospectus — including Financial Information; Material Facts; Risk Factors; Legal Proceedings and Regulatory Action; Material Contracts; and Audit Committees and Corporate Governance — with modified disclosure requirements.

Ultimately, evidence will be drawn in support of the thesis that incremental reform, within the limited sphere of patent-backed securities, can ensure consistency in achieving the Securities Act's purposes of investor protection and market efficiency. Through the use of financial engineering in intangible asset finance, the decoupling of patents could have positive effects on innovation and growth in the life sciences sector and high-value enterprise like it. The economic, social, and public health benefits associated with this growth warrant meaningful consideration.

II. BARRIERS TO INNOVATION: THE PATH FROM BENCH TO BEDSIDE

(a) Introduction

The *Securities Act* seeks to foster investor protection and efficiency through its disclosure requirements. Capital markets depend upon the use of information in a manner facilitating capital flow to high-value enterprise. This concept is known as “informational efficiency”. Capital market imperfections in this respect — the classic “market for lemons”²⁰ phenomenon — result in financing constraints.

The high-technology sector generates the new knowledge that is the *condition precedent* of economic development, and is thus a prototype of “high-value enterprise”. It follows logically that the breakdown of disclosure requirements into informational *inefficiency*, and the financing constraints which are a byproduct of that, can barricade the existing flow of capital from reaching this high-value enterprise — thus hampering, to a proportionate extent, economic growth.

The biotechnology and pharmaceuticals sector is the second-largest high-technology industry in the 12 OECD countries.²¹ The effects of informational inefficiency are not exclusive to the economy: the treatment and cure of chronic, non-

²⁰ GA Akerlof, “The Market for Lemons: Quality Uncertainty and the Market Mechanism” (1970) 84 QJ Econ 488.

²¹ OECD Directorate for Science, Technology and Industry, Economic Analysis and Statistics Division, *ISIC REV. 3 TECHNOLOGY INTENSITY DEFINITION: Classification of manufacturing industries into categories based on R&D intensities* (7 July 2011) at 5, online: Organisation for Economic Co-operation and Development <<http://www.oecd.org/sti/ind/48350231.pdf>>.

communicable diseases like cancer are found in commercialized life sciences research. This objective, important from a public health standpoint, necessitates translation of basic research into clinical application - a vital, albeit capital-intensive, condition precedent. This article illustrates those dynamics in the life sciences sector.

(i) *The Life Sciences Sector: A Paradox of Efficient Market Theory*

The life sciences sector is, within the paradigm of efficient market theory, a paradox. On one hand, it rivals the advent of the telephone: stem cell therapies are curing debilitating forms of quadriplegia, and diseases that have confounded conventional medicine are being unraveled by human genome sequencing.²² Society is on the verge of revolutionary breakthroughs in treating disease, cancer in particular. On the other hand, capital flow has slowed to a drought termed the “valley of death”²³ by industry professionals.

This capital shortage not only prevents investment, but innovation. While seed-stage biomedical research may be occurring at the bench, it is not “translated” into commercialized clinical applications at the bedside. “Translational research” refers to the movement of promising “seed-stage” research into preclinical studies — including identifying biomarkers, target and pathway validation, and animal model development — to generate “proof of concept” (POC).²⁴ This process enables that research to proceed through clinical trials, federal review and approval, and, ultimately, approved clinical applications that can be commercialized for medical use.

These occur in the form of new molecular entities (NMEs) and biologic license applications — both of which have sharply declined per dollar of investment. While 2012 saw \$48 billion spent on research, and \$125 billion on clinical development, only \$6 billion was spent on translational efforts.²⁵ The failure of translational research precludes medical discoveries from being translated into useful products — and, it follows, the improvement of stock performance,²⁶ economic growth, and public health.

(b) **Barriers to Innovation: The Path From Bench to Bedside**

Seventy percent of Canada’s university research is conducted in the life sciences, primarily with respect to cancer and heart disease. The preponderance of

²² JM Fernandez, RM Stein & AW Lo, “Commercializing Biomedical Research Through Securitization Techniques” (2012) 30:10 Nat Biotechnol 964 at 964 [“Biomedical Research”].

²³ *Ibid.* at 965.

²⁴ Milken Institute, *Fixes in financing: Financial innovation for translational research* (April 2012), online: Milken Institute <<http://www.milkeninstitute.org/pdf/FixesInFinancing.pdf>> [*Fixes in Financing*].

²⁵ *Ibid.* at 2.

²⁶ SM Paul et al, “How to Improve R&D Productivity: The Pharmaceutical Industry’s Grand Challenge” (2010) 9 Nat Rev Drug Discov 203 at 203 [“R&D Productivity”].

investment occurs in the energy, clean technology, and IT industries.²⁷ Canada, operating as a net exporter of ideas, underperforms in its *translation* of research into high-value products.²⁸

Biomedical innovation is subject to particularly acute credit constraints: it is riskier, more expensive, and more difficult to finance with traditional sources of capital.²⁹ Innovative firms cannot secure capital for a host of reasons: investment returns are uncertain, they have little collateral to secure debt, and their capital — mostly intangible — is both difficult to redeploy and characterized by relevant bankruptcy costs.³⁰ Commercializing one drug takes 14 years and \$1.3 billion, and for each success, there are 50 failures³¹ — rendering innovation unpalatable to many investors' risk preference. These odds are exacerbated by recent challenges: declining prescription-drug spending and rising drug-development costs; shrinking R&D budgets; the discovery of biomarkers limiting patient populations for certain drugs;³² the 2012 patent cliff; regulatory uncertainty after the Vioxx (rofecoxib) dispute and healthcare reform decision; lower risk tolerance among venture capitalists; unprecedented market volatility; and the heightened level of financial uncertainty from ongoing repercussions of the financial crisis.³³ While other industries may share these challenges, it is difficult to identify another so heavily burdened by all of them.

The main barriers to innovation, interrelated with these challenges, are presented here.

(i) *Ever Greening and the Focus on Blockbusters*

In granting a monopoly in exchange for public disclosure, the *Patent Act*³⁴ seeks to promote inventiveness.³⁵ The above pressures, however, led some firms to recoup costs by extending that patent monopoly by way of secondary and tertiary protection, producing a bottleneck effect.

This “ever greening”,³⁶ which funnels two-thirds of R&D capital to the development of duplicative drugs, rather than the qualitative breakthroughs presented by

²⁷ Wallace Imen, “Stubborn Innovation Gap Persists in Canada” *The Globe and Mail* (25 May 2012), online: The Globe and Mail <<http://www.theglobeandmail.com>>.

²⁸ *Ibid.*

²⁹ JM Fernandez, RM Stein & AW Lo, “Biomedical Research”, *supra* note 22 at 964.

³⁰ R Carpenter & B Petersen, “Capital market imperfections, high-tech investment and new equity financing” (2002) 112:477 *Econ J* 54 at 54.; BH Hall, “The Financing of Research and Development” (2002) 18:1 *Oxf Rev Econ Pol* 35 at 40.

³¹ “Should Patents on Pharmaceuticals Be Extended to Facilitate Innovation?” *The Wall Street Journal* (23 January 2012), online: The Wall Street Journal <<http://online.wsj.com>>.

³² *2010 Annual Global Corporate Default Study and Rating Transitions* (30 March 2011), online: Standard & Poor's <<http://www.standardandpoors.com>>.

³³ JM Fernandez, RM Stein & AW Lo, “Biomedical Research”, *supra* note 22 at 964.

³⁴ *Patent Act*, RSC 1985, c P-4.

³⁵ *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 S.C.C. 61.

³⁶ *Ibid.*

innovative drugs,³⁷ has been criticized by the Supreme Court of Canada. Despite a near doubling of aggregate R&D (from \$68 billion in 2002, to \$127 billion in 2010), the number of new drugs has not changed appreciably.³⁸ Without change, it is suggested that market forces will likely result in a dearth of innovative products in the biomedical sector. Polarization of the pipeline towards late-stage drug development is unsustainable. Ultimately, firms will possess insufficient innovation to replace revenue loss from successful products' patent expirations.³⁹ Ironically, these efforts will compound the effects they seek to circumvent.

(ii) *Non-Practicing Entities (NPEs) or "Patent Trolls"*

While biomedical R&D may result in a patent, the path from bench to bedside is an uphill battle. In the last two decades, the number of patent lawsuits filed in U.S. district courts had tripled to 3,260;⁴⁰ in 2012, they constituted 58 percent of all lawsuits filed.⁴¹ This is largely the result of offensive suits launched against patent-holders by non-practicing entities (NPEs), or "patent trolls," with an average \$2 million cost for patent-holders,⁴² on whom the burden of proof is imposed.

While large companies can file thousands of pre-emptive patent applications in emerging industries, startups are easy prey once their products show promise.⁴³ Having spent \$3 million to succeed in one such patent trial, the threat of five more forced the iPhone's Siri voice recognition software developer to sell his technology to a patent troll — whose stock price subsequently jumped by 70 percent.⁴⁴ The MIT researcher, largely known as one of the most innovative thinkers in computer speech, has now left the industry altogether.⁴⁵ In this respect, the consequences of NPEs are the suffocation of innovation and economic growth.⁴⁶ In 2011, NPEs cost the US economy \$29 billion — as a tax on innovation, that's more than 10 percent of the \$247 billion spent on R&D in 2009.⁴⁷ That qualified as "decimation" —

³⁷ Dean Baker, *Financing Drug Research: What are the Issues?* (22 September 2004), online: Center for Economic and Policy Research <<http://www.cepr.net>>.

³⁸ Evaluate Pharma, *World Preview 2016* (May 2010), online: Evaluate Pharma <http://www.atebion-bds.com/pdfs/evaluatepharma_world_preview.pdf>.

³⁹ Paul et al, "R&D Productivity", *supra* note 26 at 203.

⁴⁰ *Ibid.*

⁴¹ S Jeruss et al, "The America Invents Act 500: Effects of Patent Monetization Entities on US Litigation" (2012) 11 *Duke L & Tech Rev* 357.

⁴² Mark Gibbs, "A Patent Troll Wants to Charge You for E-mailing Your Scans" *Forbes* (5 January 2013), online: *Forbes* <<http://www.forbes.com>>.

⁴³ *Ibid.*

⁴⁴ Charles Duhig & Steve Lorr, "The Patent, Used as a Sword" *New York Times* (7 October 2012), online: *New York Times* <<http://www.nytimes.com>>.

⁴⁵ *Ibid.*

⁴⁶ *Ibid.*

⁴⁷ JE Bessen & MJ Meurer, "The Direct Costs from NPE Disputes" (2012) 99 *Cornell L Rev* (forthcoming), online: Social Science Research Network <<http://ssrn.com/abstract=2091210>>.

reduction by a tenth,⁴⁸ leading to executive action following the *Leahy-Smith America Invents Act*.

Until reform of this system occurs, another strategy will be necessary to stymie NPEs and enable downstream development of biomedical innovation by entities capable of successfully protecting, enforcing, and commercialize rights.

(iii) *Patent Thickets: The “Anti-commons” of Biomedical Research*

A third barrier to biomedical innovation in the form of patent thickets, a dense web of overlapping IP rights which impedes translation of early-stage assets into commercialized products.⁴⁹ When the cost of entry for patenting is raised such to the extent that it has a negative impact on social welfare, an “anti-commons” is established, where scarce resources are under-used because too many owners can block each other.⁵⁰ Deleterious effects include increased litigation and pendency of patents and growing uncertainty about validity of pending and granted patents,⁵¹ all of which exacerbate the hold-up of innovative biomedical products, which is detrimental to public health. Patent thickets impose significant barriers to innovation, economic growth, and public health, and have thus been a concern to antitrust agencies, and European⁵² and U.S. regulators for over a decade.⁵³

⁴⁸ Steven Levy, “The Patent Problem” *Wired* (13 November 2012), online: [Wired <http://www.wired.com>](http://www.wired.com).

⁴⁹ C Shapiro, “Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting”, in AB Jaffe et al, *Innovation Policy and the Economy*, (Cambridge, MA: MIT Press, 2000) at 119.

⁵⁰ MA Heller, & RS Eisenberg, “Can Patents Deter Innovation? The Anti-commons in Biomedical Research” (1998) 280 *Science* 698 [“Deter Innovation”].

⁵¹ *Ibid.*

⁵² A Arundel & P Patel, “Strategic Patenting: Background Report”, (2003) online: http://proinno.intrasoft.be/reports/documents/TCW15_background_paper.pdf; D Harhoff, “Patent Quantity and Quality in Europe — Trends and Policy Implications”, in B Kahin & F Foray, eds, *Advancing Knowledge and the Knowledge Economy* (Cambridge, MA: MIT Press) at 331; D Harhoff et al, “The Strategic Use of Patents and its Implications for Enterprise and Competition Policies. Final Report for EC ENTR/05/82” (8 July 2007), online: European Commission, <http://www.en.innotec.bwl.uni-muenchen.de/research/proj/laufendeprojekte/patents/stratpat2007.pdf>.

⁵³ Federal Trade Commission, *To Promote Innovation — The Proper Balance of Competition and Patent Law and Policy* (October 2003), online: Federal Trade Commission <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>; Federal Trade Commission, *Anti-trust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition* (April 2007), online: Federal Trade Commission <http://www.ftc.gov>; *The Evolving IP Marketplace: Aligning Patent Notice and Remedies With Competition* (March 2011), online: Federal Trade Commission <http://www.ftc.gov/os/2011/03/110307patentreport.pdf>.

(iv) *Prohibitive Transaction Costs and Limited Competence of Upstream Patent Holders*

While public institutions are the most common source of innovative biomedical research, they struggle inordinately to maintain an adequate foothold to actively patent these discoveries.⁵⁴ The decision to commercialize arises early in R&D, when outcomes are uncertain; potential gains, speculative; and the value of downstream products indeterminately justified relative to the costs of the anti-commons.⁵⁵

Universities, which produce approximately two-thirds of seed research, are often ill-equipped to handle multiple transactions for acquiring licenses to use research tools; negotiation delays stifle research, while reliance on obsolete public domain technologies fails to garner favor in grant competitions.⁵⁶ With limited resources and competence, the fast-paced, market-oriented bargaining,⁵⁷ and high transaction costs associated with bundling IP rights are often prohibitive of the firm's decision to continue with the remainder of the battle: commercialization.

In contrast to public institutions and small start-up firms, corporations with substantial legal departments may have more substantive resources to bring a product to market.⁵⁸ Being more skilled in patent enforcement, patent acquisitions by these corporations can reduce litigation while moving capital to innovators, which enhances incentives to innovate.

(c) Implications for Public Health and Economic Growth

In 2009, cancer accounted for almost a quarter of mortality in the U.S, and was the second leading cause of death. A male's lifetime risk of developing cancer is one in two; a female's, one in three.⁵⁹ The failure to translate basic biomedical research in the life sciences results in a deficit of innovative healthcare, which is compounded by the subsequent economic cost of the potential life years lost (PLYL). Data from an isolated cohort of cancer patients quantified this cost at approximately 890,000 PLYL, or \$89 billion annually — a net present value of \$2.2 trillion.⁶⁰ A permanent 1 percent reduction in cancer mortality has a present value of nearly \$500 billion; a cure, approximately \$50 trillion.⁶¹

Paradoxically, despite 70 percent of Canadian R&D being invested in the life sciences, virtually none of those discoveries are being translated into commercialized drugs presenting qualitative breakthroughs, but rather, to the development of

⁵⁴ MA Heller & RS Eisenberg, "Deter Innovation", *supra* note 50.

⁵⁵ *Ibid.*

⁵⁶ *Ibid.*

⁵⁷ *Ibid.*

⁵⁸ *Ibid.*

⁵⁹ American Cancer Society, "Lifetime Risk of Developing or Dying from Cancer", (29 November 2012) online: American Cancer Society <<http://www.cancer.org>>.

⁶⁰ Eric Budish et al, *Do Fixed Patent Terms Distort Innovation? Evidence from Cancer Clinical Trials* (22 August 2013), online: MIT <<http://economics.mit.edu/files/8651>>.

⁶¹ Kevin Murphy & Robert Topel, "The Value of Health and Longevity" (2006) 114 J Polit Econ 871.

duplicative drugs. This is not where reductions of cancer mortality, or any other significant healthcare gains, are to be found. If stagnancy in healthcare is to be overcome, the privatization of biomedical research must be more carefully deployed — in a manner conducive to both upstream innovation, and downstream product development and commercialization.⁶² It is clear that the life sciences sector needs novel approaches to early-stage drug development that improve value creation, better manage risk, create access to new capital sources, and lower the cost of that capital. Instead of backing early-stage companies to create the next generation of start-ups, what is needed is the financing of a diverse field of promising products. What is needed are models that break down the R&D value chain to offer an acceptable return on investment (ROI) through each stage of development, effectively spreading the investment risk and reward throughout the entire R&D process.⁶³

III. A CATALYST FOR INNOVATION: INTANGIBLE ASSET FINANCE

As Section II illustrates, the amount of innovative biomedical research exceeds available capital flow for translation into commercialized products.⁶⁴ This deficit mandates a more comprehensive solution than public funding. Linking a public health objective, like cancer, to a profit motive may seem heretical. Financial incentives, however, can mobilize a broader set of stakeholders and a more expansive pool of assets,⁶⁵ initiating a virtuous cycle of investor confidence that magnifies the likelihood of success.⁶⁶ The role of finance in accomplishing this brand of innovation will be considered here.

The paradox of high-value enterprise in the life sciences with insufficient capital flow defies efficient market theory. Rather than jettisoning the prospectus, this section will illustrate a more measured response, adapting the scrutiny of existing intangible asset disclosure in the prospectus to ensure *consistency* in informational efficiency, regardless of the economic landscape.⁶⁷ Because the majority of value in the life sciences resides in off-balance-sheet patents disembodied from conventional accounting standards, informational *inefficiency* exists. It is proposed that this inconsistency, rather than the vehicle of the prospectus itself, is the defining element in precluding adequate disclosure, investor protection, and market efficiency. By the end of this section, financial instruments with the capacity of encompassing and governing this “shadow economy” are presented as a means of ensuring consistency in those objectives.

⁶² MA & Heller, RS Eisenberg, “Deter Innovation”, *supra* note 50.

⁶³ Milken Institute, *Fixes in financing*, *supra* note 24.

⁶⁴ Fernandez, Stein & Lo, “Biomedical Research”, *supra* note 22 at 964.

⁶⁵ *Ibid.*

⁶⁶ *Ibid.*

⁶⁷ NI 41-101, *supra* note 6 at s. 8.6(1)(c). If the issuer is a venture issuer or an IPO venture issuer that has not had significant revenue from operations in either of its last two financial years, disclose a breakdown of material components of (c) intangible assets arising from development; Companion Policy to National Instrument 41-101, *General Prospectus Requirements*.

(a) Shortcomings of Traditional Financial Instruments in the “New” Economy

(i) The Failure of Intangible Assets to be Appropriately Valued in Finance

It is in intangible asset finance that the prospectus, with its disclosure of earnings, cash flows, and book values,⁶⁸ and comparably less scrutinized disclosure of intangibles, most seriously fails to reflect enterprise value. This is due to a distortion in the accounting process of periodically matching costs with revenues.⁶⁹ While intangible assets, like patents, are immediately expensed, their benefits are recorded at a later time, divorced from those original investments.⁷⁰ In this manner, the rigor and uniformity of securities law governing tangible assets fails to encompass intangibles, compromising information symmetry.⁷¹ Here, potential financial models for reinstating consistency and confidence in the capital markets will be explored.

(ii) Going Forward: Instruments for Intangible Asset Valuation

The shifting economic landscape demands a determination of the best method of understanding, and communicating, the divergence of an issuer’s market valuation from its book value.⁷² Three models exist in the literature. The first, and default, model attributes divergence to a vague, ill defined “intangible asset class”, and ceases with the exercise. As discussed, this threatens investor protection and market volatility.⁷³ A more liberal model supplants traditional financial instruments entirely with a new reporting paradigm.⁷⁴ In a third model, accounting standards quantify those assets that are generated internally.⁷⁵

This article proposes a fourth, alternative model commensurate with the shifting economic landscape outlined in Section II. While more tempered than the “new economy” liberalization discourse, it is also more successful in maintaining the delicate balance of conservatism and innovation struck by securities law. With over 500 years of practice in understanding financial statements for over 560 trillion in total assets, interference would render assets *more* uncertain, and consequently less valuable. Overbroad reform of financial reporting would thus be injurious to investor protection and market efficiency. Incremental reform of the existing body of securities law, however, can adapt to these intangible assets. This will ensure that

⁶⁸ Baruch Lev & Paul Zarowin, “The Boundaries of Financial Reporting and How to Extend Them” (1999) 37:2 J Accounting Res 353 at 354.

⁶⁹ *Ibid.*

⁷⁰ *Ibid.*

⁷¹ *Ibid.*

⁷² Wayne S Upton Jr, “Financial Accounting Series, Special Report: Business and Financial Reporting, Challenges from the New Economy” (April 2001), online: Financial Accounting Standards Board <http://www.fasb.org/articles&reports/sr_new_economy.pdf> at 2.

⁷³ *Ibid.*

⁷⁴ *Ibid.*

⁷⁵ *Ibid.*

the rigor and uniformity of disclosure of *material facts* relating to a security's *underlying asset class* is consistently applied within the capital markets. In the following section, two financial instruments, which accomplish this with respect to patents, are presented.

(b) Intangible Asset Finance: Patent-Backed Securities as Bridging Mechanisms for Translational Research in the Life Sciences Sector

(i) Introduction to Intangible Asset Finance: Prevalence of IP-Backed Securities

IP-backed securities are a slowly developing asset class, growing from \$380 million in transactions in 1997 to \$1.13 billion in 2000 (See Appendix B).⁷⁶ The class commenced with the \$55 million securitization of royalties on copyrights of David Bowie — “Bowie Bonds” — and extended to deals with Rod Stewart, Tom Clancy, and Toni Morrison.⁷⁷ This extended to film companies like Twentieth Century Fox, DreamWorks SKG, and \$650 million sale of bonds backed by cash flows from films slated for production by Polygram, Inc. over a three-year period⁷⁸ In sports, Ascent Entertainment, owner of Denver’s NBA and NHL franchises, raised funds for its Pepsi Center Arena by issuing \$130 million in asset-backed securities.⁷⁹ These novel forms of financial engineering are only just beginning to be applied to patents.

(ii) Patents as Key Players in Intangible Asset Finance

The most tangible forms of IP, patents enjoy the most robust legal protection, and have the greatest effect on the commercial success and market value of companies.⁸⁰ Patent databases also operate as powerful sources of data.

Patent value stems from a legally conferred monopoly on the manufacture, distribution, and sale of a patent.⁸¹ This value extends to the licensing or assign-

⁷⁶ David Edwards, *Patent Backed Securitization: Blueprint for a New Asset Class* (2001), online: Gerling NCM <http://www.securitization.net/pdf/gerling_new_0302.pdf> [Blueprint].

⁷⁷ Jennifer Sylva, “Bowie Bonds Sold for Far More Than a Song: The Securitization of Intellectual Property as a Super-Charged Vehicle for High Technology Financing” (1999) 15 Santa Clara Computer & High Tech LJ 195.

⁷⁸ *Ibid.*

⁷⁹ *Ibid.*

⁸⁰ “An Economic Analysis of Royalty Terms in Patent Licenses” (1983) 67 Minn L Rev 1198 [“Royalty Terms”].

⁸¹ C Odasso & E Ughetto, “Patent-backed Securities in Pharmaceuticals: What Determines Success or Failure? (2011) 41:3 R&D Management 219”, online: European Policy for Intellectual Property <http://www.epip.eu/conferences/epip04/files/UGHETTO_Elisa.pdf> [Patent-backed Securities]; JA Agiato, “The Basics of Financing Intellectual Property Royalties” (2002) in B Berman ed, *From Ideas to Assets: Investing Wisely in Intellectual Property* (New York: John Wiley & Sons, Inc, 2002).

ment of some or all of the IP in exchange for periodic royalty payments.⁸² These characteristics render patents, if collateralized by the royalty streams that they generate, revenue-generating assets capable of exploitation. Data indicates that there is sufficient capital available for the continued emergence of this asset class — between 1990 and 1998, patent-licensing revenues increased by almost 700 percent to \$100 billion, exhibiting a compounded annual growth rate at approximately 28 percent.⁸³ The share of market valuation assumed by intangible assets has since continued to rise.

(iii) Patent-Backed Securities: A New Intangible Asset Class

The method for the exploitation of patents occurs through their securitization — the conversion of those assets, or their accompanying cash flow, into marketable securities. The assets are transferred into a separate legal entity, usually a Special Purpose Vehicle (SPV) or “portfolio.”⁸⁴ Both terms will be used interchangeably here. Securities, contingent upon the payments received by those assets, are issued to the new asset holder.⁸⁵ In this respect, the IP is delinked from market value such that it alone forms the underlying asset of the security. The credit and performance attributes of the asset-backed securities are dependent on underlying assets, rather than concerns relating to ancillary business activities and attendant risks.

In this way, its value can be extracted from the vague, undifferentiated 50-84 percent of a firm’s market valuation. Through the use of patent-backed securitization, the share of market value that lays locked in intangible assets can be “unlocked,” and capital more efficiently redirected to promising enterprise. The result is that a firm is enabled to then borrow money against the value of its intangible assets, and the stream of cash flows that was otherwise to accrue to it as a result of those assets.⁸⁶ This permits the asset holder to acquire greater amounts of cash⁸⁷ for less expense than commercial bank loans.⁸⁸

(iv) Overcoming the Capital Flow Barriers of Traditional Finance

Despite the great need for increased capital and translational research in the life sciences sector, the trend of intangible asset securitization is only beginning to develop in the life sciences sector. While this can be attributed in part to the aforementioned risks posed in the industry, it is argued here that this primarily results

⁸² Law Commission of Canada, *Leveraging Knowledge Assets: Reducing Uncertainty for Security Interests in Intellectual Property* 2004, online: Dalhousie Library <<http://dalspace.library.dal.ca/handle/10222/10279>>.

⁸³ *Blueprint*, *supra* note 76.

⁸⁴ Malcolm S Dorris & Edward J O’Connell, “Problem Cases in Bankruptcy” (1995) 50 *Bus Law* 527 [“Problem Cases”].

⁸⁵ Edwards, *Blueprint*, *supra* note 76.

⁸⁶ “Royalty Terms”, *supra* note 80 at 1230.

⁸⁷ Sam Adler, “David Bowie’s \$55 Million Haul: Using a Musician’s Assets to Structure a Bond Offering” (1997) *Ent L & Fin* 5.

⁸⁸ Dorris & O’Connell, “Problem Cases”, *supra* note 84.

from the *informational inefficiency* engendered by the shortcomings of securities law, and disclosure requirements, in the context of intangible asset finance. In this section, the myriad ways in which securitization instruments can serve to *outweigh* the risks plaguing the industry, to a degree sufficient to present a favorable risk-reward profile for investors and attract capital to the sector, will be presented. This will be followed by a discussion of disclosure requirements, sufficient to improve *informational efficiency*.

Large pharmaceutical companies obtain capital through public equity, by selling shares on the stock exchange. This option is unavailable to upstream patent holders, like universities since at the earlier stages of drug development, they cannot yet establish similarly favorable trajectories (of growing sales and profits) over a period of several years.

To these upstream patent holders, debt finance from banks and other institutions are a second option. Such institutions, however, have low risk tolerance. Loans, made against personal guarantees and liquid assets, often require collateral exceeding their value threefold. This risk appetite is diametrically opposed, in multiple respects, to the intangible and high-risk nature of investment in early-stage, preclinical biotechnology.

The next viable sources of funding for actors with seed-stage biomedical research is private equity: angel and venture capital (VC) investors, which still play a limited role in many countries. This industry, however, exacerbates the difficulties posed by the investor's desire for strong *risk-reward profiles* to the emerging and promising discoveries of the life sciences sector.

VCS center on risk and exit opportunities, generally providing capital to highly profitable firms with above-average future growth prospects, a strong market share and significant competitive advantages over rivals, and a superior management team, with an aim to achieve above-average returns while minimizing investment risks.⁸⁹ They review about five hundred business plans to make five investments, on average.⁹⁰

In contrast, the most valuable assets — the seed-stage, pre-clinical research forming the core of *innovative* clinical applications, which might be the next blockbuster drug — present an even less favorable risk-reward profile. Early-stage research requires significant capital, and competes with dominant market players. From 2001 to 2010, life sciences VC funds had an average internal rate of return (IRR) of -1 percent;⁹¹ the compound annual rate of return (ARR) of pharmaceutical stock market indexes is approximately 0 percent. A recent survey found that 40 percent of VC funds planned to decrease pharmaceutical investment, and 42 percent to increase investment in non-FDA regulated health services.⁹²

⁸⁹ Ian Ellis, *Maximizing Intellectual Property and Intangible Assets: Case Studies in Intangible Asset Finance* (November 2009), online: Athena Alliance <<http://www.athenaalliance.org>> [*Intellectual Property*].

⁹⁰ *Ibid.*

⁹¹ Fernandez, Stein & Lo, "Biomedical Research", *supra* note 22 at 964.

⁹² National Venture Capital Association & Medical Innovation-Competitiveness Coalition, *Vital Signs: The Crisis in Investment in U.S. Medical Innovation and the Impera-*

When VC funding is in fact secured, additional backing is often required. A second round of equity investment can be problematic: companies may not want to dilute current equity, and the prospective of a “down round” — a lower or similar valuation compared with the original position — is even more unattractive.⁹³

Patent-backed securities are a unique alternative to traditional bank loans because they generate more capital, and may either have a fixed or floating interest rate. Bonds are also preferable to a sale of IP because licensing revenue generally increases over time due to an ever-expanding market. Additional benefits are outlined in the next section.

For the purposes of investor protection, and ensuring this capital flow is as fair and efficient as possible, the following section will present two models for patent-backed securitization, and discuss how securities law can evolve to ensure investor protection, in the form of disclosure of facts material to the underlying asset.⁹⁴

IV. A BRIDGE FROM BENCH TO BEDSIDE: PATENT-BACKED SECURITIES

(a) Introduction

In section II, the high-value enterprise of the life sciences sector, and the barriers to innovation it currently faces, were outlined. The need to look for new sources of capital flow, which can facilitate the translation of basic biomedical research into commercialized products, was addressed. In times of economic crisis when equity rounds are difficult and IPOs impossible, an increased focus on capital efficiency, the alternative proposal of “financial engineering”⁹⁵ — raising capital by selling royalty or revenue rights — may prove capable of bridging this fundamental paradox in the life sciences sector. If such a model were feasible, the barriers to innovation posed by ever greening, non-practicing entities, and patent thickets might be overcome, and corresponding public health and economic benefits realized. Two models of patent-backed securities will be presented here as a means of bridging this “valley of death” in the life sciences sector.

(b) Types of Patent-Backed Securities

(i) Royalty Securitization Companies

The first patent-backed security is an emerging class of business entities, drug-royalty securitization companies, which adopt a securitization approach to financing life sciences companies. This includes companies like Royalty Pharma (New York, NY, USA), Cowen Healthcare (Stamford, CT, USA) and DRI Capital (Toronto, ON, Canada). These investment vehicles acquire ownership interests in the royalty streams of late-stage, approved drugs. To make risk-reward profiles more attractive for investors in a risky sector, those interests are combined into a single

tive of FDA Reform (6 October 2011), online: National Venture Capital Association <<http://nvcaccess.nvca.org>>.

⁹³ Ellis, *Intellectual Property*, *supra* note 89.

⁹⁴ *Securities Act*, *supra* note 1.

⁹⁵ Fernandez, Stein & Lo, “Biomedical Research”, *supra* note 22 at 964.

portfolio. In this manner, the royalty securitization company assumes the future risks and rewards of ownership. The latter includes the ability to issue securities on royalties *divorced from* the holder's liabilities.

The patent holder, in exchange, is liberated from the full term of the patent and royalty stream, and conferred increased liquidity. This allows the patent holder to immediately recoup the initial investment, which facilitates accelerated turnover and innovation within the sector.

Universities are the primary drivers of life sciences research, and also operate as rich sources of seed-stage biomedical innovation. American universities now collect more than USD \$700 million *per annum* in patent royalties, executing over 3,300 licenses a year.⁹⁶ In Canada, where 70 percent of R&D is spent on life sciences research, the benefits are self-perpetuating. The establishment of royalty securitization companies rewards Canadian innovation with upfront liquidity, which can further biomedical research. One example is Royalty Pharma's securitization of Yale's patents, 911, 200 and 942, 686, related to HIV drug Zerit, generating \$115-million upfront for the construction of a new research facility.

While single-asset securitization, requiring a stable, predictable, cash flow, remains risky in the context of the life sciences sector, portfolio approaches mitigate this risk. DRI Capital is the first of a select group of diversified pools of pharmaceutical patent royalties, offering greater structural stability and risk diversification. With sufficient programs in a portfolio, revenues are more easily valued, and make more attractive from a risk-reward perspective. A second case study is Royalty Pharma. During chemotherapy, about half of patients develop neutropenia, which increases the risk of serious infection. This is treated primarily by Neupogen® (filgrastim) and Neulasta® (pegfilgrastim), or granulocyte colony stimulating factor (G-CSF). Discovered by Memorial Sloan Kettering (MSK)⁹⁷ in 1988, G-CSF is a genetically engineered version of a naturally occurring protein, the body's primary defense against bacterial infection. Essentially, it stimulates white blood cell (neutrophil) production in bone marrow. This reduces infection frequency and severity in chemotherapy, and makes treatment possible where it previously was not. In 1991, MSK licensed patent US 4961926 A⁹⁸ to Amgen for marketing as Neupogen®/Neulasta®. Since, it has become cancer's standard of care,⁹⁹ and a blockbuster with combined 2011 sales of \$5.3 billion.¹⁰⁰

⁹⁶ Edwards, *Blueprint*, *supra* note 76.

⁹⁷ JL Gabrilove et al, "Phase I Study of Granulocyte Colony-Stimulating Factor in Patients with Transitional Cell Carcinoma of the Urothelium" (1988) 82:4 J Clin Invest 1454.

⁹⁸ "Methods for Prevention and Treatment of Mucositis with Granulocyte Colony Stimulating Factor", US Patent No 4961926, (19 November 1987), online: United States Patent and Trademark Office <<http://www.patft.uspto.gov>>.

⁹⁹ Office of Technology Development, "Success Stories", online: Memorial Sloan-Kettering Cancer Center <<http://www.mskcc.org/research/office-technology-development/success-stories>>.

¹⁰⁰ Mari Serebrov, "Amgen Running to Win in Both Lanes of Biosimilar Race" *BioWorld*, online: BioWorld <<http://www.bioworld.com/content/amgen-running-win-both-lanes-biosimilar-race-0>>.

MSK is the second-highest ranked cancer hospital globally,¹⁰¹ and by 2004, its R&D funding was fully dependent on its royalties from patent US 4961926 A: approximately 25 percent of MSK's financial assets. Rather than enduring the 20-year patent term, MSK sold 80 percent of its royalty interest to Royalty Pharma for an upfront payment of US \$405 million in 2004. This enabled MSK to construct a new facility for further cancer research.

Royalty Pharma, the largest of these companies, has interests in over 30 products, including blockbusters like Humira (adalimumab), Remicade (infliximab), Atripla/Truvada (emtricitabine, tenofovir), Januvia (sitagliptin) and Rituxan (rituximab). It has assets of over \$8 billion as of May 2012, of which \$4.1 billion is securitized debt with the acquired royalty streams of approved drugs serving as collateral. All three rating agencies have rated its most recent debt issue, a successful offering of \$600 million with excellent terms, "investment grade." This is an important designation, rendering the debt eligible for purchase under the policies of institutional investors like pension funds, endowments and foundations. Despite broader market turmoil, its received royalties performed 10 percent better than forecasted.

This concludes the discussion of royalty securitization companies. See Appendix C for examples of a portfolio of assets, since adopted in Canada by firms like DRI Capital in Toronto, as opposed to the single asset issued by Yale, Zerit. See also Appendices C and D for a model of the patent-backed security portfolio.

(ii) *Mega funds*

The above model for royalty securitization companies illustrates the potential to stimulate innovation and economic growth in the life sciences sector, over and above the returns experienced through traditional financial instruments, by collateralizing the royalty streams of pharmaceutical patents. While the economic benefits presented by this first model are clear, they are limited to *indirect* stimulation of innovation in the life sciences sector — they monetize revenue-generating, late stage IP assets, the *proceeds of which* can be used to invest in new seed-stage R&D or its translation into commercialized products.

An alternative patent-backed security exists, however, which is capable of monetizing *early-stage, pre-clinical* research. Although this is the most risky form of innovation, it also possesses the greatest potential to yield innovative therapies with significant public health benefits. While royalty securitization companies invest in approved products and candidates in late-stage clinical development, they do not engage innovation at the seed-stage.¹⁰² It is at this stage that the most prominent public health discoveries are made, with the most expansive potential. Rather than constraining this vital early-stage research to the current limits of traditional financing, patent-backed securitization — is the ideal financial instrument to stimulate investment and innovation as the focus shifts to early, and more uncertain, stages of drug development.

¹⁰¹ *Top-Ranked Hospitals for Cancer*, online: US News & World Report <<http://health.usnews.com/best-hospitals/rankings/cancer>>.

¹⁰² Fernandez, Stein & Lo, "Biomedical Research", *supra* note 22 at 964.

The model best suited for translating *all stages* of innovation into commercialized products assumes the form of the “mega fund,” recently proposed by Andrew Lo of the Massachusetts Institute of Technology.¹⁰³ Similar to a royalty securitization company, a large, diversified portfolio or SPV is created, with the additional requirement that it fund more speculative, early-stage R&D in exchange for a percentage of future royalties or proceeds from the subsequent sale of the IP. This novel asset class is described as a “research-backed obligation” (RBO). Assets include the initial capital raised from investors, all after-acquired R&D and licenses, and all profits generated by those activities or their later sale. The full range of development, from preclinical research to new drug applications, is covered by this new asset class. Financing for these portfolios is structured as a combination of both equity and securitized debt,¹⁰⁴ including royalty interests and licensing agreements.

(A) Risk Diversification for Equity Holders Through Tranches

Speculative, early-stage RBOs, with higher potential default rates, do not present risk-reward profiles as favorable as their AAA-rated later-stage counterparts, like Pfizer’s Enbrel, a rheumatoid arthritis medication accounting for 32 percent of DRI Capital’s portfolio value. Many institutions, like pension funds, are not permitted to invest in non-investment grade assets, effectively excluding early-stage research from the market.

Financial engineering can address this. The answer to securing capital for *both* of these risk levels in the life sciences sector is *diversification* — a tool used extensively in finance, but not, as of yet, applied to biomedical innovation as proposed by Andrew Lo. By separating these different classes of risk — early and late-stage discoveries — into distinct classes or “tranches,” the mega fund balances risk and expected return, which satisfies a much broader palate for investors, generating access to all stages of the pipeline.

Tranches are ordered from senior, which must be satisfied first, to junior. If the assets generate insufficient cash flow to satisfy all promised payments to bondholders, the most senior tranche will be paid first, until the available cash is exhausted. Correspondingly, the senior tranche is the least likely to suffer losses, and has the lowest risk and offers the lowest yield; this tranche is most attractive to risk-sensitive investors like money market funds, banks, and smaller pension funds.¹⁰⁵ More junior tranches with higher loss and correspondingly higher yields are attractive to risk-tolerant investors like large pension funds, endowments, and high-net-worth private investors.¹⁰⁶ Finally, the most junior tranche is often structured as equity, and has no promised payments, but unlimited upside potential once bondholders are repaid in full; the “equity tranche” is palatable to the most risk-tolerant investors, including hedge funds and deep pocketed institutional inves-

¹⁰³ *Ibid.*

¹⁰⁴ *Ibid.* at 969.

¹⁰⁵ *Ibid.*

¹⁰⁶ *Ibid.*

tors.¹⁰⁷ The size and order of tranches is known as the SPV's "capital structure," and supports a more flexible framework for securing financing in the life sciences sector: regardless of how risk-averse an investor is, there is likely a satisfactory tranche within the SPV.¹⁰⁸

RBOs can also be structured to have varying maturities, ranging from short-term (for more impatient investors, like commercial banks) to long-term (for pension funds and sovereign wealth funds). By allowing for a range of maturities, a mega fund provides a more palatable portfolio for a broader cross section of investors. Simultaneously, the shorter-term pressures of generating earnings and preparing for an initial public-equity offering are reduced, which might otherwise lead to a distressed sale of promising early-stage assets.¹⁰⁹ Typical securitizations employ debt maturities of 15 years or less; for example, in 2007, DRI Capital issued \$356 million of 8- and 15-year bonds backed by royalty rights to pharmaceuticals Enbrel, Remicade, Preotact, and FluMist.¹¹⁰

(c) Benefits

(i) Patent Holders

(A) Limited Credit Exposure

A bankruptcy-remote vehicle (SPV) minimizes the credit exposure of the borrowing entity. Because the underlying asset is treated as severable, the loan is usually non-recourse, and the borrower, shielded. Investor, credit analyst, and lender concerns of creditworthiness decreases in proportion to their concern with underlying asset quality.¹¹¹

(B) Lower Cost of Capital and Improved Capital Structure and Ratings

Delinking assets also permits access to capital markets at higher-grade debt levels than those obtainable through traditional sources like VC, which may reduce dilution to existing shareholders. Lowering debt coupons, and moving debt off-balance-sheet, reduces overall debt service levels and improves coverage ratios.

As outlined in Section III, the ability to secure loans against intangible assets like IP becomes particularly relevant for early-stage companies in the biomedical sector. Credit ratings essentially determine a security's level of protection against credit loss; both in absolute terms, and vis-a-vis other categories of ratings. If the *pro forma* payment of royalties to the SPV is quantifiable and demonstrably capable of supporting interest payments on the issuance of bonds, the SPV can be evaluated at a higher rate. While an originator, such as a start-up or educational institution, may not be eligible for an investment grade rating, an independently evaluated SPV may be.

¹⁰⁷ *Ibid.*

¹⁰⁸ *Ibid.*

¹⁰⁹ *Ibid.*

¹¹⁰ *Ibid.*

¹¹¹ Edwards, *Blueprint*, *supra* note 76.

Finally, credit enhancements, minimizing default risk by ensuring fulfillment of payment and access to underlying sources of credit, can contribute to a higher investment rating. These are either *internal* cash reserve accounts, established by the originator, or more expensive *external* finance, from traditional sources like banks. Credit enhancements fully exploit the security's commercial potential in two ways: increasing the likelihood of reaching maturity without default, a high credit rating is more likely. Secondly, it protects assets as a last line of defense in the event of default.

(C) Increased Liquidity

A primary benefit is the patent holder's liberation from the term of the licensing agreement, generating immediate net cash proceeds for R&D, facility/asset modernization, debt repayment, and working capital requirements.

(D) Greater Leverage of Intellectual Property

Securitization leverages underexploited IP assets and harnesses their value.

(E) Tool in Corporate Finance, Mergers and Acquisitions

Recently, life sciences companies have focused on risk reduction and increased operating efficiency, establishing reliable revenue streams by engaging in an increasing number of mergers, acquisitions, consolidations, licensing deals, and joint ventures.¹¹²

Patents communicate asset picture and earnings potential to the financial community;¹¹³ aware of the effect of patents on financial and competitive advantage, analysts examine IP capabilities when evaluating earnings potential and competitive prospects.¹¹⁴ Royalties are a very strong asset in mergers and acquisitions, and assets with certified valuation and documented, delinked profitability are even more useful as leverage in M&A transactions and leveraged buyouts. A patent-backed security may also fund acquisition, issuing debt collateralized by IP in a target company to achieve an IP-leveraged buyout.

(F) Flexibility of Debt Finance

Debt finance can be more "patient" than private or public equity by specifying longer maturities; ten- to twenty- year maturities are not atypical for corporate bonds.¹¹⁵ As an example, the Massachusetts Institute of Technology issued \$750 million in 100-year bonds at the historically low rate of 5.623 percent. VC horizons

¹¹² *Ibid.*

¹¹³ Kevin G Rivette & David Kline, "Discovering New Value in Intellectual Property" (2000) Harv Bus Rev, online: PCT Capital <<http://www.pctcapital.com/pdfs/Harvard.pdf>> [New Value].

¹¹⁴ *Ibid.*

¹¹⁵ Fernandez, Stein & Lo, "Biomedical Research", *supra* note 22 at 965.

are considerably shorter, as are the quarterly earnings cycles and intra-daily price fluctuations of public companies.¹¹⁶

Bonds issued with different maturities can accommodate different investment horizons and investors. By tailoring its investment horizon to suit the programs within the portfolio, early-stage research can be emancipated from financially driven business deadlines, and permitted to follow the most scientifically productive path.¹¹⁷

This is of particular import to the life sciences sector, where untimely interruptions due to financial constraints destroy considerable economic value — even their potential can alter strategic research direction during early-stage discovery. Tailoring horizons eliminates these effects while maintaining financial discipline with periodic interest payments.¹¹⁸

(ii) Originators, Underwriters, Lenders, and Insurers

Early entrants to the patent-backed securitization industry can claim prime territory in the market, and develop the experience to control deal flow later on. As the market develops, rewards could be substantial. Lenders and insurers could reap similar benefits. Greater risk diversification of existing portfolios would also be permitted.

(iii) Investors, Traders and Speculators

(A) Bankruptcy-Remoteness

Bankruptcy concerns are dictated by the structure of transactions underlying the SPV. Where legal ownership of payment rights is transferred, a sufficient nexus exists between the SPV and the asset to ward off threats of bankruptcy. A more limited bundle of rights, in the form of licensing, can be complex. This is addressed in Section IV.

(B) Facilitation of Niche Investments: An A La Carte Approach Permitting Refined Bets on Technology

Securitization permits unbundling of technology risk from management and other operational risk, facilitating the flow of capital into smaller, discrete units, which can afford an improved risk/reward profile.¹¹⁹ This a la carte approach to risk permits refined bets on technology, allowing direct participation and speculation in narrow niches, or specific patents, rather than buying into the whole business. The liquidity of technology shares or options is superior to the usual sale or IPO.

There are limitless applications of this type of financial technology, including SWIPS (IP Swaps) creating cash flows from non-correlated technology, and novel hedges that diminish technology specific risk as opposed to corporate risk. These

¹¹⁶ *Ibid.*

¹¹⁷ *Ibid.*

¹¹⁸ *Ibid.*

¹¹⁹ Edwards, *Blueprint*, *supra* note 76.

instruments differ from now popular industry holders, which retain all the business risks (market, operational, and financial) of the companies, of which they are comprised; they replace these risks with the opportunity to bet on or hedge with the underlying IP itself.¹²⁰

(C) Decreased Market Volatility and Investment Risk

The decoupling of IP from business risks could have a salubrious effect on the market for, and development of, life sciences products. Excess speculation and volatility in the late 90s stemmed from the inability to value IP. The creation of a secondary market for IP, and the parallel rise in insurance products, will decrease volatility and risk, resulting in proportionate increases in investment and return and lowered costs of capital.

(iv) Economy: Competitive Economies of Scope and Scale

While traditional finance's risk adverse decision-making is economically rational decision-making, it becomes perverse on a larger scale. Innovation is essential to a high-performing economy, excelling on measures like income per capita, productivity, social program quality, and the functioning of healthcare.¹²¹ When capital markets systematically suffocate innovation, the longitudinal impacts can be devastating. As these jurisdictions develop innovation-related business methods, they specialize in knowledge-intensive, high-value-added goods and services and achieve insurmountable productivity gains relative to those who fail to innovate.¹²² Given the anticipated demand of current healthcare consumer demographics, dependency on foreign supply will exact inordinate healthcare costs on jurisdictions failing to implement securities legislation for innovation.

As an example, the passage of *Proposition 71*, spearheading innovation in stem cell research, forecasts a ten-year, \$3 billion windfall for California. Termed the new "gold rush", Boston's research and investment community emigrated to harness this growth.¹²³ While Canada's federal R&D budget (\$7 billion annually) is one of the highest, it ranks 14th of 17 countries for innovation,¹²⁴ and its global competitiveness continues to slide.¹²⁵

As demonstrated above, securitization can establish a secondary IP market, decreasing volatility, risk, and capital cost, and increasing investment, innovation, and return. As more companies leverage intangible assets and seek to maximize the unrealized value of their asset portfolios through licensing, selling, or acquiring technology, a more mature capital market for IP will develop. IP promises to be the

¹²⁰ *Ibid.*

¹²¹ The Conference Board of Canada, *Innovation* (2012), online: Conference Board of Canada <<http://www.conferenceboard.ca/hcp/details/innovation.aspx>>.

¹²² *Ibid.*

¹²³ Kristen Philipkoski, *The Stem Cell Gold Rush Wired* (4 November 2004), online at: Wired <<http://www.wired.com>>.

¹²⁴ Mary Bitti, "Overcoming Obstacles to Commercialization" *Financial Post* (13 May 2007), online: Financial Post <<http://business.financialpost.com>>.

¹²⁵ *Ibid.*

driving force behind commercial success in the future, and economies which fail to effectively legislate this development and create opportunities for effective IP management will lag behind those economies that do. This will have drastic implications for not only the efficiency of capital markets, but in stimulating technological innovation and generating access to the products of that innovation.

(v) Public Health: Increased Innovative Medical Products with Reduced Time to Market

IP-backed securities, and accompanying reform of the relevant disclosure requirements in securities legislation, present a meaningful avenue for establishing this change in the life sciences sector. For the above reasons, the more efficient capital markets facilitated by patent securitization can spur corresponding efficiencies in public health. More effective capital flow can increase life cycle drug development efficiencies, decrease time to market, and optimize pipeline value and return on investment (ROI).

Furthermore, incremental reform of securities legislation can serve to funnel capital to those areas where it is most needed. Increased investment in early-stage drug development can effectively combat problems concomitant with existing business models, like “ever greening”. With its inherent ability to efficiently allocate capital to discrete *units* of technology most likely to succeed, patent-backed securities can supersede the “guessing game” of the current biotech business model, attaining a higher number of “wins”. Such funds can handle risk more adeptly than small pharmaceutical firms dependent on development of one or two key compounds,¹²⁶ and can efficiently produce both novel therapies and immediate liquidity for the rapid turnover of early-stage innovation. Despite the “valley of death” of translational research, the doubling of R&D spending — from \$68 billion in 2002 to \$127 billion in 2010 — has produced a 20-year backlog of oncology compounds waiting to be investigated.¹²⁷ This enables rapid scale-up and gains in technological advances, and the potential to outpace competitors in the modern “gold rush”.

Third and finally, the “mega fund” model — unlike business models polarized to strong market-to-book ratios like those of Roche or Genentech — secures its ROI from robust life science technology, not allegiance to another arbitrary determinant. Rather than a mutual fund restricted to investment in publicly traded companies, a mega fund does not discriminate between startups, companies, royalty streams, IP, or other assets.¹²⁸

(d) Conclusion

Reflecting a growing level of comfort with royalty deals as a funding source, the dollar value of deals more than quadrupled to \$1.7 billion in 2008 from \$400

¹²⁶ Fernandez, Stein & Lo, “Biomedical Research”, *supra* note 22 at 965.

¹²⁷ Felix Salmon, “Can Securitization Save Medical R&D?” *Reuters* (1 October 2012), online: Reuters <<http://blogs.reuters.com/felix-salmon/2012/10/01/can-securitization-save-medical-rd/>>.

¹²⁸ Fernandez, Stein & Lo, “Biomedical Research”, *supra* note 22 at 965.

million in 2006.¹²⁹ Global pharmaceutical sales were estimated as high as \$800 billion in 2009, with the patent licensing generating estimated annual royalties in excess of US \$100 billion.¹³⁰

The life sciences sector's size and growth potential, the significant financing and capital needs of "drug royalty rights" owners, and the anticipated market demand for bio therapeutics, speak to the value patent-backed securities. The life sciences sector stands to experience improved innovation and growth as a result of the above benefits, accruing to three classes: patent holders; originators, underwriters, lenders, and insurers; and investors, traders, and speculators. Finally, economic and public health advantages warrant consideration of incremental securities law reform facilitating these securities.

In Section V, a proposal is presented for incremental securities law reform, comprised of modified disclosure requirements appropriate to patent-backed securities. Several indicia will be presented which achieve this objective within the existing mechanisms, scope, and legislative purposes of securities law.

V. A PROPOSAL FOR INCREMENTAL SECURITIES LAW REFORM: MODIFIED DISCLOSURE REQUIREMENTS FOR PATENT-BACKED SECURITIES

(a) Introduction

While the proposed methods of securitization played a role in the financial crisis, it has also provided compelling evidence that, if used responsibly, it is a highly effective means of gathering large amounts of capital in a relatively short period of time, which can play a transformative role in socially important initiatives. Rather than shying away from such instruments, a more measured response may be to acknowledge their strengths, address their weaknesses and use them wisely to meet the most pressing social challenges. Perhaps the most effective remedy may be to recognize the potential for speculation to emerge in any industry, and to ensure that those investors who are ill-suited to such boom/bust cycles do not become victims of their destructive forces. More positively, if speculative behavior is a fact of economic life, it may be worthwhile to redirect some of this energy toward social priorities such as reducing the burden of disease.

It is in this respect that the role of securities law in regulating *deployment* of capital becomes important. Securities law seeks to improve investor protection and market efficiency. Regulation of disclosure for intellectual property, like the patent, is not clearly developed. Before the advent of modern securities law, however, tangible asset disclosure was not necessarily simple. It was only through legislative reform that enormous amounts of economic activity now proceed safely and efficiently. The problem of intangible asset securitization is a subset of a larger issue,

¹²⁹ Brian Gormley, "Royalty Pharma Deals Aren't Just for Start-Ups Anymore" *The Wall Street Journal* (30 September 2009), online: Wall Street Journal <<http://blogs.wsj.com>>.

¹³⁰ Malcolm S Dorris, Jostava AO Strathman & Kira N Brereton, "Securitization of Pharmaceutical Royalties: A Prescription for Market Growth" *Dechert On Point* (February 2010), online: Dechert LLP <<http://www.dechert.com>> ["Pharmaceutical Royalties"].

which is how the law can best facilitate capital flow for enterprises with valuable capital other than tangible assets. Due to uncertainty in cash flow forecasts and the specific risk factors of IP assets, an assessment of the value and risk profile of patents is one of the most critical components of securities reform.

Disclosure for a special purpose issuer of asset-backed securities will generally explain the nature, performance and servicing of the underlying pool of financial assets, the structure of the securities and dedicated cash flows, and any third party or internal support arrangements established to protect holders of the asset-backed securities from losses associated with non-performance of the financial assets or disruptions in payment.

Specific requirements are established for asset-backed securities under s.10.3 of National Instrument 41-101 for Prospectus Requirements. The nature and extent of required disclosure may vary depending on the type, quality and attributes of the assets comprising the pool, and on the contractual arrangements, and overall structure of the transaction, through which holders of the asset-backed securities take their interest in such assets. Generally, however, an issuer of asset-backed securities should, when preparing its long form prospectus, include full, true and plain disclosure regarding the financial assets underlying the securities, the originator of the assets, and the material attributes of the underlying securities.¹³¹

In the following section, a series of indicia will be proposed that can serve as reliable indicators of patent value, thus providing investors with information on the underlying assets in an SPV and allowing for calculation of returns. This will contribute to a valuation of portfolios that reflects market reality, rather than hypotheses.¹³² This will also buffer against the likelihood of sharp declines and panic selling when the market's valuation differs from the portfolio manager's.

(b) Measures of Intangible Asset Value: Criteria for Inclusion in Disclosure Requirements

Baruch Lev proposes that any individual issuer should present measures possessing three criteria. These criteria will be used to present several indicia as incremental reforms to disclosure requirements for patent-backed securities. It is suggested that providing these indicia would fulfill the purposes of the *Securities Act* by allowing full, true and plain disclosure of material facts relating to the issued security's underlying assets.

¹³¹ Ontario Securities Commission, *Statement of Priorities for fiscal year 2009-2010*, online: Ontario Securities Commission <http://www.osc.gov.on.ca/documents/en/About/wwd_2009-2010_statement-of-priorities.pdf>; Ontario Securities Commission, *Securities Regulatory Proposals Stemming from the 2007-08 Credit Market Turmoil and its Effect on the ABCP Market in Canada* (October 2008), online: Ontario Securities Commission <http://www.osc.gov.on.ca/documents/en/Securities-Category1/csa_20081006_11-405_abcp-con-paper.pdf>.

¹³² Fernandez, Stein & Lo, "Biomedical Research", *supra* note 22 at 965.

(i) *Quantitative*

Firstly, the indicia should be quantitative, and capable of making a difference in user decisions. They should be representationally faithful, verifiable, and neutral. Qualitative aspects, such as patent cross licensing, can be provided as an annex.

(ii) *Standardized*

They should be standardized, comparable for valuation and benchmarking purposes.

(iii) *Empirically Relevant*

Thirdly, and most importantly, the indicia should be confirmed by empirical evidence as relevant attributes, measurable with sufficient reliability. A significant statistical association may be established, for example, between those indicia and indicators of corporate value, like stock return or productivity improvement.¹³³

(c) Proposed Modified Disclosure Requirements: Indicia for Patent Valuation

A set of modified disclosure requirements enabling companies, investors, and finance professionals to promote, develop, and profit from intangible asset finance in the form of patent-backed securities, will now be presented.

There are 22 in total, falling under: Financial Information; Item 29: Other Material Facts; Item 21: Proof of Risk Factors; Item 23: Legal Proceedings and Regulatory Action; Item 27: Material Contracts; and Item 19: Audit Committees and Corporate Governance. Should supplementary information be required, existing mechanisms of confidential disclosure and material change legislation¹³⁴ can balance the ends of investor protection with disclosure proving “unduly detrimental” to the issuer.

(i) *Financial Information*

(A) Introduction: Financial Information in the Intangible Asset Context

Under s. 56 OSA(1), “A prospectus shall provide full, true, and plain disclosure of all material facts relating to the securities issued or proposed to be distributed.” and (2) “The prospectus shall contain or be accompanied by . . . financial statements.”

Fair value for appraisal purposes means “intrinsic value”, and while “market value may be considered in proper cases in determining intrinsic value . . . [it] is not the sole or basic test . . .”.¹³⁵ This is nowhere more true than in the realm of

¹³³ Baruch Lev, *Intangibles: Management, Measurement, and Reporting* (Washington: Bookings Institution Press, 2001).

¹³⁴ *Securities Act*, supra note 1 at s. 75(3); *General Prospectus Requirements*, OSC NI 51-102 (29 November 2012), s. 7.1(2) [NI 51-102].

¹³⁵ *Roessler v. Security Savings & Loan Co.* (1947), 72 N.E. 2d 259.

intangible assets. The particular obstacles faced in the valuation of IP assets will be addressed here. It is for this reason that the cornerstone of both an effective IP strategy firm, as well as in the capital raising process, is a company-wide IP audit. This requires the coordination of a wide range of players, operating together in a well-documented and fluid process: legal counsel, corporate planners, financial staff, research and development managers, senior management, engineers, scientists, marketing staff, and licensing staff.¹³⁶ Identifying all of the core and non-core intangible assets that could currently bring value to a company permits management to create an effective IP strategy coinciding with company objectives and priorities, as well as to establish a clear picture — equivalent to the financial information requirement under the prospectus legislation — to facilitate the raising of debt and equity through a patent-backed securitization with appropriate risk diversification.

(i) Intellectual Property Audit

While the traditional auditing procedure usually evaluates tangible assets in financial statements, such statements are incomplete to the extent that they fail to provide a realistic appraisal of intangible IP assets.¹³⁷

To correct this problem, an IP audit should be undertaken in order to meet a series of objectives, including: (1) determination of the origin of IP assets, (2) determination of the extent of the owner's interest in the IP rights of those assets; (3) determination of the scope of IP rights that any third party may have in the assets; (4) evaluation of the company's policies and procedures for creating and protecting its IP rights in its assets; (5) analysis of defects in existing IP assets which either have diminished, or may in the future diminish, the value of those assets; (6) institution of corrective measures to eliminate those defects; (7) provision of recommendations to help restore full value to any flawed IP assets; (8) recommendation of new policies and procedures to provide more expansive protection for future creation and management of the company's core IP assets; (9) preclusion or lessening of potential liability from third party infringement claims which may result from the company's development of a new product; and (10) a realistic financial valuation of the company's IP assets.¹³⁸

As an example, investors must ascertain who is responsible for maintaining and enforcing the patents, and whether the party has the necessary resources to do so. Whether the underlying license agreements account for related technology developed subsequent to the execution date of the license agreement is also an important factor. Other measures might include: a certification of up-to-date maintenance fees; a review of chain of title, an assessment of the validity of claims in the subject patents; and a public database search for patent infringement litigation.¹³⁹ A thorough assessment may include disclosure of post-issuance patent office activity neg-

¹³⁶ Gollin, *Monetizing Intellectual Property*, *supra* note 13.

¹³⁷ *Ibid.*

¹³⁸ Venable LLP, *The Effective Management and Value Maximization of Intellectual Property* (1 April 2000), online: Venable LLP <<http://www.venable.com>> [*Effective Management*].

¹³⁹ Dorris, Strathman & Brereton, "Pharmaceutical Royalties", *supra* note 130.

actively impacting the scope of the patent claims at issue, namely, any interference, re-examination or reissue; an analysis of the claims in the subject patents relative to the royalty-generating commercial activities to gauge whether they might provide a commercially valuable exclusivity for the relevant market; and a right-to use analysis to assess whether the licensee will be free to practice the royalty generating commercial activities without infringing the patent rights of another party.¹⁴⁰ It may also involve an assessment of a third party's ability to "design around" the patent claims to appropriate the technology disclosed in the specification without infringing the patent claims. The methods of assessment should ideally be repeated for each national jurisdiction in which the subject royalty-generating commercial activities are likely to occur.

The IP audit is sufficiently quantitative, standardized, and empirically relevant to serve as reliable indicia of the assets underlying the issued security.

(ii) Strength of Credit Enhancement Mechanisms

Finally, the strength of the credit enhancement mechanisms, the flexibility of the deal architecture, and the adoption of a portfolio diversification strategy are other key factors relevant to the success of a securitization. Enhancements minimize risk of default by ensuring payment, increasing the likelihood of reaching maturity, and protecting assets in the event of default. In this respect, their existence, either in the form of *internal* or *external* cash reserves, is a quantitative, standardized, and empirically relevant fact material to the IP underlying the security, and worthy of disclosure in the prospectus.

(iii) Flexibility of Deal Architecture

Flexibility and customization of the vehicle can add solidity to the deal structure and increase the overall probability of success of the transaction. The ability to add assets to the asset pool increases deal flexibility. Furthermore, the size and order of tranches, known as the "capital structure", supports a more flexible framework for securing financing in the life sciences sector: regardless of how risk-averse an investor is, there is likely a satisfactory tranche within the SPV.¹⁴¹ In this respect, information about the capital structure can also prove relevant to the likely profitability of issued securities. This information is sufficiently quantitative, standardized, and empirically relevant to warrant disclosure.

(iv) Portfolio Diversification Strategy

Patent-backed securities, and particularly those in the business of early-stage life sciences, are always vulnerable to the risk of default or underperformance on royalty streams. This risk is mitigated by the diversity of the underlying patents themselves. This diversification lowers the risk that the underperformance of any one income stream will result in the deal's default. To address this, the number of IP assets is sufficiently quantitative, standardized, and empirically relevant to warrant disclosure.

¹⁴⁰ *Ibid.*

¹⁴¹ *Ibid.*

(B) Item 29: Other Material Facts — Evidence-Based Indicia of Patent Value**(i) Length of the Patent Term**

Discussed in section (B)(ii).

(ii) Future-Oriented Financial Information — Sales According to Patent Duration

A key disclosure requirement to investors regarding the financial viability of the underlying asset is the length of the patent, directly analogous to existing securities regulation-surrounding reserves in oil and gas royalty trusts. There are a finite, verifiable number of years remaining in the patent term associated with each underlying patent; this is comparable across various patents. Finally, the length of the patent term is directly tied to the ability to recoup profits from its associated monopoly. Disclosure requirements can be sufficiently *quantitative, standardized, and empirically relevant*.

Form 51-101F2 (Appendix F), required to be included with all oil and gas royalties, which consists of a report on reserves data by independent qualified reserves evaluator. This is based on statutorily defined disclosure requirements by independently qualified auditors and experts as well as management. An analogous evaluation could be provided, for example, in the existing patent itself, which will clearly delineate the patent term. This protects investors in oil and gas by clearly delineating empirical data over the lifetime of the reserve demonstrating profitability over time (Appendix G). In the intangible-asset market, analogous data could be established, taking into account market forces and other variables idiosyncratic to that market. This could be done by an independent evaluator, with a specialty in that area and competent in market analysis and valuation, to ensure objectivity, comparability, and empirical relevance of these indicia.

As such, investors could have greater confidence in their investment and in the capital markets, while simultaneously contributing to the fairness and efficiency of those markets. Securities regulation can penalize any material misstatement with regard to this patent expiry period, or the failure to disclose any material changes to said period.¹⁴²

It also remains open to question whether, or to what extent, patent-backed security issuers should be required to disclose the lengths of patents on competitors — which also implies generics and the drop-down effect on the underlying asset in question.

(iii) Regulatory Data Exclusivity Periods

Regulatory approval is required for a new drug application (NDA) or biologics license application (BLA) before marketing a new drug or biologic in Canada. Market exclusivity may be accorded for a limited time, known as the data exclusivity period. This can occur independently of, or in addition to, the term of patent-related market protection.

¹⁴² *Securities Act*, *supra* note 1 at s. 75(3); NI 51-102, *supra* note 134 at s. 7.1(2).

The Federal Court affirmed the constitutionality of the Data Protection Provisions of ss. 30(3) of the *Food and Drug Regulations*¹⁴³ in 2009, permitting eight years of market exclusivity for innovative new drugs in Canada. Approval will not be granted for a generic version of a previously approved version of the drug for that period, regardless of patent protection. The scope and length of this protection is quantifiable, standardized, and empirically relevant on the same grounds as patent protection, and as such should be part of the information provided to investors regarding the underlying intangible asset class.

(iv) Number of Patent Citations as Indicators of Stock Performance

A company's intrinsic value is not often recognized by investors. In the pharmaceutical sector, one might expect the most appropriate indicator of this value to be R&D expenses. However, a company's periodic R&D expenditures as the sole innovation-related item required to be disclosed in financial statements is too coarse an indicator for valuation of the nature, quality, and expected benefits of its science and technology efforts.¹⁴⁴ Investors cannot glean from R&D cost data the substantial differences between companies in terms of innovative capabilities,¹⁴⁵ and various innovative activities are not adequately captured within the formal classification of R&D in existing securities legislation, and as such are not reported separately to investors. These indicia lack the requisite quality of possessing empirical relevance, and thus are *excluded* from the material facts otherwise included in the modified disclosure requirements.

Meta-analyses reveal that, in fact, the most significant correlation with patent value is, in fact, the *number of citations it receives from subsequent patents*.¹⁴⁶ In search of timely and relevant indicators of companies' innovative capabilities and outcomes, Deng, Lev, and Narin identified patent citations to be useful indicators for investment research and analysis of R&D-intensive companies in a ten-year longitudinal study.

A typical U.S. patent cites about eight earlier U.S. patents, one or two foreign patents, and one or two non-patent references, usually to scientific papers and meetings.¹⁴⁷ Patents most frequently cited by others are usually of high financial value; companies owning those patents are likely to benefit from their commercial exploitation. Thus, Zhen et al. argue, the best time for investors to buy stock in a company is not once its value has been fully realized by the market, but when enough information is available to make an educated decision about the company's prospects at a point in time prior to when everyone *else* has realized the company's potential value. This study identifies that time as when the company's patents are becoming cited frequently by other patent seekers, often midway into the product development process or slightly beforehand.

¹⁴³ CRC, c. 870, s. C.08.004.1.

¹⁴⁴ Z Deng, B Lev & F Narin, "Science and Technology as Predictors of Stock Performance" (1999) 55:3 *Financ Anal J* 20.

¹⁴⁵ *Ibid.*

¹⁴⁶ *Ibid* at 21.

¹⁴⁷ *Ibid.*

The Lanjouw-Schankerman quality index is a composite index built on the number of claims, backward references, forward citations received in the first five years of patent life, and family scope. The index is correlated with the economic value of a patent and can be considered an indirect measure of the probability that a patent can generate enough cash flows to be securitized.¹⁴⁸ This index serves to incorporate indicia 7–10, and serves as a *quantitative, standardized, and verifiable* measure grounded in *empirical relevance*.

(v) Number of Backward Citations

A meta-analysis by Harhoff et al. demonstrates several other evidence-based indicators of patent value. In their study, the measure of references to the patent literature (backward citations) carries significant positive coefficients in all technical fields.

(vi) Number in Patent Family

Discussed in Section (B)(vii).

(vii) Ratio of Successful Opposition Cases

Measures of family size and observed outcomes of opposition cases contribute to an approximation of patent value, and logically so — a successful defense against opposition and annulment claims is a particularly strong predictor. Presumably, valuable patents are more likely to be attacked in this process, and the stronger patent rights survive, amounting to a two-tiered selection process with a highly informative outcome.¹⁴⁹

This information is readily available and easily assimilated into prospectus requirements to both permit informed valuation of profitability by investors, while also stimulating innovation, economic growth, and the efficiency of capital markets. In sum, indicia of *backward citations, family size, and outcome of opposition cases* meet the three requirements of being *quantitative, standardized, and empirically relevant*.

(viii) Drug Classification — New Biologic Entity (NBE) or New Chemical Entity (NCE)

Since new biological entities treat targeted diseases, they are more difficult to develop and manufacture than new chemical entities, and thus impose greater barriers to entry.

Empirical evidence also generally supports the first-mover advantage theory in pharmaceuticals, first-in-class drugs have a competitive advantage over follower molecules that are later market entrants.¹⁵⁰ New biologic entities are most often

¹⁴⁸ JO Lanjouw & M Schankerman, “Patent Quality and Research Productivity: Measuring Innovation with Multiple Indicators” (2004) 114 *Econ J* 441.

¹⁴⁹ D Harhoff et al, “Citations, Family Size, Opposition and the Value of Patent Rights” (2003) 32 *Res Pol’y* 1343 at 1345.

¹⁵⁰ C Odasso & E Ughetto, *Patent-backed Securities*, *supra* note 81.

first-in-class, and thus have a significantly higher likelihood of sustained revenue gains and market share than new chemical entities.¹⁵¹ Drug classification is sufficiently quantitative, standardized, and empirically relevant to warrant inclusion in disclosure.

(ix) Market Size

Biomedical products competing in large markets with low competition are superior candidates for securitization, as they are poised to be more successful at generating sufficient cash flow.¹⁵² The size of markets to which SPV assets belong can be determined by identifying their four-digit Anatomical Therapeutic Class (ATC) code, the average worldwide sales of that ATC according to industry data, and determining a corresponding score for that asset. Data for sales by ATC exist in databases (See Appendix H).

For example, in the previous case study of Royalty Pharma's Neulasta® patent, a score would be assigned as follows. The ATC of Neulasta is L03AA13: an immunostimulant in the "antineoplastic and immunomodulating agents" class. This class is not in the top 20 for worldwide sales. Thus, Neulasta would be awarded a higher score for market size. This score is sufficiently quantitative, standardized, and empirically relevant for disclosure.

(x) Competition in Therapeutic Class

As mentioned in *Indicium* (12), Drug Classification, the first-mover advantage favors earlier market entrants. The level of competition can be determined by identifying the asset's Anatomical Therapeutic Class, and then identifying the number of compounds in the same class that were already marketed in that jurisdiction prior to approval of the asset.¹⁵³ By determining the number of earlier market entrants, the difference in their residual market life, and the different types of molecules, a score can be determined which is sufficiently quantitative, standardized, and empirically relevant to warrant disclosure.

(C) Item 21: Risk Factors: Risk of Technological Obsolescence

This relates to the appropriate extent of disclosure regarding "material changes" in the market. Although this was held to be irrelevant in *Danier*, such implications may take on an added meaning in the pharmaceutical context, where more affordable or efficient access to a life saving medical treatment can quickly relegate a pharmaceutical patent to the Dark Ages.¹⁵⁴ Although new blockbuster diabetes medications were completed as recently as several years ago, for example, the discovery of IGF-2 and the underlying genetic makeup responsible for the absence of insulin production in the body may lead to a cure — rendering any subsequently developed diabetic treatments relatively superfluous.

¹⁵¹ *Ibid.*

¹⁵² *Ibid.*

¹⁵³ *Ibid.*

¹⁵⁴ *Kerr v. Danier Leather Inc.*, 2007 SCC 44, 2007 CarswellOnt 6445, 2007 CarswellOnt 6446, [2007] 2 S.C.R. 331 (S.C.C.).

In relation to investor protection, the intention should not be to guarantee an investor would not incur a loss. Rather, the intention should be for investors to understand the risks by having the “fullest possible knowledge to enable it to distinguish the different types of investment activity available”.¹⁵⁵ Furthermore, risk is mitigated by the disclosure of material facts relating to the appropriate *valuation* of patents, indicated in the proposed model above. Those patents possessing the greatest value within that formula — underlying patent assets with a higher quality in terms of scope, technical novelty and usefulness, and longer residual patent life, as discussed in further detail here — are likely to reduce the risk of technical obsolescence and sales losses. As such, two indicia are proposed to be included in the modified disclosure requirements for securities with an underlying intangible asset in the form of a life sciences patent.

(i) Proof of Trade-mark Registration

Certain drugs have characteristics which guard against the obsolescence risk — a primary characteristic being strong brand recognition, made manifest in a registered trade-mark. While an underlying patented drug has a limited legal life, a trade-mark may be renewed at 15-year intervals, without limitation, on payment each time of the necessary renewal fees. The popularity of existing brands can be difficult for new market entrants to overcome, even if the new product might actually be superior to the better-known one. This common market phenomenon erects a high barrier against the entry of would-be competitors, mitigating risk of successful development and marketing of superior products.¹⁵⁶

This indicium — proof of a registered trade-mark — complies with Baruch Lev’s three requirements: it is *quantitative*, *standardized*, and *empirically relevant*. S.13(1)(a) of the *Trade-marks Act* establishes legislative requirements for a trade-mark’s “distinctiveness” (the strength of its brand recognition).¹⁵⁷ As of the date of filing, it must “actually distinguish” the wares, a characteristic which is “acquired through use” of the mark in Canada.¹⁵⁸ An example would be the trade-mark, “Tylenol”, whose distinctiveness precludes otherwise bioequivalent acetaminophen from overtaking its monopoly in the life sciences sector. To be successfully registered under s. 30, an application must include a statement of the specific wares associated with the mark, the date from which the mark has been used in association with said wares, and the intention to use the mark throughout Canada.¹⁵⁹ As such, proof of registration *ipso facto* demonstrates distinctiveness of a trade-mark, and thus constitutes acceptable quantitative indicia. It is representationally faithful, verifiable, and neutral.

In respect of the second criteria of standardization, the *Trade-marks Act* is federal legislation, and thus registration can be used to compare the issuer’s associ-

¹⁵⁵ *Report of the Attorney General’s Committee on Securities Legislation in Ontario* (Toronto: Queen’s Printer, 1965) [the “Kimber Report”] at para 1.12.

¹⁵⁶ Dorris, Strathman & Brereton, “Pharmaceutical Royalties”, *supra* note 130.

¹⁵⁷ *Trade-marks Act*, RSC 1985, c T-13.

¹⁵⁸ *Boston Pizza International Inc. v. Boston Chicken Inc.*, 2003 CarswellNat 583, 2003 CarswellNat 2012, [2003] F.C.J. No. 395 (Fed. C.A.).

¹⁵⁹ *Ibid.*

ated wares with other drug products (which may or may not have trade-marks associated with their wares).¹⁶⁰

Thirdly, economic effect is felt once trade-mark protection has been granted; a registered mark is valuable to the “extent that it carries with it some degree of monopoly power.”¹⁶¹ It is established that a registered trade-mark is *empirically relevant*: firms with well-known marks are able to corner the consumer with effective advertising, put up market entry barriers for other firms, and thus create monopoly profits.¹⁶² This forms the basis for their role in IP law. They provide an incentive to develop goodwill, as the subsequent grant of a trade-mark monopoly generates significant economic benefit.

(ii) Clinical Trial Data: Number of Indications/Uses of Pharmaceutical Patent

Another factor that should be disclosed to investors is the multiple applications of a drug to a variety of conditions, or for a variety of uses.¹⁶³ In biomedical terms, this is described as the “indication” (either approved or “in development”). A pharmaceutical product with multiple uses increases revenue-producing potential and helps to alleviate the possible payment stream interruption if a competitor develops a superior drug to treat the primary condition for which the drug was developed.¹⁶⁴ Such information is sufficiently quantitative, standardized, and empirically relevant to indicate underlying asset value.

(D) Item 23: Legal Proceedings and Regulatory Actions

(i) Litigation and Product Liability Issues

All IP rights, even registered rights, are inherently prone to attacks on their very validity. This is the systemic and inherent nature of IP law, which confers limited, but powerful, monopolies in order to increase overall consumer welfare. If it turns out that a patent should not have been granted due to the existence of prior art, that a trademark has been permitted to become generic, or that a copyright has been claimed on unoriginal work, the bargain is broken and the “right” is vulnerable if any attempt is made to enforce it.¹⁶⁵ If removed from its actual source, dissociated from its goodwill (perhaps due to bankruptcy) and applied to inferior goods or services, a trademark may be of very little value, at best, or become invalid at worst, although this danger varies in severity across different jurisdictions.¹⁶⁶ Even a copyright, the most readily transferable and “liquid” of intellectual properties,

¹⁶⁰ *Trade-marks Act*, *supra* note 157.

¹⁶¹ AG Papandreou, “The Economic Effect of Trademarks” (1956) 44 Calif L Rev 503 at 504.

¹⁶² D Shanahan, “The Trademark Right: Consumer Protection or Monopoly?” (1982) 72 Trademark Rep 233 at 240.

¹⁶³ Dorris, Strathman & Brereton, “Pharmaceutical Royalties”, *supra* note 130.

¹⁶⁴ *Ibid.*

¹⁶⁵ Knopf, “Security Interests”, *supra* note 4.

¹⁶⁶ *Ibid.*

possesses limited value in that his or her moral rights are unassignable; even if irrevocably waived, those rights can lose value if the author is noncompliant in participating in adaptations, derivative works, or sequels.¹⁶⁷

IP rights that are rendered unenforceable are, rendered, to a proportionate degree, worthless. Illustrations of this include a one-day, 28 percent jump in Affymetrix stock price, for example, following settlement of a patent infringement suit.¹⁶⁸

Existing securities regulation provides investors with disclosure regarding existing or pending litigation surrounding the securities. In the context of patent-backed securities, those provisions should be adapted to the unique context of pharmaceuticals and the legal challenges launched against drug patent rights. This information is sufficiently quantitative, standardized, and empirically relevant to warrant disclosure within the prospectus.

(ii) Clinical Trial Data and Evidence of Regulatory Compliance

Because royalties are based on the sales revenue of a patented pharmaceutical product, investors need information about any potential changes in regulatory oversight.

When a sponsor decides it would like to market a drug in Canada, a “New Drug Submission” (NDS) is filed with the Therapeutic Products Directorate. The NDS details preclinical and clinical studies, therapeutic claims and side effects, and other data regarding drug safety, effectiveness, and quality. If the claims are supported, a Notice of Compliance (NOC) is issued. Once a new drug is on the market, it remains subject to a continuing and ongoing review and discovery process. Distributors are required to report any new information relating to adverse effects, or failure to achieve therapeutic effect, as well as any additional safety information. The identification of previously unknown issues with a given drug, or inadherence to manufacturing or quality control requirements, may result in further restrictions on the manufacture, sale or use of that drug. Certain instances mandate a problematic drug’s market withdrawal, entirely.

Furthermore, product liability lawsuits have commonly led to the voluntary or mandated withdrawal of pharmaceutical products from the market. Even if the claim does not result in withdrawal, litigation may significantly devalue associated royalty rights. In this respect, even if the IP is isolated to an SPV, it is nonetheless dependent on the revenue generated by royalty payment rights and will be adversely affected if the underlying drug is subject to lawsuits, regulatory restrictions, or withdrawal from the market.

Existing regulatory mechanisms are available to address the regulatory and product liability hurdle. Because the regulatory mechanism is already in place through public registries in both Canada and the US, the administrative function for reporting this information in a standardized format is readily available. A tailored continuous disclosure requirement could be imposed for patent-backed securities in the pharmaceutical industry. Prior to regulatory approval, royalty-backed securities can be mandated to disclose standardized regulatory information about the underlying assets. To permit flexibility with the evolution of the biotechnology and bio

¹⁶⁷ *Ibid.*

¹⁶⁸ Rivette & Kline, “New Value”, *supra* note 113.

therapeutics market, such disclosure may include, but need not be limited to, clinical trial data for Phases I-IV, rates of effectiveness, and comparison to existing controls in the market. Secondly, following regulatory approval, the patent-backed security issuer may be mandated to disclose evidence of compliance with any and all manufacturing and quality control requirements, as well as to disclose the results of the ongoing standardized regulatory review and discovery process. Such information is quantitative, standardized, and empirically relevant to the underlying asset class, and thus should warrant inclusion in disclosure requirements.

(E) Item 27: Material Contracts

(i) Degree of Cooperation

Development partnerships, joint ventures, and cross-licensing are common means of acquiring the necessary technology and resources for commercialization in the life sciences. These arrangements involve risks, however, associated with their definition, coordination of common activities and IP management. If issues of appropriability, IP protection, or information asymmetry arise, frictions can obstruct the original value of such collaborations.¹⁶⁹ Determining whether an IP asset was internally developed or licensed out, as well as the number of licensing steps established until market launch, can provide a sufficiently quantitative, standardized, and empirically relevant measure to warrant disclosure.¹⁷⁰

(ii) Executory or Non-Executory Contracts (“Contingent Payment Rights”) in Bankruptcy

In a patent-backed security, the patent-holder transfers a bundle of rights to an SPV. Two different circumstances may arise: (1) the SPV can “own” these rights in a variety of legal forms. It may be the outright owner of the patents themselves, and receive associated royalties under a license agreement with one of the product marketing companies. (2) With respect to other products in the portfolio, however, the SPV may possess a more limited bundle of rights — rather than a direct interest in the related patents, it may instead own various “contingent payment rights”. These interests would represent the right to receive amounts based on the royalties payable, pursuant to the licensing of the patents.

Technologies engage in “cross licensing” with competitors, often requiring use of each other’s patents. Insofar as third party rights are concerned, this introduces complexity: not only from a purely “conveyancing” point of view, but from a strategic and business viewpoint as well.¹⁷¹ In the case of “contingent payment rights”, or other interests representing the right to receive amounts based on royalties, the uncertainty negatively impacts the risk-reward profile. This presents demonstrable material considerations, which should be made available to investors. These considerations become particularly important in circumstances of bankruptcy of any of the parties to the contracts creating the royalty payments rights. The form

¹⁶⁹ Odasso & Ughetto, “Patent-backed Securities”, *supra* note 81.

¹⁷⁰ *Ibid.*

¹⁷¹ Knopf, “Security Interests”, *supra* note 4.

in which the SPV owns the royalty payment rights directly impacts how its rights to receive royalty payments are affected in such circumstances.

More specifically, it is of critical importance whether the contract governing the payment royalty rates will be deemed an *executory* or a *non-executory contract* by a Bankruptcy Court. Until bankruptcy reform in 2009, it was unclear whether companies restructuring under the relevant statutes could disclaim IP licenses¹⁷². Pursuant to the *Bankruptcy and Insolvency Act (BIA)*,¹⁷³ *Companies' Creditors Arrangement Act (CCAA)*,¹⁷⁴ and associated jurisprudence,¹⁷⁵ most courts view license agreements as executory contracts. The CCAA (s. 32(6)) and BIA (s. 65.11(7)) were amended to provide that, as long as co-party obligations in an IP agreement are fulfilled, a disclaimer does not affect the right to use, or enforce, the IP.¹⁷⁶ In this respect, the protection afforded to licensees is nearly absolute, subject to any limitations courts read into the provisions.¹⁷⁷

However, the 2009 amendments also left open some uncertainties, rendering licensees at significant risk if a licensor restructures. This should be clearly delineated under Item 27: Material Contracts in order to permit licensees to address potential consequences of licensor insolvency. Contractual provisions material in circumstances of licensor bankruptcy should be clearly delineated. Such provisions include, but are not limited to, the following: apportionment of royalties between IP and technical support in software licenses, upfront payment of maintenance fees for patents and registration fees for trademarks. Firstly, neither the BIA nor the CCAA define IP, or specify whether registration is required. As such, the rights that accompany an IP license typically include more than just the narrow use of the IP, such as the right to receive upgrades and maintenance and to modify and copy the IP. It remains to be seen how expansively the licensee's "right to use" the IP will be interpreted by courts.

One prospectus or portfolio example is Pharma Royalty Trust, which clearly displays both the underlying drug, i.e. Neulasta®, and its "marketer", Amgen, along with: the marketer's credit rating (S&P or Moody's); the indication (either approved or "in development — applications, formulations); the product's sales rank; the product's therapeutic ranking; annual sales; and the original seller of the royalty (typically universities). This case study demonstrates a quantitative, quantifiable, and empirically relevant measure of asset value. If this level of risk would defeat investor confidence in public markets, regulators could disallow contingent

¹⁷² Adam M Slavens, "Beyond Legislative Reform: Intellectual Property Licenses Under Canadian Bankruptcy Law" (2009) 22:1 Commercial Insolvency Reporter 7, online: <http://www.torys.com/Publications/Documents/Publication%20PDFs/AR2009-52.pdf> [Legislative Reform].

¹⁷³ *Bankruptcy and Insolvency Act*, RSC 1985, c B-3.

¹⁷⁴ *Companies' Creditors Arrangement Act*, RSC 1985, c. C-36.

¹⁷⁵ Slavens, "Legislative Reform", *supra* note 172.

¹⁷⁶ Industry Canada, *Summary of Key Legislative Changes in Chapter 47 of the Statutes of Canada, 2005, and Chapter 36 of the Statutes of Canada, 2007* (8 February 2012), online: Industry Canada <<http://www.ic.gc.ca/eic/site/bsf-osb.nsf/eng/br01782.html>>.

¹⁷⁷ Slavens, "Legislative Reform", *supra* note 172.

payment rights from being deemed issuable as securities unless registered as an exemption.

(F) Item 19: Audit Committees and Corporate Governance

(i) Disclosure of Specialized Focus on Management Team

Existing prospectus requirements exist for disclosure of management competence to assuage investors and their confidence in capital markets; precedent exists supplementing and enforcing this. However, while profit margins and increasing profitability in general business is one thing, it is arguable that successful management and accurate business judgment surrounding pharmaceutical royalty assets is another matter altogether. The majority of patent-backed security issuers, although few, consist of management teams with staff specializing in Medicine, Oncology, and Business — in that order.

While existing mechanisms exist in securities regulation to provide full, true, and plain disclosure regarding management, such regulations should be adapted in the intangible asset context to represent the expertise for that industry. It is proposed that information be provided about both management committees, as well as the investment committees determining when and where to invest.

This could include detailed description of those committees' collective experience in healthcare (clinical research, sales, and marketing operations) and finance (structured finance, venture capital, investment banking and capital markets). An established track record over the past fiscal years of identifying leading therapeutics and blockbuster products within portfolios, for example, for critical care indications or treatments for serious medical conditions, would also be relevant. Such documentation would be illustrative of the performance of management and investment committees and their ability to deliver superior value to shareholders, and could be appropriately modeled after existing securities legislation. This information is sufficiently quantitative, standardized, and empirically relevant to warrant inclusion in existing disclosure requirements.

(ii) Disclosure of Experience in Intellectual Property Management

Intangible assets comprised 73 percent of collective net worth in 1999, making intangible asset management a *core competency* “in every department, the executive suite, and boardroom.” Even the most thorough product development plans and market strategies will fail to prevent loss of market share and margin erosion if a company is not prepared. Indeed, corporate law has evolved to acknowledge this trend as well. A growing consideration for corporate managers is the threat of management, board, and director liability through shareholder lawsuits for failing to make “best efforts” to guide research and development away from infringement problems, as well as to conduct an IP audit.¹⁷⁸

As such, evidence of a management committee prepared to respond to crises like, for example, competitors' rolling out of a better product threatening sales and market position, the initiation of litigation for patent infringement, or the challenge

¹⁷⁸ *Effective Management*, *supra* note 138.

of a company's quarterly earnings forecast by a Wall Street analyst.¹⁷⁹ Modeled after existing securities legislation, such information is sufficiently quantitative, standardized, and empirically relevant, and should be made clear to potential investors in the prospectus.

(G) Non-Disclosure in Patent Law: Confidential Disclosure and Material Change Legislation

Another valuation problem that has been identified is inherent in the negotiation process itself of early-stage financing; existing prospectus-level disclosure requirements are inadequate to balance the reasonable desire of lenders or investors to know as much as possible about the underlying technologies with the reasonable anxiety of the entrepreneur, in need of capital, to disclose what may be unpatented technology or trade secrets to others. While it is proposed that the above valuation model should offer a progressive alternative to assuage many investor concerns, there are further mechanisms of securities regulation which currently exist should supplementary information be required. This could be conducted through the use of confidential disclosure and material change legislation, qualified by the establishment that disclosure would be "unduly detrimental" to the interests of the issuer, such that investor protection is secured as well.¹⁸⁰

(d) Conclusion

While there have only been a few publicly reported securitizations related to drug royalty payment rights, including the BioPharma Royalty Trust, Royalty Pharma Trust, Paul Capital's Royalty Securitization Trust and the DRI Capital Inc. transactions, the pharmaceutical market generates approximately US \$800 billion annually, making the patent-backed security worthy of exploration.¹⁸¹ The challenges outlined above, including assessment of validity of the underlying patent, litigation, and regulatory impact, may be mediated if presented in disclosure requirements in an quantitative, standardized, and empirically relevant form. In this article seventeen indicia have been selected which warrant inclusion in the following categories of the prospectus: Financial Information, in the form an IP audit; Evidence-Based Indicia of Patent Value, under Item 29: Other Material Facts; Risk of Technological Obsolescence, in Item 21: Risk Factors; Litigation Data, in Item 23: Legal Proceedings and Regulatory Actions; Executory or Non-Executory Contracts in Event of Bankruptcy, in Item 27: Material Contracts; and Disclosure of Management Team and Intellectual Property Management, in Item 19: Audit Committees and Corporate Governance. If this can facilitate investor decision-making, and an appropriate risk-reward profile with regard to patent-backed securities, the securitization industry will likely cultivate a new asset class, as it has many once-unique asset types.

¹⁷⁹ *Ibid.*

¹⁸⁰ *Securities Act*, *supra* note 1 at s. 75(3); NI 51-102, *supra* note 134 at s. 7.1(2).

¹⁸¹ Edwards, *Blueprint*, *supra* note 76.

VI. CONCLUSION: SUPPORT FOR INCREMENTAL SECURITIES LAW REFORM

(a) Fulfillment of the Legislative Objectives of Investor Protection and Efficient Capital Markets

This article has addressed the question of whether an improved legal climate for the use of IP as collateral would be useful to lenders, investors, and borrowers over the long term as an alternative to traditional financial instruments. In Section I, the balance struck by securities law between conservatism and innovation was identified, along with the challenges posed by a shifting economic landscape comprised of intangible assets. In Section II, the life sciences sector was chosen to illustrate the current barriers to the flow of capital to high-value enterprise, resulting in decreased innovation and economic growth. These included the existence of “ever greening”, non-practicing entities, patent thickets, and onerous transaction costs on upstream patent holders. In Section III, the tool of intangible asset finance was introduced as a means of harnessing the value of IP assets, and leveraging them through their securitization. This was proposed as a method of bridging the “valley of death” of translational research at the bench, to clinical applications at the bedside. In Section IV, a case study of the instrument of patent-backed securities was conducted with regard to the life sciences sector, exploring financial instruments including drug royalty securitization companies and mega funds. Several benefits to three classes were outlined: patent holders; originators, underwriters, lenders, and insurers; and investors, traders, and speculators. The long-term impacts of improved innovation on both a competitive economy, and disease mortality and public health, were noted. In Section V, quantitative, standardized, and empirically relevant indicia were presented as measures of asset value in patent-backed securities. Twenty-two indicia were selected as incremental reform of securities law in the form of modified disclosure requirements. It was suggested that these indicia could supplement existing areas of the prospectus, including Financial Information; Material Facts; Risk Factors; Legal Proceedings and Regulatory Action; Material Contracts; and Audit Committees and Corporate Governance.

By making slight modifications to existing securities regulation in the limited sphere of patent-backed securities, the *Securities Act*'s purposes of investor protection and market efficiency can be consistently fulfilled. Through the use of financial engineering in the context of intangible asset finance, the decoupling of patents could have a salubrious effect on the market for high-value enterprise like the life sciences and promote innovation. The economic, social, and public health benefits of this innovation warrant meaningful consideration of incremental securities law reform to facilitate this process.

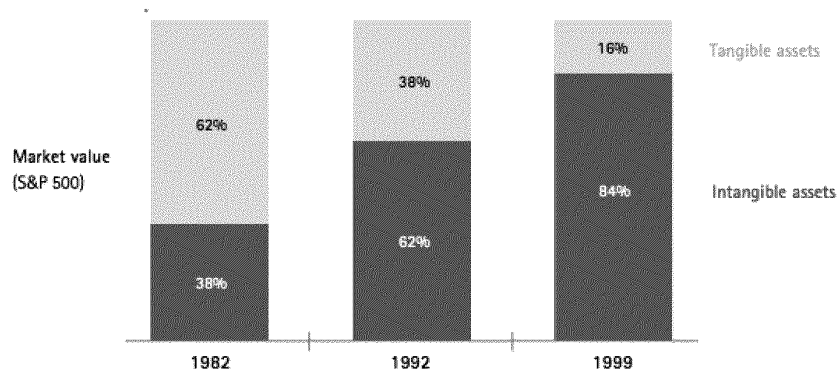
As more companies leverage intangible assets and seek to maximize the unrealized value of their asset portfolios through licensing, selling, or acquiring technology, a more mature capital market for intellectual property will develop. Intellectual property promises to be the driving force behind commercial success in the future, and economies which fail to effectively legislate this development and afford opportunities for effective intellectual property management will lag behind those economies that do. This will have drastic implications for not only the efficiency of capital markets, but in stimulating technological innovation and generating access to the products of that innovation.

Despite the challenges, the opportunities present in the securitization of intellectual property are commensurate with those of the Industrial Revolution. Securities law, and its disclosure requirements, should be incrementally reformed to achieve investor protection and market efficiency, and to realize the opportunity presented by intangible asset finance.

Appendix A — Intangible Assets as a Proportion of S&P 500 Market Value

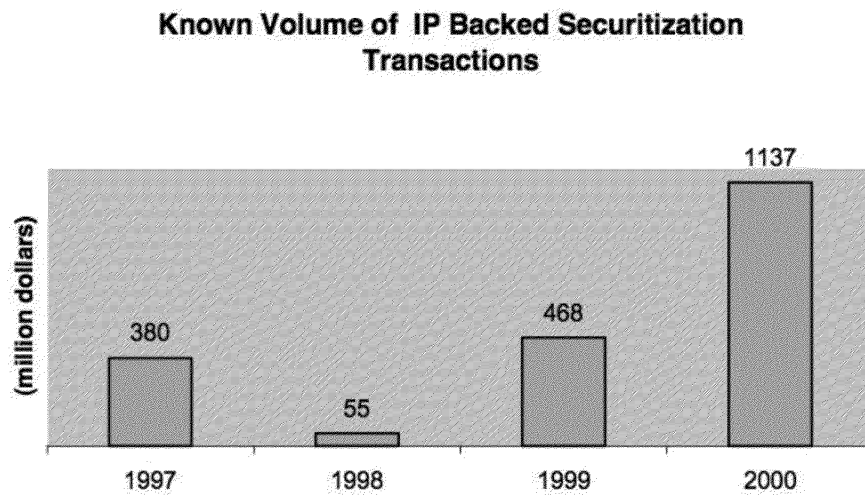
Changing asset base

Over the past two decades, intangible assets have become the key value drivers in the economy.

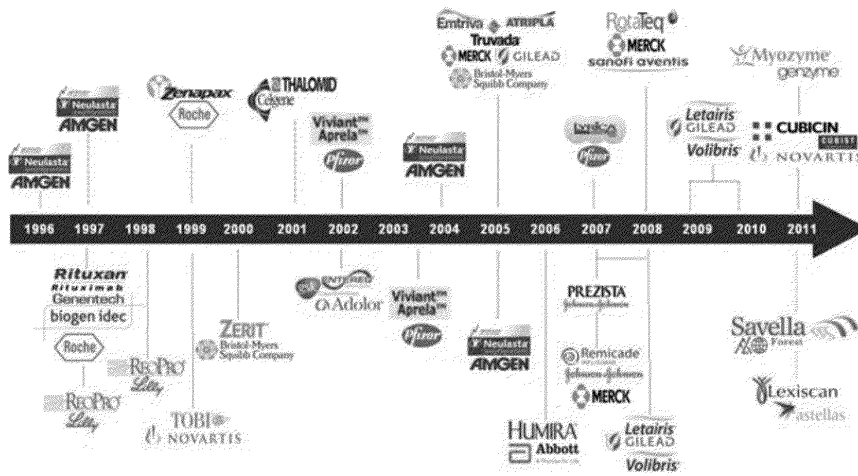


SOURCE: JÜRGEN H. DAUM, *INTANGIBLE ASSETS AND VALUE CREATION*, JOHN WILEY & SONS, 2002

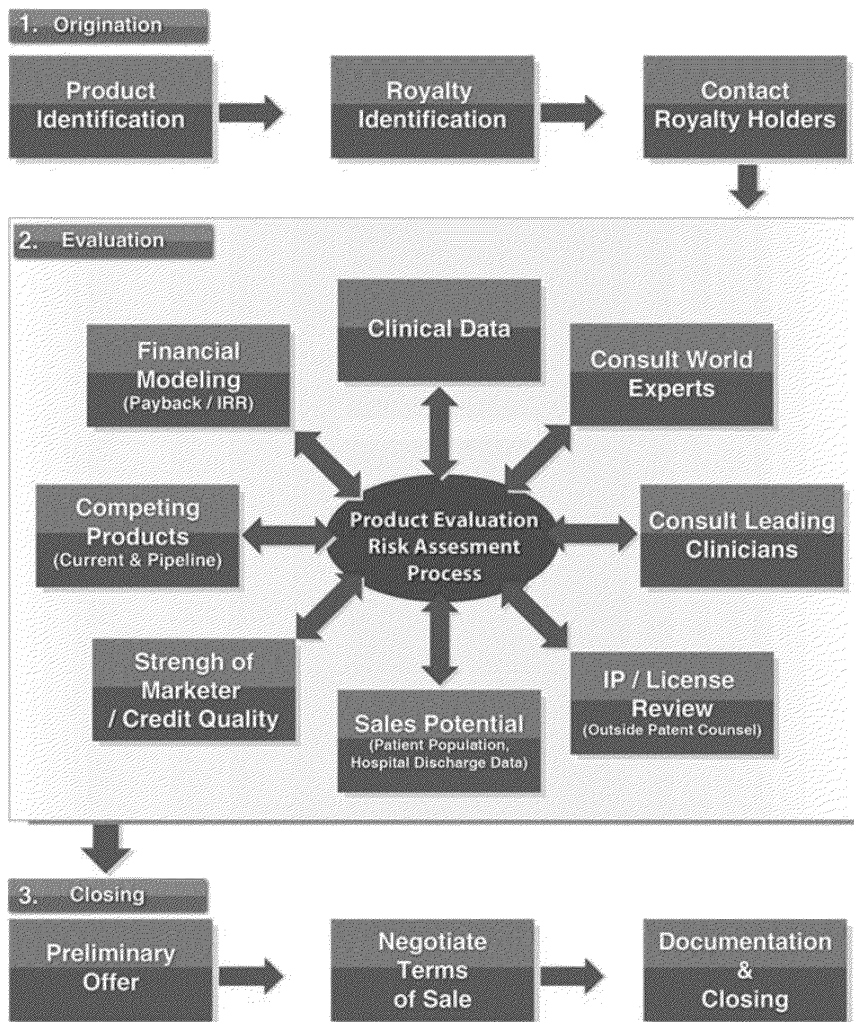
Appendix B — Known Volume of IP-Backed Securitization Transactions



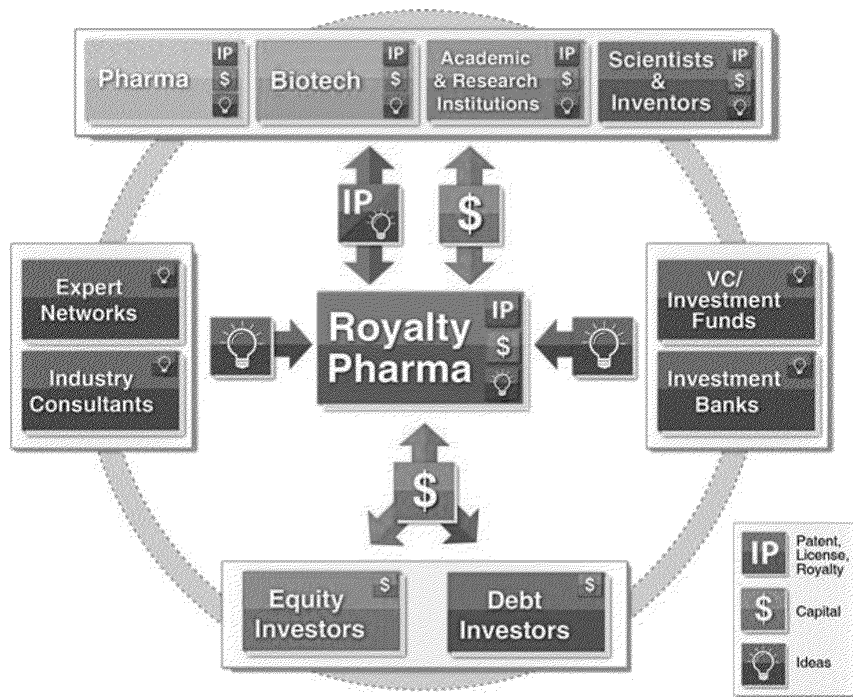
Appendix C — Patent-Backed Security Portfolio Case Study



Appendix D — Patent-Backed Securitization Case Study



Appendix E — Patent-Backed Securitization Framework Case Study



Appendix F — Report on Reserves Data, Form 51-101F2

“Note: [30 Dec 2010] — The following is a consolidation of Form 51-101F2. It incorporates the amendments to this document that came into effect on December 28, 2007 and December 30, 2010. This consolidation is provided for your convenience and should not be relied on as authoritative.”

Form 51-101F2 — Report on Reserves Data by Independent Qualified Reserves Evaluator or Auditor

This is the form referred to in item 2 of section 2.1 of National Instrument 51-101 Standards of Disclosure for Oil and Gas Activities (“NI 51-101”).

1. Terms to which a meaning is ascribed in *NI 51-101* have the same meaning in this form.¹⁸²
2. The report on *reserves data* referred to in item 2 of section 2.1 of *NI 51-101*, to be executed by one or more *qualified reserves evaluators or auditors independent of the reporting issuer*, must in all material respects be as follows:

Report on Reserves Data

To the board of directors of [name of reporting issuer] (the “Company”):a

1. We have [audited] [evaluated] [and reviewed] the Company’s reserves data as at [last day of the reporting issuer’s most recently completed financial year]. The reserves data are estimates of proved reserves and probable reserves and related future net revenue as at [last day of the reporting issuer’s most recently completed financial year], estimated using forecast prices and costs.
2. The reserves data are the responsibility of the Company’s management. Our responsibility is to express an opinion on the reserves data based on our [audit] [evaluation] [and review].
We carried out our [audit] [evaluation] [and review] in accordance with standards set out in the Canadian Oil and Gas Evaluation Handbook (the “COGE Handbook”) prepared jointly by the Society of Petroleum Evaluation Engineers (Calgary Chapter) and the Canadian Institute of Mining, Metallurgy & Petroleum (Petroleum Society).
3. Those standards require that we plan and perform an [audit] [evaluation] [and review] to obtain reasonable assurance as to whether the reserves data are free of material misstatement. An [audit] [evaluation] [and review] also includes assessing whether the reserves data are in accordance with principles and definitions presented in the COGE Handbook.
4. The following table sets forth the estimated future net revenue (before deduction of income taxes) attributed to proved plus probable reserves, esti-

¹⁸² For the convenience of readers, CSA Staff Notice 51-324 *Glossary to NI 51-101 Standards of Disclosure for Oil and Gas Activities* sets out the meanings of terms that are printed in italics in sections 1 and 2 of this Form or in *NI 51-101, Form 51-101F1, Form 51-101F3* or Companion Policy 51-101CP.

mated using forecast prices and costs and calculated using a discount rate of 10 percent, included in the reserves data of the Company [audited] [evaluated] [and reviewed] by us for the year ended xxx xx, 20xx, and identifies the respective portions thereof that we have [audited] [evaluated] [and reviewed] and reported on to the Company’s [management/board of directors]:

Independent Qualified Reserves Evaluator or Auditor	Description and Preparation Date of [Audit/ Evaluation/ Review] Report	Location of Reserves (Country or Foreign Geographic Area)	Net Present Value of Future Net Revenue (before income taxes, 10% discount rate)			
			Audited	Evaluated	Reviewed	Total
Evaluator A	xxx xx, 20xx	xxxx	\$xxx	\$xxx	\$xxx	\$xxx
Evaluator B	xxx xx, 20xx	xxxx	xxx	xxx	xxx	xxx
Totals			\$xxx	\$xxx	\$xxx	\$xxx ²

5. In our opinion, the reserves data respectively [audited] [evaluated] by us have, in all material respects, been determined and are in accordance with the COGE Handbook, consistently applied. We express no opinion on the reserves data that we reviewed but did not audit or evaluate.

6. We have no responsibility to update our reports referred to in paragraph 4 for events and circumstances occurring after their respective preparation dates.

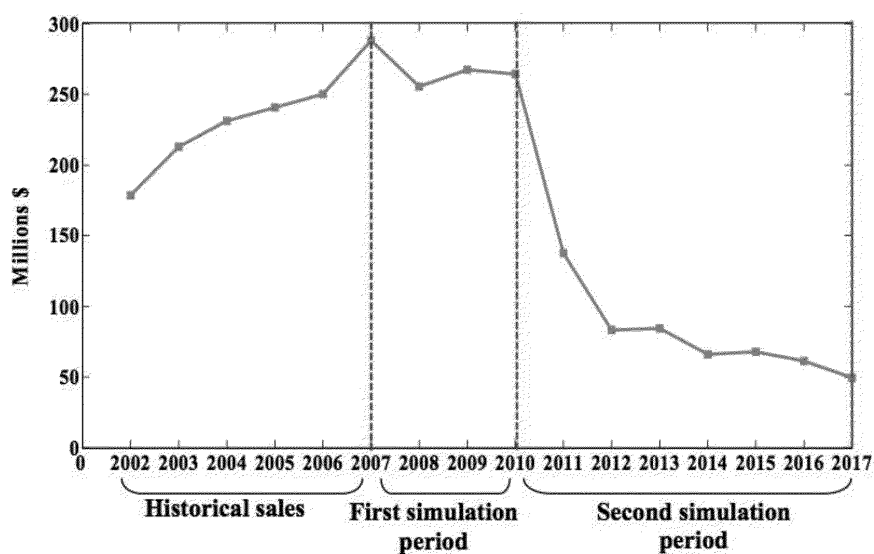
7. Because the reserves data are based on judgements regarding future events, actual results will vary and the variations may be material.

Executed as to our report referred to above:

Evaluator A, City, Province or State / Country, Execution Date
[signed]

Evaluator B, City, Province or State / Country, Execution Date
[signed]

Appendix G — Future Oriented Financial Information
Potential Drug Sales according to Patent Duration



2007-2017: Expected residual life; 2010: Patent expiration

Appendix H — Global Sales Data for Anatomical Therapeutic Classes¹⁸³

Top 20 Therapeutic Classes 2012

	2012		2011		2010		2009		2008		
	Rank	Sales (US\$Bn)	% Growth	Sales (US\$Bn)	% Growth	Sales (US\$Bn)	% Growth	Sales (US\$Bn)	% Growth	Sales (US\$Bn)	% Growth
Global Market		856.1	1.8	841.2	4.8	802.5	5.6	760.1	6.8	711.9	5.2
ONCOLOGICS	1	61.6	5.1	58.6	3.9	56.4	8.8	51.8	8.6	47.7	12.4
PAIN	2	56.1	2.7	54.6	3.7	52.6	3.1	51.1	5.7	48.3	6.2
ANTI-HYPERTENSIVES, PLAIN & COMBO	3	51.6	(3.5)	53.4	(2.7)	54.9	0.7	54.5	3.8	52.5	(3.1)
ANTI-DIABETICS	4	42.4	8.2	39.2	11.7	35.1	14.3	30.7	13.2	27.1	10.3
MENTAL HEALTH	5	41.6	(13.8)	48.3	4.6	46.2	7.6	42.9	1.8	42.2	4.7
RESPIRATORY AGENTS	6	39.7	1.4	39.2	7.5	36.5	8.6	33.6	10.7	30.3	6.1
ANTI-TIBACTERIALS	7	38.8	(3.7)	40.3	(1.5)	40.9	3.4	39.5	5.4	37.5	4.0
LIPID REGULATORS	8	33.6	(14.2)	39.1	3.9	37.7	4.8	35.9	4.9	34.2	(1.0)
AUTOIMMUNE DISEASES	9	27.8	15.1	24.1	14.6	21.1	16.8	18.0	18.4	15.2	19.5
ANTI-ULCERANTS	10	26.0	(2.4)	26.6	(6.7)	28.5	(5.1)	30.1	0.7	29.9	0.3
OTHER CARDIOVASCULARS	11	19.2	8.6	17.7	9.1	16.2	8.3	15.0	8.5	13.8	6.3
HIV ANTIVIRALS	12	18.9	10.2	17.2	9.7	15.6	14.4	13.7	15.3	11.9	12.9
NERVOUS SYSTEM DISORDERS	13	18.8	4.8	18.0	5.6	17.0	(0.6)	17.1	(15.6)	20.3	9.2
OTHER CNS	14	16.7	4.5	15.9	4.8	15.2	6.6	14.3	5.4	13.5	—

¹⁸³ IMS Health, *Top 20 Therapeutic Classes 2012*, (2013) online: IMS Health <http://www.imshealth.com/deployedfiles/ims/Global/Content/Corporate/Press%20Room/Top-Line%20Market%20Data%20&%20Trends/Top_20_Therapeutic_Classes_2012.pdf>.

Top 20 Therapeutic Classes 2012

	2012		2011		2010		2009		2008		
	Rank	Sales (US\$Bn)	2012 % Growth	Sales (US\$Bn)	2011 % Growth	Sales (US\$Bn)	2010 % Growth	Sales (US\$Bn)	2009 % Growth	Sales (US\$Bn)	2008 % Growth
VITAMINS & MINERALS	15	13.9	3.7	13.4	6.4	12.6	6.1	11.9	9.0	10.9	8.3
VACCINES (PURE, COMB, OTHER)	16	13.8	3.9	13.3	13.7	11.7	8.1	10.8	(1.0)	10.9	(0.7)
COUGH COLD	17	12.7	2.4	12.4	6.1	11.7	—	11.7	10.7	10.5	6.6
PLATELET AGGREGATION INHIBITORS	18	12.6	(23.3)	16.4	4.4	15.7	3.8	15.1	9.2	13.8	10.8
HOSPITAL SOLUTIONS	19	12.1	8.8	11.1	7.1	10.4	8.1	9.6	8.5	8.9	10.4