



**Nicholas Tyacke**

**Partner**

nicholas.tyacke@dlapiper.com

**Sydney**

T: +61 2 9286 8502

M +61 478 491 092

Nicholas Tyacke is a leading patent and intellectual property lawyer and litigator. He is dual-qualified (Australia and the United States) and offers a level of experience unique to the Australian market, with over 25 years' experience advising and acting for many of the world's leading life sciences and technology companies in Australia and the United States with respect to their patent, intellectual property and regulatory issues and disputes. Nicholas heads DLA Piper's Life Sciences practice in both Australia and the Asia-Pacific, and leads DLA Piper's Life Sciences Intellectual Property practice in Australia.

Nicholas advises clients with respect to all aspects of patent law, particularly in relation to patent issues and disputes in the life sciences and technology sectors, as well as copyright and trade mark law, particularly as they relate to the internet and high technology.

Nicholas has been involved in a number of Australia's and the United States' most significant patent cases and has established a reputation acting as a member of global teams representing clients in complex, multi-jurisdictional matters. He has advised and acted for many of the world's leading life sciences companies in Hatch-Waxman patent disputes in the United States and in the Australian component of equivalent complex patent litigation. He has acted for clients in patent disputes before trial courts, intermediate appeal courts (the United States Court of Appeals for the Federal Circuit and the Full Court of the Federal Court of Australia) and final appeal courts (the Supreme Court of the United States and the High Court of Australia) in both jurisdictions.

Nicholas also advises life sciences companies on a broad range of regulatory issues including registration of pharmaceuticals and medical devices and technologies, promotion of products, pricing, compliance with industry codes, and clinical trials.

Nicholas is also a technophile and he has used his knowledge and understanding of technology to help numerous clients resolve multi-million dollar technology related legal disputes.

- Intellectual Property and Technology
- Patent Litigation
- Trademark and Copyright
  
- Life Sciences
- Technology

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**Patents - Life Sciences**

- Advised and acted for Wyeth in one of the largest and most complex life sciences patent litigations ever in Australia, involving three separate proceedings against eight separate parties (including the Commonwealth of Australia) in respect of their claims on undertakings as to damages ordered in return for interlocutory injunctions preventing the launch of generic extended release venlafaxine products. These three cases, which involved a six week trial, were the first cases in Australia to address claims on undertakings as to damages in pharmaceutical patent litigation by generic pharmaceutical companies, their suppliers and the Commonwealth of Australia.
- Advising and acting for Pfizer in Australia's first biologic / biosimilar patent dispute, as well as several other patent disputes, involving six adverse parties, relating to Pfizer's patents covering the process for producing etanercept, the active ingredient in Pfizer's blockbuster biological medicine Enbrel®. We have already achieved success in this ongoing matter before Australia's highest court.
- Advising and acting for Israeli innovator pharmaceutical company, Neurim Pharmaceuticals 1991 (Ltd), in patent amendment, infringement and revocation proceedings against two generic pharmaceutical companies in relation to Neurim's patent covering Neurim's prolonged release melatonin medication for the treatment of primary insomnia characterised by non-restorative sleep. This ongoing case has already established new law in several areas, including in relation to patent amendment. We worked as part of a global team, managing and coordinating strategy across numerous jurisdictions.
- Advising and acting for Pfizer and Pharmacia in patent infringement and revocation proceedings in relation to Pharmacia's patent covering the parecoxib reconstitutable powder injectable formulation for Pfizer's Dynastat® pain medicine.
- Advised and acted for Warner-Lambert in patent infringement and revocation proceedings in relation to Warner-Lambert's patents relating to pregabalin, the active ingredient in the blockbuster pain medicine Lyrica®. We worked as a part of a global team in this multi-jurisdictional patent dispute.
- Advised and acted for Pfizer in patent infringement and revocation proceedings with respect to Pfizer's patents relating to sildenafil, the active ingredient in its blockbuster erectile dysfunction medication Viagra®. We worked as a part of a global team in this multi-jurisdictional patent dispute.
- Advised and acted for an American global pharmaceutical company in relation to patent issues relating to a number of the company's products. This included acting for the company in multiple proceedings in Australia, and co-ordinating proceedings in other Asia-Pacific jurisdictions, as part of a global team involved in multi-jurisdictional patent infringement and revocation proceedings with respect to a family of patents relating to the company's successful anti-cancer treatment product. In the main Australian proceedings, the company successfully resisted a challenge to the patent term extension of one of the patents-in-suit, successfully amended the claims of that patent in the course of litigation and successfully obtained an interlocutory (preliminary) injunction enjoining the marketing of two generic competitors' products. The proceedings established an important set of guiding principles in Australia for determining when an interlocutory injunction will be granted in pharmaceutical patent infringement cases.
- Advising and acting for Neurim in the Australian Patent Office in patent opposition proceedings relating to Neurim's application for a patent for a novel prolonged release mini-tablet melatonin formulation.
- Advising and acting for many of the world's top multinational innovator pharmaceutical companies on patent issues and disputes relating to a wide variety of their products including anti-cancer medications, proton pump inhibitors, selective serotonin reuptake inhibitors, calcium channel blockers, selective 5-HT<sub>3</sub> receptor antagonists, JAK inhibitors, statins, pain medications, atypical antipsychotics, antihistamines, arthritis medications, anti-fungal medications, smoking cessation medications, vaccines, antibiotics, and insulin.
- Acted for many of the world's top multinational innovator pharmaceutical companies in patent disputes against almost 40 generic pharmaceutical companies, including almost every generic pharmaceutical company in Australia.
- Advising and acting for many of the world's top multinational innovator pharmaceutical companies on patent - including patent term extension, patent portfolio management and patent litigation - and non-patent (including data exclusivity) strategies to maximise the commercial life of their product portfolio.
- Advised the world leader in implantable hearing solutions on a number of patent issues regarding a family of electrical and mechanical engineering patents in the field of hearing aids and hearing implants.
- Advised and negotiated on behalf of a leading biotechnology company in relation to the licensing of a family of RNAi patents.
- Advised and acted for a leading biotechnology company in a Federal Court appeal of a patent office opposition regarding a patent for the perfusion culturing of cells.
- Acted for one of the world's premier veterinary pharmaceutical companies in an appeal from the decision of the Australian Patent Office relating to a patent directed to an equine anthelmintic formulation.

## Patents - Technology

- Acted for eight of the world's leading manufacturers of bar code scanning technology and one of the world's leading manufacturers of computer vision technology in a patent infringement action brought by a US inventor in relation to a family of patents directed to bar code scanning and machine vision technology. The case, which was appealed to the United States Supreme Court, established an important new defence to patent infringement.
- Advised several leading telecommunication companies on a number of patent issues relating to a variety of telecommunication technologies.
- Acted in patent infringement proceedings of an innovation patent directed to a real time pre-paid call access system.

### Copyright / Technology

- Acted in one of Australia's largest copyright and software licensing disputes, involving one of Australia's largest computer networks and spanning several decades of computer and network technology.

### Regulatory - Life Sciences

- Advising numerous life sciences companies on a broad range of regulatory issues including registration of pharmaceuticals and medical devices and technologies, promotion of products, compliance with industry codes, and clinical trials.

## CREDENTIALS

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### Professional Qualifications

- Solicitor of the Supreme Court of New South Wales, 1992
- Solicitor of the High Court of Australia, 1992

### Prior Experience

Prior to returning to Australia, Nicholas practised for seven years in New York at one of the United States' largest and leading specialist patent litigation law firms.

### Recognitions

- Chambers Life Sciences - Asia-Pacific and Australia Guides - Band 2.
- Chambers (Global) Intellectual Property and Life Sciences Guides – Foreign Expertise in USA
- IAM Patent 1000 (Silver)
- Managing IP Stars (notable practitioner)

Nicholas leads the Asia Pacific life sciences team, which is currently ranked in Chambers as Band 1

Feedback on Nicholas includes

*"One of the very best practitioners in the country", polished courtroom performer Nicholas Tyacke has practised extensively in the United States as well as Australia. Tyacke is especially accomplished in life sciences matters."* IAM Patent 1000

*"He has remarkable skill and expertise and is particularly good with US clients as he has experience in USA IP litigation and understands well the issues which may be important for a US client in Australia. He is particularly responsive to the client's needs and there has not been a question after years of being with him that he has not responded to thoughtfully and right away."* Chambers Intellectual Property and Life Sciences guides

*"Hotshot litigator Nicholas Tyacke ... is a prime pick for pharmaceutical multinationals seeking someone to run the distance in cross-border clashes"* IAM Patent 1000

*"He's got a very good understanding of the science, and he's very good at working with offshore clients. He seems to be an indefatigable worker – he's available nearly the whole time and is working in each of the time zones needed in order to liaise and speak to the lawyers working in different jurisdictions. He's very good at running a number of balls at the same time."* Chambers Intellectual Property and Life Sciences guides

*"He is very analytical and dedicated. Also, he is ... very responsive, and if he doesn't agree with you he'll tell you exactly why and he'll discuss it with us. I think he is first class. He is so creative and always sees the footfalls before you enter – he is proactive.."* Chambers Intellectual Property and Life Sciences guides

*"Nick is a very good patent lawyer and he has a good grasp of the legal side of that area of the law, but he also gets very much into the technical side, more so than lawyers often do here in Australia. ... He throws himself 110% into a matter. He's great to work with."* Chambers Intellectual Property and Life Sciences guides

## Courts

- Supreme Court of New York
- Supreme Court of the United States
- United States Court of Appeals for the Federal Circuit
- United States Court of Appeals for the Second Circuit
- United States District Court for the Eastern District of New York
- United States District Court for the Southern District of New York

## Memberships

- Copyright Society of Australia
- Computer Law Association Inc
- International Trade Mark Association
- Intellectual Property Society of Australia and New Zealand
- American Intellectual Property Law Association

## INSIGHTS

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Regular contributor to DLA Piper's life sciences page.

## Publications

### **Patent eligibility of diagnostic methods in Australia confirmed: *Ariosa Diagnostics, Inc v Sequenom, Inc* [2021] FCAFC 101**

29 June 2021

For many years, the following question awaited judicial determination under Australian law: is a DNA-based diagnostic method patent eligible subject matter? The Full Court of the Federal Court of Australia has confirmed that diagnostic methods involving the practical application of "natural phenomena" can be patentable inventions in Australia.

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### **Practical Law Life Sciences Australian chapter**

15 March 2021

DLA Piper Life Sciences sector Australia authored Thomson Reuters Practical Law Company's 2019/2020 multi-jurisdictional guide for Life Sciences in areas of medical product regulation, product liability, pharmaceutical IP and competition

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### **New hope for the patentability of computer implemented inventions in Australia?**

22 June 2020

There have been a string of cases in Australia looking at whether computer implemented inventions (including software) should be patentable. Until now the news has been bad for start ups, software developers and those with online products and services, with the Courts finding such inventions unpatentable. There may now be a way forward.

So why did Aristocrat succeed where Rokt failed? What was it about Aristocrat's patent that caused the judge to find that it contained patentable subject matter? And what does the future now look like for computer implemented patents in Australia?

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## Is your computer implemented method now patentable in Australia?

28 May 2020

On 21 May 2020 the Full Federal Court of Australia handed down the much anticipated decision in *Commissioner of Patents v Rokt Pte Ltd* [2020] FCAFC 86. The Full Court, found that a scheme, even if new and ingenious, cannot be made patentable subject matter merely because it can or must be implemented using generic computer technology. This further confirmed the position on patentability of computer implemented inventions previously adopted by the Full Court in *Encompass Corporation Pty Ltd v InfoTrack Pty Ltd* [2019] FCAFC 161.

If you develop software, or work with companies that develop software, you should be aware of this decision and the impact it may have on the ability to obtain patents in future.

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## New TGA transparency measures for prescription medicines in Australia

15 April 2020

In a development that has the potential to have a significant impact on the life sciences sector in Australia, including patent litigation in that sector, the Australian Government has recently approved the following two enhanced transparency measures for prescription medicines under evaluation by the Therapeutic Goods Administration (TGA). The TGA is seeking feedback until 9 June 2020 in relation to the implementation of these measures. How much of an impact these transparency measures will have will depend on the details of their implementation.

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## Practical Law Life Sciences Australian chapter

27 February 2020

DLA Piper Life Sciences sector authored Thomson Reuters Practical Law Company's 2018/2019 multi-jurisdictional guide for Life Sciences in areas of distributing and marketing of drugs, product regulation, product liability and competition.

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Nicholas has written extensively about patent, intellectual property and life sciences issues. He is a regular contributor to Thomson Reuters Practical Law Life Sciences Australian chapters and a regular contributor to Cortex (the DLA Piper life sciences blog).

## Events

Nicholas regularly presents on patent, intellectual property and life sciences issues.