

APAA Emerging IP Rights Committee Report

Special Topic: “Business Method and the Laws of Nature, As Discussed by the US Supreme Court in Mayo v. Prometheus”

Hong Kong Group

I. U.S. Supreme Court’s ruling

Section 101 of the U.S. Patent Act provides that “whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof may obtain a patent therefor, subject to the conditions and requirements of this title,” ie. novelty and non-obviousness. This is, however, qualified by the underlying legal principle that laws of nature, natural phenomena, and abstract ideas are not patentable. Applying the legal principles expounded above, the U.S. Supreme Court examined the claimed process in Mayo patent as embodied by the three steps and concluded that the subject matter of the patent, namely the correlation between the concentration of thiopurine metabolites and likelihood of efficacy or harmful side-effects of the treatment, was not patentable as a matter of natural law and that the three steps were not sufficient to transform an un-patentable law of nature into a patent-eligible application thereof.

The Supreme Court grounded the above ruling on factual observations and legal reasons which are summarized below:

1. The “administering” step – the relevant audience
The “administering” step advised the doctors to treat patients suffering from auto-immune diseases with thiopurine drugs. Since doctors had long been applying thiopurine drugs to treat the relevant patients before the development of the claimed process, the Supreme Court held that this step only served to identify the relevant audience (namely the doctors who were treating patients with auto-immune diseases) and lacked additional features that would otherwise transform the un-patentable nature of the claim.
2. Wherein clauses – a description of the natural law
The “wherein” clauses described the relationship between the concentration of thiopurine metabolites in the blood on the one hand, and the efficacy or toxicity of the treatment on the other hand. Since this relationship was quintessentially governed by the natural laws, these clauses, in delineating this relationship, merely

served to recite the natural laws and, at most, recommend doctors to take those natural laws into account when making a decision in treating the patients concerned. As such, the Supreme Court held that these clauses were not patentable subject matter.

3. Determining step – a well-known activity

The “determining” step advised the doctors to determine the level of thiopurine metabolites in the blood without specifying the use of any particular methodology. Since the methods for determining the relevant metabolites were well-known amongst doctors and researchers in the field before the development of the claimed process, the Supreme Court held that this step merely described a “well-understood, routine, conventional activity” previously engaged in by scientists in the field and was therefore not a patentable subject matter.

4. Three steps – failure to transform the un-patentable claim

Given that metabolite level – drug efficacy correlations were un-patentable as a matter of the natural laws, the three steps, when viewed holistically, were held to “add nothing to the laws of nature” that was not already present when the steps were considered separately.

In summary, the Supreme Court opined:

“To put the matter more succinctly, the claims inform a relevant audience about certain laws of nature; any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately. For these reasons [...] the steps [were] not sufficient to transform the un-patentable natural correlations into patentable application of those regularities.”

5. Likelihood to tie up doctor’s treatment decisions

The claimed process advised doctors to administer thiopurine drugs to the relevant patients, measure the levels of thiopurine metabolites in their bloodstream thereafter, and evaluate those measurements in light of the statistics set out in the patent. According to the Supreme Court, by forcing the doctors to consider Prometheus’ correlations as embodied by the patented statistics, the claimed process would likely confine the range of decisions available to doctors subsequent to treatment if they were to avoid patent infringement.

6. Likelihood to inhibit future innovation

Given that the subject matter of the subjective patent concerned natural laws, and that the claims were expressed in “highly general language covering all processes that make use of the correlations after measuring metabolites,” the Supreme Court held that upholding the subjective patent would risk tying up the use of the underlying natural laws, thereby inhibiting their use in the making of future innovations.

For the reasons given above, the Supreme Court unanimously agreed that the subjective patent should be invalidated on the ground that the claimed process was not patent eligible.

II. Patent Law in Hong Kong

Under the Patents Ordinance (Cap 514 Laws of Hong Kong), an invention is patentable if it is susceptible of industrial application, is new and involves an inventive step.

The following shall not be regarded as inventions:-

- (a) a discovery, scientific theory or mathematical method;
- (b) an aesthetic creation;
- (c) a scheme, rule or method for performing a mental act, playing a game or doing business, or a program for a computer;
- (d) the presentation of information.

Patentability of subject-matter or activities referred to in the above shall be excluded only to the extent to which a patent or patent application relates to such subject-matter or activities as such.

A method for treatment of the human or animal body by surgery or therapy and a diagnostic method practised on the human or animal body shall not be regarded as an invention which is susceptible of industrial application but this shall not apply to a product, and in particular a substance or composition, for use in any such method.

An invention the publication or working of which would be contrary to public order or morality shall not be a patentable invention; however, the working of an invention shall not be deemed to be so merely because it is prohibited by any law in force in Hong Kong.

A plant or animal variety or an essentially biological process for the production of plants or animals, other than a microbiological process or the products of such a process, shall also not be patentable.

III. Impact of Mayo decision on Business Plan Methods and Other Technologies

Assuming that the Mayo decision is enforceable and business plan methods are patentable in Hong Kong, the decision has an effect not only on business methods but also on inventions that are based on scientific researches.

In the absence of Mayo decision, whether an invention is patentable or not depends on what technical contribution the invention as a whole makes to that already known in the art. There must be some technical advance on the prior art in the form of a new result for an invention to be patentable. In determining patentability of any claimed invention, the court in Hong Kong usually looks to the UK court for guidance. Following the 2006 [Court of Appeal](#) judgment in [Aerotel v Telco and Macrossan's application](#), the UK Patent Office has adopted the following test when it is called upon to determine the patentability of a particular invention:-

- (1) properly construe the claim
- (2) identify the actual contribution
- (3) ask whether it falls solely within the excluded subject matter
- (4) check whether the actual or alleged contribution is actually technical in nature.

The above approach, which considers the claim as a whole and asks whether the inventive contribution resided only in excluded matter, has some aspect of a novelty consideration in determining what the inventive contribution is differs from the approach adopted in Mayo decision which suggested that a distinct and separate assessment of patent-eligibility be conducted before moving onto considering novelty and obviousness.

Leaving open what additional or significant features a subject matter that is not in itself eligible for patent protection should have for it to be transformed to become patent eligible in the Mayo decision, applicants of business method patents should draft their claims to include additional and more limiting/specific steps in the place of more generalised steps in order to limit the monopoly to what the inventive contribution can reasonably justify.

If the court is to follow the Mayo decision and applies it by analogy to business model patents, this will make it more difficult for business methods owners to pass the patent

eligibility test. Another way of protecting their inventions may be by way of trade secrets and/or copyright (if appropriate) as opposed to patents.