

# Martin A. Hay & Co.

White Cottage  
33 Castle Hill  
Prestbury,  
Cheshire SK10 4AS  
UNITED KINGDOM

Tel: (+44) 1625 820032  
Fax: (+44) 1625 828494

E-mail: [martinahay@martin-a-hay.com](mailto:martinahay@martin-a-hay.com)

## **DG Competition European Commission**

8<sup>th</sup> December, 2008

By email: [COMP-SECTOR-PHARMA@ec.europa.eu](mailto:COMP-SECTOR-PHARMA@ec.europa.eu)

Dear Sirs,

### **RE: PHARMACEUTICAL SECTOR ENQUIRY PRELIMINARY REPORT**

I write further to my letter of 3<sup>rd</sup> December, 2008.

There is a further, very important point that I need to make. It concerns secondary patents – those protecting salt forms, crystal forms, etc, and their importance to start-up innovators.

I think that the recent decisions of Patent Offices and the Courts on the validity and enforceability of secondary patents in the pharmaceutical area already reflect a prejudice against what is perceived to be ever-greening of exclusivity for medicines. However, this “prejudice” works against companies wishing to invest in the development of compounds that are not provided with adequate primary (i.e. novel compound or first medical use) protection. In my experience, it is the small and medium sized companies that are most disadvantaged by this “prejudice”, because they lack the internal resources to be able to create these kinds of invention. For example, it is very difficult to find new salt or crystal forms, or formulations, if you do not employ the right technical experts or have the necessary large-scale plant and machinery. I have also observed that generic companies wanting to develop a proprietary side tend to select older compounds as their clinical candidates, and therefore are also very dependent on secondary patents. Over my career, I have seen countless compounds excluded from development by companies, especially small ones, on the grounds that there is no certainty that they will be able to obtain sufficient exclusivity to support clinical development.

The patent system has to treat the secondary patents of those with a strong primary patent position the same as those without. If the patent system is to continue to provide the main incentive for the development of new medicines, then secondary patents must be respected.

Ultimately, what is important is whether the term and breadth of exclusivity available is sufficient to support the development and commercialisation of new medicines. It does not matter whether this exclusivity comes from primary patents, secondary

patents or some new form of intellectual property right (as I would advocate). The decisions made by Patent Office Examiners and Judges are made in the context of the cultures in which they live, and inevitably reflect any prejudices of wider society. The speed of light, and its relationship to energy and mass is fixed. The patentability of new medicines ebbs and flows like the tide.

Once again, may I say that I think that the pharmaceutical sector needs a new kind of intellectual property right, which I would call a registered development right. It would be a kind of hybrid between a patent, a trademark and marketing (data package) exclusivity. Applicants would file an application for the right, probably at a Patent Office. The application would identify the medicine (name or structure) and would be published shortly after filing. It would then be examined to see if another application had been filed earlier for the same or a *prima facie* obvious equivalent of it (e.g. a homolog). If the application were for a *prima facie* equivalent, the Applicant would be required to provide data showing why the compound was not an equivalent. Third parties would have the right to file oppositions based upon compounds that they already have in development. The Applicant would have to have a *bona fide* intent to develop the compound. The right could be extinguished if the Applicant was not diligent in pursuing the development (to prevent abuse of the right). The term of exclusivity would run from the date when the medicine is first approved for marketing. It would be set based upon what term appears to be needed to encourage development of sufficient medicines in a given field.

The benefits of having this new right would be:- legal certainty for investors in both the innovative and generic sectors; a huge increase in the pool of compounds that could be selected for clinical development; an increase in the number of new medicines being developed, and a flexible tool that would enable policy makers to encourage companies to invest in the development of compounds in areas of greatest medical need. The challenge would be for the public healthcare systems to be able to develop effective systems for quickly taking up and exploiting the increased choice of products that would become available.

If it would be helpful, the undersigned would be willing to draft an outline Regulation for consideration by the Commission.

Yours faithfully,

Martin A, Hay