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INTELLECTUAL PROPERTY

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No Patent Infringement When Exporting One Component of a Multi-Component Medical Test Kit

The patent law prohibits exporting from the US "all or a substantial portion of the components of a patented invention" for assembly abroad.

Promega licensed a patent for a genetic testing kit. In turn, Promega sublicensed the patent to Life Technologies who manufactured all but one component of the kit in the UK. The one component was made in the US and shipped to the UK where it was combined with the other components to make the kits.

Promega sued Life Technologies for patent infringement on the basis that the latter was selling kits outside of the licensed field of use.

The US Supreme Court concluded that a "substantial portion" under the law referred to a quantitative rather than a qualitative amount. And the Court decided that "components" referred to "plural" components, not a single component.

Therefore, Life Technologies did not infringe.

COMMENT:

To the lay person, having this issue go to the US Supreme Court may be puzzling. How much can one argue about whether "components" means "components" or just a "component"?

Electronically Transferring Medical Records is Not Patentable

Dr. Salwan filed a patent application for transferring electronic medical records (EMR) in a physician-patient network. Network users could also schedule appointments, watch educational videos, and submit insurance claims.

The Federal Circuit concluded that the patent claims were an "abstract idea of billing insurance companies and organizing patient health information."

Further, "EMR information . . . is received, stored, and selectively retrieved to generate reports", which is merely the "automation of a 'method of organizing human activity' with respect to medical information."

The Federal Circuit found that the patent claims were "directed to well-known business practices" using a generic computer. Therefore, the claims were not patentable.

COMMENT:

The case decision was non-precedential but nevertheless reiterated that simply moving information around is not enough for patentability.

Doctor May Not Avoid Patent Infringement, Even if Patient Required to Practice Invention

In *Eli Lilly v. Teva*, the former owned a patent to a method of administering a chemotherapy drug. The patent required treatment with folic acid and vitamin B12 before receiving the chemotherapy.

Teva sought FDA approval to market a version of Eli's drug. According to Teva's dosing instructions, the doctor was to administer the vitamin B12 and the chemotherapy, but the patient was to self-administer the folic acid. Importantly, the instructions indicated that the doctor should "instruct patients" to take the folic acid.

Eli sued for infringement on the theory that Teva induced others to infringe.

According to the patent laws, induced infringement is predicated on direct infringement. If no one person performs all steps of a method patent claim, then direct infringement only occurs if the "acts or one are attributable to the other such that a single entity is responsible for the infringement."

The Federal Circuit pointed out that the evidence showed that the patient must take the folic acid, as instructed by the doctor, if the patient wanted the chemotherapy drug.

This was sufficient for direct infringement by the doctor.

COMMENT:

This case points out that if a patent requires independent acts by a doctor and a patient, problems of establishing infringement may exist.

FDA is Not a Prior Inventor of Patented Invention

During the FDA approval process, Cumberland Pharmaceutical told the FDA that the absence of a stabilizing agent in its drug would raise concerns about safety and efficacy. The FDA requested justification for including the stabilizing agent. Upon approval, the FDA reminded Cumberland of its promise to evaluate the drug without the stabilizing agent.

When Cumberland obtained positive test results of the drug without the stabilizing agent, Cumberland filed a patent application. It then obtained FDA approval on the agent-free drug.

Eventually, Cumberland sued Mylan for infringement of the latter's version of the agent-free drug. At issue was whether Cumberland "derived" its invention from the FDA.

The Federal Circuit concluded that FDA's request for justification of the stabilzing agent is not a suggestion to eliminate the agent. Moreover, FDA's request was not a prior conception of the invention.

COMMENT:

Having FDA requests for information become conceptions of inventions would have created poor precedence.

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