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DOES YOUR PATENT ENABLE ANOTHER TO MAKE AND USE YOUR INVENTION?

It must, in order to satisfy the patent laws that require that the patent specification teach those in the art how to "make and use the invention without undue experimentation."

In *Idenix v. Gilead,* the patent was for a method of treating hepatitis C virus ("HCV"), a leading cause of chronic liver disease. The treatment used a compound having a specific chemical and stereochemical structure. Certain atomic groups in the compound could be substituted in particular up or down positions.

It was undisputed that there were "billions of potential" atomic groups that could be used in the compound. The issue was whether one skilled in the art "would know, without undue experimentation", which atomic group "would be effective for treating HCV."

The Federal Circuit explained that at least the following factors govern:
1.) the quantity of experimentation necessary
2.) whether the patent discloses specific working examples of the invention
3.) the amount of guidance presented in the patent
4.) the nature and predictability of the field

The Court found the patent lacked enablement. It pointed to the "many thousands" of atomic groups that "meet the structural limitations" of the patent but "not all of which are effective to treat HCV", as well as the "unpredictability of the art".

COMMENT: Patent claims are often drafted broader than the experimental examples disclosed. Doing so leaves open the possibility for patent invalidity based on lack of enablement.

FINDING RELATIVES BASED ON DNA SIMILARITY IS NOT PATENTABLE

23and ME sued Ancestry.com for patent infringement over the former's patent for finding family relatives.

The district court dismissed the complaint on the basis that the patent contained "patent-ineligible subject matter." Without explanation, the Federal Circuit affirmed the district court decision.

The patent explained that it used recombinable DNA which was an improvement over past genetic testing techniques that used Y-chromosome DNA and mitochondrial DNA.

The patent described obtaining DNA samples, determining a degree of relatedness by a comparison test, and then reporting the results.

The comparison test used identical by descent ("IBD") regions of DNA which are lengths of nearly identical genetic material with shared ancestry. However, IBD comparison is a fundamental concept in genetics, as well as the relationship between degree of DNA similarity and degree of family relationship.

The district court found that the patent was for a correlation that exists in nature – the more recombinable DNA that is shared between two people, the closer the degree of a relationship.

COMMENT: This might be seen now as a classic example of reporting results from known analytical concepts – which means no patentable subject matter.