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DISPUTES IN THE HEALTHCARE AND LIFE SCIENCES INDUSTRY

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MINI-ROUNDTABLE

DISPUTES IN THE HEALTHCARE AND LIFE SCIENCES INDUSTRY



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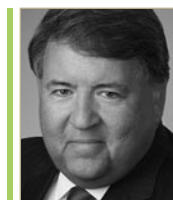
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Gregory K. Bell frequently testifies as an expert witness on damages in intellectual property, finance and antitrust litigation in courts and arbitration proceedings in North America, Europe and Australia. Dr Bell's business consulting engagements focus on the economics of business strategy, working with firms to develop sustainable competitive advantages in specific product markets.

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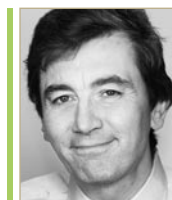
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Jürgen Dressel is responsible for the global litigation strategy at Novartis Pharma IP with focus on patents. In 2002 he joined the generics group in the Novartis patents department and in 2004 returned to the originator business and became responsible for patents primary care. From 2007 to 2014 he headed patent litigation outside the US, and in 2014 switched to his current role. Mr Dressel's main experience is preparing for and executing patent litigation between originators and generics.

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George B. Breen has been a litigator for over 25 years and Chairs the Health Care and Life Sciences practice group at Epstein Becker Green. Mr Breen is a member of a variety of professional organisations; he Chairs the Health Care Liability and Litigation Practice Group of the American Health Lawyers Association and is a past president and member of the board of directors of the District of Columbia Defense Lawyers Association. He is also a frequent lecturer and author on issues related to health care fraud and abuse, corporate compliance, and trial practice and is a member of Law 360's Health Editorial Advisory Board.

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Michael Frisby became a partner at Stevens & Bolton LLP in 1997, having trained in London. He deals with litigation, arbitration, adjudication and ADR and provides risk management advice. He is ranked as a "leading individual" by the legal directories. His experience includes handling contractual, regulatory and investigatory, product liability and fraud issues for life sciences clients. Mr Frisby is a CEDR Accredited Mediator and a Fellow of the Chartered Institute of Arbitrators.

CD: What types of dispute are commonly taking place in the healthcare and life sciences sector? Furthermore, what do you see as being the underlying cause of the disputes that have taken place in the sector in recent months?

Bell: Innovation is the lifeblood of the life sciences sector. It is the focus of value creation and it is at the heart of the sector's most significant disputes. Three types of these disputes tend to dominate life sciences: patent infringement issues, antitrust issues involving patent settlement agreements, and collaboration concerns. Patent disputes have been and remain a constant in the sector. Patent issues are likely to attain an even higher profile as large-molecule products, or biologics, mature and biosimilars begin to come to market. Biologics tend to be supported by a large portfolio of patents and operate under a fundamentally different regulatory regime than small-molecule products. Unlike conventional pharmaceuticals, there's no direct equivalent to the US 'Orange Book', which might make for a burdensome process to identify relevant patents. As the marketplace for biosimilars evolves, many of the more familiar metrics used in patent disputes – such as the rate of substitution and price differentials – are expected to be of little use. Interest in patent settlement deals remains high. These

issues go to the very heart of dispute resolution and the ability of parties to resolve patent disagreements without the burden of litigation. The Supreme Court's Actavis decision suggests a 'rule of reason' approach to the valuation of patent settlement

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*George B. Breen,
Epstein Becker & Green*

agreements and the potential for anti-competitive harm. As a result, we expect there to be continued litigation regarding the potential for anti-competitive behaviour in association with patent settlements and the related entry of generic and eventually biosimilar products.

Breen: Healthcare and life sciences companies continue to face exposure to lawsuits brought under the False Claims Act (FCA). The FCA is the US government's most powerful tool for combating fraud and applies to any project or program that receives federal funding. Violations of the FCA

can impose civil liability on any entity or person who submits, or causes to be submitted, a false or fraudulent claim for payment, or who creates, or causes to be created, a false statement material to a false or fraudulent claim. Under the FCA, private parties known as 'relators' may bring FCA claims on behalf of the government – these are 'qui tam actions' – and receive a varying percentage of any recovery, depending on whether the government elects to intervene in the lawsuit. Relators largely drive the number of cases filed, and there is plainly a financial incentive for them to do so. The US Department of Justice (DOJ) has said that its FCA 'agenda' is driven by cases identified by relators. Significantly, in fiscal year 2015, the DOJ reported that it had recovered more than \$2.8bn from lawsuits filed by relators and paid out \$597m to relators as their share of the funds recovered.

Dressel: In the pharma space we continue to see mainly patent disputes between originators and generic companies, much less so between originators. In order to justify and recoup investment into the lengthy, costly and risky research and development of medicines, pharmaceutical companies need to ensure market exclusivity for the limited time period provided by patents. Therefore, the originators often have to initiate patent infringement actions against generics, while the generics frequently want to clear the way by starting patent invalidation or declaratory non-infringement

actions. In the past, predominantly, blockbuster drugs were the target of generic competitors. However, in the meantime the exclusivities of smaller products have been challenged, and there has also been more and more patent litigation in emerging markets such as India and China. While of course there are still significant differences, the courts in these countries have become more familiar with technically complex patent matters and also more efficient and harmonised with global patent litigation standards.

Frisby: Commercial and IP disputes are the most common. IP is an important area for most life sciences companies and IP rights are often such valuable assets that all necessary steps will be taken to protect them across all jurisdictions. On the other side of the fence, a successful revocation action can offer substantial rewards and open the market. Recent developments have seen activity around skinny label and second medical use, prompted by a desire to maximise the return on molecules where there will have been a substantial amount invested to bring it to market in the first place. Commercial issues are a regular cause of disputes. General licensing and manufacturing problems, payment and issues arising from regulatory decisions all give rise to disputes and claims for damages. Public procurement and challenges to the award of tenders seems to be an area where disputes are arising more and more.

CD: Can you highlight any key cases in this sector, and what importance they hold?

Dressel: The following patent litigations from different jurisdictions are, in my opinion, particularly important for the pharmaceutical industry. In Europe, currently for the first time, the enforcement of so-called second medical use patents are being tested in court against so-called skinny-label generics in which patented indications have been deleted from the generics' label, but the drug nevertheless is used for the 'carved-out' indication. The outcomes have been mixed as expected, but will show whether clinical inventions can be effectively protected, thus providing sufficient incentive to invest in research in this important field of innovation – some exemplary cases are *Warner-Lambert vs. Actavis*, and *KKH vs. Pfizer*. In *Lexmark vs. Impression Products* the full panel of the US-Court of Appeal of the Federal Circuit confirmed that domestic patents are not automatically exhausted by the sale of cheaper goods abroad in lower-income countries, meaning they can still be enforced against importers, although the Supreme Court had decided differently for copyrights. In India, the Delhi High Court Division Bench reversed an earlier decision and thus upheld important globally acknowledged principles of patentability and infringement of pharmaceutical compound patents.

Frisby: The Consumer Rights Act 2015 has provisions that are intended to make it easier for companies to litigate on the ground of competition infringement, for example by introducing opt-out class actions and making it easier to bring standalone infringement actions. We will have to see whether in practice this increases the amount of litigation. In any event, competition law has been active with significant infringement decisions in the last few years and follow-on damages actions. There have been some significant decisions from the Supreme Court recently on commercial contract issues. *The Cavendish Square* and *Parking Eye* cases have formulated a new approach to penalties and the practical impact is likely to make it more difficult to successfully attack a liquidated damages clause as a penalty. The *Marks & Spencer* decision on implied terms points to a different approach to the question of whether terms should be implied into contracts.

Breen: Of significance to healthcare and life science companies this year is the Supreme Court's anticipated decision in *Universal Health Services vs. United States ex rel. Escobar* which will address the viability of the implied certification theory of FCA liability. Courts have recognised two types of actionable false claims – 'factually false claims' and 'legally false claims'. Legally false claims concern situations in which goods or services are provided in violation of a statute, regulation or other legal

requirement. There are two subcategories: express false certifications and implied false certifications. The validity of the implied false certification theory, namely, that submitting a claim impliedly certifies compliance with a law irrespective of an actual certification, has been hotly contested by entities working in these industries.

Bell: A couple of Supreme Court cases come to mind. The first is the *Actavis* case dealing with the rule of reason approach to the assessment of patent settlement agreements. The second is the *Caraco* case which has started to focus attention on the 'skinny labels' issue and the debate over incentives for continued development of new methods-of-use for established products. In the 'skinny labels' circumstance, patents protecting a molecule or method-of-use may expire, but other method-of-use patents remain valid. We are seeing more of these types of disputes. How they will be resolved and how incentives for the continued development of existing products for other uses may be established are likely to be key questions going forward. Part of the difficulty in highlighting specific cases is that more and more of the disputes in the life sciences sector are taking place in arbitration, where the

outcomes are often private and the public elements of decisions are not detailed.

CD: Are more parties turning to mediation or arbitration to resolve their disputes in this sector? Conversely, what steps should parties take if high-stakes litigation is the option pursued?

"There have been some significant decisions from the Supreme Court recently on commercial contract issues."

*Michael Frisby,
Stevens & Bolton LLP*

Breen: The past few years have seen some moderate growth in the use of alternative dispute resolution mechanisms (ADR) in actions brought under the FCA. Critically, these cases are highly fact-specific and often involve complex and detailed regulatory issues. The potential damages at issue in these cases are significant. The FCA provides for an award of treble damages in addition to penalties, per claim, currently ranging from \$5500 to \$11,000,

and an adverse verdict can have potentially ruinous consequences. As a result, not all cases are suitable for ADR.

Bell: The modern life sciences sector is a global market; accordingly, the structure, venue and scheduling flexibility offered by arbitration makes it an attractive option for dispute resolution. In particular, we are seeing more disputes related to commercially reasonable efforts in development or marketing collaborations being referred to arbitration. In the context of arbitration, we have seen witness conferencing, or 'hot-tubbing', to be an invaluable tool as business and economic issues come together. One of the advantages of pursuing high-stakes litigation is the broader discovery that tends to be allowed. Such broad discovery may be necessary to bring to light the full range of issues and their consequences.

Frisby: There certainly seems to have been a growth in international arbitration. It is generally easier to enforce an award internationally than a judgment. The courts often provide the best option for pre-emptive remedies prior to arbitration. IP infringement cases are generally dealt with through the courts. Mediation is valuable in both arbitration and litigation but used too early the issues may be too unclear or the parties not ready to settle, and if used too late significant costs might have been incurred; so timing is key. If litigation or arbitration is

contemplated, planning and project management is paramount, secure factual, expert and documentary evidence early, establish short and long term strategies, and get a clear and early understanding of strengths and weaknesses. Businesses should see the dispute as an extra part of their work stream for its duration. It will pay dividends in the long run.

Dressel: There is one jurisdiction, Portugal, where conflicts between originators and generics have to be resolved by arbitration, because the specialised, but unfortunately overwhelmed, commercial courts no longer take such patent cases. There the limitations of an arbitration system become apparent when there is only a limited number of arbitrators with suitable technical expertise who are appointed again and again by the same parties, which has led to a criticism of bias. In some other jurisdictions, like Switzerland, court mediation is an important element of patent litigation leading to high settlement rates at the Patent Court. While alternative dispute resolution mechanisms are not yet heavily used in patent litigation between originators and generics, and one can foresee many challenges which still would need to be worked out, they might gain importance – for example, in terminating patent litigation, damages calculations or patent disputes between originators.

CD: In your experience, what are some of the challenges that commonly arise in healthcare and life sciences disputes? Do

these issues influence the way disputes should be handled?

Frisby: Adopting a strategy that delivers speedy resolution is often a key requirement. In litigation, injunctive relief may be available and hearing times in the commercial court are pretty good at the moment. Recent initiatives, such as the shorter and flexible trials pilot scheme, offer a faster resolution for certain claims. Accessing documents can be difficult. The limited disclosure regime in arbitration can present problems or opportunities and may affect the way you run a case. Accessing documents held by a third party – the NHS, for example – can be tricky. Funding costs, managing adverse risk and cash flow is often a challenge but some of the litigation funding options are attractive. Working with funders means the client shares some of the upside but it can offer good value. In a complex area such as life sciences, expert evidence can be crucial. Choosing your expert carefully is vital.

Dressel: Some of the biggest challenges in pharmaceutical patent litigation are that frequently legal fields outside patent law need to be integrated early. One example is regulatory law for concurrent clinical data exclusivities or patent term extensions.

Another is competition law in view of ever closer, but unfortunately difficult to predict, scrutiny of patent enforcement and litigation settlements by antitrust

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*Gregory K. Bell,
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authorities in the absence of reliable case law. In view of global harmonisation, which as a matter of principle is welcome for avoiding national silos leading to even less predictable decisions, this trend is likely going to affect more and more countries. Another challenge is that, especially in emerging markets, the enforcement of patents is often heavily influenced by pricing and access-to-medicine discussions requiring a comprehensive strategy including communication from the start addressing these valid concerns, of which patent enforcement is only one aspect among many.

Bell: One of the greatest challenges in life sciences disputes relates to ‘prices’. Plaintiffs or

claimants often allege that pricing should have been different, often pointing to public statements from company officials or industry benchmarks for support. The difficulty, of course, is that there are many different price measures. Is it the price that the patient pays? Is it the price that the insurer pays? Is it the price that the retailer pays? Net prices matter, but different customers pay different net prices for good commercial reasons. Further, those prices tend to be kept confidential, again for good commercial reasons. Finally, the net prices paid may not be determined for several months after a transaction, as performance under rebate agreements is evaluated. Thus, though life sciences tends to be a sector where there is good data on sales volumes of competing products, it also tends to be a sector where there is often very poor data regarding the net prices of competing products paid by different stakeholders. Unfortunately, the variability in the definition and determination of 'price' has led to some poor scholarship and potentially errant verdicts.

Breen: One of the concerns for entities involved in FCA litigation is the potential repercussions associated with an unfavourable verdict. A finding of liability under the FCA can expose an individual or entity to possible exclusion from participation in federal healthcare programmes. In other words, loss

of an FCA case can lead to the loss of the ability of an individual or entity to submit bills, or cause bills to be submitted, to recover, or to receive, funds from any federal healthcare programme. This could include administrative, clerical and other activities not directly related to patient care or the provision of

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*Jürgen Dressel,
Novartis Pharma AG*

any healthcare related services. This result is often described as the 'atomic bomb', because it has the potential to destroy not only an entity's federal business but also its commercial business.

CD: What advice would you give parties involved in a dispute across multiple jurisdictions? How does this potentially complicate the process?

Bell: It is not uncommon for collaboration disputes to extend across multiple jurisdictions. These

disputes tend to end up in arbitration. Two aspects of these cases will be particularly important. First, it will be important to select experienced arbitrators who can assess not only the legal issues but also appreciate the different commercial issues that will arise. Second, it will be important to recognise the distinct aspects of the commercial market in the different jurisdictions and ensure that the analysis is conducted and the case presented with these differences in mind. One must be particularly careful with respect to leaping to broad generalisations across the set of jurisdictions without fully appreciating the differences among the markets and the consequent effects.

Breen: In connection with FCA cases, healthcare and life sciences entities often face the involvement of myriad state governments. This is due, in part, to a proliferation of enacted state FCAs. At present, 29 states and the District of Columbia have enacted FCAs. Significantly, in the context of Medicaid programs, which are funded jointly by the federal and applicable state government, states have been incentivised to enact a statute that provides the same level of relief as the federal FCA – as determined by the Department of Health and Human Services' Office of Inspector General (OIG). If a state enacts a statute approved by the OIG, the Deficit Reduction Act of 2005 provides that "the Federal medical assistance percentage" of any amounts recovered in an action brought under such a statute

will be "decreased by 10 percentage points". In short, states can recover an additional 10 percent of any recovery if they bring an action under a qualified FCA. Significantly, in attempting to resolve a combined federal and multistate dispute, it is critical that entities ensure that all involved parties are brought to the table; resolving a matter at the federal level and leaving open a multistate inquiry does not conclude the matter for the client. In many instances, it is the entity that needs to coordinate this effort – the various government agencies do not consistently do so.

Dressel: Most of the time, at least in the defence of market exclusivities for big products, there will be a great deal of parallel patent litigation occurring in several jurisdictions against multiple generics. This requires a sophisticated preparation and execution of a consistent, nevertheless flexible, global litigation strategy, early appointment of external counsels, early selection of technical experts, careful observation and analysis of individual markets, and close and continuous collaboration with the internal business partners, both in global and local functions. Often disputes will arise in grey areas of patent law where there is a genuine possibility of arguable cases for both sides. This leads to a high likelihood of conflicting decisions from different jurisdictions and therefore requires good expectation management with internal stakeholders.

Frisby: It is important to have a clear aim and strategy at the outset. Don't just plan how you are going to prove your claim and defeat any anticipated counterclaim but also think about enforcement. Geographically, where are the assets you plan to enforce against, and what is that jurisdiction's attitude to enforcing an award or a foreign judgment? The answer might cause you to rethink your strategy. Where multiple jurisdictions are available, forum shopping may be appropriate. Managing and coordinating the disputes across all jurisdictions is important. You need to have a consistent case but try and pick your fight; winning on a key issue in one jurisdiction could lead to a settlement of the whole dispute. Working with colleagues that you can trust and who know the market in their jurisdictions is also important. Time spent on carefully preparing a case and project management is a wise investment.

CD: In your opinion, how important is it for healthcare and life sciences companies to have effective strategies and contracts in place to mitigate the risk of disputes arising in the first place?

Frisby: It is important to consider where a business is vulnerable to disputes arising – it might be supply chain, IP or other issues that particularly affect a particular business. Try and identify your risks. In commercial contracts, dispute escalation

clauses can be useful, although personally I do not favour compulsory early mediation. An institutional arbitration provision is often well worth considering. On IP issues, recognise that if you seek to enforce there is a good chance you will be met with a revocation cross claim. It is sensible to prepare and anticipate that in all potential jurisdictions and plan for it before initiating action. A big threat to all businesses currently is cyber. Review and identify the risk to your business and put plans, systems and training in place and keep it under review. When a potential problem emerges, early and prompt specialist advice can make all the difference.

Dressel: In the pharmaceutical industry, effective contracts are essential, for example, for patent licences and any collaboration or agreement where IP might be generated. At least in the area of defending patent-based market exclusivity against generic companies, the originators must have an effective global patent enforcement strategy in place early on. However, in many respects conflicts leading to litigation still seem unavoidable due to opposing interests. While the originators fear the increasingly rapid market erosion caused by generics launching before the expiry of patent exclusivity, the generics generally strive to be the first on the market ahead of their generic competitors when they still can enjoy higher market share and margins. Additionally, the legal uncertainty around antitrust makes the contractual mitigation of these business risks, and

thus the avoidance or early termination of patent litigation, difficult.

Breen: Given the enforcement climate in which healthcare and life sciences companies operate, it is critical that an effective corporate compliance programme be in place to mitigate exposure to FCA cases. The DOJ places great emphasis on the role of corporate boards of directors as part of this process. At a minimum, this means that a board ought to ensure that there is in place a corporate reporting system to the board relating to compliance with applicable laws and benchmarks as to goals and functions for the compliance programme as described in the US Federal Sentencing Guidelines, OIG's voluntary compliance programme guidance documents, and published OIG Corporate Integrity Agreements. Also important is periodic documentation of employee training and quality control activities, a process to confirm that the scope and adequacy of the compliance programme is adaptive to changing conditions, a formal plan to stay up to date with the changing regulatory and legal compliance landscape and charters or similar documents defining the organisation's audit, compliance and legal functions. Firms

should also establish a formal process to ensure that appropriate access is granted to information needed by the audit, compliance and legal entities within the organisation, set clear expectations for receiving specific types of compliance information from members of the management team, and ensure regular comprehensive reports, including information about the organisation's risk mitigation and compliance efforts.

Bell: For better or worse, disputes are a mainstay of the life sciences industry and it would be negligent for a manufacturer to operate without strategies in place to reduce the likelihood of disputes arising or to address disputes efficiently and effectively once they arise. Nonetheless, no contract can be written to cover all possible exigencies; the best that one can do is exercise sound professional judgment in the drafting of contracts and in the execution of contractual responsibilities. It is important to minimise the distraction that disputes might provide for commercial operations. As a result, several companies have now taken to creating dossiers on their deals, setting aside valuation documentation in case an antitrust complaint drops over their transom several years later. 