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Patent Office Provides New Guidelines On What is Patentable

The past few years have been filled with confusion about what is patentable - especially for patent owners in the life science and medtech industries.

The US patent office recently took another step to clarify that question by issuing new guidelines to be followed by patent examiners. However, the guidelines do not have the "force and effect of law."

First, the new guidelines indicate that non-patentable "judicial exceptions" include abstract ideas such as "mathematical concepts, certain methods of organizing human activity, and mental processes." They also include "**laws of nature and natural phenomena**."

Second, the guidelines indicate that a judicial exception can be patentable if it is "integrated into a practical application."

"Integrated" occurs when the patent claim "imposes a meaningful limit on the judicial exception, such that the claim is more than a drafting effort designed to monopolize the judicial exception."

Also, "integrated" occurs when (1) there are "additional elements recited in the claim beyond the judicial exception" and (2) "evaluating those additional elements individually and in combination to determine whether they integrate the exception in a practical application."

"Additional elements" include an (1) "improvement in the functioning of a computer, or an improvement to other technology or technical field", (2) **"effect[s] a particular treatment of prophylaxis for a disease or medical condition"**, (3) "uses a judicial exception in conjunction with a particular machine or manufacture that is integral to the claim", and (4) effects a transformation or reduction of a particular article to a different state or thing."

Third, even if there is no integration above, the patent claim is patentable if there is an inventive concept. This includes claim limitations that are 'well-understood, routine, conventional activity."

COMMENT:

Do the guidelines make patentability determinations more predictable? Perhaps, since they supersede several prior guidelines that an examiner could pick from to reject a claim.

On the other hand, the guidelines do not have the force of law. Therefore, an examiner may find a claim patentable and a judge may find otherwise.

Bedside Patient Monitoring is Not Patentable

A recent Federal Circuit opinion in *Univ of Fla v. General Electric* made no mention of the new USPTO guidelines on patentability.

The University of Florida Research Foundation (UFRF) owned a patent entitled "Managing Critical Care Physiologic Data Using Data Synthesis Technology". According to the patent, it addressed the problem of "acquir[ing] bedside patient information using pen and paper methodologies" which can be "time-consuming and expensive" and "transcription errors can occur".

According to the Federal Circuit, the patent is a "quintessential 'do it on a computer' patent: it acknowledges that data from bedside machines was previously collected, analyzed, manipulated, and displayed manually, and it simply proposes doing so with a computer." Moreover, the patent did not claim "any specific improvement to the way computers operate."

Further, the "patent 'fails to provide any technical details for the tangible components, . . . instead predominately describ[ing] the system and methods in purely functional terms.'"

Therefore, since the patent "claims do no 'more than simply instruct the practitioner to implement the abstract idea . . . on a generic computer", the invention was not patentable.

COMMENT:

UFRF argued that its invention converted physiologic data from a machine specific format into a machine independent format and therefore improved computer functioning.

However, the patent itself may have over-emphasized its replacement of pen and paper, which made the other arguments by UFRF difficult to persuade.

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