

Article Information

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Who owns what? Why life sciences companies need intellectual property policies

Companies in the life sciences industry generally live or die by the strength of their Intellectual Property (IP). An IP policy is an invaluable tool in helping you create clarity around IP ownership and to establish processes maximising your organisation's chances to identify and protect valuable IP being created in a timely manner.

Why you need an IP policy

Life science companies seek to develop and bring novel drugs, devices, diagnostics and digital health technologies to market. Only a small percentage of promising research and development achieves commercial release, with many falling short despite large amounts of resources being invested. Protecting the intellectual property (IP) for the research and development that does make it to market is crucial to recoup research and development investments.

Life science companies, for whom IP is their core asset, face a number of industry-specific issues when it comes to protecting their IP. It is common for life science companies to work collaboratively, so that employees and research collaborators may have additional affiliations and other external employers. Early in your organisation's journey, you might not even have employees, but work exclusively with consultants and advisors who are also contracted to other organisations. People with multiple affiliations may be working on research for your organisation at the same time using the resources or IP of the other organisation they are working for. Finally, researchers working with your organisation might also have academic roles and face pressures to publish research results which may potentially conflict with your organisation's aim of patenting before publication.

A built-for-purpose IP policy is an important way to ensure that all relevant personnel understand the important IP processes and obligations of your organisation, that questions of ownership of IP are resolved consistently and in a timely manner and overall that opportunities to commercialise the IP of your organisation's research and development are not encumbered.

IP issues for the life science sector

Who does your IP policy apply to?

Chances are your life sciences company is making use of Australia's great pool of bright, creative and inventive researchers and commercial managers whilst collaborating with overseas partners. This may involve a range of different people with different skillsets on the Board of Directors, on your scientific or clinic advisory boards or acting as consultants or employees.

Sometimes these talented people will not just work with you, but also have a number of other employers or affiliations. For example:

- someone may work for your company whilst also holding an appointment at a university or medical or public sector research institute. This alone has the potential to create significant uncertainty over who is bound by your organisation's IP processes and obligations.
- a researcher on your organisation's advisory board may not be clear as to the expectations as to whether to disclose certain matters about pre-existing IP to your organisation. Without an IP policy that clearly articulates those

processes, the researcher may not make a timely disclosure of that pre-existing IP.

It is therefore important to ensure that your organisation considers carefully:

- the range and circumstances of personnel that the IP policy needs to cover; and
- what obligations to impose on relevant personnel working with you in the creation and development of your organisation's IP.

What type of IP can you assert ownership over?

Your organisation may simply want to assert ownership over all IP that anyone working with you in any capacity creates or develops. This may well work for full-time personnel of your organisation with no other affiliations. However, the reality for a large proportion of life science companies is that personnel may have multiple employers and affiliations. Careful consideration needs to be given, for example, reasonable expectations of a consultant working a few hours a week for you, while working the remainder of the time at a medical research institute.

Determining IP ownership usually will not be as simple as claiming that any IP created during those hours that personnel work for your organisation is yours, while any IP developed outside those hours does not. Well drafted IP policies consider a range of factors including working hours, the duties of the personnel, the use of resources and facilities, the impact of commercial or government funding and clear processes for seeking approval to undertake other research activities in outside roles and managing conflicts of interest. . Litigation over IP ownership can be prohibitively expensive so the setting of clear expectations in an IP policy can be a worthwhile investment in managing IP ownership risks.

Special classes of IP may or may not be relevant to particular organisations. Where personnel in your organisation have academic teaching roles or PhD supervisory roles in external universities, it may be important for your IP policy to provide clear guidance around those activities and your organisation's expectations around relevant IP. Finally, any IP policy addressing ownership over IP generated by personnel with multiple affiliations should go hand-in-hand with the organisation's other policies such as any conflict of interest policy. It is important to note that an IP policy cannot stand on its own. The organisation's IP policy, employment contracts, standard consultancy agreements and advisory board terms of reference need to be considered holistically to achieve a cohesive and practicable IP approach for your organisation.

Disclosure Policy

One important procedural matter for any IP policy is a clear expression of the requirements for personnel to disclose inventions and creation of other forms of IP. To be in the best position possible to decide on how to proceed with any possible IP protection, it is crucial that there are clear and practical processes to ensure that your organisation is made aware of its creation as early as possible. This will enable your company to assess:

- how best to seek protection over the IP,
- whether there are risks to be managed around the invention relying on third parties' IP,
- if your organisation wants to allocate resources to develop the IP further or if other commercialisation options should be pursued such as out-licensing the IP.

Of course, timely IP disclosures also allow you to prioritise finite resources between different research and development activities and discontinue activities which are no longer relevant.

The disclosure process should not just be focussed on disclosures of new IP created but should also capture information about third party IP owned that may be needed enable development or commercialisation of your organisation's newly created IP. Being informed of the needs for such enabling IP in a timely manner gives your organisation the best opportunity to pursue any required in-licensing agreement in a more even negotiating position (rather than well down the track when your organisation may have no option but to take whatever terms a licensor demands).

Of course, whilst disclosure processes should be comprehensive, care should be taken to avoid creating unnecessary complexity in the disclosure process that neither the personnel (nor your organisation) will practically be able to follow. A practical process is more likely to ensure maximum compliance, resulting in your organisation being in the best possible position to manage IP disclosures.

The issue of publications

Your organisation may collaborate with researchers who have academic roles with KPIs around regular publication . Publication of collaborative research results may be something that your organisation is willing to support provided that IP protection is first obtained.

To be able to obtain a patent, the invention must be, amongst other things, novel. Publishing the research, presenting the research at a conference, or even discussing the research with other researchers outside your organisation who are not under a clear confidentiality obligation to your organisation may result in an invention being no longer novel and may defeat your organisation's ability to obtain patent protection.

It is, therefore, important that an IP policy has clear processes on:

- disclosure of research and inventions that could result in IP as early as possible;
- the procedure to determine whether or not protection over the intellectual property will be sought,
- the timeframes required for publications to be deferred to allow IP protection to be obtained and/or particular confidential information removed from the publication; and
- a clear expectation of when the scientist might be free to publish the research findings.

The IP policy should detail any internal structures such as IP commercialisation committees that may be involved in such a process. The processes should be tested with your organisation's patent attorneys to ensure that they provide realistic timeframes for IP protection to be obtained.

Of course, the processes for publication need to be carefully considered in advance rather than your organisation seeking to deal with an impending publication deadline at the time and without a clear process to follow.

Conclusion

For life sciences companies, their IP can be their most important and valuable asset. A well-drafted IP policy should create clarity around IP ownership and establish processes maximising your organisation's chances to promptly identify and protect valuable IP being created.

An IP policy does not stand on its own. The IP policy should work together with the organisation's other policies, employment contracts, consultancy agreements, collaboration agreements, board charters and advisory committee terms of reference to achieve a cohesive and practicable approach to protecting your organisation's IP.