Patenting aerospace medicines – the final frontier?

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Research and development (R&D) into aerospace medicine can be viewed as falling into one of two camps: that aimed at adapting an existing 'terrestrial' medicine for use in the aerospace environment; and that which is being newly developed for treating conditions that occur primarily or uniquely in aerospace.

Adaptations of existing pharmaceutical formulations, delivery devices and packaging may, for example, have to account for differing temperature, pressure and other physical conditions of storage or use. If these developments are not only new but also overcome specific technical problems or provide unpredictable advantages, then they may well be protectable from copying or independent, later development by competitors. Specific patents covering these developments could be obtained, regardless of any patent protection already in place (or expired) on the existing medicine.

Broader protection may be available for active ingredients (AI) newly-developed to treat unique, aerospace-related conditions. As well as the AI itself, manufacturing processes, pharmaceutical formulations and uses of the AI in general may be patentable.

Alternatively, an existing drug could be trialled for such specific conditions, in which case, although the drug may be identical to one already having a marketing authorisation, its specific use or method for treating a particular condition in aerospace may be patentable.

PROTECTION AND ENFORCEMENT

Patent protection and enforcement are subject to national or regional laws and procedures. For example, a UK patent on a medicine would not prevent its manufacture, sale or use in the USA; for this, a US patent would be required. The question then arises as to whether such patent laws apply in aerospace, for example, in the International Space Station (ISS).

The modules of the ISS are each operated by one of the partner space agencies of Canada, Europe, Japan, Russia and the United States. The International Space Station Intergovernmental Agreement (IGA) now clarifies that the country in which a space object is registered retains control and jurisdiction (including for patents) over that space object. The main aim of the IGA is to mitigate the risk of potential infringement by each partner of each others' intellectual property rights (IPRs), so they have agreed to create specific marking procedures to protect the ownership and confidentiality of each other's data and goods, and those of relevant third parties (e.g. their contractors).

If an action for infringement were called for, this would have to be taken under national laws. Therefore, patent protection for aerospace medicines should be considered for each territory that has registered space objects (primarily ISS countries and China) . Innovators may also want to consider patenting in jurisdictions in which patentable medicines are likely to developed, manufactured and/or launched into space.

OWNERSHIP OF INVENTIONS MADE IN SPACE

Not all aerospace medicines will be invented on Earth. The long-term presence of R&D teams in the unique environment of the ISS provides an opportunity for medical innovations eligible for patent protection (and use either in space or on Earth).

However, the IGA only determines the country of inventorship (according to the ownership and registry of the ISS module in which the invention has taken place); it does not impact who owns the invention or where a patent for it can be filed. These matters are determined under the laws of the country concerned. However, special provisions apply to the European modules (e.g. the Columbus Laboratory): any European partner can elect to deem an activity to have occurred within its territory.

Space activities are increasingly moving from being state-owned to private and commercial activities, or operate under international co-operation schemes governed by an international legal framework. ISS participants from industry or academia will have their ownership rights and obligations determined by their agreements with each other and/or the relevant partner agency.

CONCLUSION

While the full panoply of IP protection and enforcement already familiar in the life sciences field is available to aerospace medicines, there are additional considerations to when 'aerospace' extends to space itself. Specific laws and regulations such as the IGA must be considered, especially for determining which terrestrial laws apply to protection, infringement and ownership of IPR. Furthermore, the complexity of inter-relationships and agreements governing space activities need careful analysis, particularly from an ownership perspective.

If you have any queries regarding this topic, or other pharmaceutical or biotechnological matters, please contact Julie at ***jbm@aathornton.com*** *or visit our website* ***aathornton.com***