BRITISH GENERIC MANUFACTURERS ASSOCIATION

SECONDARY MEDICAL USE PATENTS

BGMA Position

INTRODUCTION

Given recent comments, and NHS England's policy position[1] on the use of Pregabalin (Lyrica®) for neuropathic pain, the BGMA wishes to clarify its position about secondary medical use patents:

- The generic medicines industry respects valid patents: they are an important part of the virtuous circle enabling originator drug companies to deliver returns on their research investment before competition from generic medicines releases benefits to patients and the NHS.
- The generic medicines industry seeks to avoid infringement of valid patents but is prepared to commence proceedings to revoke a patent where there is doubt about its validity.
- The BGMA stands ready to play its part in finding an effective way forward if there are systemic issues to be resolved to ensure that valid patents are upheld, whilst ensuring that generic medicine manufacturers are able to market products for the non-patented indications.

Competition from generic medicines following the expiry of relevant patents on originator medicines brings significant benefits for patients and the NHS. Generic competition increases patient choice and access to medicines; reduces the increasing cost burden for the NHS, providing headroom for investment in other treatments; and incentivises innovators to develop new medicines which will initially be free from that competition. It is critically important for patients and the NHS that these benefits are maximised by the optimal use of generic medicines.

PATENT FILING STRATEGIES AND SECONDARY MEDICAL USE PATENTS

Typically, an originator drug is protected by many patents for the first 15 years or so of its life, as documented by the European Commission's sector inquiry into the pharmaceutical industry[2]. The generic medicines industry respects valid patents: they are an important part of the virtuous circle enabling originator drug companies to deliver returns on their research investment before competition from generic medicines releases the benefits to patients and the NHS outlined above.

Patents may apply to different elements of the originator medicine, for example the active ingredient (which confers the broadest protection for the patentee), its manufacture, product formulation and /or its therapeutic use(s). In particular, where a drug is licensed for different indications, the originator may have been granted a patent for one or more specific indications and those patents are likely to expire after the expiry of patents covering the active ingredient.

In these cases, the patentee's monopoly right is limited only to those specific indications which are covered by the later (narrower) therapeutic use patent which still remains in force. So, notwithstanding any legal challenge

[1] http://www.england.nhs.uk/wp-content/uploads/2015/03/pregabalin-guidance.pdf
[2] http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/

to any specific patent, generic medicine manufacturers must be able to market a product for the non-patented indications in order to release the benefits that that will bring to patients and the NHS as soon as the earlier (broader) patent rights have expired.

GENERIC ENTRY INTO THE LEGITIMATE OFF-PATENT MARKET

Since a generic medicine is likely to have been granted a marketing authorisation for all indications for which the originator drug is licensed, the generic medicines manufacturer will typically delete any patented indications from the Summary of Product Characteristics ("SmPC") and Patient Information Leaflet ("PIL") following the procedure set out by CMD(h)[3] and EMA[4]. Since the EMA's guidance refers expressly to the maintenance of safety related information for public health reasons, the BGMA would consider it inappropriate for patent holders to use the inclusion of such safety sections (even where they relate only to the patented indications) in the generic product's SmPC as evidence of patent infringement.

Generic medicine manufacturers will, however, refrain from marketing their medicine for the patented indication[5]. In this way, generic manufacturers respect valid medical use patents. Where there is doubt about a patent's validity, and a generic medicines manufacturer believes that it is inappropriately delaying access to those benefits, then it is open to that manufacturer to challenge the validity of the patent in court. Indeed, it is in the wider public interest for invalid patents to be revoked and removed from the patent register.

In the BGMA's view, it is inappropriate for patent holders to intercede with others in the supply chain in a way which may reduce the uptake of the generic medicine for the non-patented indications and so diminish the benefits which would otherwise be enjoyed by patients, the NHS and taxpayers.

CONCLUSION

The UK benefits from an extremely efficient originator and generic manufacturing industry and supply chain, as well as a healthcare system that drives savings. Actions which undermine that efficiency act against the interests of patients, the NHS and the taxpayer. If there are systemic issues which need resolving to ensure that valid medical use patents are respected whilst making sure that the benefits of generic medicines competition are fully enjoyed by patients, the NHS and taxpayers at the appropriate time, the BGMA stands ready to play its part in finding an effective way forward.

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[3] http://www.hma.eu/20.html

[4] http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000035.jsp& (question 17 states: "Information directly related to the patented indication can be deleted from sections 4.1. therapeutic indications, 4.2. posology and method administration and 5.1. pharmacodynamic properties of the summary of product characteristics. For public health reasons, safety related information in sections 4.3 to 4.8. of the SPC should be maintained.")

[5] Subject to any decision to launch at risk across all licensed indications based on an assessment of and/or an ongoing challenge to the validity of the relevant therapeutic use patent.