

April 30, 2014

Ms. June E. Cohan  
Legal Advisor  
Office of Patent Legal Administration  
United States Patent And Trade Office

Re: Product Claim of 5-Methyl Amazonic Acid in USPTO Guidances

Dear Ms. Cohan,

It is set forth in the analysis of a product claim of 5-methyl amazonic acid that: 5-methyl amazonic acid is structurally different than naturally occurring amazonic acid; this structural difference has resulted in a functional difference; and therefore 5-methyl amazonic acid is markedly different than naturally occurring amazonic acid.

I have been working for a Japanese pharmaceutical company for thirty six years until retired four years ago. It would be still a useful procedure in drug discovery to screen and identify natural products (“seeds” for medicine) having a pharmacological or biological activity likely to be therapeutically useful and modify the structure thereof to develop more effective compounds (“lead compounds”), the functions of which are substantially the same as the original natural products. Such lead compounds are usually selected by evaluating the pharmacological or biological activity, selectivity, safety and ADME (Absorption, Distribution, Metabolism, and Excretion) thereof, and finally clinical development candidates are selected from such lead compounds. A series of such lead compounds including clinical development candidates are very valuable for a pharmaceutical industry as its property to be protected by a product claim. It is also well known even a slight change in structure brings unexpected results in such pharmaceutical field.

Therefore, if 5-methyl amazonic acid is one of such lead compounds derived from naturally occurring amazonic acid, although 5-methyl amazonic acid and amazonic acid have substantially the same function for treating cancer, I believe a product claim of 5-methyl amazonic acid shall be recognized to be eligible under 35 U.S.C. §101.

Under such circumstance, I would like to propose the following amendment regarding the analysis of a product claim of 5-methyl amazonic acid in order to clarify the intention thereof as an example of a product claim of a product which is slightly

different in structure than a naturally occurring product and protect the valuable property of the pharmaceutical industries in the world. It would be very pleased if USPTO could accept my proposal to improve the present Guidances.

#### Claim 2 5-Methyl Amazonic Acid

Present Analysis: Factor a) is satisfied. The 5-methyl amazonic acid is structurally different than naturally occurring amazonic acid (because of the addition of the 5-methyl group), and this structural difference has resulted in a functional difference (5-methyl amazonic acid stimulates the growth of hair in addition to treating cancer). While a functional difference is not necessary in order to find a marked difference, the presence of a functional difference resulting from the structural difference makes a stronger case that the structural difference is a marked difference. Therefore, 5-methyl amazonic acid is markedly different than naturally occurring amazonic acid.

Amended Analysis: Factor a) is satisfied. The 5-methyl amazonic acid is slightly different in structure than naturally occurring amazonic acid (because of the addition of the 5-methyl group). However, this structural difference has resulted in a significant functional difference (5-methyl amazonic acid stimulates the growth of hair in addition to treating cancer) or a significant functional improvement (5-methyl amazonic acid has significantly improved the effectiveness for treating cancer in terms of the pharmacological or biological activity, selectivity, safety or ADME thereof). Therefore, 5-methyl amazonic acid is markedly different than naturally occurring amazonic acid. While a functional difference is not necessary in order to find a marked difference, the presence of a functional difference resulting from the structural difference makes a stronger case that the structural difference is a marked difference.

Sincerely yours,

Kuniyuki Oda, Ph.D.  
Intellectual Property Director  
Intellectual Property  
National Institute of Agrobiological Sciences  
Japan