



Galapagos

Andrew H. Hirshfeld
Deputy Commissioner for Patent Examination Policy
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**Comments from Galapagos on Guidance For Determining Subject Matter Eligibility
Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural
Products**

Dear Mr Hirshfeld,

Galapagos is a clinical stage biotech company focused on developing novel mode of action medicines. Headquartered in Belgium, the Company employs 400 people at sites in Belgium, France and the Netherlands, and we are working to bring novel treatments to patients in need in diseases such as cystic fibrosis, rheumatoid arthritis, cancer and infectious diseases.

One of the key requirements for us to commit to the lengthy and expensive research and development efforts required to bring a product to market, is clarity with respect to the intellectual property we are able to obtain. Therefore, we welcome the efforts by the USPTO to ensure consistency in the examination of patent applications.

However, we are deeply concerned that the guidance issued recently on determining subject matter eligibility, and which is being followed by the Examiners, is overbroad. This has the result that protection is being denied to inventions which would normally have been considered patentable, and in fact which are considered patentable in other territories. In particular, it would seem that the requirements of patentability, in particular inventive step, are being confused with those of patent eligibility, so as to remove from patent protection whole areas of research. This is clearly seen in the requirement for the subject matter of the claim to be "significantly different" from the judicial exception. This, in one step, reduces the incentives for pharmaceutical companies to invest in areas such as natural products (historically a valuable source of pharmaceutical active ingredients) and diagnostic testing, which has been acknowledged by the FDA as playing an important role in determining which therapies are the safest and most effective for a particular patient¹. We submit that these should be considered patent eligible subject matter, and that then their patentability should be determined as with inventions in other fields of technology.

¹ <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm352230.htm>



Therefore, we fully support the comments made by the Chartered Institute of Patent Attorneys and by Paul Cole. We strongly urge the USPTO to take these into consideration when updating the present guidelines.

Yours sincerely,

A handwritten signature in blue ink that reads "Maria Nichol". The signature is written in a cursive, flowing style.

Maria Nichol, D.Phil, EPA CPA
Vice President, Intellectual Property