Nicola Baker-Munton is the Chief Executive Officer of Stratagem Intellectual Property Management Limited which she founded in 1999. At Stratagem, Nicola has pioneered strategic management of IP through her strong commercial experience and belief that IP clients require expert advice as part of an overall defined plan for maximising the value of IP assets. Nicola is also an accredited mediator providing dispute resolution in the IP and general corporate arenas. Nicola has a joint degree in Biology and Biochemistry and qualified as a UK and European Patent Attorney at the Wellcome Foundation Ltd in 1991.

Colin Loveday is internationally recognised as an experienced litigation lawyer specialising in the defence of class actions, complex commercial litigation and product liability claims. He is one of the leaders of the Clayton Utz Class Actions team and head of the national Product Liability group. Colin has been continuously involved in the development of Australian class action practice and procedure for over 20 years. He has defended some of Australia’s most high-profile class actions involving complex consumer product and financial services claims. He has worked extensively with lawyers in other jurisdictions in the co-ordinated defence of multinational claims, developing international defence strategies and working with international expert witnesses. He also advises corporations and financial institutions on securities class actions and in regulatory investigations and inquiries.

Colin also has a broad experience advising manufacturing and pharmaceutical clients on regulatory requirements, labelling and advertising issues, product recalls and hazard alerts.

Emily Larose is a partner in the Litigation Group at Cassels Brock LLP in Toronto, Canada and a member of the firm’s cross-disciplinary Life Sciences team. She provides advice and representation to stakeholders in various regulated industries, with specific expertise working with Health Canada-regulated clients. Emily has experience advising on all manner of regulatory issues, risk management and policy matters and applies her regulatory expertise to product liability and class action litigation.
Selma Ünlü heads the life sciences regulation and IP practice of the firm.

She advises multinational innovator pharmaceutical companies on a wide range of matters including licensing agreements, pricing and reimbursement, marketing authorization procedures, clinical trials, observational study projects, pharmacovigilance, product recall and promotion practices.

She further handles all anti-corruption and compliance matters, creates compliance system in new start-ups and handles anti-corruption due diligences, give compliance trainings.

She also handles complex product liability actions caused by possible adverse effects of drugs and food products.

She formed medical device association and assisted the association as a legal counsel for many years. Mrs. Ünlü is currently the legal advisor to the Healthcare Products Association which is active in the areas of pharmaceuticals, medical devices and food supplements and assisting the association to comment on draft legislations and negotiate with MoH on draft legislation in the name of the association. She also chairs food supplement working group and co-chair medical device group in the Healthcare Products Association.

She is also a IP litigator and handle all life sciences related IP litigations including patent litigations as well together with her scientific team. She is regularly recognized as a leading IP litigator by WTR, Legal 500 and Chambers.

She is a frequent speaker at domestic and international conferences. She is the author of Turkey Chapter of The Life Sciences Review.

She holds an undergraduate degree in law from Marmara University Faculty of Law and a Diploma in Private International Law from Wolverhampton University, UK.
Biotechnology & Pharmaceutical Sector 2015

In our Biotechnology & Pharmaceuticals Roundtable we spoke with five experts from around the world to discuss the recent regulatory changes and interesting developments in their jurisdiction. Our chosen experts discuss how to build and monetise a patent portfolio, outline opportunities stemming from the shift in focus towards biologics, and comment on the challenges caused by an ageing population and growing life expectancy. Featured regions are: the United States, Canada, Turkey and Australia.

1. Who are the main regulators and what are the key legislations that apply to biotechnology & pharmaceuticals in your jurisdiction?

Larose: Drugs are primarily regulated in Canada by Health Canada under the Food and Drugs Act and the regulations thereto. Biologics are a specifically identified subcategory of drugs under the Food and Drugs Act regime, with special requirements.

Biotechnology in the food sector is regulated by the Canadian Food Inspection Agency under a number of legislative regimes including the Health of Animals Act, the Plant Protection Act, the Seeds Act, the Fertilizers Act, and the Fees Act. Biotechnology in pest control products is regulated by the Pest Management Regulatory Agency under the Pest Control Products Act.

Loveday: The Therapeutic Goods Administration (TGA) is responsible for regulating therapeutic goods in Australia including prescription medicines, vaccines, medical devices, blood and blood products. The TGA is part of the Australian Government Department of Health.

The key legislative instruments are the Therapeutic Goods Act 1989, the Therapeutic Goods Regulations 1990, the Therapeutic (Medical Devices) Regulations 2002, the Therapeutic Goods (Charges) Act 1989 and the Therapeutic Goods (Charges) Regulations 1990. There are also a raft of other legislative instruments that regulate such things as excluded goods, manufacturing principles and guidelines, pharmacopoeias, product information and advertising codes.

Unlu: All biotechnology and pharmaceuticals for human use, including the medicines developed on the basis of biotechnological methods, are governed by the Ministry of Health (“MoH”) and its affiliated institutions such as the Turkish Pharmaceuticals and Medical Devices Institution (“TITCK”). The key legislation applicable to pharmaceuticals for human use include without limitation the Law on Pharmaceuticals and Medical Preparations, Regulation Regarding Licensing of Pharmaceuticalcs for Human Use and Regulation Regarding Clinical Trials for Pharmaceuticals and Biological Products. Patent protection for pharmaceuticals which may be granted under the Decree Law No.551 Regarding Protection of Patent Rights (“Decree Law”) is further implemented by the Turkish Patent Institute (“TPI”) and courts.

O’Connell: Prescription medicines, medical devices and vitamins and minerals are all regulated by the Therapeutic Goods Administration (TGA) under the Therapeutic Goods Act 1989 (TG Act) and must be registered on the Australian Register of Therapeutic Goods (ARTG) before being supplied in Australia. Medicines Australia, which represents innovative pharmaceutical companies, also administers the Medicines Australia Code of Conduct which sets standards for the marketing and promotion of prescription medicines. The Medical Technology Association of Australia is an equivalent body for the medical technology industry. The Gene Technology Regulator also administers the Gene Technology Act 2000 which regulates the use of genetically modified organisms.

2. Can you talk us through the development & approval process for new products entering the market?

Larose: All drugs require pre-market approval for sale in Canada. In order to obtain this approval, sufficient scientific evidence must be collected to show that the drug in question is safe, efficacious and of suitable quality.

In the case of pre-market approval for biologics, additional chemistry and manufacturing information is required to establish the purity and quality of the product. This includes evidence to ensure that the biologic is not contaminated by an undesired microorganism or by another biologic. Biologic manufacturers must outline in detail the method of manufacture of the biologic and an inspection of the manufacturing facility, known as an On-Site Evaluation (OSE) is required.

Unlu: In accordance with the Licensing Regulation, all the medicinal products for human use is required to be licensed by the MoH before it can be marketed or distributed in Turkey. The general procedure is initiated with an application to the MoH with docu-
ments containing certain information about the applicant, product and product specifications or results of any clinical trials and the good manufacturing practice certificate. Under the Licensing Regulation, the duration for issuance of a marketing authorisation period is foreseen as maximum of 210 days, although this is not followed in practice. In particular, good manufacturing practice site inspection for imported products can delay obtaining marketing authorisation by four to five years. Once the marketing authorisation is obtained, it is further required to obtain a price and sales permit from the MoH before the relevant product can be offered to the market.

O’Connell: In Australia, therapeutic products (including medicines, medical devices and biologics) must not imported, exported, manufactured or supplied unless they are included on the Australian Register of Therapeutic goods (ARTG).

Before being included on the ARTG, the TGA will evaluate the medicine on the basis of quality data (including composition, batch consistency, stability, sterility and impurity content), pharmacology, toxicology and clinical data. Evaluations of over the counter (OTC) medicines vary depending on whether the medicine is considered a clone of another medicine, whether it complies with an existing monograph (for example, these exist for ibuprofen and paracetamol) or whether it is a new product which requires the submission of quality, safety and efficacy data. Similarly, medical devices are assessed, depending on their risk level, on the basis of quality, safety and performance data. It is also necessary to establish that appropriate systems are in place to monitor the ongoing performance and safety of the device. For biologics, proposed risk management systems, quality, efficacy and safety data, clinical and non-clinical development are all assessed, as well as the justification for using the biologic for the intended use.

Generic products are assessed for whether they have the same quantitative composition of therapeutically active substances (of similar quality) as the originator product, whether they have the same pharmaceutical form and whether the generic product is bio-equivalent and has an equivalent safety and efficacy profile. Similarly, for biosimilars, it is necessary to demonstrate that the biosimilar is “similar” in physicochemical, biological, immunological, safety and efficacy characteristics as the registered biological medicine, however because of inherent variability, a biosimilar manufacturer cannot rely wholly on the clinical data of the reference product and must submit its own clinical data.

3. Have there been any recent regulatory changes or interesting developments?

Larose: Fairly significant changes to Canada’s Food and Drugs Act were passed at the end of 2014. These amendments focus primarily on safety of therapeutic products once they are approved and on the market. Much of the detail of the implementation of these changes has been left to yet unpublished Regulations, there is no question that the amendments reflect a significant increase in Ministerial oversight and powers, including regarding recalls, ordering label changes, etc.

Other ongoing initiatives include an overhaul of Canada’s orphan drug framework and a change in Health Canada’s regulatory approach to commercial reprocessing of medical devices originally labelled for single use.

Unlu: The Clinical Trial Regulation Regarding Pharmaceuticals and Biological Products were amended in 2014 for the purpose of, among many others, covering the clinical trials for biological products. The Regulation Regarding Promotion of Medicines for Human Use has gone under minor amend-
lobbying activities conducted by the

generic pharmaceutical industry, such
amendments were removed. We will see the developments on the subject matter in the near future.

O’Connell: The shift in focus away from traditionally synthesised molecules to complex biologics derived from biological processes has been significant. The regulation of biosimilars in Australia is still in its early days, however EU Guidelines on the regulation of biosimilars have recently been adopted. Under these Guidelines, a sponsor of a biosimilar must submit comparative clinical (pharmacokinetic and pharmacodynamic) studies, non-clinical studies (relating to differences in response between the reference and biosimilar products), clinical safety and immunogenicity data and propose a post-marketing surveillance plan to monitor immunogenicity.

The Trans Pacific Partnership which is currently being negotiated may also lead to extended data-exclusivity periods. Currently Australia provides at least five years of data protection consistent with its obligations under the Australia-US Free Trade Agreement. An additional three years has been canvassed in Trans Pacific Partnership negotiations with 12 years potentially being imposed for biologics.

4. What systems can be put into place to minimise the risk of litigation?

Larose: We see a lot of spill-over of US-litigation in Canada in the pharmaceutical and biotechnology space. A key difference is that, in the product liability context, many of these will be in the form of proposed class action cases here. The most common theme of these cases is that the manufacturer provided insufficient information to the consumer (either directly or through a learned intermediary) about the risks of the product and therefore failed in its duty to warn. Ensuring that companies have robust pharmacovigilance programs in place is vital to being armed to defend these types of cases.

We have found it extremely beneficial when companies coordinate their US and Canadian litigation strategies. This allows us to ensure consistency in the defence approaches in the two jurisdictions and enables the company to take advantage of efficiencies and synergies.

Loveday: Risk management is a challenging and resource intensive area. Patient safety must always be the focus.

Exploring product quality and efficacy as well as potential safety issues are key in the drug development phase. Risks are managed at least in part by compliance with prescribed clinical trial guidelines and procedures which require ethics approval as well as regulator notification or approval.

It is only when real world experience of a drug or device is obtained that product safety issues often emerge, can be better understood and managed. How a company monitors and manages adverse events and its own record keeping has been a common feature of pharmaceutical product liability claims.

Unlu: Freedom-to-operate search (“FTO”) helps companies to detect third-party patents that prevent an invention’s commercial exploitation and provides the company whether their product may be subject to a potential infringement issue or not. FTO assessments may cover the sections of: the search criteria (keywords, IPC classes etc.); statement of the relevant documents, followed by a section of analysis of potential infringement vis-à-vis the pertinent documents.

Also, it should be known that there is not a patent linkage system which simply refers to a practice by some nation-
al regulatory authorities of denying approval of generic drugs that are linked to an existing patent. On the other hand, the MoH grants six years data exclusivity to the original manufacturers and as long as such period does not expire, the third parties should not make abridged applications to the MoH by relying on the pre-clinical and clinical data attached to the application for a marketing authorisation of an original medicinal product. Six years of protection starts from the first licensing date in the Customs Union Area. As long as the patent protection related to the original product continues even the data exclusively period ends for the original product, any further act such as sales permit, entry into list of reimbursement or releasing the generic product may constitute a patent infringement and therefore it would be prevented by obtaining preliminary injunction from the court. Therefore, the companies even obtains market exclusivity enhancing your own patent portfolio.

O’Connell: As an IP owner, it is imperative to have a clear IP strategy and rigorous policies for implementing that strategy. For example, it is important to have arrangements in place with employees and contractors to make sure that there is no dispute as to ownership of IP or opportunity for a would-be infringer to claim a lack of entitlement. Policies relating to documenting and reporting IP developed by employees and consultants and strict confidentiality obligations relating to new IP are also critical to ensure that IP can be properly protected and asserted. Counter-claims relating to invalidity often increase the cost and complexity of litigation.

The status of existing intellectual property (both that which is owned and that which is licensed from third parties) must also be periodically reviewed to ensure validity is maintained and any gaps or future gaps in IP protection are quickly identified. As part of this periodic review, it is also important to conduct regular IP searches in the field (for example, new patent filings) to ensure that developed products do not infringe third party IP. Monitoring competitor IP registrations is often prudent in this context, both to ensure competitors are not infringing owned intellectual property and to avoid future ventures infringing third party IP.

5. How has big pharma diversified strategies in order to combat the effects of the patent cliff?

Larose: In addition to mergers, acquisitions and licensing agreements, we have seen companies implementing various strategies to address end of patent life concerns in Canada. A number of companies have launched their own generic product lines (often under a separate corporate entity or corporate division). We are also increasingly seeing loyalty programs that encourage patients and their prescribers to continue with the branded drug, after it is off-patent.

While reverse-payment settlements (also known as “pay for delay” agreements) are certainly an option, statements recently issued by Canada’s anti-trust regulator may have a chilling effect. Specifically, in 2014, Canada’s Commissioner of Competition issued a white paper in which he stated that the Competition Bureau would closely scrutinize these types of arrangements under both the criminal and civil provisions of the Competition Act. Accordingly, companies seeking to implement a reverse-payment settlement may wish to obtain a formal written opinion from the Bureau.

Baker-Munton: There are a variety of ways of tackling product per se patent expiry. The key starts with planning the protection strategy from the start, in terms of product selection based on quality and length of patent cover, term adjustment (USA) term extension availability (up to five years) and reliance on alternative forms of protection such as data exclusivity. Filing follow-on patents covering new uses, doses, formulations, high yielding processes of manufacture etc., to reduce the ap-
peal of the primary market alone, can hugely extend the monopoly on the product: development of second and third generation products which enhance the primary offering can be critical – building a solid brand in the form of the trade mark can be incredibly effective to maintain brand loyalty.

O’Connell: As has been the trend globally, in Australia the principal strategy has been to in-license promising drug candidates and partner with other innovators to capitalise on potential innovation. Similarly, there has also been significant M&A activity as big pharma looks to strategic acquisitions to provide critical inventive stimulus and to bolster product pipelines. While opportunities are considered globally, there has been a significant focus on strategic investment in Asia. For example, biotechnology is a key area of investment for the Chinese Government and China has also seen a significant increase in private acquisitions and licensing in the biotechnology and pharmaceuticals sector.

Partnering opportunities provide important opportunities for smaller innovative companies with a focus on pharmaceuticals, biotechnology and medical devices to gain access to funds, resources and expertise to commercialise promising IP.

6. What strategies can be put into place to improve R&D productivity?

Loveday: The supply of medicines in Australia is principally funded by the Federal Government via the Pharmaceutical Benefits Scheme (PBS). Increasingly successive Federal Governments have sought ways to reduce the cost to Government of the PBS. This in turn places increasing economic pressure on companies and the need to factor in price disclosure provisions and devise novel pricing proposals into R&D initiatives.

O’Connell: The commercial value of R&D can be improved by having rigorous value assessment strategies early in the development process. Objectively applying criteria relating to, for example, economic potential or therapeutic outcome is one way of achieving this objective. Similarly, considering potential applications for innovations outside traditional or core fields can dramatically increase return on investment.

Collaborating with other, often smaller R&D companies and universities can also provide important R&D stimulus and improved productivity. For example, working closely with university research groups in core fields to identify promising research and innovation early can be a lucrative strategy both in relation to providing commercialisation opportunities and to enable diversification of in-house R&D.

In Australia, tax incentives also translate into added value for R&D investment dollars.

7. Are there any positives to be taken from the widespread patent expiration?

Baker-Munton: The effect of global patent expiry on a product, simply opens the market to the generics for that one product. The greatest effect is when a platform technology for example “humanised” antibodies or cell-based expression systems became, and in the future become, available. All astute biotech companies will plan carefully to assess the point at which they can enter the market with an offering, or to utilise the technology without the need for licence, and therefore the cost of paying royalties. Constructing contracts to ensure payments do not extend beyond patent expiry unless there is significant and valuable knowledge as part of the licence is critical and often not well negotiated.

O’Connell: From an economic perspective, patent expiry represents the end of a monopoly and the opening of the market to competition which has the potential to provide benefits for consumers. In particular, widespread patent expiry reduces the cost of publicly funded medicines.

Patent expiration also provides significant business opportunities for generic players and follow-on biotechnology companies. For example, key molecules coming off-patent represent an opening in the market for these molecules that generic pharmaceutical companies can capitalise on to increase their standing in the market and overall share of the generics business.

Molecules coming off patent have also provided an impetus for a shift in focus away from traditional molecules synthesised by chemical methods towards complex biologics derived from biological sources. Biologics (and biosimilars) represent a significant opportunity for investment and potentially represent a move away from the traditional originator – generic divide as “originator” companies increasingly look to competitors’ biologic products for opportunities to launch biosimilars.
8. What markets currently provide the best investment opportunities?

O’Connell: The shift in focus towards biologics represents a significant opportunity for investment in a new range of treatments. As the focus moves away from traditional “simple” compounds manufactured by synthetic processes towards complex molecules prepared by intricate biological processes, opportunities to capitalise on R&D and investment in IP protection in this field are increasing exponentially.

It has also been interesting to see the traditional role of the “generic” pharmaceutical company shift as competitive innovator companies identify the field of biologics and biosimilars (compounds that are “biosimilar”, but not “bioequivalent” to a reference innovative product) as fertile ground for launching follow on products after patent expiry.

9. How can companies build and monetise a patent portfolio to replicate the success of intellectual property in the technologies sector?

Baker-Munton: The same process of creating and commercialising a patent portfolio will apply regardless of sector.

The planning and management is key. It is necessary to consider the nature of the product or process, where it will be sold and manufactured, and where the competition will be active. Plan to build layers of protection in core territories thinner layers in territories of lower risk. With an existing portfolio analyse it; consider its strengths and weaknesses, determine what constitutes value in the portfolio. Avoid costly filings where they cannot succeed or filing in territories where they is no or limited threat. Consider whether you can exploit the portfolio in all application if not seek partners for full exploitation. As importantly consider if you can be blocked, as investment in patents is costly and if someone else can block you, the investment will be wasted.

O’Connell: Proper patent protection is key to building a strong IP portfolio. This requires sound IP policies to ensure that IP developed in-house is protected. These policies should include strict requirements for reporting inventions and maintaining the confidentiality of those inventions until patent protection is obtained. It is also critical to ensure that IP protection is as broad as possible, for example by obtaining broad patent protection that covers wide application of the invention in both current and potential markets.

A strong, strategically orientated patent portfolio is also the most effective way to attract investment funding to capitalise on the investment made in R&D and IP protection.

10. What role can mergers & acquisitions play in opening access to new markets?

Unlu: Turkey has been an attractive and active market in terms of mergers & acquisitions in the last 10 years in relation to various sectors including pharma. Transactions included both acquisition of national Turkish companies by global pharma leaders and implementation of global mergers & acquisition transactions which were effected in various countries including Turkey. Mergers & acquisitions provide great opportunities for opening access to new markets in many cases. Initially, when the transactions involve one foreign company acquiring a Turkish target company, the purchaser mostly benefit from the target company’s existing market experience and establishment for entering into Turkish market. Especially, the expanded sales forces and distribution channels support management of enlarged product portfolios following closing of transactions.

Baker-Munton: A merger or acquisition seeks to unite the resources, assets and knowledge of two parties for the purpose of creating something of greater value than the two parts. This will only be achieved if there is clear complementarity between those assets leading to potential synergy. Intellectual property in the form of patents, designs, trademarks, copyright, know-how and materials are often key assets contributing to that complementarity. The use of a combined portfolio of Intellectual Property can, directly through the acquisition remove competitors from a market. The combined portfolio may deter new entrants or mean existing competitors do not get financed, but in many cases it may enable the leveraging of the existing IP in new fields and by providing an effective monopoly it should open up new markets.

O’Connell: Strategic M&A provides an opportunity to broaden therapeutic focus and expand existing R&D programs to access new or complementary markets. With the advent of widespread patent expiration for blockbuster drugs, pharmaceutical companies are under increasing pressure to provide pipeline revenue streams. Strategic
acquisitions in new markets (for example, acquisition of new products in various stages of development) or complementary therapeutic fields can provide return on investment that is less costly and attracts a lower risk profile than significant investment in early stage R&D relating to unproven therapies.

For small and medium size companies with a small number of promising products, M&A activity can offer important access to expertise and resources to commercialise those products more cost effectively.

11. How do demographic trends and new disease patterns affect the future direction of biotechnology and pharmaceuticals?

Unlu: Statistics show that Turkey has an ageing population which increases the healthcare needs and expenses further. Therefore, the official policies focus on decreasing the healthcare expenses in various ways such as increasing the awareness of the public in terms of responsible consumption of pharmaceuticals, supporting local manufacturing of pharmaceuticals and implementing lower exchange currencies in fixing the prices of imported products. New disease patterns also affect the future direction, such as rare diseases which require treatment with orphan drugs. Turkey does not have systematic data gathered with respect to prevalence of rare diseases initiated by the State, yet the studies and screenings conducted by various pharma companies show that Turkish population is inclined to be diagnosed with various rare diseases. The State aims to focus on this area in the long run by spotting the demographic results and enacting a specific legislation for management of orphan drugs, yet this is not expected to be achieved in near future. The new disease patterns and demographic trends also affect the future direction of biotechnology as they increase the need to development of biotechnology based solution in additional to conventional products and treatment methods.

O’Connell: Most significantly, the ageing population and increased life expectancies will significantly increase demand for healthcare generally and medicines in particular. Similarly, there is likely to be an increased demand for treatment of age-related disease states such as arthritis, Alzheimer’s, cardiovascular disease and osteoporosis. With increasing obesity, treatments for type-2 diabetes are also likely to be highly sought after.

Population growth and increased wealth in developing markets such as China and India are also likely to give rise to a dramatic increase in demand for pharmaceuticals and biotechnological products. Strategies for doing business, and importantly, protecting IP in these markets is likely to be critical.

12. What key trends do you expect to see over the coming year and in an ideal world what would you like to see implemented or changed?

Larose: The development of new regulations to the amended Food and Drugs Act will be very closely watched by the Canadian biotechnology and pharmaceutical community.

In terms of what I’d like to see – I am really interested in the development of Canada’s orphan drug regime. Health Canada defines these as drugs used to treat life-threatening, seriously debilitating, or serious chronic conditions that affect a very small number of patients.

Unlike a lot of other countries, Canada does not have a separate regulation to address access to orphan drugs that have not gone through the usual new drug review and approval process.

Right now, in order for a patient to have access to an unapproved drug, a physician must make a patient-specific application under the Special Access Program. Back in 2012, Health Canada advised that a new orphan drug approach was coming to improve access to orphan drugs. I would love to see this move forward to implementation in the next 12 months.

Loveday: Pricing and reimbursement issues have been and will continue to be challenging. The PBS has provided Australians with access to high quality and important medicines. However, with a very large budget deficit to address, cuts to the PBS are inevitable and with this comes troubling access issues.

Unlu: Turkey will go through elections at the beginning of this June and many developments such as legislation changes have been awaiting completion of these elections. Therefore, no major change is expected until the end of the first half of the year. Afterwards, depending on the new structure of the political powers, there may be certain improvement in the long-awaited areas such as the enactment of the Draft Patent Law. Moreover, the official healthcare policies of the State may be subject to certain changes which
we still expect to focus on decreasing the healthcare expenses. In an ideal world, we would like to see enactment of the Draft Patent Law as soon as possible with going under certain revisions to eliminate the current shortcomings of the draft. Additionally, we would like the MoH to take effective actions in various matters which the pharma industry has long been suffering from such as the exchange rates applied in pricing of the imported products, orphan drugs, and inconsistent implementations of the MoH in relation to issuance of marketing authorisations.

**Baker-Munton:** An evident key trend in patenting is reduced scope of geographical coverage based on cost, in particular of translation. Most companies need to be thinking about reducing the size of the patent specification through more careful drafting as this will mean protection can be afforded in more territories and for more inventions – one large expensive patent family does not provide the matrix of cover that is more robust. Planning the patent families that warrant global coverage based on where the products will be sold/ processes run, where competitors may be active, where inventors may be based and where deals based on the patents may need to be made, will help focus. Other changes it would good to see would be clearer protection for digital health products; a huge and emerging market that is hard to protect using current forms of IP, and tax savings earlier in the process (through R&D tax credits for IP) not just for the larger companies through Patent Box which is a tax reduction applied to profit.

**O’Connell:** The regulation of biosimilars is likely to develop significantly as an increasing number of biologics come off patent. In Australia, the regulatory position relating to biosimilars is being closely watched. In order to attract investment in the Australian pharmaceutical and biotechnology industries, more certainty around the approval process for biosimilars is required. Similarly, a clear position relating to the likely treatment of biosimilars under the Pharmaceutical Benefits Scheme is necessary, and more specifically, whether there will be an opportunity for biosimilars to be substituted at pharmacy level for the reference biologic. Currently, Australian regulators have indicated that substitution of biological reference products with a biosimilar is not appropriate without a physician’s approval because the inherent variability between biosimilars and the reference biologic (and indeed inherent in the biologic itself) means that the safety and efficacy profile of the reference product may not necessarily apply to the biosimilar.

The outcome of the Trans Pacific Partnership negotiations in relation to increasing data protection periods (from the current five years) could also dramatically affect both reference biologic and biosimilar manufacturers.