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Insights: Alerts

TSP Diagnostic Claims: Solving the Vanda-Akamai Dilemma for Diagnostic Claims

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If you work in the field of diagnostics and are concerned with recent court decisions limiting our ability to patent diagnostic inventions when based on natural phenomena, I believe I have a practical solution for you. A solution, that while not perfect, should serve us well until legislative action provides a more perfect remedy.

In this short note, I want to propose a solution to the divided infringement concerns arising from diagnostic claims that avoid the subject matter eligibility rules by adding an active step of treating a patient. The proposed solution is a three-step-passive [TSP] diagnostic claim. In a TSP diagnostic claim, there is a first active step of *selecting* a patient who has been diagnosed using an otherwise ineligible method of *diagnosing* (step 2) and a third active step of *treating*. In the TSP diagnostic claim, the diagnostic step is a passive step relative to the party carrying out the other two active steps. The diagnostic step is carried out by a diagnostic service provider with the person selecting and treating patients undertaking the two active steps.

By rendering the diagnostic step passive, the person selecting and treating becomes a direct infringer. The party conducting the diagnostic step becomes potentially liable for patent infringement as an indirect infringer. The specific theory of liability would be under inducement to infringe. Inducement to infringe occurs when the party wants to let others know that they are able to perform the diagnostic assay. Accordingly, a TSP diagnostic claim should be of interest to a diagnostic service provider, who wants to advertise the availability of a particular diagnostic assay to medical professionals treating patients.

Let us presume that professor Smith discovers that patients with skin cancer who also exhibit excess amounts of biomarker X are best treated with a combination of drugs Y and Z. Here is a illustrative TSP diagnostic claim:

> A method of treating skin cancer comprising the steps of:
> i. selecting a person with skin cancer having a diagnosis of biomarker X in excess of 10 ng/ml;
> ii. treating the person with Drug Y in combination with drug Z.

Compare the TSP diagnostic claims to a standard method of treating claim where the addition of a selection step would typically be considered superfluous and not best practice:

> A method of treating skin cancer comprising the step of treating the person with drug Y in combination with drug Z when the person has biomarker X in excess of 10 ng/ml.

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I submit that a diagnostic company interested in selling diagnostic services or kits for treatment of skin cancer would take a license under a TSP diagnostic claims; but, would not want to license the typical method of treatment claim.

For an actual example of a TSP diagnostic claim, see US Pat. No. 10,261,091.

> 1. A method of treating a prostate cancer patient who is responsive to cancer antigen specific active immunotherapy (CASAI) using prostatic acid phosphatase as a target cancer antigen where the method comprises the steps of: i. **selecting** a prostate cancer patient with white blood cells who has been treated with a cancer antigen specific active immunotherapy (CASAI) using prostatic acid phosphatase fused to granulocyte macrophage colony-stimulating factor as a target cancer antigen to activate the patient's white blood cells under ex vivo conditions and who has an increase in reactive antibody levels in two or more non-target predetermined biomarker antigens of prostate cancer where the increase in reactive antibody levels is determined using an immunoassay that detects reactive antibody levels for at least four of the following predetermined biomarker antigens of prostate cancer: PSA, KLK2, KRAS, ERAS, LGALS8, and LGALS3 compared to a baseline antibody level from before CASAI treatment; and, ii. **treating** the prostate cancer patient with CASAI using a target cancer antigen comprising prostatic acid phosphatase fused to granulocyte macrophage colony-stimulating factor to activate the patient's white blood cells under ex vivo conditions.

If you want more details on this solution, please reach out to me.

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