

Keywords: Anticipation, kit claim, instructions, functionally related.

General: Claimed method for extracting RNA allowed by Examiner; however, claim directed to kit for extracting RNA properly rejected by Examiner as anticipated because new instructions for known kit merely teaches new use of existing product.

In re Ngai

70 U.S.P.Q.2d 1862 (Fed. Cir. 2004)

May 13, 2004

I. Facts

In the study of ribonucleic acids (RNA), the amount of RNA that experimenters can extract from cells is typically quite small. Therefore, experimenters must employ a process of “amplification” where the material is duplicated many times over to assemble a quantity sufficient for experimentation. Further, because some RNA strands may be difficult to detect in cells, another process called “normalization” may be employed to enhance the experimenter’s ability to detect low levels of RNA.

Ngai invented a new method for amplifying and normalizing RNA. His ’608 application which is directed to this invention contained 20 claims. Claims 1-18 are method claims, and claims 19 and 20 are kit claims. Claim 19 is reproduced below:

A kit for normalizing and amplifying an RNA population, said kit comprising instructions describing the method of claim 1 and a premeasured portion of a reagent selected from the group consisting of: oligo dT biotinylated primer, T7 RNA polymerase, . . . DNA pol I, buffers and nucleotides. (emphasis added).

Ngai does not dispute that the prior art teaches a kit comprising instructions and a buffer.

The Examiner allowed method claims 1-18 but rejected kit claims 19 and 20 as unpatentable under 35 U.S.C. §102 and §103, respectively. The Board reversed the rejection of claim 20 and affirmed the rejection of claim 19. The Board agreed with the Examiner that prior art anticipates claim 19 because it reaches each and every limitation of the claim including instructions and a buffer agent. The Board concluded that the only difference between the prior art and claim 19 is the content of the instructions, such content not “functionally related” to the kit. *See In re Gulack*, 217 U.S.P.Q. 401 (Fed. Cir. 1983)

II. Issue

Are the content of the instructions functionally related to the kit so that claim 19 should have been allowed?

III. Discussion

No. Affirmed. The contents of the instructions are not functionally related (or interrelated) to the kit. Ngai is not entitled to patent a known product by simply attaching a set of instructions to that product.

Ngai relied on *In re Gulack*, 217 U.S.P.Q. 401 (Fed. Cir. 1983) to argue that the addition of new printed matter to a known product makes the product patentable. Ngai quoted from *Gulack*: the “[d]ifference between an invention and the prior art cited against it cannot be ignored merely because those differences reside in the content of the printed matter.” Ngai argued that because prior art does not reach a limitation of “instructions describing the method of claim 1,” claim 19 cannot be anticipated.

The PTO argued that Ngai's claim merely teaches a new use for an existing product. Thus, according to the PTO, Ngai can claim the new use as a method, but he cannot claim the existing product itself. The PTO argued that in order to qualify under *Gulack*, the printed matter must be functionally related to the underlying object. The PTO relied on a different passage of *Gulack*: "[t]he critical question is whether there exists any new and unobvious functional relationship between the printed matter and the substrate."

The dispute between Ngai and the PTO reduced to the question of the proper meaning of *Gulack*. The Federal Circuit thought that the PTO had the better interpretation of *Gulack*. In *Gulack*, the Board rejected a claim directed to a circular band designed for mathematical and educational purposes. The invention comprised "(1) a band, ring, or set of concentric rings; (2) a plurality of individual digits imprinted on the band or ring at regularly spaced intervals; and (3) an algorithm by which the appropriate digits are developed." The rejection was premised upon the fact that a circular band with items printed upon it was well known in the art. The Federal Circuit reversed, finding that the numbers had a functional relationship to the band itself. The Federal Circuit stated that the digits were "related to the band in two ways: (1) the band supports the digits; and (2) there is an endless sequence of digits – each digit residing in a unique position with respect to every other digit in an endless loop. Thus, the digits exploit the endless nature of the band." Although the prior art disclosed a band with printed matter, the Federal Circuit in *Gulack* concluded that the prior art neither disclosed nor suggested these two features.

The present case, however, is dissimilar from *Gulack*. In *Gulack*, the printed matter and the circularity of the band were interrelated, so as to produce a new product useful for "educational and recreational mathematical" purposes. Here, the addition of a new set of instructions into a known kit does not interrelate with the kit in the same way as the *Gulack* numbers interrelated with the band. In *Gulack*, the printed matter would not achieve its educational purpose without the band, and the band without the printed matter would similarly be unable to produce the desired result. Here, the printed matter in no way depends on the kit, and the kit does not depend on the printed matter. As the *Gulack* court pointed out, "[w]here the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability."

IV. Conclusion

If the Federal Circuit were to adopt Ngai's position, anyone could continue patenting a product indefinitely provided they add a new instruction sheet to the product. This was not envisioned by *Gulack*. Ngai is entitled to patent his invention of a new RNA extraction method, but he is not entitled to patent a known product by simply attaching a set of instructions to that product.