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DAMAGES IN THE PHARMACEUTICAL & BIOTECH SECTOR

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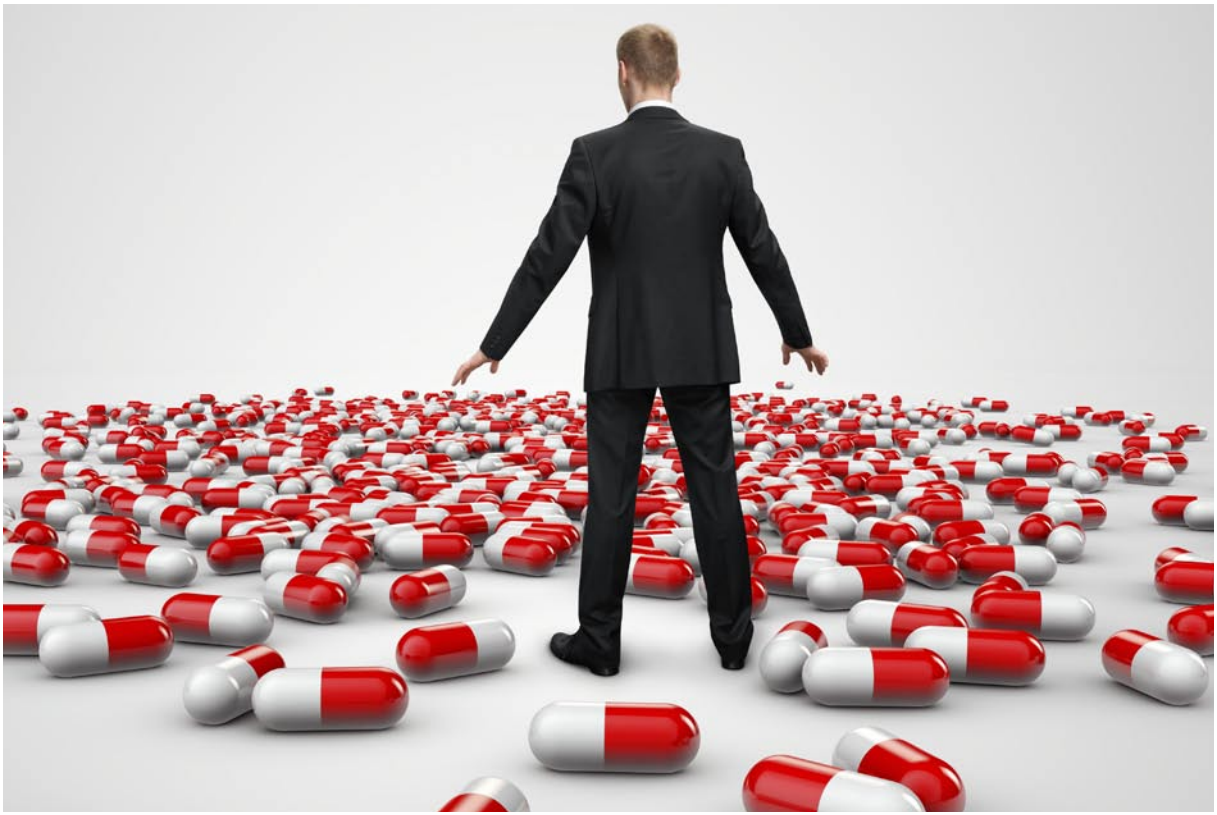
MINI-ROUNDTABLE

DAMAGES IN THE PHARMACEUTICAL & BIOTECH SECTOR



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Iain M. Cockburn is the Richard C. Shipley Professor in the School of Management at Boston University, where he teaches and performs research in the areas of business strategy, intellectual property, economics of innovation, and management of high tech companies. Much of his research work focuses on business and public policy issues in the life sciences and information technology sectors. He is published widely in leading journals in economics and management Professor Cockburn has provided expert economic testimony on patent damages, breach of contract, and antitrust in numerous in matters before federal and state courts and arbitration panels.

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Gregory Bell frequently testifies as an expert witness on damages in intellectual property, finance and antitrust litigation in courts and arbitration proceedings in North America, Europe and Australia. Dr Bell's business consulting engagements focus on the economics of business strategy, working with firms to develop sustainable competitive advantages in specific product markets. He has led numerous projects concerning game theory and competitive strategy, global launch strategy, product pricing and positioning, capital budgeting and real options and cost-benefit analyses.

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Caroline Zayid practices civil litigation with an emphasis on class actions, administrative law and professional liability. She has acted as counsel in several class action proceedings, including such high-profile cases as the Bre-X and Walkerton cases. Current class action retainers of note include representation of a manufacturer in a complex product liability case, and representation of a mutual fund company in defence of allegations of market timing. Ms Zayid represents clients in the pharmaceutical industry before the Federal Court and Federal Court of Appeal in connection with the Patented Medicines (Notice of Compliance) Regulations.

CD: Could you provide an overview of the challenges associated with assessing the value of a potential award, and the factors that need to be taken into consideration when calculating damages?

Cockburn: Fundamentally, the challenge is to reconstruct the market under the assumption that the allegedly illegal conduct did not take place. How much better off would the claimant have been in that circumstance? Determining exactly how this assessment is done will differ from case to case. Typical considerations include: how might the claimant's activities have differed had the challenged conduct not taken place? What course of action would the respondent have taken had it not committed the allegedly illegal conduct? And how might third-party participants in the market have responded? These considerations often require a detailed analysis of the marketplace, including the attributes of relevant products sold by the claimant and the respondent, the valuation of these attributes by purchasers, the degree of price responsiveness, competitive strategies pursued by various players, and the like.

Bell: Some challenges include the perspective and consideration of potential future damages. On perspective, the claimant and respondent may have different valuations based on inconsistent expectations or opportunities, which requires an award consideration that addresses the reasonable outcome based on information, opportunities and activities of both parties as well as market conditions. On the potential for future damages, awards are typically backward-looking but might need to address continuing harm, sometimes under different assumptions or methodologies. There are examples from many types of disputes. For example, would a royalty rate for past infringement necessarily be appropriate for ongoing infringement? Can sales recover from a suboptimal launch, or will they always lag what they otherwise would have reached? Is the harm from a delayed marketing authorisation limited to the time value of money or are opportunities irrevocably lost? Do lost profits awards fully compensate for contested generic or biosimilar entry?

Zayid: A major challenge in assessing damages awards in this sector is realistically reconstructing what the market would look like but for the wrong at issue in the litigation. The pharmaceutical and biotech space is highly competitive, so the determination of damages often depends on how the market would have responded to changes, such as if a product infringing a patent had not been available, if a lawsuit had not been commenced, if a representation had not been made, or if a product launch had not been delayed. The factors to be considered are numerous and depend on the

circumstances, but include trends in product pricing, plans for product marketing, and the regulatory frameworks in the jurisdictions in which the product was sold.

CD: How would you characterise the specific challenges that arise in connection with the biotech/pharmaceutical sector, as opposed to other sectors? Do tailor-made evaluation strategies need to be utilised for this industry?

Bell: All damages analyses need to be tailored to the specific facts at hand. Where pharmaceuticals are concerned, an important consideration is the product's stage in its lifecycle and in the lifecycle of the associated therapeutic category. Is the product new to market and still building awareness, or has it become part of an established prescribing regimen? Is it used in conjunction with other products to treat different conditions? Is it a first-line product in the treatment of a condition or is it reserved for more severe cases? The product itself also may be subject to generic entry or perhaps one of the competitors in the category has been subject to generic entry. Where a claimant's principal competing products are other branded products, there are issues involving the price and non-price strategies that are appropriate for the product's stage in its lifecycle. Generic entry involves a range of other issues, frequently including erosion in brand sales as payors encourage or require the substitution of generic for branded products and are forcing competition away from the prescribing behaviour of physicians and are instead focused on the dispensing behaviour of pharmacists – which product will they stock and dispense to fill a prescription with generic alternatives? There is literature that offers empirical trends on many of these issues, but business judgment and experience often come into play, as well to ensure that the damages model is grounded in the characteristics of the therapeutic category or categories in which the product competes. One interesting area where there is relatively little historical guidance or analogue behaviour involves biosimilars, also called subsequent-entry biologics.

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>
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Zayid: The pharmaceutical sector in particular is highly regulated, which imposes a unique set of challenges for damages assessment. Evaluating the value of a claim requires a legal team familiar with the industry, so the effects of the regulatory regime on the availability, timing of launch and pricing of products can be considered. Three examples from the Canadian pharmaceutical industry come to mind. First, the regime provides that if an equivalent generic drug is available, it must be dispensed rather than the brand equivalent, with some exceptions. The practical effect is that once a generic drug is available, it overtakes most of the market from a brand-name drug. Second, the approval regime for new drug listings is conditional on the drug not infringing existing patents. An allegation that a proposed drug infringes another drug patent can delay the drug's launch for two years. Third, the prices of patented medicines in Canada are regulated by a government agency, and such pricing determinations can significantly influence a damages award.

Cockburn: The biotech/pharmaceutical sector is unique in that it addresses therapies that are selected by physicians, largely covered by payers including private insurers or government programs, and then used by patients, all under the jurisdiction of significant regulations. Each of these parties is motivated by different goals and incentives, and is subject to different constraints, creating a complex environment for assessing damages. Harm from an alleged anticompetitive activity, for example, may be mitigated or eliminated if physician behaviour would not have changed in the absence of the activity, or if the cost control mechanism embraced by payors shield patients, be it via fixed copayments or prior approval requirements. The relationships between these parties – physicians, payers, patients, and regulators – also create complex economic and financial relationships that need to be considered. Rebates and discounts to payers result in net prices that are often unobservable; these price concessions are often shared with other payers based on contracts or regulations. Patients often pay only a small portion of the cost of therapy, based on their insurance coverage, which means that they are often insulated from the economic factors that might otherwise affect therapy choice or compliance. All of these factors often need to be considered when positing a credible alternative scenario for what would have happened in the absence of the challenged conduct, and properly taken into account when constructing a viable damages methodology.

CD: How are intangible assets – such as intellectual property, reputation, and

commercial prospects – addressed during litigation? What methods might be used to establish their value?

Zayid: Thorough analysis of business records and meaningful consultation with industry experts is essential from the outset of litigation. Counsel should start the document collection process immediately upon being retained. Financial records speak not only to profits and losses, but to prospects for growth and the amounts invested in the development of intellectual property. Moreover, internal reports such as product marketing plans can be used to assess and demonstrate the value of intangible assets such as intellectual property. Once collected, experts can conduct a preliminary assessment of value and advise as to what further information is needed from the client and the opposing party. Helpful experts include economists – particularly those with academic interest as well as practical experience in the sector – and specialists in the subject matter who can provide relevant context – for instance, in a pharmaceutical patent case, a specialist physician can speak to how the drug in question benefits patients, as compared to other products on the market.

Cockburn: The value of any asset can be thought of as the discounted cash flows associated with it. This principle applies equally to intangible and tangible assets. In many cases, such as those involving the valuation of lost opportunities, it may be feasible to estimate directly the future stream of cash flows associated with the commercial prospect. Challenges that arise there include ensuring that reliable forecasts are used, including forecasts of the market as a whole, market shares, prices, costs, and so forth. There can frequently be debate among experts as to the pros and cons associated with the use of different forecasts. Again, sound application of economic principles, plus the application of good business judgment, is the order of the day.

Bell: 'Goodwill' is a frequent issue in damages valuation, but discerning what exactly that means is often challenging. Typically 'goodwill' is used in a relatively general context meant to embody some combination of brand reputation or contribution to societal welfare, as opposed to the formal definition in financial statements. In these circumstances, it is often difficult to determine how the so-called goodwill would be expected to contribute to value and how that contribution may have been diminished by alleged wrongs. Claimants may allege loss of reputation or other intangible assets, without any substantive attempt to quantify those losses. One of the fundamental challenges to addressing those claims is being able to apportion a change in the value of an intangible asset to the behaviour at issue. A company's reputation, for example, is a complex aggregation of many pieces of information

from a multitude of sources and built upon a number of products, issues and statements. Isolating the discrete amount of harm, much less its associated valuation, can be very challenging.

CD: Have any recent, high-profile cases exemplified the main issues surrounding the calculation of damages in the biotech/ pharmaceutical sector?

Cockburn: Some of the most interesting recent damages decisions actually involve patent litigation in other industries. For instance, courts in the US have issued a number of decisions involving patents in the information technology sector, where products are highly complex, containing large numbers of interoperating or interdependent components, and may embody hundreds, or even thousands of patented inventions. These complex products typically have many different attributes that may drive value by consumers. These decisions speak to the need in damages analyses to carefully assess the incremental contribution of a patented technology within the broader context of the product and its various attributes. While this is obviously a central issue for electronics and software products, it is likely to become increasingly relevant in the life sciences sector as products become more complex. Biologics are a case in point, frequently entailing not just large, complex molecules, but also the use of research tools in the discovery process and highly sophisticated methods of manufacturing. The products typically come to market with an increasingly large and complicated burden of 'upstream' intellectual property, both developed internally by the product's sponsor and licensed in from a variety of organisations. Large royalty stacks and accompanying anti-stacking provisions built into the agreements under which these pieces of intellectual property are licensed can create a very challenging scenario if a new patent or patents are thrown into the mix. I suspect the kinds of apportionment issues faced in software, electronics, and telecommunications are going to play a much larger role in the life sciences sector.

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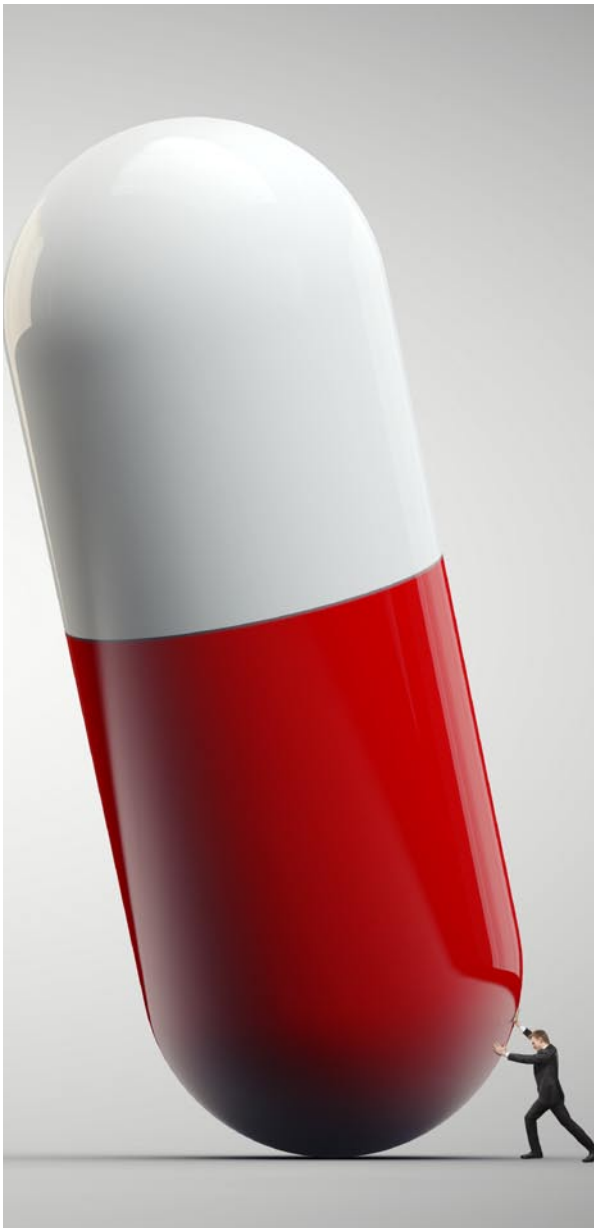
> *Caroline Zayid, McCarthy Tétrault LLP*



Bell: The high-profile cases do not need to be in the biotech/pharmaceutical sector to be interesting. After all, judges and arbitrators do not typically specialise in life sciences. The most interesting factors surrounding recent cases are actually coming from antitrust class actions, but are often applicable in many other contexts. While the increasing focus on technical rigor in addressing class certification has been a welcome development in general, the emphasis on concordance between theories of liability and associated damages methodologies is particularly appreciated. In addition, we are seeing an increasing amount of litigation focused on failed relationships between collaborators, such as failed co-development, co-marketing, and co-promotion agreements, many of which tend to tout commercially reasonable efforts as the standard against which actions, not results, are to be measured.

Zayid: Two important Canadian cases demonstrating the challenges of reconstructing what the market would have looked like but for the wrong at issue in litigation are currently underway. First, in *Merck & Co, Inc. vs. Apotex Inc.*, *2013 FC 751,* the Court confirmed that whether an infringer could have overtaken the market by taking a non-infringing alternative course of action is irrelevant to the assessment of damages. Particularly in light of mandatory generic substitution rules in Canada, this decision was significant for determining the

composition of the market for damages assessment. An appeal of this decision was argued in January 2015, and is currently under reserve. Second, the Supreme Court of Canada will soon hear the appeal of *Sanofi-Aventis et al vs Apotex et al, 2013 FCA 186*, which will address how damages should be modelled when a generic drug faced an unwarranted delay in coming to market. Specifically, should the court assume the generic would have faced competition? If so, how is each competitor's market share determined? The key issue is how to compensate for losses, without overcompensating by awarding damages for sales that never would have been made in the real world.

CD: Apart from the generally higher median damages awarded, why has the jury trial rather than the bench trial evolved as the preferred option for damages claims over the last few years?

Bell: As an economist and testifying expert, I am not aware that the jury trial has evolved as a preferred option compared to bench trials or arbitration. Instead, I have found that each venue allows the opportunity for a vigorous case, but the skills and approaches differ based on whether the audience is a single judge, a jury or a tribunal. Jury trials benefit from a clear, linear teaching approach. Bench trials can sometimes address more sophisticated issues and models, depending on whether the judge is experienced in addressing the intricacies of the life sciences sector. Aribtral tribunals sometimes offer a guarantee of experience in the sector, since the parties can select the arbitrators. In addition, the opportunity for expert conferencing allows for a direct dialogue that can assist the arbitrators, so long as the experts remember to include the tribunal in their discussions.

Zayid: Jury trials are actually quite rare for civil cases in Canada, and are virtually non-existent for complex civil matters such as damages claims in the pharmaceutical and biotech sector. There is no right to a jury trial in a civil action in Canada, although in some jurisdictions a party may request it. The Federal Court, which has primary responsibility for intellectual property claims, and, as a result, many actions in this sector, does not allow jury trials.

Cockburn: Certainly there are a range of legal issues that have contributed to the relative prevalence of jury trials; and it is difficult to have any particular insight into these issues. What is clear from the expert perspective, however, is that jury proceedings require an exceptional degree of clarity and immediacy in the presentation of damages analyses. The ability to summarise complex analyses in an intuitive and user-friendly fashion is paramount; damages experts need to be able to 'teach'. From my perspective, this differentiates those experts who

deeply understand the issues from those who have engaged only superficially. My years of teaching in the academic classroom have certainly given me an appreciation of the challenges inherent in conveying complicated issues to an audience with a wide range of backgrounds and different levels of engagement in the material.

CD: What advice what you give plaintiffs pursuing damages? How important is reliable and well-grounded expert analysis and testimony?

Zayid: Expert analysis is essential, and can make or break a case. Parties should begin collecting relevant documents and retaining experts promptly upon the start of the action, and implement a well-thought out document preservation plan. It is very helpful for parties to connect external counsel directly with in-house staff responsible for those financial and other documents that will be needed for expert analysis; this will help to greatly streamline the document collection process. Furthermore, in-house counsel and external counsel should work together to connect experts with internal staff, in the presence of counsel. This can ensure experts have all the information they need to conduct a comprehensive analysis, and allows an internal resource familiar with the business to confirm that the information the expert is analysing is clear and accurate.

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>
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Cockburn: Reliable expert analysis and testimony is always critical, as courts are not shy about excluding expert opinions that are deemed to be unreliable or based on analysis that does not use an appropriate methodology. This isn't just an issue for plaintiff experts, but applies equally to experts for defendants. At the same time, the opinion has to be grounded in the economic and business context. In the specific case of issues involving the pharmaceutical and biologics industries, damages analysis that doesn't adequately account for a product's stage in the lifecycle, competitor responses and the interaction among patients, physicians and payors might be considered unreliable, or at least insufficiently grounded in the

norms of the industry. In my experience, it is critical that expert testimony be based on both knowledge of the institutional and competitive environment of the dispute, and on technical expertise sufficient to develop a damages analysis which meets the standard demanded by the courts. Unfortunately, this combination of skills and background is not common, and this kind of expert may be hard to find.

Bell: Whether plaintiff or defendant, the advice would be the same, and much of it would include crafting a reliable damages approach based in the appropriate commercial context. In addition, we would encourage counsel to get an early, reasonable read on potential damages. This has two immediate and practical advantages. First, even an initial ballpark estimate of the potential damages at issue will inform efforts and provide guidance on the scope of the engagement and whether continued litigation is warranted. Second, an early look at damages can help focus the discovery process and avoid later disappointments from missing information or inefficiencies from pursuing blind alleys. Of course, getting an early read on potential damages also facilitates coordination with liability theory and technical reports, even in bifurcated matters, which can help ensure consistency across different phases of the litigation.

CD: How do you see the issue of awarding damages in the biotech/pharmaceutical sector developing in future? Can courts keep pace with the burgeoning intangible asset economy?

Zayid: There is one issue which is particularly relevant for pharmaceutical product liability class actions in Canada. The courts have reconstituted the doctrine of 'waiver of tort' to potentially assist plaintiffs seeking to recover against manufacturers of pharmaceuticals and medical devices. The concept is that the defendant should be required to disgorge any profits or revenues earned as a result of the alleged wrong even if the claimant cannot prove actual damage. To date, we have seen many pleadings motions where the waiver of tort claim has been allowed to stand. In the future, we will find out whether a court will actually allow such recovery in the absence of a proven loss.

Cockburn: There will always be patent litigation involving the challenging by generics of patents held by innovators, and this will continue to give rise to damages issues. We also see breach of contract issues between collaborators being a big part of damages work going forward. Contractual disputes involving co-development or co-promotion agreements are reasonably common, and will also continue to present a range of interesting damages issues. Damages issues also arise from antitrust litigation such as the recent 'pay for delay' cases.

These are cases launched against parties to patent settlement agreements that allegedly delay generic entry. Going forward, a big unknown is how market entry by biosimilars may affect patent damages in the biologic space. Courts and experts will need to work through the effects on prices and sales of innovator biologics that result from entry by clinically similar products that may not be interchangeable at the pharmacy.

Bell: We expect that damages assessment in life sciences will only get more intense and important with significant biosimilar and biobetter entry. These therapies may encompass a broader range of intellectual property, with more sophisticated manufacturing and distribution requirements than more standard small-molecule products. With the complexity there may be a greater utilisation of specialised collaborative efforts with consequent implications for subsequent disputes, whether they be related to the intellectual property, the activities of commercial partners aimed at developing or commercialising the therapies, or competition issues. Notwithstanding the increase in complexity, a key issue will remain the ability to clearly articulate and prove the linkages necessary to isolate harm and support credible damages assessments. CD