

Sector Track Record:

Human Health

The human health sector is a very large sector, covering small molecule as well as biological therapeutics, and vaccines. Other related sub-sectors include drug delivery technologies, clinical diagnostics, medical devices and instrumentation, biotechnology and clinical trials. The pharmaceutical sector is dominated by a number of very large multinational companies, with a number of important regional companies and a large number of SMEs making up a smaller but still significant proportion of the overall market.

Sector lead: **Ronnie Georghiou**

Following over six years of managing late-stage global clinical trials with big pharma, Ronnie Georghiou joined IP Pragmatics in 2007. To date he has led two long-term commercialisation projects within public research institutes, helped establish 3 Start-up companies and provided COO, business development and competitive intelligence and licensing support to a number of SMEs, government research and university clients. He has been directly involved in securing >£5M (public and private funding) for client commercialisation opportunities Worldwide. From Oct 2010 to Jan 2015, Ronnie successfully established the Australia & New Zealand subsidiary office in Sydney that continues to operate and grow today. His specific focus is on commercialising products and services that include Pharma, Biotech, Medical Device, Diagnostic, OTC and FMCG opportunities. He holds a BSc (Hons) in Medical Biochemistry from University of London and an MBA from Imperial College.

Recent Experience:

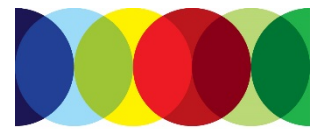
This section highlights some of the recent Human Health projects and partnerships that IP Pragmatics has been directly involved with:

- Supporting the development of a business plan, start-up and fundraise of a pharma SME and appointed COO to set up and coordinate a Ph2a Proof-of-Concept clinical trial.
- Leading business development and term sheet negotiations with a NASDAQ listed company on behalf of an SME client.
- Supporting the due diligence and negotiation of the licensing of a diagnostic device platform, giving an Australian company the exclusive worldwide rights to the human health applications for a disposable point-of-care diagnostic device and associated TB test, in a deal worth Aus\$ 0.5million.
- Leading contract negotiations on behalf of big pharma clients under the Innovative Medicine's Initiative for 20 IMI projects valued at €5-10 million each.
- Advising on the operations and business development of a pharma Market Access services business.



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- Helping a UK client to negotiate and secure a licence from Eiken Chemical Company to ensure freedom to operate with their isothermal molecular assays, including accompanying the client to meetings in Japan.
- Undertaking the initial business case and proof of concept fund raising which led to the successful formation of a new spinout company, ProKyma Limited, which provides instrumentation and consumables to the In Vitro Diagnostics sector.
- Undertaking valuations for a meningitis B vaccine clinical phase candidate and a respiratory syncytial virus pre-clinical vaccine candidate for a Dutch government institute, including providing business development support to help the client complete a major joint development and licensing agreement.



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Technology Sample Clients

Pharmaceuticals	Glaxosmithkline and Pfizer Glide Pharma InterAct Partnership Investment Company The Babraham Institute Cell Medica BlackStar Ventures Dolon Ltd Medical Warwick Ventures	Durham University Monash University Japan IP Imperial College Institute Cancer Research OzStar Therapeutics Pty Ltd TCS Cellworks University of Newcastle Walter and Eliza Hall Institute of
Human vaccines	Alta Innovations Lonza Ploughshare Innovations Public Health England	Queens University Belfast RIVM, Netherlands Univ Birmingham Warsaw Institute
Medical devices	Auckland University of Technology (AUT) Bangor University Bristol University Glyndwr University	Heriot Watt MediWise Ulster University University College Dublin
Diagnostics	Otago Innovation (NZ) Atomo Diagnostics Momentum Biosciences Tyrian Diagnostics Ltd	
Biopharmaceuticals	Murdoch Childrens Research Insitute, Melbourne University of Glasgow Premas Biotech	
Natural bioactives	Aber University Australian Bioactives Campus Kjeller Centre for Process Innovation	Leicester University Marinova Ltd Pennog Limited Royal Botanic Gardens Kew

Case Studies

Glaxosmithkline and Pfizer

The Innovative Medicine's Initiative (IMI) (www.imi.europa.eu) is a pan European, €2 billion initiative funded jointly by the EU and the European Federation of Pharmaceutical Industries and Associations (EFPIA), designed to reduce bottlenecks in drug discovery and development. Annually IMI launches a number of projects each involving ~ 20 partners comprising Universities, SME's and EFPIA. IP Pragmatics provided contract negotiation support to two large pharmaceutical companies on a number of strategic collaboration, evaluation and licensing deals. We liaised closely with the company's scientific, legal, patents and compliance groups to ensure alignment with company objectives whilst maintaining an appreciation of the position of the other parties.

IP Pragmatics has led contract negotiations on behalf of big pharma clients since the initiative was launched, totalling 20 IMI projects valued at €5-10 million each. Our experience in working with pharma, SME and academic clients means we have an in-depth understanding of the IP and scientific drivers from the perspective of all these organisations, and are therefore able to offer pragmatic solutions with a win-win solution for all involved. Our expertise in this area has been reflected in finalisation of many different consortia IMI agreements, repeat business from our large pharma clients and a large network generated through interaction with the multitude of partners involved in IMI.

Murdoch Childrens Research Institute (MCRI)

The Murdoch Childrens Research Institute (MCRI) has made a significant clinical breakthrough for children suffering from peanut allergies. By combining a peanut allergen immunotherapy with the administration of probiotics, researchers at MCRI have been able to induce desensitization and sustained unresponsiveness in children with peanut allergy.

To date, MCRI has evaluated the effectiveness of this combination treatment in a 60 patient, ethics approved randomised controlled clinical trial with an overall duration of intervention of 18 months. Both primary and secondary end points were met for this clinical trial. The key market challenge will be how government regulators and the market will view this opportunity. Together with a regulatory advisor, IP Pragmatics has supported MCRI to understand the therapeutic opportunity in the context of FDA guidelines and the implications from a product manufacturing and R&D perspective.

These findings have fed into a funding application to develop a 'regulatory-ready' treatment regimen for subsequent clinical validation and commercialisation.



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Glide Pharma

IP Pragmatics worked with Glide Pharma, a speciality pharma company, to provide competitive intelligence and business development support for a specific application of its novel drug delivery platform technology in the diabetes market. The Board of this SME was keen to characterise this market opportunity and identify partnering options for product development. IPP delivered a comprehensive strategic analysis that included:

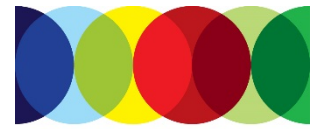
- Market Assessment – Market Size, Geography, Key Drivers, Positive and Negative Market Trends
- Competitive &/or Partnering Landscape – key companies to consider as potential partners or competitors in the market, generics competitors, pricing considerations.
- Evaluation of key players
- Evaluation of in-house development

IPP brought its industry experience, along with a combination of desk research (i.e. public records, news reports, subscription competitive intelligence tools, subscription patent searching & mapping tool) and continual dialogue with key company staff members to create a relevant and practical strategy document. The result was a realistic overview of the opportunity and relevant strategic considerations, together with a series of recommendations for next steps which were subsequently taken forward to realise this specific market application of the company's drug delivery platform technology.

InterAct Partnership

IP Pragmatics ran the InterAct Project (www.interactpartnership.co.uk) from 2004 to 2011. The project is a unique partnership between six leading UK government research organisations covering amongst other areas the commercialisation of environment, animal health, human health, aquaculture and agriculture related research. IP Pragmatics' role has been to assist the partners with a bottom-up, technology led and a top-down, market led analysis of new commercialisation opportunities that could be created through combining the partners' IP, know-how and R&D services. Over the project's past 6 years IPP has helped the InterAct partners identify more than 220 potential opportunities. These opportunities ranged from new spin-out company concepts, new product licenses and new enhanced commercial service or R&D offerings. These opportunities were initially assessed using published, proprietary and direct market/industry contacts to identify if a market existed for the product or service. Using this analysis around half of the opportunities were progressed to more detailed market entry strategy analysis including identification of partners and competitors.

IP Pragmatics has also been actively involved in the subsequent exploitation of these opportunities through: business planning and fund raising for new ventures; marketing and negotiation of new licenses; business planning and marketing of new commercial service offerings across a range of industries including the animal health sector. To date 46 exploitation vehicles have resulted from this work; a number of which are with companies in the human health and diagnostics sector.



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Investment Company

An independent investment and financial advisory company required independent valuations of three potential investment opportunities. These investments involved the purchase of intellectual property relating to therapeutic products in clinical development for psoriasis and for hepatitis C. The company approached IP Pragmatics to provide detailed commercial valuations of the therapeutics at 'arms-length' to satisfy their investors. The valuations were carried out on a tight timetable as there was a time constraint associated with when the investments could be made. The analysis began with an overview of each disease area, the current and predicted future market and competitor products. The company development plans were also examined. After an initial analysis of the information supplied, we drafted a series of questions for discussion with the companies developing the therapeutics. These discussions allowed IPP to gain deeper insight into the products and enabled an informed assessment of the commercial value of the products. The valuations were carried out using a risk-adjusted net present value (rNPV) analysis as well as a review of comparable deals:

In each case, a comprehensive report was provided to enable the company to make a decision about whether to go ahead with their investments or not. The decision was made to invest in one of the opportunities.

Health Protection Agency (HPA)

IP Pragmatics has worked with the HPA including the Health Protection Culture Collections (<http://www.hpacultures.org.uk/>) over several years (from 2004), particularly through the InterAct project (see above) and a 4 year initiative (HPA Capacity Building) to enhance the HPA's ability to identify, commercialise exploit their products and services. HPACC includes the European Collection of Cell Cultures, one of the largest suppliers of cell cultures to researchers (both academic and commercial) in Europe. With respect to the HPACC, we assisted with reviewing and enhancing marketing and distribution strategy to target strategic partners and (cell culture) end users in emerging markets. In addition, we also helped to successfully spin-out the HPACC's cell culture inventory software system to form LabMACS (<http://www.labmacs.com/icast-software>).

Otago Innovation, New Zealand

Otago Innovation has patented improved diagnostic methods for detecting Antimullerian hormone (AMH), in two distinct forms, namely proAMH and AMHN,C. The clinical assessment of ovarian function is widely determined using assays specific for Anti-Mullerian Hormone (AMH) for fertility and other potential applications.

Following business development efforts, Otago has been approached by potential licensees for this AMH technology. To further quantify the market opportunity for the AMH diagnostic technology IP Pragmatics was appointed by Otago to carry out a brief market and comparable deal analysis in order to help inform Otago's licensing strategy and headline deal terms.



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Based on the diagnostics' deal experience within the team, IP Pragmatics assessed the existing market size and uses for AMH in human and animal health fields, performed diligence on the prospective licensees, outlined development and licensing considerations for IVD in the context of the AMH technology and recommended a deal structure and value to the Client. These findings provided the client with a clear framework and context to drive negotiations with the licensee.

Auckland University of Technology (AUT)

IP Pragmatics worked closely with AUT Enterprise, Auckland to evaluate the optimal commercialisation strategy for their novel CPAP mask for obstructive sleep apnoea. Based on detailed secondary research and primary feedback from industry experts the University was able to make an informed decision on the prototype.