



OFFICE OF THE DIRECTOR GENERAL

TAKEDA PHARMACEUTICAL COMPANY LIMITED,

Appellant,

APPEAL NO. 01-2010-0001
Application No. 1-2004-00241
Date Filed: 18 June 2004

-versus-

DIRECTOR OF THE BUREAU OF PATENTS,

Appellee.

For: PHARMACEUTICAL COMPOSITION

x-----x

NOTICE

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Director, Bureau of Patents
Intellectual Property Office
Taguig City

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Documentation, Information
and Technology Transfer Bureau
Intellectual Property Office
Taguig City

[Faint handwritten notes and stamps]

GREETINGS:


Please be informed that on 21 April 2014, the Office of the Director General issued a Decision in this case (copy attached).

Taguig City, 21 April 2014.

Very truly yours,

[Signature of Robert Nereo B. Samson]

ROBERT NEREO B. SAMSON
Attorney V


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DATE: *[Signature]*
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OFFICE OF THE DIRECTOR GENERAL

TAKEDA PHARMACEUTICAL COMPANY
LIMITED,

Appellant,

- versus -

DIRECTOR OF THE BUREAU OF
PATENTS,

Appellee.

X-----X

Appeal No. 01-2010-0001

Application No. 1-2004-00241

Date Filed: 18 June 2004

For: "PHARMACEUTICAL
COMPOSITION"

DECISION

TAKEDA PHARMACEUTICAL COMPANY LIMITED ("Appellant") appeals the decision of the Director of the Bureau of Patents ("Director") sustaining the Final Rejection of the Appellant's claim for priority in the present divisional application on the grounds that the said divisional application was filed beyond the reglementary period within which to file a divisional application as provided for under Sec. 17 of Republic Act No. 165.¹

On 18 June 1996, the Appellant filed before the IPOPHL Bureau of Patents a patent application for a "pharmaceutical composition" with Serial No. 53475 (parent application) claiming priority date of 20 June 1995 with reference to Japanese Application No. 153500-1995.

On 30 July 2002, the Examiner in Charge issued Office Action Paper No. 14, stating that:

Claims 1 to 59 are under consideration.

Claim 1 is objected to for linking eight (8) different synergistic pharmaceutical combinations comprising an **insulin sensitivity enhancer** in combination with at least one member selected from the group consisting of:

- A) an α glucosidase inhibitor
- B) an aldose reductase inhibitor
- C) a biguanadine
- D) a statin compound
- E) a squalene synthesis inhibitor
- F) a fibrate compound
- G) a LDL catabolism enhancer
- H) an angiotensin converting enzyme

Claim 1 should be divided and redrafted into combinations A-H and the redrafted claims included in the groupings below.



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It appears that the present claims constitute several distinct inventions for which a single patent cannot be issued to cover them.

Pursuant to Rule 115 and as per Office Memorandum identified as TSE/71-3, restriction to one of the groups of claims is required:

XXX

XXX

XXX

Group XXVI = includes a) claims 15 to 27 drawn to a synergistic combination of compound of the formula II or a pharmacologically acceptable salt thereof in combination with an insulin secretion enhancer and/or an insulin preparation. b) claim 57 drawn to its method of treating diabetes or diabetes complications

XXX

XXX

XXX

Restriction is required for the reason that the claims include:

- a) different synergistic combinations comprising different compounds which would require different fields of search;
- b) different methods of using each of the different combinations which would likewise require different fields of search.

Applicant's response to be complete must include a provisional election of one of the above mentioned groups even if the requirement for restriction is traversed.


On 30 September 2002, Appellant filed its Response to Office Action Paper No. 14, stating that:

Applicant provisionally elects *Group 26* directed to *claims 15-27* drawn to "*the combination of compound of the Formula II or a pharmaceutically acceptable salt thereof in combination with an insulin secretion enhancer and/or insulin preparation*" and *claims 57* drawn to "*method of treating diabetes or diabetic complications*".

Applicant manifests that divisional applications will be filed in due course.

On 18 June 2004, after a period of almost one (1) year and nine (9) months, the subject divisional application with Application No. 1-2004-00241 was filed by the Appellant, claiming the priority date of the above-mentioned parent application. However, the claim to the priority date was denied on account of its being filed beyond the reglementary period within which to file a divisional application. In denying the claim to priority date, the Examiner in Charge cited Section 17 of Republic Act No. 165, which provides that:

Section 17. *Multiple inventions in one application.* - If several independent inventions which are not so closely related as to be proper in one application are claimed, the Director may require the application to be restricted to a single invention in the same manner as notifications of defects in the application. A later application filed for an invention divided out shall be considered as having been filed on the same day as the first application provided the later application is filed within four months after the requirement to divide becomes final, or within such additional time, not exceeding four months, as may be granted. (emphasis supplied)


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In light of the denial of the claim of priority for the divisional application, the Examiner in Charge noted that such application shall be examined under Section 9 of Republic Act No. 165.² Since the claim for priority was denied, U.S. Patent No. 5,965,584, whose claims the Appellants sought to adopt for the subject divisional application, shall be cited to reject the subject claims on account of lack of novelty.

In its response dated 30 November 2004, the Appellant sought the reconsideration of the Examiner's findings, arguing that:

- a. In Paper No. 14, there was an omission to fix the specific period for compliance. It did not even include a statement that the requirement to divide or file the divisionals must be made within four (4) months from mailing date of Paper No. 14 if the requirement to divide becomes final at that point.

The Appellant further contended that Section 17 of Republic Act No. 165 did not apply, since the Appellant filed its divisional patent application as a *voluntary* divisional patent application. It argued that its response to Paper no. 14 indicated that "divisional applications will be filed in due course". Appellant claimed that "[s]ince this divisional patent application was filed during the pendency of parent application no. 53455, the claim of priority for this divisional patent application must therefore be retained".³

In Office Action Paper No. 6⁴, the Examiner denied the Appellant's request for reconsideration, and maintained that "[t]he present application cannot be considered as a voluntary divisional application because it was filed as a result of the examiner's requirement to restrict the claims of the parent application (Paper No. 14 issued to Serial No. 53455). A voluntary application is filed at applicant's choice and not in compliance with an Office Requirement".

In a letter dated 21 July 2005, the Appellant filed a supplemental response, manifesting that the claims included in the subject divisional application are not covered by the original groupings of claims included in Paper No. 14 or that these claims are "not exactly" the same claims as those included in the groupings of claims set out in Paper No. 14 pertaining to the parent application.

In its Appeal to the Director of Patents, the Appellant reiterated its argument that the subject application was a voluntary divisional application and was not filed as a result of a restriction requirement. The Appellant again argued that the claims in the present divisional application are different from those in Paper No. 14 referring to the parent application.

Resolving the Appeal, the Director of Patents concurred with the Examiner's finding that the subject divisional application can not be considered a voluntary divisional application since it was indeed filed as a result of the examiner's requirement to restrict the claims of the parent application. The Director further held that the Examiner was correct in denying the request of the applicant/appellant

Official Action marked as Paper No. 4 in Patent Application No. 1-2004-00241 dated 30 September 2004.
Appellant's Response to Paper No. 4 in Patent Application No. 1-2004-00241 dated 30 November 2004.
Dated 11 March 2005.

DATE: _____

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relating to the claim of priority date of the parent application, since the said divisional application was filed beyond the reglementary period within which to file a divisional application under Section 17 of Republic Act No. 165. The Director likewise subsequently denied the Appellant's Motion for Reconsideration filed on 16 March 2009, via Resolution dated 13 August 2010.

Dissatisfied, the Appellant filed the present Appeal, arguing that the four-month reglementary period under Section 17 of R.A. 165 does not apply to the present divisional patent application; that the present application claims specific compounds that were not explicitly included in the restriction requirement, and thus, should be considered a voluntary divisional patent application; and that the present application should be considered as a continuation application.

The issue in this appeal is whether the Director was correct in denying the Appellant's claim to the priority date of the parent application, for having been filed beyond the reglementary period.

In its Memorandum of Appeal, the Appellant argues that the Director erred in holding that the four (4) month reglementary period under Section 17 of Republic Act No. 165 applies to the subject divisional application. It argues that "the statement of appellant in its letter dated September 30, 2002 did not contain a reference to non-elected claims of Paper No. 14" and that "[h]ad it been the intention to file divisional patent applications directed to non-elected claims, it would have categorically mentioned the same in the letter, and *paragraph 1) (b) of Memorandum Circular TSE/65-6* would have applied".

In this regard, it is clearly borne by the records of this case that the Examiner in Office Paper No. 14, expressly required the restriction of the claims of the parent application. Paper No. 14 clearly states that:

Claim 1 is objected to for linking eight (8) different synergistic pharmaceutical combinations comprising an **insulin sensitivity enhancer** in combination with at least one member selected from the group consisting of: XXX

Claim 1 should be divided and redrafted into Combinations A-H and the redrafted claims included in the groupings below.

It appears that the present claims constitute several distinct inventions for which a single patent cannot be issued to cover them.

Pursuant to Rule 115 and as per Office Memorandum identified as TSE/71-3, restriction to one of the groups of claims is required: XXX

Restriction is required for the reason that the claims include:

- a) different synergistic combinations comprising different compounds which would require different fields of search;
- b) different methods of using each of the different combinations which would likewise require different fields of search.


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Applicants' response to be complete must include a provisional election of one of the above mentioned groups even if the requirement for restriction is traversed. (*Emphasis supplied*)

To this requirement, the Appellant in its letter dated 30 September 2002 stated that:

This is in response to office action marked *Paper No. 14* which term of compliance ends on *September 30, 2002*.

Applicant provisionally elects *group 26* directed to claims 15-27 drawn to "*the combination of compound of the Formula II or a pharmaceutically acceptable salt thereof in combination with an insulin secretion enhancer and/or insulin preparation*" and claims [sic] 57 drawn to "*method of treating diabetes or diabetic complications*".

Applicant manifests that divisional applications will be filed in due course. (*Emphasis supplied*)

The Appellant's argument that its letter dated September 30, 2002 did not refer to non-elected claims of Paper No. 14 and that it would have categorically mentioned if it intended to file divisional patent applications relating to such non-elected claims, is absurd and appears to be a mere attempt to justify its long period of delay in filing the subject divisional application.

In the first place, the statement "[a]pplicant manifests that divisional applications will be filed in due course" in the Appellant's 30 September 2002 letter could not have referred to anything else but the non-elected claims. The 30 September 2002 letter of the Appellant specifically stated that such letter was in response to Office Paper No. 14. In Office Paper No. 14, the Examiner had already stated that the initial claims constituted several distinct inventions, for which a single patent could not be issued to cover all such claims. Office Paper No. 14 then required that the claims be restricted, to which the Appellant complied with in its 30 September 2002 letter, electing group 26 which refers to claims 15-27 and claim 57. The Appellant's 30 September 2002 letter is thus clear, its manifestation that divisional applications would be subsequently filed could not have referred to anything else but the claims that were not covered due to its restriction of the application to group 26 for claims 15-27 and 57.

In the second place, the Appellant's argument that "[h]ad it been the intention to file divisional patent applications directed to non-elected claims, it would have categorically mentioned the same in the letter, and *paragraph 1) (b) of Memorandum Circular TSE/65-6* would have applied" is likewise unacceptable. The application of the law on patents and its implementing rules and regulations cannot be made dependent on the mere statement of the applicant as to what it had really intended in hindsight. What is clear is that the Examiner in Paper No. 14 had required that the claims be restricted to less than what was originally claimed in the parent application, and that the Appellant in its letter dated 30 September 2002 complied

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with such restriction and made the manifestation that it would file subsequent divisional applications.

This Office agrees with the Resolution of the Director dated 13 August 2010, which correctly held that:

Memorandum Circular TSE/65-6 (Subject: DIVISIONAL APPLICATIONS FILED IN COMPLIANCE TO EXAMINER'S REQUIREMENT), which was also mentioned by the Examiner as the basis for the denial of applicant-appellant's claim for priority date, is worth mentioning. It, in part, provides:

In determining whether or not a divisional application is entitled to the filing date of the parent case, examiners should be guided by the last sentence of Section 17 (RA 165) which reads as follows:


"Section 17. Multiple inventions in one application.
xxx... A later application filed for an invention divided out shall be considered as having been filed on the same day as the first application provided the later application is filed within four months after the requirement to divide becomes final, or within such additional time, not exceeding four months, as may be granted.

In accordance (with and) to promote uniform practices in the implementation of the above provision, the following should be observed in the computation of the four-month period:

- 1) When a divisional application is filed as a result of the examiner's initial requirement to restrict the parent case to one or two or more inventions, the four-month period shall be counted from the date this Office receives a response to such initial requirement (as shown by the date stamped on the paper as received by the Office) containing either of the following:
 - a) A provisional election or election of one invention for prosecution without traversing the requirement for restriction, and
 - b) Cancellation of claims drawn to the other invention or inventions leaving claims to one invention, whether or not applicant indicates a desire to file a divisional application or applications for the non-elected inventions.

- 2) When the initial requirement is traversed and if upon consideration xxx"

In the instant case, the initial requirement for restriction by the examiner, Office Action Paper No. 14, was issued on July 30, 2002 requiring applicant-appellant to elect a claim from Groups 1-27, whether such groups elected would be traversed or not. Applicant-appellant submitted its response on September 30, 2002, electing claims 15-27 and 57 under Group XXVI, for prosecution in the above


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parent application and manifesting that a divisional application will be filed in due course. Said election of claims 15-27 and 57 under Group XVI, it must be noted, did **not traverse any of the other non-elected claims and, therefore, pursuant to 1a of the abovementioned Memorandum Circular TSE/65-6, the running of the reglementary period of four months commenced on September 30, 2002, the date when applicant-appellant submitted its reply to said Office Action No. 14.**

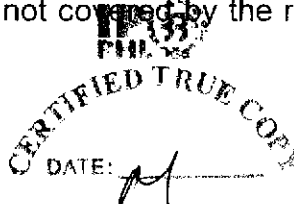
Thus, applicant-appellant should have filed the divisional applications, such as this instant case (Serial No. 1-2004-00241), within said four-month reglementary period commencing on September 30, 2002 and until January 30, 2003. But it did not. Instead, it filed this instant divisional patent application, only on June 18, 2004, or **after almost twenty-three (23) months from the time the initial requirement to divide the application was issued by the examiner.** Thus, applicant-appellant could not fault the examiner for denying this divisional application's claim for priority of the parent application.

The Appellant's argument that the Examiner failed to indicate when the restriction requirement became final, so as to serve as the reckoning point for the reglementary period within which to file the divisional application, also deserves scant consideration. The Appellant did not contest the restriction requirement in its letter dated 30 September 2002, in order to seek the reconsideration of the requirement to restrict the claims. For failure of the Appellant to present any argument to contest the propriety of the restriction requirement, it escapes us how the Appellant could argue that the requirement is anything but final. Moreover, it was incumbent upon the Appellant, as represented by its counsel, to exercise diligence in prosecuting its patent application. It was thus tasked with the knowledge of the applicable regulations and reglementary periods relevant to its application. Hence, it has to suffer the consequences of this act or omission that is lacking in the exercise of standard care, which an ordinarily prudent person bestows upon the person's important business.⁵ Its failure to file the present divisional application in time cannot be attributed to the lack of an explicit indication of the due date for filing the same in the Office Actions issued by this Office in the parent application.

The Appellant further argued in its Appeal that the Director erred in rejecting its argument that the subject application contains specific compounds that were not explicitly included in the restriction requirement. According to the Appellant, the claims of the present application are directed to compositions and method of treatment claims of specific compounds that were not included in the restriction requirement under Office Paper No. 14. It contends that the Director failed to take such argument into serious consideration in the Resolution of its Motion for Reconsideration.

This Office disagrees. The records of this case clearly show that the Director carefully considered the Appellant's argument that the subject application introduced claims as to specific compounds which were allegedly not covered by the restriction

⁵ *Fernandez v. Tan Tiong Tick*, G. R. No. L-15877, 28 April 1961.


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requirement of the parent application. We find no cogent reason to disturb the Director's Decision dated 17 February 2009, where it was correctly held that:


The argument that the filing of the divisional application is a voluntary divisional application, for the reason that the claims subject of the said divisional patent application are not the same as the claims subject of the parent application included in Paper No. 14 issued to parent Application No. 53455 because the subject claims were not previously presented in the said parent application; and that the said claims have been limited to defined sensitivity enhancers which were not previously and/or specifically claimed in the Parent Application and could not have been considered as part of the first restriction requirement, is not tenable.

The applicant/appellant recognized that the subject matter of the claims of the divisional application *is covered* by the general claims as restricted in the parent application and therefore it can not be argued that the more specific claims could not have been considered as part of the first restriction requirement. The resulting limited language of the claims of the said divisional application only showed that further examination of the said claims in the other jurisdiction to which the claims of the said divisional application was adopted, had caused the applicant to limit the scope of said claims to their limited allowable form.

Lastly, the Appellant's argument that the subject application can be considered as a continuation application in accordance with the 1993 Edition of the Rules of Practice in Patent Cases issued on August 23, 1993, is likewise untenable. At the onset, this argument is contradicted by the Appellant's position that the subject application contains claims not included in the general claims of the Parent Application. More importantly, in its letter dated 30 November 2004, in response to the Examiner's denial of the claim for priority date of the parent application due to the filing beyond the reglementary period, nowhere did the Appellant claim that it was filing a continuation application. Its sole argument was that the divisional application was a voluntary one filed on its own initiative and not due to the restriction requirement in the parent application. In all its pleadings, the Appellant had been continuously arguing that it had filed a voluntary divisional application, and to adopt a drastic change in its theory at this belated stage appears to be a mere attempt to justify its long period of delay in filing the subject divisional application.

This Office adheres to the policy of securing protection to inventors and promoting patent protection and recognizes the need to have an effective industrial property system. The Rules and Regulations on Inventions that streamlined the administrative procedures in granting patents were promulgated to achieve this policy and objective. The reglementary periods fixed in the Rules and Regulations on Inventions are essential for the effective and orderly administration and disposition of patent applications. Aptly, procedural rules are not to be belittled or disregarded simply because their non-observance may have resulted in prejudice to a party's substantive rights.⁶

⁶ *Lazaro v. Court of Appeals*, 330 SCRA 208 (2000).



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In this regard, it is in the interest of justice that in patent examinations there should be strict implementation of the time limits and reglementary periods within which applicants must prosecute their applications. The grant of patent protection is an exception to the general rule of prohibiting monopoly. It is, thus, in the interest of the public that in order to balance this privilege and private interests of the inventors, that patent laws should provide a stringent application process which inventors should strictly comply with in order to secure patent protection.

WHEREFORE, premises considered, the instant appeal is hereby DISMISSED. Let a copy of this Decision be furnished to the Director of the Bureau of Patents and the library of the Documentation, Information and Technology Transfer Bureau for information, guidance, and records purposes.

SO ORDERED.

21 APR 2014 Taguig City.


RICARDO R. BLANCAFLOR
Director General


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