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IP INFRINGEMENTS IN THE LIFE SCIENCES SECTOR

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MINI-ROUNDTABLE

IP INFRINGEMENTS IN THE LIFE SCIENCES SECTOR

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CD: Reflecting on the last 12-18 months, what are some of the general trends you have seen in terms of intellectual property (IP) infringements arising in the life sciences sector? How would you characterise the frequency of these cases?

Bell: The trend that has most captured our attention recently is the IP litigation surrounding biosimilars. Now that biosimilars are reaching the marketplace, there are a host of IP and competition issues to be addressed in the courts, starting with patent infringement, but also including other areas, such as commercial success, pricing and contracting and competition among biologic products. The emergence of 'biobetters' – biosimilars that offer advantages over the original biologic – will also add depth to traditional IP considerations. In combination with indication expansion, the existence of biobetters will likely require further consideration of segmented demand, placing more attention on the ability to identify why and for what indications patients are using a particular therapy and building on the considerations raised by 'skinny labelling' cases.

Zullow: Over the past 18 months there has been an increase in Biologics Price Competition and Innovation Act (BPCIA) biosimilars litigation and biosimilars *inter partes* reviews (IPRs). One interesting aspect of BPCIA litigation is that some of the companies that traditionally developed brand-named small molecule products, and were plaintiffs in Hatch-Waxman litigation, are now developing biosimilars and finding themselves in the position of defendants in BPCIA litigation.

Yi: In Canada, we are seeing an increase in litigation involving biologic and biosimilar products similar to the trends being seen in the US. This has started to turn the traditional rivalry between innovative and generic drugs on its head. Additionally, in September 2017, sweeping amendments to the Patented Medicines Notice of Compliance (PMNOC) regulations came into force which dramatically changed the litigation landscape in this industry. This resulted in a wave of litigation just before the new regulations came into force, likely due to potential for uncertainty under the new regime, but we are now seeing increasing numbers of cases under the new regime.

Madigan: Litigation across all types of IP remains frequent, and the life sciences sector has seen a particular uptick. IP owners continue to be embroiled in disputes involving brand and generic competition, with litigation involving biosimilars seeing a notable increase. At the same time, manufacturers of pharmaceuticals and medical devices are experiencing infringement on their IP – trademarks,

copyrights and patents – in both the US and globally in the form of unlawful counterfeiting and diversion.

Schneider: Perhaps the biggest trend is the rise in biosimilar patent litigation. In 1984, Congress passed the Hatch-Waxman Act, which provided an abbreviated approval process for "small-molecule" generic drugs that are made by chemists in labs. Brand-name drug manufacturers list their patents in the Food and Drug Administration's (FDA) 'Orange Book', and generic drug manufacturers indicate for each patent whether they will wait for it to expire or challenge validity or infringement. Generic approval can be stayed for 30 months while the parties engage in litigation. The past 30 years have seen hundreds of these Hatch-Waxman litigations. In 2009, Congress passed the BPCIA, which set up an abbreviated approval process for generic biologics, referred to as biosimilars. Compared to small-molecule drugs, biologics typically are larger, more complex drugs that are made from living cells, and sometimes are so complex that their chemical structure may not be completely known. Instead of listing patents in the Orange Book, under the BPCIA the brand-name manufacturer and the biosimilar manufacturer exchange patent lists and contentions on infringement and validity, which may trigger litigation. We are now seeing biosimilar litigations ramp up, with about two dozen cases that are pending or have been settled in the past 12 to 18 months. These cases are often more complex than Hatch-Waxman litigations in their scope and subject matter.

CD: To what extent is the life sciences sector susceptible to IP infringements?

Zullow: With respect to Hatch-Waxman litigation, compound patents typically cannot be avoided. That said, companies continue to attempt to design around patents that claim specific polymorphs, formulations, pharmacological characteristics, manufacturing processes or delivery devices, among other things. The volume of life sciences patent litigation is empirical proof of the life sciences sector's susceptibility to allegations of IP infringement.

Yi: There is a lot of potential for IP infringement in the life sciences sector given the wide variety of types of patent claims that could cover products in this industry, ranging from compound, to use, process and method patent claims. Additionally, as software acting as medical devices become more ubiquitous, we may see an increase in copyright, trademark and design patent cases covering all aspects of the software. From a patent perspective, pharmaceutical products in this industry tend to have multiple patents covering various aspects of the product. Potential infringers tend to be strategic about potential entry points which almost always results in litigation relating to the product at some

point. This is especially because under PMNOC regulations, there is a mechanism by which a potential infringer can recover damages for delayed market entry if it is successful in a patent challenge. This encourages potential infringers to be more aggressive in attacking patents.

Madigan: Piracy has expanded into the life sciences, reaching epidemic proportions as a result of e-commerce platforms and expanding foreign markets. In fact, counterfeiting has become the largest criminal enterprise in the world. This has required manufacturers to be vigilant and implement effective measures to reactively shut down and proactively prevent counterfeiting and the collateral damage it causes.

Schneider: The generic drug and biosimilar sectors are often involved in patent infringement cases. However, unlike other sectors, such as electronics or computers, there are pharma-specific statutory frameworks that may govern aspects of the litigation. In Hatch-Waxman cases, the framework was designed to time litigation so it could conclude before the generic is on the market, but that does not always occur. If a product is launched at-risk before a decision is reached in a case, damages may be at issue.

Bell: Beyond life sciences, we are not aware of any other sector in the economy where so much value is concentrated in IP, and individual elements of IP, as opposed to whole portfolios of related IP, as might be more the case in the high tech or consumer electronics industries. As a result, the pursuit of IP and IP protection is integral to the life sciences sector. It is difficult, costly and time-consuming to identify viable targets that survive to become approved therapies. Accordingly, the need to protect those targets and the related investments is of paramount importance.

> **"Piracy has expanded into the life sciences, reaching epidemic proportions as a result of e-commerce platforms and expanding foreign markets."**
>
> *R. James Madigan III, Patterson Belknap Webb & Tyler LLP*

CD: Have any recent, high-profile IP infringement cases caught your attention? In what ways might they impact the wider life sciences landscape?

Yi: *AstraZeneca v. Apotex* revamped the utility analysis in Canada, likely bringing it more in line with other jurisdictions. This will likely result in fewer patents being invalidated for lack of utility and improve certainty for patentees. We have seen some attempts to rebrand the promise doctrine under the invalidity attacks of sufficiency of disclosure and overbreadth of patent claims. The Federal Court of Appeal (FCA) has recently heard an appeal of a motion to amend pleadings to add these types of attacks. However, that decision is currently outstanding. Recent jurisprudence has confirmed that in quantifying the remedy for patent infringement – whether a patentee's damages or a disgorgement of the infringer's profits – the availability of non-infringing alternatives (NIA) is a consideration. However, the FCA has set the standard of proof high, and, in the case of *Apotex Inc v ADIR* (2017), reaffirmed the high burden. It is notable that since *Lovastatin*, no court has accepted a non infringing alternative (NIA) defence. Finally, there are a pair of cases under the new PMNOC regulations relating to the drug Herceptin that are the first cases under the new regime.

Madigan: Over the last few years, the US Supreme Court has shown an increasing interest in patent cases. This interest has been more attuned to larger policy concerns and less to questions of core patent doctrine. In 2015, the Court ruled in *Teva Pharmaceuticals USA Inc. v. Sandoz Inc*. that the Federal Circuit must apply a "clear error" not a *de novo,* standard of review to the district court's factual findings on issues of claim construction. This appeared to have been aimed at enhancing judicial efficiency and reducing litigation costs by giving more deference to the district court. And in two major decisions last year, the Supreme Court scaled back the rights of patent holders – in *TC Heartland v. Kraft Foods Group*, by making it more difficult for patent holders, patent assertion entities in particular, to establish venue over a defendant, and in *Impression Products v. Lexmark*, by holding that any authorised sale by a patent holder, whether domestic or abroad, exhausts all patent rights. Moreover, in *WesternGeco LLC v. Ion Geophysical Corp*., the Supreme Court recently reversed the Federal Circuit and allowed the patentee to seek recovery of profits it lost overseas as a consequence of infringing acts in the US. These decisions appear to be part of a trend in which the Supreme Court is concerned with the scope of the US patent system in the 21st century. It will be very interesting to see if the trend continues and whether the Supreme Court can keep up with the constantly-changing industries its rulings are affecting.

Schneider: This year was interesting because the US Supreme Court issued two decisions on the same day relating to proceedings before the US Patent & Trademark Office called IPRs. These decisions affect the life sciences sector, particularly because many

patents related to biosimilars are involved in parallel court and IPR proceedings. In the America Invents Act (AIA) of 2011, Congress created additional ways to challenge the validity of issued patents at the Patent Office. Some argued that IPRs were unconstitutional because they took away patent rights without involvement by a court. In *Oil States Energy Services, LLC v. Greene's Energy Group, LLC*, the Supreme Court held that IPRs were not unconstitutional, at least not on the grounds raised in that case. On the same day, the Supreme Court also addressed the institution of IPRs in *SAS Institute Inc. v. Iancu*. IPRs are started when one party files a petition for review asserting that one or more claims of a patent are invalid. For example, if a petitioner challenged 10 claims of a patent, the Patent Office might institute a review of claims one to five but decline to consider the patentability of claims six to 10. The Supreme Court held that this practice violated the statute, and the Patent Office must decide the patentability of all claims the petitioner has challenged.

Bell: There have been a number of particularly interesting recent cases in which enhanced damages were an issue of prominence. Following *Halo Electronics v. Pulse Electronics*, a number of cases have sought enhanced damages. The implications for wilfulness seem particularly relevant, as do recent rulings that consider when the sales at issue occurred, relative to litigation. It will be interesting to see how these issues are resolved, as precedents that affect the expected significant damages awards are likely to affect behaviour.

Zullow: *Vanda v. West-Ward* caught my attention. Section 101 defences have had a lot of traction over the past few years, particularly with respect to claims directed to personalised medicine. The patent asserted in *Vanda* relates to a method of treating schizophrenia wherein dosage is adjusted based on the patient's genotype. West-Ward asserted, among other things, a Section 101 defence. The district court ruled that West-Ward infringed the asserted claims and did not prove that they are invalid. With respect to Section 101, the court found that while the asserted claims depend on laws of nature, the claimed genotype testing and results were not proven to be routine or conventional. The Federal Circuit affirmed the validity finding, but in doing so concluded – contrary to the district court – that the claims were not directed to a law of nature. The Federal Circuit recently denied West-Ward's petition for rehearing *en banc*. If this case stands, it will likely impact life sciences litigation because it takes a broader view of the scope of subject matter that is patent eligible.

CD: When it comes to enforcing IP rights, how important is it to first conduct an IP audit and risk assessment? What

considerations should companies make during this process?

Madigan: A company should not wait until it has an immediate need to enforce its IP rights. An audit can provide tools and means to minimise or avoid enforcement issues. US companies spend billions of dollars innovating and building their brands. Rights holders must understand the value of their IP portfolio and, while it may seem obvious, the full contents of that portfolio, which can include patents, copyrights and trademarks, as well as trade secrets, know-how and domains. Companies often know how to use their IP portfolio to serve their business objectives, but it is equally important to understand exposure to infringement and the source of that exposure. For patentees, do they face an at-risk-launch or adversarial IPR proceeding? For trademark and copyright holders, is there a potential for counterfeits or knock-offs? And for all rights holders, is there exposure to litigation? Only upon assessing the IP portfolio and the associated risks can companies implement best practices to manage and protect those assets.

Schneider: In the pharmaceutical sector, patents at issue may be listed in the Orange Book or exchanged by the parties prior to a litigation. In a BPCIA litigation, for example, the parties may have exchanged detailed patent non-infringement or invalidity contentions before suit. Given that information, the parties may assess whether they have a basis under Rule 11 of the Federal Rules before filing a suit or raising counterclaims, or they could be subject to sanctions. In addition, the parties may have a better ability to assess the risk of winning or losing a case, as opposed to a sector where this type of detailed information is not typically provided by the adversary prior to suit.

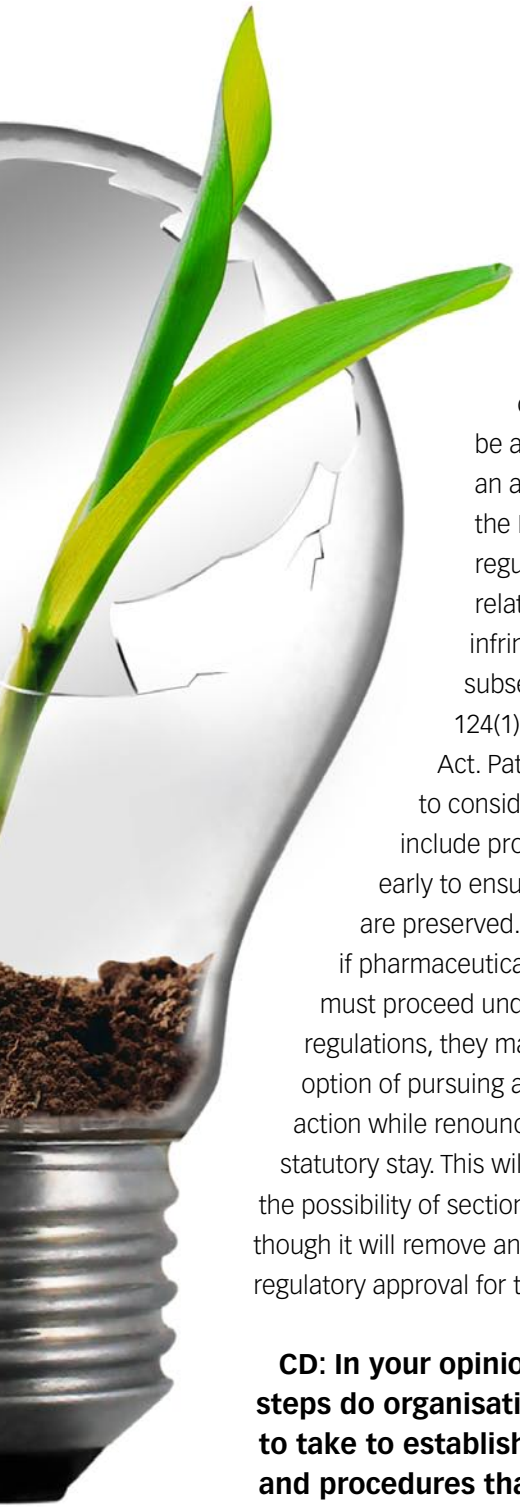
> **"As a consultant for life sciences companies, I note that they often take sophisticated approaches to managing their IP and risks."**
>
> *Gregory K. Bell, Charles River Associates*

Bell: As I am not an attorney, I cannot really comment on enforcing IP rights, however, as a consultant for life sciences companies, I note that they often take sophisticated approaches to managing their IP and risks. Development targets

and approved products are critical assets, whether they were developed internally or licensed in. So, assembling the resources to protect those assets is very important. But, in addition to defending patents and products or identifying gaps in patent protections, there is an important commercial aspect to this process, identifying potential collaborators as well as competitors. Whether developing new combination regimens or combining related information, the effort to protect IP may also provide the impetus for new business.

Zullow: An IP audit and risk assessment helps a company understand how IP contributes to its competitiveness and bottom line. Such audits typically entail considering, at minimum, the life of a patent, whether it covers the company's products, the importance of the patent and its estimated value. Such audits help companies determine how much time and money should be spent to enforce a given patent. In some parts of the life sciences space, such as Hatch-Waxman litigation, a formal IP audit may not be needed to conclude that a patent should be enforced. This is because under the Hatch-Waxman Act, instituting a suit results in a 30-month stay of FDA approval of a generic product. Considering that many pharmaceutical products have annual sales of hundreds of millions of dollars or more, it does not take much analysis to conclude that initiating a Hatch-Waxman patent infringement suit has value for the patent owner. Before enforcing a pharmaceutical patent, however, it is also important to critically assess the patent's strengths and weaknesses and develop strategies to maximise the litigation value of the patent.

Yi: The new regime under the PMNOC regulations is speedy and unforgiving. As such, client side risk assessment and preparation for when products are nearing the end of their life cycle is critical. Early document collection and getting in touch with inventors – to the extent they have left the company – is vital to ensure that court-imposed deadlines can be met. The first few months of a new PMNOC action are very burdensome on patentees, so the earlier these issues can be addressed, the better. There are also open questions regarding how patents that include process claims are to be addressed under the new PMNOC regulations, such as whether or not



such claims could or should be asserted in an action under the PMNOC regulations or as a related action for infringement under subsection 54(1) or 124(1) of the Patent Act. Patentees will have to consider patents that include process claims early to ensure their rights are preserved. Additionally, if pharmaceutical companies must proceed under the PMNOC regulations, they may consider the option of pursuing an infringement action while renouncing the statutory stay. This will eliminate the possibility of section 8 damages, though it will remove any legal bars to regulatory approval for the generic.

CD: In your opinion, what steps do organisations need to take to establish policies and procedures that can effectively monitor and detect potential IP infringement?

Schneider: In the pharmaceutical sector, a company's possible infringement may come up during various disclosures required by the Hatch-Waxman Act or BPCIA. Because pharmaceuticals cannot be sold without FDA approval, companies with patent-protected drugs may receive advance notice when companies are trying to make generic or biosimilar versions of drugs. In different sectors, companies may need to monitor their competitors' products and gather business intelligence to determine potential infringement.

Bell: Early assessment of competitive intelligence is a critical step in the process. Developing a cogent system in which marketplace information, research and development insights, manufacturing process improvements and so on, can be collected and disseminated quickly allows for the prompt identification of potential infringement concerns. It is important to stay on top of the literature, conference presentations and announcements of clinical trials.

Zullow: It is useful for companies to monitor the activities of their competitors and the marketplace to see whether there is anything that might infringe a patent. This may entail developing a regular sampling and testing protocol, or conducting regular searches

of publicly available information, such as published patent applications and the internet, to determine the existence of, and identify, potential infringers.

Yi: Health Canada has started publishing new drug submissions (NDSs) and supplemental new drug submission (SNDSs) under review – submissions under review lists – for new active substances and Class IV medical devices. As many biosimilar drug applications will proceed by way of NDS, monitoring the NDSs under review will provide a good indicator of potential infringement in that space. Abbreviated new drug submissions (ANDSs) that are under review are not published, which makes monitoring small molecule products more difficult, and likely the first indication of potential infringement will come from delivery of a notice of allegation (NOA). As such, patentees should be monitoring their patent portfolio and preparing for potential IP infringement and litigation when patents covering a product are nearing the end of their life or term. Litigation in other jurisdictions is also a good indicator of whether there may be potential infringement in Canada.

Madigan: The tools are out there for companies to monitor, detect and stop infringement. As e-commerce platforms and foreign nations increasingly attempt to encourage investment and foster growth, they are becoming more willing to cooperate and engage with trademark, patent and copyright holders to shut down, or take down, illegal offerings. It must be stressed, though, that jurisdictions – geographical and virtual alike – will not do the work for innovators and manufacturers. Accordingly, it is vital that companies actively identify and surveil markets, electronic and brick-and-mortar alike. Companies must strengthen contracts to include audit clauses, territory restrictions and exclusive sourcing. They should also monitor and audit customers and leverage outside counsel, law enforcement and other third-party experts.

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>
> *David Yi,*
> *Norton Rose Fulbright Canada LLP*

CD: Could you outline the methods that can be utilised to calculate damages

which accurately reflect the loss experienced by an IP owner? What are the main factors that may impact the quantum of damages claimed?

Bell: Much has been written regarding the calculation of damages in IP disputes. *Panduit* and *Georgia-Pacific* characterise general frameworks and issues regarding lost profits and reasonable royalties, respectively, but these simply echo the considerations that damages would be expected to consider even without the guidance. For all of the appropriate complexity that may surround some damages calculations, the fundamental issues are the same. You must determine how many infringing units were sold, estimate how many of those units could have been sold by the patent holder, calculate the patentholder's lost profit associated with those units, including any price erosion, relative to the patentholder's actual sales, and apply the reasonable royalty rate to the remaining sales of the infringing units. The devil, of course, is in the details. And while there are a number of issues that arise in properly calculating lost profits or determining a reasonable royalty, we would like to highlight two of them. The first issue is price erosion. This can be a significant consideration in the pharmaceutical industry where generic drugs, and, to some extent, biosimilars, typically sell at reduced net prices compared to the innovator therapy. While price erosion paths have been studied, what is less established is how much the innovator price may have increased with generic entry, as well as whether price erosion stimulated demand and whether demand stimulation offsets demand decreases that might follow from the cessation of marketing support for the innovator therapy. The second issue is the damages consequences of non-infringing alternatives. The existence of these alternatives may dramatically affect damages calculations, but the challenge is often to demonstrate the existence of a non-infringing alternative that may not have been deployed prior to the litigation or may not satisfy all attributes of the product at issue. In addition, efforts typically are required to determine the costs of the non-infringing alternative and possible impacts on demand.

Zullow: Patent damages are typically calculated as lost profits caused by sales made by an infringer or as a reasonable royalty that would have been received on each sale of the infringing product. Issues often arise, however, regarding what portion of the profits should be attributed to the claimed invention. Another interesting issue relates to whether damages can be recovered for extraterritorial activities. In Hatch-Waxman and BPCIA litigation, damages often are not at issue because the defendant has no commercial sales. However, that is not always the case. For example, in *Amgen v. Hospira*, a BPCIA litigation in the District

of Delaware, Amgen sought damages based on Hospira's manufacture of large quantities of product prior to FDA approval or commercial launch. The damages question was whether the Section 271(e)(1) safe harbour, which protects manufacture of products solely for uses reasonably related to development and submission of information to FDA, protected Hospira's activities. A jury awarded damages of $70m dollars based on Hospira's pre-launch and pre-approval activities. Hospira filed post-trial motions relating to, among other things, the damages award. The district court recently ruled that the damages award would stand. The case and its anticipated appeal are being closely watched because of the potential implications on the availability of pre-launch and pre-approval damages in life sciences litigation.

Yi: Under the Patent Act, subsection 55(1) holds an infringer liable to the patentee and to "all persons claiming under the patentee" for all "damage sustained", after the grant of the patent, "by reason of the infringement". This language therefore imports a calculation of lost profits that could and would have been made "but for" the infringement and accordingly, a requirement that the damage sustained be causally connected to the infringement. Additionally, "persons claiming under the patentee" broadens the scope of potential plaintiffs, and therefore the nature of the damages calculation. Other provisions of the Patent Act provide for the potential for a disgorgement of the infringer's profits, an equitable remedy, and reasonable compensation for the period between patent publication and issuance. Finally, although there is no doctrine of wilful infringement comparable to the treble damages available in the US, in 2017, the Federal Court awarded punitive damages for blatant wilful infringement that was double the amount of the compensatory damages.

Madigan: The harm to a brand can often be difficult to quantify. So can actual compensatory damages. The law accounts for that by putting remedies in place that turn on the nature and extent of the defendant's infringing conduct and putting the burden on the defendant when his actions have made actual damages difficult to determine and calculate. In trademark and copyright law, this can include statutory damages. For a plaintiff who is seeking to recover actual damages – or lost profits in the patent context – it is necessary to understand the relevant market in which the manufacturer is competing with the infringing product. It is also critical to understand and be able to identify the value of the trademark, or with a patent-practicing product, the value of the patented and unpatented features. This puts the IP owner in the best position to assess and prove its damages.

Schneider: US patent law generally provides two frameworks for evaluating patent infringement

damages – a reasonable royalty or lost profits. The Patent Act states that a patentee is entitled to no less than a reasonable royalty in cases of infringement and this is generally determined by calculating the amount the parties would have agreed to in a hypothetical negotiation at the time of infringement. A patent holder can only obtain lost profits if it can prove that it would have made the infringer's sales but-for the infringement, which can be disproven by factual circumstances such as the existence of non-infringing alternatives. Patent holders can also seek preliminary or permanent injunctions or pre- and post-judgment interest, and either party may be able to seek attorneys' fees in certain exceptional situations.

CD: What general advice would you offer to parties in terms of presenting robust evidence to support a claim for IP infringement and related damages?

Zullow: It is important to support the damages that you seek to recover. Accordingly, if you are going to seek lost profits, you need to be able to prove causation – lost sales being caused by an infringement and not something else. With respect to price erosion, it is important to have a defensible market and economic analysis based on well-accepted methodologies and that avoids speculation. Too often, parties focus on maximising damages in an 'all or nothing' approach rather than advocating positions that seek a lower recovery but have a higher probability of being accepted by a court or jury.

"With respect to price erosion, it is important to have a defensible market and economic analysis based on well-accepted methodologies and that avoids speculation."

Keith A. Zullow, Goodwin Procter LLP

Yi: Engaging experts early is important to developing a robust case. Experts can provide early consulting on general strategies for presenting the strongest case so that there is a unified theory from start to finish. Experts can also identify gaps in productions in a timely way. This will ensure effective use of discovery, early engagement and development of expert reports. In addition to early engagement of top quality experts who will provide the substantive evidentiary support, top quality

counsel are needed to help translate the technical expertise to terms and language that can be understood by the judge.

Madigan: Many potential infringers are no longer hiding in the shadows, but are instead offering infringing products online on public platforms and through their own websites. That provides manufacturers with the opportunity to monitor the market, track infringers and make purchases of infringing product that can serve as the cornerstone of a lawsuit and a basis for preliminary injunctive relief.

Schneider: You cannot underestimate the value of expert testimony. In a patent infringement case, parties will typically have experts on a range of technical issues, as well as economists who evaluate damages and commercial success of the patent. Experts need to be able to write detailed reports, defend their positions in deposition and on cross examination, and, most importantly, explain their position to a layperson judge or jury.

Bell: Our advice is simple: make sure the damages claim is rooted in knowledge of the industry. The life sciences sector is complex, with many different participants and interests. To an outsider, the system can seem byzantine or counterintuitive, so a damages claim will not be effective unless it can explain both why the system works as it does and why the damages claim is consistent with that explanation. Participating companies already know the marketplace well, so harnessing market research and strategic documentation is essential for effective damages claims. A critical aspect is often understanding and explaining pricing. There are a variety of prices, price concessions and stakeholders in the life sciences sector, so when addressing 'price', it is essential to identify which price is charged to which party and when.

> **"The coming years are likely to bring a rise in biosimilar litigation, as the market for biologic drugs and biosimilars grows and matures."**
>
> *Heather M. Schneider, Willkie Farr & Gallagher LLP*

CD: Looking ahead, how do you expect the approach to IP infringement issues to evolve in the years ahead? Are there any particular trends and developments you expect to see in the life sciences space?

Yi: We expect that life sciences litigation in Canada will become more streamlined because of the more aggressive timelines under the new PMNOC regulations. We have seen courts increasingly encouraging parties to narrow issues and focus on the determinative issues, rather than taking a kitchen sink approach to IP litigation. However, there is also increased complexity that comes with litigating biologic and biosimilar products. Requirements imposed by Health Canada and other regulators in respect of these products will also dictate the nature of litigation relating to these products. For example, there is some ambiguity as to whether approval for some biosimilar products can proceed by way of an ANDS, or if biologic drugs can even act as Canadian reference products at all. This, in turn, will determine whether or not litigation relating to biosimilar products will fall within the scope of the PMNOC regulations at all. Finally, we expect that with an increase in digital health products, we may see more IP litigation involving medical devices in the near future.

Madigan: While the level of IP infringement litigation is likely to grow in the US, and globally, many IP infringement issues will simultaneously play out in other forums. For instance, while already experiencing exponential growth in litigation, biological products and biosimilars still present a significant challenge to lawmakers and regulators around the world. As makers of biologics will continue to vie for approval, others can be expected to pursue IPR review or pursue remedies available under the federal BPCIA. As for pharmaceuticals and medical devices, manufacturers are facing counterfeiting and diversion of historical proportions. While litigation will remain necessary and effective, many companies must be prepared to directly engage e-commerce sites to have them agree to remove infringing products from their platforms, eliminate suspicious items and banish bad actors.

Schneider: The coming years are likely to bring a rise in biosimilar litigation, as the market for biologic drugs and biosimilars grows and matures. We will continue to see patent battles played out on multiple fronts, including lawsuits in federal courts and parallel IPR proceedings. It will be interesting to see the development of damages law in the biosimilar space, if products come to market before litigation is concluded, similar to the occasional at-risk launches that occurred in the Hatch-Waxman space.

Bell: Looking ahead, we expect more development of infringement issues that arise in the context of biosimilars. This will include new wrinkles for established infringement considerations, such as how to identify use by indication or channel, or incremental sales due to improvements from a biobetter, new areas for infringement claims, like the focus on manufacturing issues, which are critical for the stable production of large-molecule therapies

and the overlap with competition issues, resulting from the network of IP protections covering the molecules, methods of use and manufacturing processes.

Zullow: We expect that growth in BPCIA litigation will continue. We also expect that there will be increasing numbers of patents relating to personalised medicine and increasing litigation relating to those patents. It will be interesting to see how Section 101 jurisprudence evolves and how it impacts the strategies used in such litigations. There will continue to be a focus on IPRs in the life sciences space. Petitioners may seek IPRs to clear out problematic patents prior to launching a product or to attack patents that have already been asserted against them in a patent litigation. The Patent Trial and Appeal Board (PTAB) recently issued updates to the AIA Trial Practice Guide, which appear patent-owner friendly. It will be interesting to see how these updates impact IPR practice moving forward. CD