



Society Fellows of The American Society of Pharmacognosy

Chair of the Society Fellows
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Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir or Madam:

As the Fellows of the premier scientific society for natural products research in the United States, namely the **American Society of Pharmacognosy**, we are writing in *response to the request for written comments on guidance for determining subject matter eligibility of claims reciting or involving laws of nature*. We strongly disagree with this recent judgment concerning the "2014 Procedure for Subject Matter Eligibility Analysis of Claims Reciting or Involving Laws of Nature/Natural Principles, Natural Phenomena and/or Natural Products" for a combination of scientific reasons as well as common sense recognition of the best interests of a healthy US society.

Harnessing the forces and products of Nature has been inextricably intertwined with the development of modern human society, and the list of patents for ways in which to use these products is extensive. Examples of small molecule natural products with very useful properties include paclitaxel, an antitumor drug from the Pacific Yew Tree, the antibiotic daptomycin which is a life saving medication against skin infections, the immunosuppressive drug rapamycin from a soil bacterium, and the pain therapeutic Prialt from a marine cone snail venom. Natural products are different than synthetic compounds in that they have been molded in a biological context through eons of evolution, and in many cases, represent highly optimized ligands to receptors or enzyme sites (e.g. further improvement of their biological effects is not possible or is insignificant).

We suggest that as the isolation of biologically active products from natural sources is currently practiced there is a strong inventive step at the level of detection of natural products in complex mixtures of compounds prepared from natural materials, thus enabling their isolation and characterization. The assays used for such detection anticipate utilities for the derived active principles not employed by Nature, nor used by the organisms producing the natural products. The producing organisms employ none of these agents for a specific biological function related to

their ultimate biomedical utility, and in addition, the active agents are usually a minor part of a complex matrix of hundreds of other compounds. Therefore, the process of discovery of these compounds, determination of their complex molecular structures and pharmacological activities, and development into useful therapeutics, all represent unexpected and creative scientific enterprises. This aspect of the integrated process of natural products discovery seems not to have been considered adequately by the court. Consequently, we strongly urge reconsideration of this decision, and suggest that this is a much more nuanced yet significant issue than is currently appreciated. Indeed, we recommend that this issue be reconsidered with the input of specialists who can more clearly delineate to the courts the inventive process involved in discovering and developing natural product pharmaceuticals.

Moreover, it is our perception that the concept of patentability of discoveries and products is one that was designed to stimulate innovation and development of new products in the interest of society, but at the same time promote communication of new ideas and thinking in the interest of societal development. This recent judgment on the un-patentability of natural products appears to run counter to both of these goals. On the one hand, it will stifle natural products research, thereby reducing the entry of new life-saving products of value to US and world health. This ruling will introduce a competitive disadvantage to health care in the US if natural products cannot be patented here, but can be patented elsewhere, such as the European Union. Moreover, expensive clinical trials will necessarily need to be conducted in the US, and this represents an investment that no company would be willing to make without patent protection; thus, the US public would lose out on access to new life saving medications. At the same time, this decision might promote the development of products that are protected as trade secrets, thereby reducing the flow of information concerning scientific developments, ultimately to the detriment of society.

For the reasons laid out above, the Fellows of the American Society of Pharmacognosy strongly urge rejection of this recent judgment concerning the patentability of natural products. This judgment is counter to the concepts of patentability of scientific discoveries, and is not in society's interest from the perspective of developing products that improve the human condition, promote enterprise, and increase scientific interchange to the benefit of all.

Sincerely on Behalf of the Fellows of the American Society of Pharmacognosy, including the undersigned,

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