
Editorial

Welcome to the second issue of the *Journal of Generic Medicines*. In the first issue, Greg Perry's Editorial and several of the papers highlighted the growing difficulties we face as an industry in terms of the intellectual property environment in which we have to operate. There have always been restrictions on generic introduction, of course, and this represented a legitimate period of exclusivity granted to innovators as a reward for the work they carried out in the healthcare field. In more recent times, however, the restrictions and associated costs have been increasing to unacceptable levels, which could, if this remains unchecked, hamper the policy makers' desire to encourage an increased use of generics to help assist in the process of healthcare cost containment.

THE ARMS RACE

Over the last decade there has been an inexorable rise in the number of intellectual property hurdles placed in the way of generics reaching the market. In the late 1970s the primary patent covering the active molecule for a given compound also encompassed claims for formulations, processes and a number of other aspects of pharmaceutical interest. By their very nature many of these claims were broad. In more recent times, and at an ever accelerating pace, these have been split into a multitude of secondary patents with the sole purpose of setting up a constant series of barriers to the entry of generics. Not only, however, are there increasing numbers of patents, but also the timing of their filing is clearly planned in such a way that the monopoly of a given compound can be extended for many years or even several decades unless this is challenged.

At first the approach was to take several basic facets of the invention and separate these out into stand-alone patents to cover process, formulation, different release methods or even methods of administration. The tactics have now been broadened even further into cover for polymorphic forms, additional process claims with associated impurity levels/purity claims and even the kinetic/*in vitro* profiles of certain controlled release forms. The latter type of patent can effectively eliminate the possibility of generic equivalents, as any product which is shown to be bioequivalent would, by definition, be infringing the patent's claims. Polymorphic forms of the active have come very much into vogue in recent years, with numerous patents covering the same active — very few of which are directly related to any improvement in the therapeutic potential of the drug itself or even any advantageous pharmaceutical characteristics. The aim is to tie down the potential generic competitor in litigation, which will often be argued on legal minutiae rather than any valid scientific argument.

Granted patents are, in effect, always deemed to be valid — after all, why would a patent office grant a patent if it did not meet the basic criteria for intellectual property protection? Well, the reason is simple: most patent offices would see it as their job to grant patents, not turn them down. We, therefore, have to question if each application receives the proper in-depth review needed to determine its true validity, novelty and inventive step, looking in particular at prior art. Clearly, each patent can be challenged during the review period; however, with growing numbers of applications, even this can represent a high level of work for each of the companies in our industry. Once granted, the patent represents a hurdle that will have to be circumvented or invalidated in order to clear the path to the marketplace after

the compound protection has expired. In Europe, particularly, this can be a major undertaking as it has to be done jurisdiction by jurisdiction with the arguments potentially shifting over time as each case comes to a new court. In the USA and Canada, the possibility of new patents being granted and further litigation periods being triggered also extends the time to resolve the cases. The costs are clearly high and growing, adding to the overall costs of the pharma industries. One could argue that it has also provoked more challenges than might have taken place under a more balanced system.

A BALANCE OF POWER?

Is there a balance to be struck here? The generics industry does not wish to challenge the right of truly innovative products to a period of exclusivity, which encourages and rewards innovation. On the other hand, the right of generics to enter the market after this period of exclusivity should also be defended. The incentive of pending patent expiry should be a spur to further innovation and not a prompt to concentrate more and more effort on defending the past. If the rise in patents' barriers continues at this rate, the dynamic could be severely damaged and the industry stagnated. So what do we need in the future to restore a reasonable balance? First, the patent examination process needs to change to one involving rigorous scrutiny for novelty and examination of prior art related to the invention claimed. Any patent that is clearly designed to block competition and is of no practical merit should not be granted. If a granted patent is then challenged, the presumption of validity should be removed and the case decided on the merits of the scientific argument alone and not on legally elegant arguments about what represents infringement. In the legal process itself there are some signs that the balance may be restored to some extent in the future, at least in the USA. Multiple 30-month stays may well disappear from the scene very soon, a trend that we have to hope will be repeated in other jurisdictions in order to speed up the final decision.

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