

Federal Circuit Patent Bulletin: *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*

July 5, 2016

"[Claiming a process by reciting] the natural ability of the subject matter to undergo the process does not make the claim 'directed to' that natural ability."

On July 5, 2016, in *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, the U.S. Court of Appeals for the Federal Circuit (Prost,* Moore, Stoll) vacated and remanded the district court's summary judgment that U.S. Patent No. 7,604,929, which related to hepatocytes capable of surviving multiple freeze-thaw cycles, was invalid under 35 U.S.C. § 101. The Federal Circuit stated:

The Supreme Court has recently articulated a two-part test for distinguishing patents that claim one of the patent-ineligible exceptions from those that claim patent-eligible applications of those concepts. Step one asks whether the claim is "directed to one of [the] patent-ineligible concepts." If the answer is no, the inquiry is over: the claim falls within the ambit of § 101. If the answer is yes, the inquiry moves to step two, which asks whether, considered both individually and as an ordered combination, "the additional elements 'transform the nature of the claim' into a patent-eligible application." Step two is described "as a search for an 'inventive concept.'" At step two, more is required than "wellunderstood, routine, conventional activity already engaged in by the scientific community," which fails to transform the claim into "significantly more than a patent upon the" ineligible concept itself. . . .

Claim 1 recites a "method of producing a desired preparation of multi-cryopreserved hepatocytes." The method requires an artisan to carry out a number of concrete steps to achieve the desired preparation: step (A) requires performing density gradient fractionation on a set of previously frozen and thawed cells to separate out the viable ones; step (B) requires recovering the separated viable cells; and step (C) requires cryopreserving the recovered cells. The end result is a preparation of multi-cryopreserved cells that can be thawed for immediate use, retaining 70% viability. . . . The district court identified in these claims what it called a "natural law"—the cells' capability of surviving multiple freeze-thaw cycles. We need not decide in this case whether the court's labeling is correct. It is enough in this case to recognize that the claims are simply not directed to the ability of hepatocytes to survive multiple freeze-thaw cycles. Rather, the claims of the '929 patent are directed to a new and useful laboratory technique for preserving hepatocytes. This type of constructive process, carried out by an artisan to achieve "a new and useful end," is precisely the type of claim that is eligible for patenting. The inventors certainly discovered the cells' ability to survive multiple

freeze-thaw cycles, but that is not where they stopped, nor is it what they patented. Rather, “as the first party with knowledge of” the cells’ ability, they were “in an excellent position to claim applications of that knowledge.” That is precisely what they did. They employed their natural discovery to create a new and improved way of preserving hepatocyte cells for later use. . . .

The end result of the ‘929 patent claims is not simply an observation or detection of the ability of hepatocytes to survive multiple freeze-thaw cycles. Rather, the claims are directed to a new and useful method of preserving hepatocyte cells. Indeed, the claims recite a “method of producing a desired preparation of multicryopreserved hepatocytes.” Through the recited steps, the patented invention achieves a better way of preserving hepatocytes. The ‘929 patent claims are like thousands of others that recite processes to achieve a desired outcome, e.g., methods of producing things, or methods of treating disease. That one way of describing the process is to describe the natural ability of the subject matter to undergo the process does not make the claim “directed to” that natural ability. If that were so, we would find patent-ineligible methods of, say, producing a new compound (as directed to the individual components’ ability to combine to form the new compound), treating cancer with chemotherapy (as directed to cancer cells’ inability to survive chemotherapy), or treating headaches with aspirin (as directed to the human body’s natural response to aspirin). . . . Here, regardless of whether the individual hepatocytes in the pool of multi-cryopreserved hepatocytes have the same effect they always had or perform in their natural way, the claims are directed to a new and useful process of creating that pool, not to the pool itself. . . .

[Defendant-Appellee] argues that our approach improperly shoehorns the step two analysis into step one: that focusing on the claims’ application of the cells’ ability to survive multiple freeze-thaw cycles in a new preservation process properly falls under step two’s inquiry into “whether the additional elements ‘transform the nature of the claim’ into a patent-eligible application.” But it is [Defendant-Appellee]’s approach, not ours, that collapses the inquiry into a single step. Under the Supreme Court’s test, some claims will be “directed to” a patent-ineligible concept and some, necessarily, will not. This is true even if “all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.” As the Supreme Court has made clear, “an invention is not rendered ineligible for patent simply because it involves” one of the patent-ineligible concepts. Indeed, to preclude the patenting of an invention simply because it touches on something natural would “eviscerate patent law.”

At step one, therefore, it is not enough to merely identify a patent-ineligible concept underlying the claim; we must determine whether that patent-ineligible concept is what the claim is “directed to.” Here, the plain claim language shows that it is not. The ‘929 patent does not simply claim hepatocytes’ ability to survive multiple freeze-thaw cycles. The ‘929 patent instead claims a “method of producing a desired preparation of multicryopreserved hepatocytes.” This new and improved technique, for producing a tangible and useful result, falls squarely outside those categories of inventions that are “directed to” patent-ineligible concepts.

Even if [Defendant-Appellee] were correct that the ‘929 patent is “directed to” hepatocytes’ natural ability to survive multiple freeze-thaw cycles, and that we must proceed to step two, we would find the claims patent-eligible at that point as well. Under step two, claims that are “directed to” a patent-ineligible concept, yet also “improve[] an existing technological process,” are sufficient to “transform[] the process into an inventive

application” of the patent-ineligible concept. The claims of the '929 patent do precisely that: they recite an improved process for preserving hepatocytes for later use. The benefits of the improved process over the prior art methods are significant. The claimed method is used to create hepatocyte preparations that no longer exhibit unacceptable loss of viability. And it allows researchers to pool samples together in advance and preserve them for later use, rather than needing to wait until enough single samples are accumulated that can be pooled and used immediately. The claimed method is patent eligible because it applies the discovery that hepatocytes can be twice frozen to achieve a new and useful preservation process.