

How to manage an in-house IP team

Sherry Knowles spent four years as chief patent counsel at GlaxoSmithKline after more than a decade in private practice. She tells **Emma Barraclough** what the experience taught her about working for pharmaceutical and biotech companies

What advice do you have for structuring an in-house team in the life sciences sector?

My experience comes from managing an IP team with a number of divisions spread across 12 countries. When you manage 200 people you quickly begin to see what is necessary to make it work effectively. Based on that experience, I have eight main recommendations:

- 1) Consider whether to organise your team globally or by expertise. GSK's IP team used to be organised geographically but after I joined we decided to restructure it along business unit lines. Of course each structure has its own merits but I think that this is the best way to align the IP function with the R&D function. It gave each R&D business a single contact group in the IP team and it allowed those people to become real experts in their own area.
- 2) Structure your IP team as horizontally as possible. Minimising the layers allows you to stay in touch with what is happening at all levels. At GSK I had 11 people – the heads of each of the IP business units – reporting to me directly. You need to get the balance right, because you don't want to overwhelm managers with too many direct reports, but at the same time you want to be able to understand properly how the whole team is operating.
- 3) Emphasise managerial substantive responsibility. By this I mean that each manager is personally responsible for the substantive work of all the people under them. A delicate balance must be maintained between fully empowering your staff, which leads to a motivated work force, and monitoring quality.
- 4) Don't forget your non-attorney staff. In our patent group up to half of the team consisted of docketing staff, paralegals and administrative assistants. These people are critical to the success of the organisation and they need to feel truly valued and regarded as peers. Ensure you take their views into account and offer continuing education programmes. You can draft the best claims but if a deadline is missed even

the most effective attorneys aren't always going to be able to solve the problem.

- 5) Encourage internal networking and information sharing. It is vital to share experiences as a team. There is great technology available these days from Skype to video conferencing that allows you to do this and you should make the time to use it, and to do it on a global basis. At GSK we had a really good IP intranet site that was updated daily with cases and policy statements as well as with internal news about the IP team.
- 6) Implement a patent quality initiative. The goal of that is improving drafting and prosecution skills. This was an area we took very seriously. We ran workshops in the US and Europe and people really enjoyed them. They grumbled when we gave them homework – no one likes homework, and that includes grown-ups – but it really focused people's attention on keeping their drafting skills sharp, and how drafting might influence the course of litigation.
- 7) The structure of the IP group must reflect the economic pressures that the business itself is experiencing. The hard fact is that every large- and mid-cap pharmaceutical company is facing head count and budgetary pressures. You need to be efficient about how you use your staff, where you file patents and how many you file and maintain.
- 8) Run customer surveys asking your clients what you do well and what you could do better. Every few years we sent questionnaires to hundreds of people in the R&D teams. We always got high rates of return which was very gratifying: it showed that people were interested in what we did and how we could improve.

What advice do you have for working with researchers to maximise effective cooperation?

The IP function needs to add value and be seen to add value. There are a number of ways you can do this.

First, understand the science as well as your client does. That can be difficult, particularly in the area of life sciences where things can get very complicated. But get up to date before meetings, if necessary by asking your client for recommendations of books and articles you should read. If you do that, you should be off to a good start.

Secondly, try not to get a reputation internally for always saying no. Attorneys tend to be naturally conservative, but it is important that you look for ways to find positive outcomes. Think strategically. That's what scientists do. If you help a researcher find a patentable way forward then there's a good chance you will have made a friend for life – or at least your career at your company!

What were the biggest lessons you learnt about managing IP from your time in-house, and what do you wish

Sherry Knowles



Sherry Knowles was senior vice-president and chief patent counsel at GlaxoSmithKline from 2006 to 2010, where she was a member of the company's Scientific Advisory Board, the Technology Investment Board, the Product Management Board and the Legal Management

Team. She oversaw work on the company's 1,900 pending US applications, over 2,200 granted US patents, over 14,000 pending foreign applications and over 15,000 granted foreign patents.

Knowles was also active in policy debates and initiatives relating to the pharmaceutical sector. She helped create and headed GSK's knowledge pool for the treatment of neglected tropical diseases in least developed countries and played a key role in litigation the company and Triantafyllos Tafas filed against rules published by the USPTO that would have limited the number of claims and continuations patent applicants could file. The USPTO ultimately withdrew the contested regulations.

In 2008 *Managing IP* included Knowles in its list of the 50 most influential people in IP and a year later GSK's in-house patent team was awarded the magazine's "In-House IP Team of the Year" title.

In June Knowles left GSK to set up Knowles Intellectual Property Strategies, a legal and consulting firm providing advice on protecting innovation, investor support and monetising assets.

you had known before?

One lesson I learned was how important it is to get involved in trying to shape global patent policies. Industry groups such as BIO, AIPLA, EFPIA, PhRMA, IFPMA and IPO are bridges between IP owners and regulators and politicians. I worked with a number of organisations on draft legislation and they were invaluable in that process. My advice to in-house counsel is to volunteer to get involved in policy debates. It would be very short-sighted for companies to limit their employees' involvement in industry organisations because of budgetary pressures. If there is going to be patent reform it needs to be reform that takes the life science industry forward. Big companies get the ear of policy makers, but each is just one company. When they come together and speak as an industry in a way that's united, that is very powerful. There's a lot of work for us to do: we now have a law on follow-on biologics that is very sparse on details and will need to be clarified through regulations or case law. The Hatch-Waxman Act critically needs updating, particularly in the area of data exclusivity and the patent term cap. We need to work on these together as an industry.

On the question of what I wish I had known before, I'm going to turn that question around. I'll tell you what I am glad I didn't know before I went in-house! I didn't know I would travel so much. I am glad I didn't: it might have made me think twice about the job and then I would have missed working with many highly experienced bright people.

How should lawyers manage the transition from private practice to in-house?

They need to understand that it will be different. There are no billable hours, which are what control your life as a private practice lawyer. It takes self-discipline to work without time sheets. On the other hand, you need to ensure that you don't work too much when you are not monitoring your output with time sheets. When I was in private practice I knew that if I reached 2,400 billable hours in a year then I needed to slow down a little. It can be hard to know that when you work in-house.

You should be prepared to do more with less. When you work for a company, everyone faces the prospect – or the reality – of tighter budgets. Many companies are acquiring other businesses but not retaining the same budget or number of people in the IP teams and that makes things tough.

You may, like me, find you are even more protective of the IP portfolio you are managing. That's why I got so involved in policy, like the litigation against the USPTO's proposed rules, amicus briefing and taking on more speaking engagements on policy issues.

But working in-house is a great lesson in practicing law. Much of the fun is being part of a bigger and more diversified team, working alongside people from the regulatory, business development and manufacturing divisions.

What can private practice lawyers do to provide a better service to their corporate clients?

I think they should have a frank conversation with the clients about their goals and the internal pressures they face. Often private practice lawyers think they understand the client's needs, but they should ask them what it is that they really want to achieve and whether there are potentially competing agendas within the company that are not apparent.

They should be sensitive about the budgetary constraints that in-house lawyers have to work within. Don't overbill, bill on a timely basis and consider flat fees.

Find out more about the client's conflict policies before inviting the in-house lawyer to dinners and events. Many companies' policies are getting stricter and you should avoid putting the lawyer in an awkward position.

Be willing to offer some freebies such as CLE programmes and telephone conferences.

Avoid bait and switch tactics. In-house lawyers are not impressed by firms that pitch with their star players but get their junior staff to do the actual work. Be honest and agree in advance who will do what kind of work. It's also very important not to pitch for work that the law firm doesn't really have the time or expertise to do.

What do you think are the biggest challenges that IP counsel in the pharmaceutical and life science sector are facing?

I think there are four. The first is the need to do more with less. IP counsel will need to be very strategic in the way that they deal with budgetary pressures while maintaining the effectiveness of their portfolios.

The second is the growing trend for large pharmaceutical and biotech companies to license-in IP rights, as opposed to creating new drugs themselves. This will affect in-house patent counsel at large companies, because they will spend more time monitoring – as opposed to carrying out – patent prosecution. It will also affect counsel at small- and mid-cap companies who will increasingly be required to think like a large pharmaceutical company so that their patent portfolio is not devalued in the course of partnering deals. I observed at GSK that many small- to mid-cap companies do not understand what large companies want to see (and not see!) in a partner's patent file. One of the

services my new firm will provide is to help bridge this gap by providing strategic advice to smaller companies during the creation and growth of their portfolios to maximise the value that the large pharma is willing to pay.

The third challenge is to win the debate over whether proprietary protection is appropriate at all in the pharmaceutical and biotech sectors, and whether these sectors should be singled out for discriminatory treatment. The undercurrents of this are seen in the debate over what is misnamed as “pay for delay settlements,” the trend of governments to encourage – and sometimes reward, as the Hatch Waxman Act does – companies trying to invalidate pharma patents, and the events around the European pharmaceutical sector inquiry.

The fourth issue is one of changing demographics and the importance of emerging markets. In the past, our sector's biggest markets were the US and Europe. That is changing and will continue to change. For that reason, IP attorneys need to get involved with helping governments in emerging markets to develop strong patent policies – particularly in China and India. It is important they convince governments that strong IP laws will benefit their domestic industries. Offering strong patent protection will send a clear message that innovation is rewarded.