BioSpectrum the business of Bio & Health Sciences

"Research Results to Business Models via IP ~ A Winding Road"

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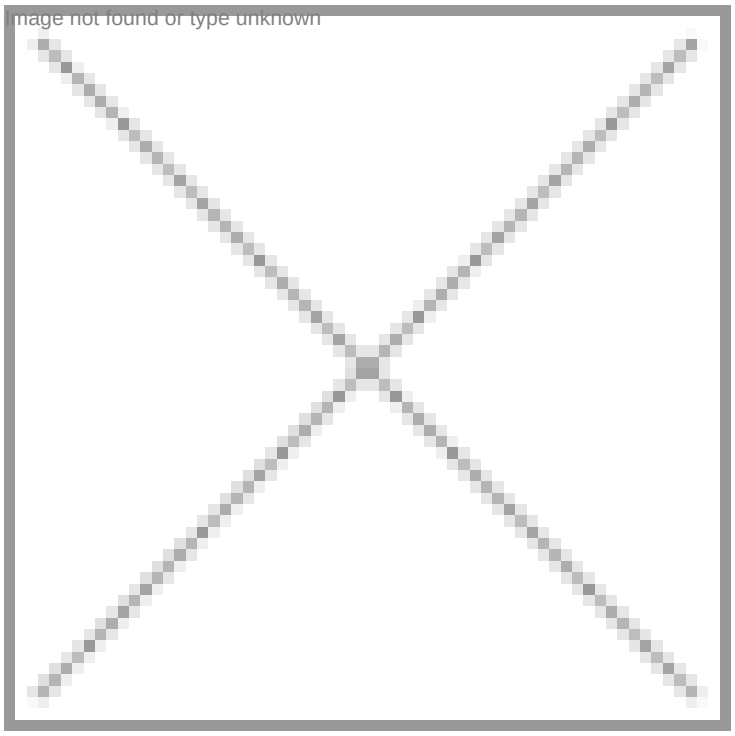
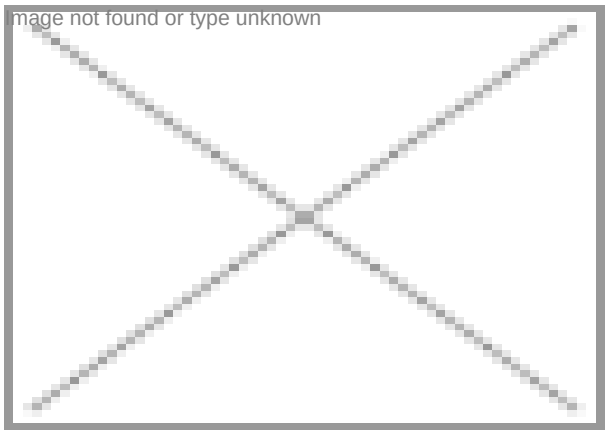




Every country in the world is influenced by its history and the outcome of that history becomes enshrined in the laws that govern our behaviour. In the UK Intellectual Property Rights (IPR) are largely decided by the Patent Act of 1997 and the Copyright, Patent and Design Act of 1998. Essentially these Acts give ownership of IP to the employer and places an onus on the employee to keep the employer informed of novel ideas, etc.

This is a relatively facile engagement in the corporate world where organisational control is accepted but more complex and difficult to influence in the academic environment where the need of the individual to publish is considered sacrosanct. The challenges that therefore face the technology transfer specialist are cultural ones whereby apparently chaotic freedom must reconcile itself to the desire for organizational control.

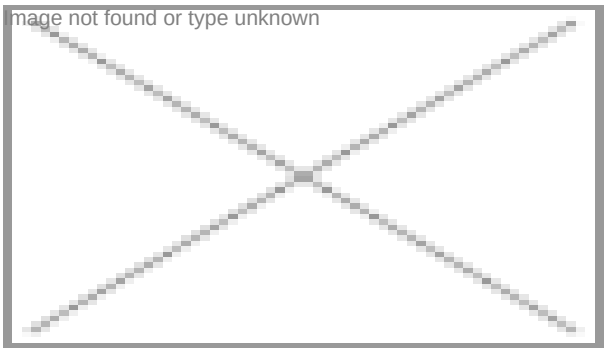
One particular mantra that helps when traversing this divide is that Letters Patent were originally conceived to ensure that ideas with commercial potential were not kept secret and that the public would be aware of the underlying technology (using this knowledge to advance research is thus a legitimate and laudable aim).

Sheffield University Enterprises Limited (SUEL), which is a wholly owned subsidiary of the University of Sheffield, is charged with generating commercial licences and new company opportunities that arise from research activities at the university. In essence SUEL has access to the output of over 5000 active research personnel and the rights to identify, protect and exploit the resultant IPR.

This relationship has, over the last 20 years (but predominantly over the last six years since SUEL came into being) generated some 50 new companies.

Over the last decade, government funding for technology transfer operations in universities has been strongly biased towards company formation and regional job creation. As a consequence, in universities that rely heavily on such support to underpin their transfer initiatives, there has been a swing away from the traditional interaction with industry, that is licensing. The pendulum is now swinging back towards a more central position where the benefits of licensing and company formation are viewed together on their relative merits. The University of Sheffield and SUEL have aggressively re-visited their licensing strategy in recent years and there are currently 25 projects being actively formatted as potential licences.

SUEL is currently configured to progress projects that fall into categories closely aligned to the university's known research strengths as recognised by the five yearly government review of research excellence in the UK university sector (the research assessment exercise). These categorizations also fit well with the cluster development strategy announced by the Regional Development Agency (Yorkshire Forward).



At present SUEL attracts about 70 new putative commercial ideas per annum from academic staff and over 90 percent of them are carried forward for further evaluation within SUEL. At the University of Sheffield the research policy actively encourages cross-disciplinary activity and SUEL also undoubtedly benefits from accessing these boundary initiatives.At this point, when the projects extracted from the plasma generator that is the university meet the cold light of business, it is apparent that the real need is for technology translation rather than technology transfer as the cultural divide between the two environments is substantial .Academics are creative, curiosity-driven, highly motivated problem solvers who are keen to disseminate the results of their endeavours so that they may be accepted or challenged. This does not always immediately endear them to business. In the past, research lead industries found that accessing this knowledge base and getting rights to arising IP was most easily achieved via consultancies and sponsored research projects. Today there is a need to scaffold emerging technologies long enough for the employer, the employee and the customer to develop a win-win scenario. But the role of technology transfer personnel is as much about persuading, cajoling and re-iterating as it is about negotiating.

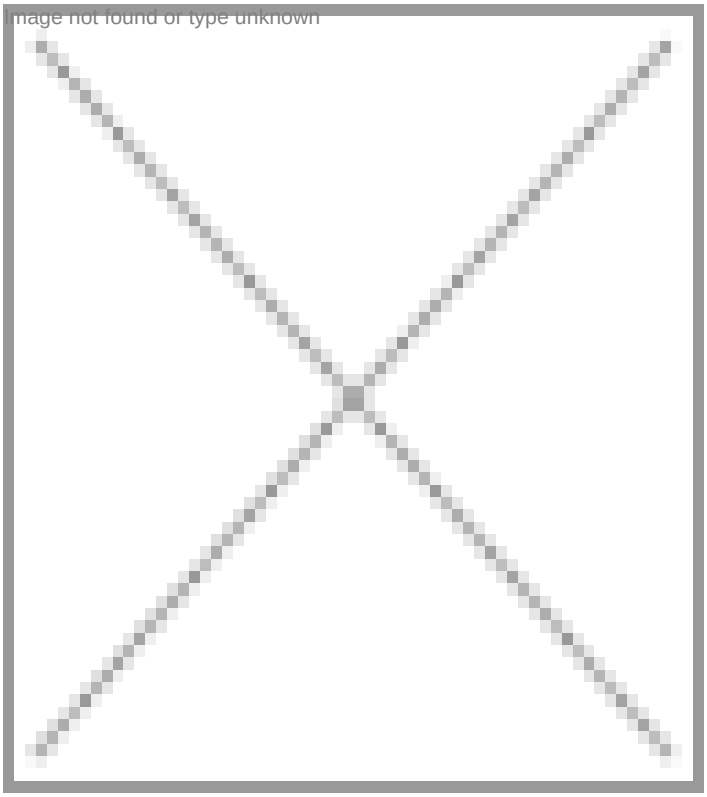
To enable the necessary interactions to occur SUEL and The University of Sheffield have agreed a formal Commercial Assessment System (CAS).

As earlier stated the university owns the IP generated by its employees. So the first gateway in CAS (CAS 0) takes place within the university as they have a duty of care to their employees. If the academic idea is not unduly encumbered by pre-existing relationships or key to the university's strategic intent it will be formally accepted into SUEL via one of the divisions. It is then the responsibility of SUEL personnel to work with the academic(s) to identify and protect any IP and to develop a business model. Specialist mentors may well be involved at this stage of exercise to complement SUEL staff. This activity takes place around the CAS 1 gateway and it should be emphasized that the people who operate at the CAS gates are expected to actively participate in the process. It is not a committee.

Once the most likely route to market has been assessed, then formal presentation to the CAS 2 gate is made and if successful, additional business resources are made available to accelerate delivery of a spin out or a licence.

The throughput of CAS is difficult to measure accurately as it is dependant upon a number of factors e.g. the material available, the number of iterations needed to properly assess potential, the discipline involved, etc.

Incidentally the Japanese kanji for theSound "CAS" is also the pictogram for harmony!



It is well understood that formation of a new company or indeed negotiation of a licence is not necessarily dependant upon having IP protection, but in a high tech environment where research is extremely competitive and rapidly moving it does need active consideration.

Working alongside a premier research lead university means that many of the technologies, which come under review, will be of a disruptive nature rather than an incremental one so the need to take a long-term stance in respect of protection is important. Furthermore the academic drive to publish means that if patenting is an option it should be done as early as possible. Patenting strategies as employed by large private corporations often involve abandoning and re-filing as a commercial ploy but because of the publication needs of academia this is a useful option generally unavailable to SUEL.

The current SUEL approach to IPR is to concentrate on patents wherever feasible and to identify the potential as early in the CAS cycle as possible. Through judicious use of qualified patent agents the earliest possible priority date is obtained and the academic groups are formally committed to an agreed patent exemplification programme for 12 months. It is also mutually agreed that failure to exemplify will result in the patent being abandoned. Advancing to full patent status is only undertaken if experimental evidence is good and a clear business strategy has been formulated via CAS.

This complex relationship between SUEL and the University of Sheffield allows commercialisation of elements from the research portfolio and the processes that underpin the relationship were not arrived at overnight. They have themselves gone through several iterations.

Even now it is an evolutionary process that is constantly re-adjusting to the demands of government policy, business legislation, the economic environment, etc. At the heart of it lie people skills rather than process and whilst it is an example of good practice it does not profess to be best practice and nor should it.

The basic model can, in the hands of committed individuals from a range of professional backgrounds, provide the core of a technology transfer system that is team driven and adaptable to a variety of circumstances.

Agilent to acquire Silicon Genetics

Agilent Technologies Inc. will acquire Silicon Genetics, a leading provider of software solutions for life science discovery.This acquisition will enable Agilent to emerge as a market leader in life science informatics market. The acquisition is subject to closing conditions, and financial details of the agreement were not disclosed.

"Silicon Genetics brings Agilent an outstanding informatics product portfolio and a strong team of people with extensive experience in software development, marketing, sales and support," said Fran DiNuzzo, vice president and general manager of Agilent's Integrated Biology Solutions business. A life science informatics team that will be an incubator for informatics products spanning DNA, RNA, protein and pathway applications would be formed. The team will work on developing the products of Silicon Genetics, the Agilent SpectrumMill proteomics workbench, the Agilent Synapsia informatics workbench and more.

Neurome to acquire Digital Gene's assets

Neurome Inc., a company which performs contract brain research for pharmaceutical and biotechnology companies besides pursuing its own in-house and collaborative research protocols, announced to purchase all the assets of Digital Gene Technologies Inc., including the TOGA technology, gene expression assays, existing datasets and know-how related to vaccine development programs. In conjunction with the asset purchase, Neurome will also acquire the entire patent estate, which includes data and discoveries generated in commercial and academic research programs with leading researchers worldwide.

The acquisition will allow Neurome to expand beyond its current core technologies in quantitative molecular neuropathology to include TOGA's gene expression based surveys designed to characterize the role of important target molecules implicated in areas of important unmet medical need. TOGA is an acronym, which stands for TOtal Gene expression Analysis.

BioDelivery closes Arius acquisition

BioDelivery Sciences International Inc. (BDSI) has closed the previously announced acquisition of Arius Pharmaceuticals. As result of the transaction, Arius has been reorganized with and into a newly formed, wholly owned subsidiary of BDSI.

Arius is a specialty drug delivery company whose portfolio of potential products will be focused on "acute" treatment opportunities for surgical and oncology patients.

Computer Sciences acquires DynPort Vaccine

Computer Sciences Corporation has announced the acquisition of Porton International Inc.'s interest in DynPort Vaccine Company LLC (DVC), a biopharmaceutical company focused on the development of biodefense biologics products. Formerly a joint venture between CSC and Porton International Inc., DVC has been the prime systems contractor for the Department of Defense Joint Vaccine Acquisition Program since 1997.

Products in development at DVC include vaccines for botulinum neurotoxin, tularemia, Venezuelan equine encephalitis, anthrax and plague, and a therapeutic blood product, vaccinia immune globulin, to treat complications of smallpox vaccination.

Bayer to acquire Roche Consumer Health

Bayer announced that it has agreed to acquire Roche Consumer Health. By acquiring this business Bayer will become one of the top three over-the-counter (OTC) consumer health companies worldwide. Additionally, Bayer will acquire Roche's 50 percent share of the 1997 Bayer/Roche joint venture in the US and five Roche production sites in Grenzach (Germany), Gaillard (France), Pilar (Argentina), Casablanca (Morocco) and Jakarta (Indonesia). The OTC business of the Japanese company Chugai, in which Roche has a majority stake, is not included. The acquired business has yearly sales of around 1 billion Euros. The 2.380 billion Euro transaction is subject to approval by relevant antitrust authorities.

Quintiles completes sale of dermatology assets

Quintiles Transnational Corp. announced the completion of the previously announced sale of assets relating to its specialty dermatology products company, Bioglan Pharmaceuticals, to BDY Acquisition Corp., a Delaware corporation and wholly owned subsidiary of Bradley Pharmaceuticals Inc. for $188.3 million in cash, including approximately $5.4 million of direct costs for transferred inventory.

Quintiles intends to use proceeds from the transaction to potentially pay down debt, to fund business growth initiatives and for other appropriate purposes.

The assets sold to Bradley's subsidiary include Bioglan's interests in certain dermatology products marketed in the US. Quintiles Transnational acquired certain assets relating to Bioglan in December 2001 and March 2002 as part of its strategy to invest in pharmaceutical products or companies that need additional resources to achieve their full market potential.

Chiron Acquires Sagres Discovery

Chiron Corporation has acquired Sagres Discovery, a privately held company, which focuses on the discovery and validation of targets with potential application to the development of cancer therapeutics. Financial terms of the acquisition were not disclosed.

"This is a unique opportunity to advance our goal of building a competitive, balanced pipeline for Chiron," said Kenneth Bair, senior vice president and head of research, Chiron BioPharmaceuticals. "Sagres has a wealth of in vivo validated targets, including kinases and antibodies, that will increase both the quantity and quality of targets available to us for development."