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Comments on the Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws Of Nature, Natural Phenomena, & Natural Products

November 9, 2014

I am late in submitting these comments, but nonetheless I am submitting in the hope that some value is obtained from this feedback.

I have serious concerns about the "Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws Of Nature, Natural Phenomena, & Natural Products" ("Guidance"). The USPTO should proceed with prudence, reconsider the complexity, and leave patent eligibility to its traditional role in determining patentability.

The Supreme Court cases on which the Guidance is predicated are narrow decisions based on specific fact patterns. Prudence dictates proceeding with caution. Yet the Guidance goes far beyond what the Supreme Court has decided. It calls into question the patent eligibility of subject matter there is no evidence it was ever the intention of the Supreme Court to withdraw.

I am most concerned about the test of "structural difference" as a test to qualify for patent eligibility. For example, in nutrition it is desirable to deliver natural products for public health, since leveraging synergy among nutrients is a fundamental principle of good nutrition, and overall nutrition has to be kept in perspective. Favoring "structural difference" for patent eligibility means that patents for structurally altered nutrients will surge and structurally altered nutrients in isolation will surge into the food supply, with dire consequences on public health. Long-term effects of structurally altered nutrients are often not apparent for decades or more.

Hydrogenated fats, which caused great harm to public health, are a painful reminder. Hydrogenation is the forced chemical addition of hydrogen into omega-6 polyunsaturated oils to make them hard at room temperatures, primarily as a cheaper and less perishable substitute for butters and oils. The process was patented by German chemist Wilhelm Normann. In 1909, Procter & Gamble acquired the US rights to the Normann patent; in 1911, they began marketing the first hydrogenated fat, Crisco (composed largely of partially hydrogenated cottonseed oil). By 1960s, hydrogenated fats had become very popular with many brands present in the international markets.

In the 1940s, Catherine Kousmine researched the effects of trans fats on cancer. In 1956 there were suggestions in the scientific literature that trans fats could be a cause of the large increase in coronary artery disease. Studies in the early 1990s, brought confirmation of the negative health impact of trans fats. In 1994, it was estimated that trans fats caused 20,000 deaths annually in the US from heart disease.

It wasn't until 2003 that mandatory food labeling for trans fats was introduced in several countries, i.e. after public health havoc was caused for nearly 100 years by hydrogenated fats. We may have to deal with consequences of hydrogenated fats for many years to come yet, because there is evidence that prenatal exposure to ill-suited lipids has negative health

repercussions throughout life. Thus there are Americans who are still suffering and may continue to suffer from ill-effects of hydrogenated fats they were exposed to earlier in life.

Therefore, we humbly request the USPTO to not take paths that put public health in serious jeopardy. Requiring "structural difference" for patent eligibility would put public health in serious jeopardy in many ways.

Patent eligibility of claims involving products of nature should be left to the tests of anticipation and obviousness (including secondary considerations). These laws were created to spark innovation particularly in the arts that are lagging, or require a new approach due to failures in prior art.

Finally, I agree with others who have noted that the Guidance puts American patent law outside international standards and threatens national competitiveness.

Thank you for your consideration.
Urvashi Bhagat
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