

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 63

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte RICHARD L. JARVEST
and MICHAEL R. HARNDEN

Appeal No. 2000-0591¹
Application No. 08/311,291²

HEARD: November 29, 2001

Before WILLIAM F. SMITH, SCHEINER and ADAMS, Administrative Patent Judges.
SCHEINER, Administrative Patent Judge.

DECISION ON APPEAL

¹ We note that this appeal is related to an appeal in application serial no. 08/357,363 (Appeal No. 2000-0599). We have considered both appeals together.

² Application for patent filed September 23, 1994. According to appellants, this application is a continuation of application serial no. 07/918,111, filed July 20, 1992, now abandoned; which is a continuation of application serial no. 07/607,403, filed October 31, 1990, now abandoned; which is a continuation of application serial no. 07/085,216, filed August 12, 1987, now U.S. Patent No. 5,075,445; which is a continuation of application serial no. 06/641,300, filed August 16, 1984, now abandoned.

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Black et al. (Black), "Biologic Properties of Human Herpesvirus 7 Strain SB," Virus Research, Vol. 52, pp. 25-41 (1997)

Neyts et al. (Neyts 1997), "Antiviral Drug Susceptibility of Human Herpesvirus 8," Antimicrobial Agents and Chemotherapy, Vol. 41, No. 12, pp. 2754-2756 (1997)

Neyts et al. (Neyts 1998), "In Vitro and In Vivo Inhibition of Murine Gamma Herpesvirus 68 Replication by Selected Antiviral Agents," Antimicrobial Agents and Chemotherapy, Vol. 42, No. 1, pp. 170-172 (1998)

THE REJECTIONS

Claims 27, 28, 43, 46, 51, 57-60, 99-103 and 109-120 stand rejected under the first paragraph of 35 U.S.C. § 112 as being non-enabled. As evidence of lack of enablement, the examiner relies on Boyd, Bacon, Reymen, Andersson, savage, Nadler, Black, Neyts 1997 and Neyts 1998. Claims 27, 28, 43, 51, 57- 60, 99-103 and 109-120 stand rejected under 35 U.S.C. § 103; the examiner relies on Hannah as evidence of obviousness.

We reverse both rejections.

DELIBERATIONS

Our deliberations in this matter have included evaluation and review of the following materials: (1) the instant specification, including all of the claims on appeal, as well as those claims held allowable by the examiner; (2) appellants' main Brief (Paper No. 53) and the Reply Brief (Paper No. 55); (3) the examiner's Answer (Paper No. 54); (4) the above-cited references relied on by the examiner; and (5) the Esser and Sutton declarations, filed under the provisions of 37 C.F.R. § 1.132, each executed July 16, 1998.

BACKGROUND

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According to the specification, 9-(4-hydroxy-3-hydroxymethylbut-1-yl) guanine, an acyclic nucleoside also known as penciclovir or PCV, “[has] antiviral activity, and [is] potentially useful in the treatment of infections caused by herpes viruses, such as herpes simplex type 1 [HSV-1], herpes simplex type 2 [HSV-2] and varicella zoster viruses [VZV].” Page 5.

Claims 22, 23, 29 through 31, 33, 35, 39 through 41, 47 through 49, 81 through 86 and 104 through 108, directed to pharmaceutical compositions comprising penciclovir and to methods of treating HSV-1, HSV-2 and VZV using the compositions, have been indicated as allowable by the examiner. Claims 27, 28, 43, 46, 51, 57 through 60, 99 through 103 and 109 through 120, directed to treating herpesvirus infections generally using the compositions, are the subject of this appeal.

DISCUSSION

Enablement

According to the examiner, “the specification, while being enabling for the scope of claims [directed to treating HSV-1, HSV-2 and VZV infections], does not reasonably provide enablement for treating herpesviruses generally.” Final Rejection, paper no. 44. The examiner maintains that “the historical record has been that translating in vitro results to in vivo results in the antiviral area does not resemble other areas, such as the antibacterial area” (Answer, page 10), that “[d]espite intensive efforts, pharmaceutical science has been unable to find a way of getting a compound to be effective for the treatment of herpesviruses generally” (Id., page 4), and “an antiviral that operates generally against a virus family is utterly without precedent” (Id., page 12), thus, “it is

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proper for the PTO to require evidence that such an unprecedented feat has actually been accomplished” (Id., page 4).

In our view, this is putting the cart before the horse. As stated in In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369-70 (CCPA 1971):

[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

In other words, “[w]hen rejecting a claim under the enablement requirement of section 112,” it is well settled that “the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement.” In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

Thus, the threshold issue here is not whether appellants have established that their disclosure is broadly enabling for the scope of the claims, rather, the issue is whether the PTO has met its “initial burden of setting forth a reasonable explanation as to why” it is not. Keeping this in mind, we consider some of the specific issues raised by the examiner in support of his position.

The examiner argues that “[a]ntiviral agents . . . operate by inhibiting one or more of the enzymes that are essential for the vital tasks of the virus, such as entering a cell, or replicating,” but “[viral] families are usually not organized on the basis of their

enzymes, but rather on structural features . . . [f]or Herpes, it is virion structure.”

Answer, pages 5 and 6. Thus, “there is no particular reason that a compound which was effective against one member of [the Herpes] family . . . would be expected to be effective generally.” Id., page 5.

The examiner also argues that “there is [no] drug which is effective generally against [any viral] family,” defining “effective” as “having actual value in treating the virus infection” (Answer, page 6), i.e. having a “therapeutic benefit,” or affording a “significant reduction in e.g. severity or duration” (Id., page 8). In illustrating his point, the examiner concedes that acyclovir, an acyclic nucleoside structurally similar to PCV, “will somewhat weakly suppress EBV⁴ replication,” and also that “there is some in vitro effectiveness of [acyclovir and gancyclovir] against EBV,” but argues that neither drug provides a therapeutic or clinical benefit in diseases linked to EBV, including “infectious mononucleosis (IM); nasopharyngeal carcinoma; Burkitts Lymphoma (BL); Post-transplantation lymphoproliferative disease (PTLD) . . . ; . . . and other T-cell lymphomas including Benign Lymphocytosis and Purtillo syndrome; some thymomas; and hairy leukoplakia.” Answer, pages 7 and 8. The examiner provides a similar illustration for CMV,⁵ noting, for example, that “CMV retinitis, . . . probably the most widespread of all CMV-associated disorders, simply does not respond to [a]cyclovir.” Answer, page 9.

If we can summarize the examiner’s principal concerns regarding the scope of the claimed invention, they are (1) that the herpesviruses as a class are too dissimilar to

⁴ Epstein-Barr Virus, classified as a herpesvirus.

⁵ Cytomegalovirus, classified as a herpesvirus.

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expect that PCV, although effective against HSV-1, HSV-2 and VZV, will be effective against other herpesviruses, like EBV and CMV ; and (2) that acyclovir (ACV) and gancyclovir (GCV), acyclic nucleosides structurally similar to PCV, have not been shown to be clinically effective in treating many of the diseases associated with herpesviruses.

Having carefully considered the record as a whole, we do not see that the examiner has come to grips with appellants' argument that "the herpesviruses share many characteristics in addition to virion structure, including encoding their own viral DNA polymerases," and the acyclic nucleosides ACV, GCV and PCV, "inhibit the viral DNA polymerases of herpesviruses, and thus herpesvirus replication and production and spread of infectious herpesviruses."⁶ Reply Brief, pages 5 and 6.

Moreover, we agree with appellants that "[e]nablement does not require that PCV be equally effective against each of the different herpesviruses, nor that PCV eradicate all of the different clinical manifestations associated with herpesvirus infections." Brief, page 20. The claims are directed to the treatment of herpesvirus infection using PCV, and appellants urge that "[t]reatment of a herpesvirus infection may encompass any effect that would reduce the production of infectious virus in an infected individual." Id. Appellants have presented evidence supporting their assertion

⁶ According to Dr. Klaus Esser, in his declaration executed July 16, 1998, "PCV, GCV and ACV are known to work by a similar mechanism of action, each compound being phosphorylated to the monophosphate by the viral thymidine kinase, and then being further phosphorylated to the triphosphate form by host cell kinases. The triphosphate form of each compound then blocks viral DNA synthesis by inhibition [sic] the viral DNA polymerase."

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that PCV is “moderately to highly active against HSV-1, HSV-2, CMV, VZV and EBV . . . and “three of six animal herpesviruses against which it was tested” (Reply Brief, pages 6 and 7) in vitro , and also “that in vitro activity of the acyclic nucleosides [ACV and GCV] correlates with in vivo activity against the herpesviruses” with respect to production of infectious virus. See the declarations of Klaus Esser and David Sutton, and, for example, Boyd, which teaches that “[p]arallels may be drawn between the measurement of infectious virus yield in cell cultures and virus shedding by patients” (page 9).⁷

In our judgment, appellants’ disclosure “contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented” and therefore satisfies the enablement requirement of the first paragraph of 35 U.S.C. § 112.

Accordingly, the rejection of the claims is reversed.

Obviousness

The examiner has rejected claims 27, 28, 43, 51, 57-60, 99-103 and 109-120 under 35 U.S.C. § 103 as unpatentable over Hannah.

⁷ We note appellants’ submission of Exhibit 1 with the Brief, consisting of several excerpts from Field’s Virology (Third Edition, Bernard N. Field et al., eds., Lippincott-Raven Publishers, pp. 441-443, 2415, 2493, 2511, 2567-2570 (1996)). Certainly it was within the examiner’s discretion to refuse to consider this submission (Answer, page 16), but we note that the excerpts appear to buttress appellants’ assertions on pages 18-20 of the Brief that in vitro activity of the acyclic nucleosides ACV and GCV correlates with in vivo activity against the herpesviruses, at least with respect to production of infectious virus.

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According to the examiner, “[t]he rejection over Hannah, which has a priority date of 1/26/84[,] turns on whether applicants are entitled to benefit of their British priority dates.”⁸ Answer, page 16. “That in turn requires enablement, which as set forth above is lacking for such scope, for these claims. Thus, both rejections turn on the same issue.” Id.

For the reasons set forth above, we find that appellants’ disclosure is enabling for these claims, therefore, according to the examiner, appellants enjoy the benefit of their British priority date, and Hannah is not prior art to the present application. Accordingly, the rejection of the claims as unpatentable over Hannah is reversed.

CONCLUSION

On consideration of the record, for the reasons discussed above, we reverse the rejection of claims 27, 28, 43, 46, 51, 57-60, 99-103 and 109-120 under the first paragraph of 35 U.S.C. § 112, as well as the rejection of claims 27, 28, 43, 51, 57-60, 99-103 and 109-120 under 35 U.S.C. § 103.

REVERSED

⁸ The present application claims benefit under 35 U.S.C. § 119 of the March 30, 1984 filing date of U.K. Application No. 8408322.

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