

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte*  
GUIDO FRANZOSO, ENRICO DESMAELE,  
FRANCESCA ZAZZERONI, and SALVATORE PAPA

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Appeal 2007-2724  
Application 10/263,330  
Technology Center 1600

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Decided: July 22, 2008

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Before DEMETRA J. MILLS, ERIC GRIMES, and LORA M. GREEN,  
*Administrative Patent Judges.*

GREEN, *Administrative Patent Judge.*

DECISION ON REQUEST FOR REHEARING

Appellants have requested rehearing of the decision entered March 12, 2008 (hereinafter “Decision”). That decision affirmed a rejection under 35 U.S.C. § 112, first paragraph, on the grounds that the Specification fails to enable the full scope of the claimed subject matter as to claims 1, 2, 25-27,

and 29; and also affirmed a rejection under 35 U.S.C. § 102(b) as to claims 1 and 2. After careful review and consideration of the arguments presented, we decline to make any substantive change in our previous opinion.

As to the Enablement rejection, Appellants argue that the “rejection seems to be based on unpredictability of treatment effects, but the claims only relate ‘method for modulating’ or a ‘method of treatment’ or ‘method of aiding,’” asserting that there “are no claims to cures.” (Req. Rehearing 1.) Appellants argue further that unpredictability, in and of itself, “does not justify rejecting claims to an invention the examiner admits is demonstrated.” (*Id.* at 2.)

We agree that unpredictability, in and of itself, is not sufficient to support an enablement rejection. The Decision did not rest solely on the unpredictability of the art, but considered and weighed the *Wands* factors, *see In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988), in the context of the scope of the claimed invention, which is drawn to using an antisense molecule to a *gadd45β* gene sequence, for example, in the treatment of degenerative disorders and other conditions caused by the effects of apoptosis in affected cells, or in the treatment of cancer (*See* Decision 8-10).

Further, as noted in the Decision:

“[T]o be enabling, the specification . . . must teach those skilled in the art how to make and use *the full scope of the claimed invention* without ‘undue experimentation.’” *Wright*, 999 F.2d at 1561 (emphasis added), quoted in *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997). Thus, “there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and how to use the invention as broadly as it is claimed.” *In re Vaeck*, 947 F.2d 488, 496 & n. 23 (Fed. Cir.

1991), quoted in *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1374 (Fed. Cir. 1999).

(Decision 7.)

Thus, while the Examiner may have admitted that “the invention has been shown to work in models correlating to conditions claimed” (Reply. Br. 3 (citing Ans. 8)), the Examiner’s admission was only to *in vitro* results, and the Examiner cited Freshny and Dermer as evidence that results obtained *in vitro* are not predictive of *in vivo* results (Decision 9), evidence that Appellants still have not rebutted. Moreover, while Appellants argue that they are not claiming a cure, “treatment” would be interpreted by the skilled artisan as requiring clinical amelioration of the disorder being treated, in this case, degenerative disorders and other conditions caused by the effects of apoptosis in affected cells, and cancer.

As to the Declaration Dr. Guido Franzoso submitted under 37 C.F.R. § 1.132 (App. Br. Exhibit A), Appellants assert that the panel admitted that they did not “understand how the knock-out mice experiments in the Declaration relate to antisense.” (Req. Rehearing 1.) According to Appellants, the “functional use of a knock-out model is to remove Gadd45 $\beta$  and leave JNKK2 active,” thus it “is a model to show the effects of total removal of Gadd45 $\beta$  on JNKK2 activation.” (Req. Rehearing 2.) Appellants argue that the use of antisense agents “results in a similar condition where Gadd45 $\beta$  is removed leading to JNKK2 activation and cell-death.” (*Id.*) Thus, Appellants assert, the rejection cannot be based on the lack of an art accepted model as knock out mice “are well known predictors of missing gene effects.” (*Id.* at 3.)

Appellants are reading statements from the Decision out of context.

That is, the Decision stated that:

[C]laim 25 is drawn to using an antisense molecule to a *gadd45β* gene sequence in the treatment of a degenerative disorder, and claim 29 uses the same agent to treat cancer. The Declaration does not provide any evidence that the knock-out mice used are art accepted models for modeling treatment of degenerative disorders or cancer.

(Decision 10.) Thus, the issue was not how the knock-out model related to antisense, but how the knock-out model related to the treatment of degenerative disorders or cancer. As we have noted, the Specification must teach the skilled artisan how to make and use the full scope of the claimed invention without undue experimentation.

As to the anticipation rejection, Appellants argue that all “Cocks teaches is the Gadd45β protein and the suggestion therein of antisense effects in humans,” asking if “that is enough to anticipate, why isn’t it enough to enable?” (Req. Rehearing 3.)

As noted by the Federal Circuit in *Rasmussen v. Smithkline Beecham Corp.*, 413 F.3d 1318 (Fed. Cir. 2005), a patent claim cannot be anticipated if the anticipatory prior art is not enabled; however, the “standard for what constitutes proper enablement of a prior art reference for purposes of anticipation under section 102 . . . differs from the enablement standard under section 112.” *Id.* at 1325. In this case, claim 1 is drawn to a method for modulating a JNK pathway by interfering with Gadd45β through the use of an antisense molecule, which encompasses both *in vitro* and *in vivo* methods. Thus, Cocks teaches the use of antisense molecules to inhibit MYD118 (Gadd45β) activity, which is sufficient to anticipate the method of claim 1.

Appellants argue further that the Decision never stated that Cocks teaches JNKK2, but the claims “relate JNKK2 as an element,” and thus Cocks cannot anticipate (Req. Rehearing 3). According to Appellants, the claimed invention is not a new benefit of an old process, but a benefit from a new process, as the inventors “were the first to demonstrate the link between Gadd45 $\beta$  and the JNK pathway and the effects of interrupting that interaction.” (*Id.*)

As was noted in the Decision, “all that is required by claim 1 is blocking the activity of Gadd45 $\beta$  through the use of an antisense molecule to a *gadd45 $\beta$*  gene sequence,” and “Cocks teaches blocking the activity of MyD118, *i.e.*, Gadd45 $\beta$ , using myd118, *i.e.*, *gadd45 $\beta$* , nucleic acid antisense molecules.” (Decision 12.) Thus, Cocks teaches all that is required by claim 1, and the ability of the antisense molecule to modulate the JNK pathway would be an inherent property of the molecule.

Note that inherent anticipation does not require intent or recognition that a prior art process achieve a result which is claimed. “Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art.” *MEHL/Biophile Intern. Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999).

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## CONCLUSION

We have considered Appellants' Request for Rehearing, but decline to make any substantive change in our previous opinion.

## REHEARING DENIED

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