

Case review: Merck defeated in BMS patent row

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In March, Merck unsuccessfully tried to invalidate a patent owned by Bristol-Myers Squibb covering metastatic skin cancer treatment. Ernest Linek of Banner & Witcoff reviews the arguments and the court's ruling.

On March 29, 2016, the US District Court for the District of Delaware denied Merck's motion to dismiss a Bristol-Myers Squibb (BMS) patent under Federal Rule of Civil Procedure 12(b)(6) regarding the patent ineligibility (based on §101) of a method of treating a metastatic melanoma.

The court's action could signal to the pharmaceutical industry that some methods of treatment claims, such as those in US patent number 9,073,994, can be the subject of §101 ineligibility analysis. Claim 1 of the patent reads as follows:

1. A method of treating a metastatic melanoma comprising intravenously administering an effective amount of a composition comprising a human or humanized anti-PD-1 monoclonal antibody and a solubilizer in a solution to a human with the metastatic melanoma, wherein the administration of the composition treats the metastatic melanoma in the human.

In its motion, Merck argued that the '994 patent claims are ineligible subject matter under 35 USC §101. According to Merck, the '994 patent is directed to a natural phenomenon and the patent claims do not transform such a natural phenomenon into a patent-eligible invention because the claims contain no inventive concept.

Merck asserted that the '994 patent claims that the natural phenomenon is the body's own mechanism for regulating the immune system. Specifically, T cells, which are part of the immune system, attack and kill cells that the immune system sees as foreign, such as cancer cells. Merck claimed that the '994 patent recites no inventive contribution beyond the natural phenomenon itself and that therefore the '994 patent covers patent-ineligible subject matter.

An infringement suit based on invalid patent claims fails to provide for relief. Therefore, Merck asserted that BMS's infringement claims should be dismissed with prejudice.

BMS responded that the '994 patent is a method of treatment claim that merely relies on the human body's ability to respond to the disease. BMS further asserted that Merck's argument "misses the point that every method of therapeutic treatment at its basic level relies on the biological activity of the patient's immune system".

According to BMS, the '994 patent relies on the body's immune system via the PD-1 pathway, but adds the step of administering a composition of anti-PD-1 antibodies for the treatment of metastatic melanoma to induce an immune response that would not otherwise occur in the patient's natural state.

BMS alleged that Merck induces or contributes to infringement of the '994 patent by making and selling pembrolizumab, which Merck sells in the US under the name Keytruda, for the treatment of patients with melanoma.

Federal Rule of Civil Procedure 12(b)(6) provides for dismissal where the plaintiff "fail[s] to state a

claim upon which relief can be granted”. A 2009 ruling held that “threadbare recitals of the elements of a cause of action, supported by mere conclusory statements”, are inadequate to state a claim. In considering a motion to dismiss, in 2008 another court said it “accept[s] all factual allegations as true, construe[s] the complaint in the light most favorable to the plaintiff, and determine[s] whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief”.

§101 describes the general categories of patentable subject matter as “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof”. There are, however, exceptions to these broad classifications. “Laws of nature, natural phenomena, and abstract ideas are not patentable,” as the US Supreme Court’s *Alice v CLS Bank* ruling held.

The contours of these exceptions have been the subject of much debate in recent years. As *Alice* said: “We tread carefully in construing this exclusionary principle lest it swallow all of patent law. At some level, all inventions ... embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.”

The two-step test

The *Alice* decision reaffirmed the framework, first outlined in *Mayo v Prometheus*, used to “distinguish patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts”.

As a first step, a district court must determine whether the claims at issue are directed to one of those patent-ineligible concepts. If yes, as a second step the court must determine “what else” there is in the claims. To answer that question, the court must consider the elements of each claim both individually and as an ordered combination to determine whether the additional elements transform the nature of the claim into a patent-eligible application.

The court must determine (1) if the patented technology touches on ineligible subject matter, and (2) whether there are sufficient inventive elements such that the invention is “‘significantly more’ than a patent on an ineligible concept” (*DDR Holdings v Hotels.com*), and “an invention is not rendered ineligible for patent [protection] simply because it involves an abstract concept” (*Alice*).

“Merck claimed that the ’994 patent recites no inventive contribution beyond the natural phenomenon itself and that therefore the ’994 patent covers patent-ineligible subject matter.”

In this case, the ’994 patent claims recite a method of treatment for metastatic melanoma in humans by intravenously administering an effective amount of a composition comprising a human or humanised anti-PD-1 monoclonal antibody and a solubiliser in a solution.

The '994 patent relies on the scientific fact that blocking activation of the PD-1 pathway enables the patient's T cells to perform their normal biological activity of removing cancer cells. By preventing PD-1 ligands from binding to the PD-1 receptor, the anti-PD-1 antibodies prevent the PD-1 pathway from suppressing the immune system which, in turn, kills and clears the body of the cancer cells.

Based on these facts, the court concluded that, contrary to BMS's contention, the '994 patent touches on a natural phenomenon by using T cells to activate the immune system. The '994 patent relies on the known scientific fact that blocking the activation of the PD-1 pathway causes this effect in the body, which enables the patient's T cells to perform their normal biological activity of removing cancer cells. This interaction is a natural phenomenon.

Thus, the remaining question before the court was "whether the claims do significantly more than simply describe these natural relations. To put the matter more precisely, do the patent claims add enough to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that apply natural laws?"

Merck contended that the process method consists of administering a synthetic substance through a single step to induce a natural reaction. However, BMS argued that administering anti-PD-1 antibodies is not a diagnostic step, but provides the treatment itself.

Bad news for Merck

In denying Merck's motion, the court found that there were material factual disputes that cannot be resolved on a motion to dismiss. Here, the factual allegations in the patent are taken as true and, when read in the light most favourable to BMS, the dismissal of Merck's motion was deemed appropriate. The court held that whether the claims amount to an implementation step is a complicated factual determination that the court could better resolve after discovery.

Additionally, since the '994 patent is entitled to a presumption of validity under 35 USC §282, the determination of the US Patent and Trademark Office that the '994 patent was patent-eligible is presumed to be correct. The court further stated that rarely can a patent infringement suit be dismissed at the pleading stage for lack of patentable subject matter.

When rule 12(b)(6) is used to assert an affirmative defence, dismissal is appropriate only if the well-pleaded factual allegations in the complaint, construed in the light most favourable to the plaintiff, suffice to establish the defence. The court said that here there is not clear and convincing evidence that ineligibility is the only plausible reading of the patent.

Accordingly, the court concluded that Merck did not meet its burden to prove by clear and convincing evidence that the '994 patent is invalid on its face for failing to cover patent-eligible

subject matter under 35 USC §101.

The case is Bristol-Myers Squibb v Merck & Co, Civil Action No. 15-572-GMS, in the US District Court for the District of Delaware.

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