"Hepato-cicles" – 101 and Freezing Livers

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Rapid Litigation Management provides a helpful "true-positive" for navigating 101 patentability post-Alice.

U.S. Patent No. 7,604,929 discloses a process for N+2 freezing cycles of hepatocytes (liver cells). Such freezing was unconventional when the patent application was filed, as multiple freezings were thought to eliminate viable hepatocytes.

> *"The '929 patented process has a number of advantages over the prior art. By separating out and re-freezing only the viable cells, the preserved hepatocyte preparations can be thawed and used later without unacceptable loss of viability. Id. at col. 3 ll. 64-67. Pooled hepatocyte preparations are also much more easily made: hepatocyte samples from single donors can be pooled together to create a composite preparation that can be re-frozen for later use."*

The patent was challenged on 101 grounds for being directed to unpatentable subject matter, arguing that hepatocyte survival is roughly a "natural" event.

Without getting into the details, 101 requires a two-part test analysis (roughly, step 1: "Is the claim directed to a disfavored/abstract category (e.g., a natural process)?", if so, step 2: "Does it include anything else to save it?"). Here, the court found that the claims

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passed the first step, obviating the need to consider the second step (although the court also provided a second step analysis to be thorough):

> *"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."*

Such thorough consideration of the first step is heartening, as courts/examiners have often been dismissing the first step and jumping straight to the second in their analysis. Getting at "the essence" of a claim in the first step is a bit like Principal Component Analysis or summarizing a novel. It can be tedious, with many opportunities to be led astray, but separating primary from secondary features is still a relatively mechanical process. So long as you consider the entirety of the inputs and their relationships to one another, the output should follow naturally.

When difficulties do arise, they're more often of the Wittgenstein-philosophical-definition variety, than problems concerning the step one 101 analysis itself (i.e., you aren't sure how to characterize an input, you got the output, but aren't sure how to interpret it, etc.). Where these "definition issues" are in the input, they're often 112 pitfalls in "101 sheep's clothing" (there are other tools for addressing 112 pitfalls). When the issues are in the output, they're often concerning the "application/nature" divide, which will require case law and technical literature to resolve.

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