



# When narrow patent claims can really work

**Recent figures from Ireland on the effect of the patent cliff are a timely reminder to CIPOs to look again at their internal practices to ameliorate the possible effect of their companies' own patent cliffs**

The effect of the pharmaceutical patent cliff is still evident around the world, with the latest fall-out cited in new figures from the Irish Exporters Association. A contraction in the Irish merchandise sector of €2.9 billion is mainly attributed to the loss of pharmaceutical exports and coincides with Pfizer's Viagra – the main ingredients of which are made in Cork – coming off patent.

As anyone in R&D knows, you cannot necessarily force the development of breakthrough compounds such as Lipitor, Viagra or Roundup. But IP counsel can put practices in place to lessen the revenue drop which occurs when a major product is out of patent.

However, recent (personal) conversations with IP counsel around the world suggest that less rigour is applied to IP strategy outside of blockbuster products.

Invention disclosure forms are the most common way that a chief IP officer (CIPO) hears of new developments. This method relies on those in R&D recognising that they have developed something of sufficient value to warrant the effort of submitting a form. Engineers, in particular, loathe writing up anything and thus there is an innate threshold to what is disclosed.

While this natural filter can be of benefit by eliminating the dross, it also means that valuable opportunities can be lost by failing to capture what is needed for sustainable revenues.

In addition, marketing is more attuned to the needs of the organisation's customers – yet often there is no structured process by which marketing can alert the CIPO of desired product improvements. Often marketing is consulted only after R&D has proceeded along the development path. And those charged with getting regulatory approval rarely have a direct line of communication with the CIPO.

However, it is essential that the CIPO gets feedback from all sectors of an organisation (and is not limited by invention disclosure forms) to ensure that a strong bottom line continues.

One of the key barriers to IP counsel being notified of incremental developments is that they are often thought to be non-inventive, unpatentable or insufficiently valuable. To counter this, there needs to be ongoing education of researchers and engineers as to how small can be valuable.

Further, as part of a cultural shift, it must be understood that it is the CIPO's job to decide what is valuable – not the researcher's.

Improvements should be recognised as inherently patentable, provided that sufficient support is given within the patent specification. Such support can be given by experimental results that highlight the advantages of the improvement over the prior art.

One approach is to assist in the design of the experimental study so that the patentability criteria can be met, rather than leaving the study parameters solely in the hands of a researcher with minimal IP training. For example, the power of selection inventions must be recognised. These can be an incremental improvement through the identification of an ideal range within a known one – that is, finding the sweet spot.

Consequently, to obtain strong patent protection, the study should have regard to the following European Patent Office guidelines:

- The selected sub-range is narrow compared to the known range.
- The selected sub-range is sufficiently far removed from any specific examples disclosed in the prior art and from the end points of the known range.
- The selected range is not an arbitrary specimen of the prior art – that is, not a mere embodiment of the prior art, but another invention (eg, purposive selection, new technical teaching).

The selection invention approach can be applied to more than just the traditional chemical and pharmaceutical industries.

Part of the education process is recognising that things such as mechanical tolerances and frequency bandwidths in electronics can have selection invention treatments applied to them.

One approach to lessen the impending effect of generics is for the CIPO to bring together a collection of marketing, commercial and technical parties to brainstorm potential improvements. This mix is essential as the ultimate outcome should be an improvement that marketing can promote to elevate the product above the generics.

Narrow patents are also very valuable when there are regulatory considerations such as Food and Drug Administration approval. An identical product of a competitor will also attract regulatory approval. If a competitor must design outside the claims of a narrow patent, this can force it to go through an expensive regulatory process for its non-infringing product, thus making it less competitive.

In this situation, narrow patent claims are usually quicker and cheaper to get to grant than broader claims.

It is critical that CIPOs are advised of ongoing developments, and not just so that they can be patented. There are many instances where continued development of a product can take it further than the original patent, leaving it without protection.

To summarise, a CIPO can add value in between blockbuster patents through good practices, including being kept informed of all developments in a product, exercising rigour around the protection of selection inventions and cultivating awareness of other sectors of the organisation, such as marketing, regulatory and R&D. To add value in this way requires education and communication with the wider organisation.

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