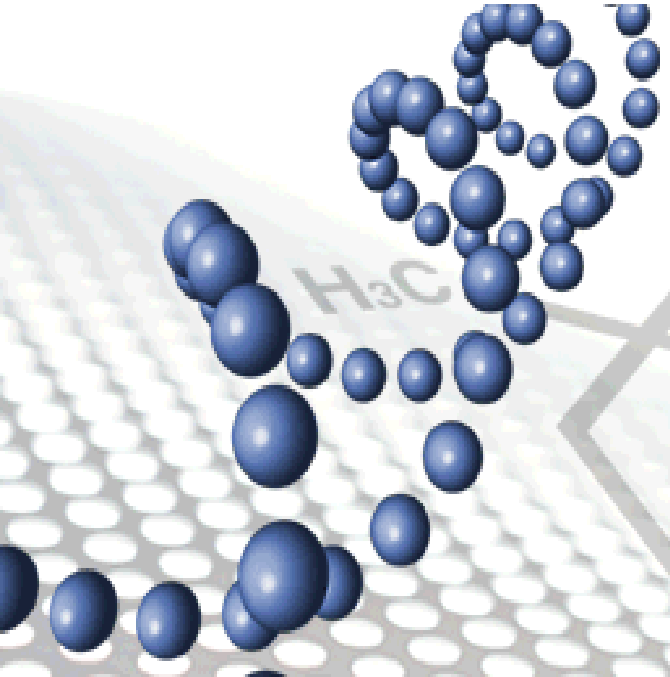
New JP Practice on Indication Carve-Out



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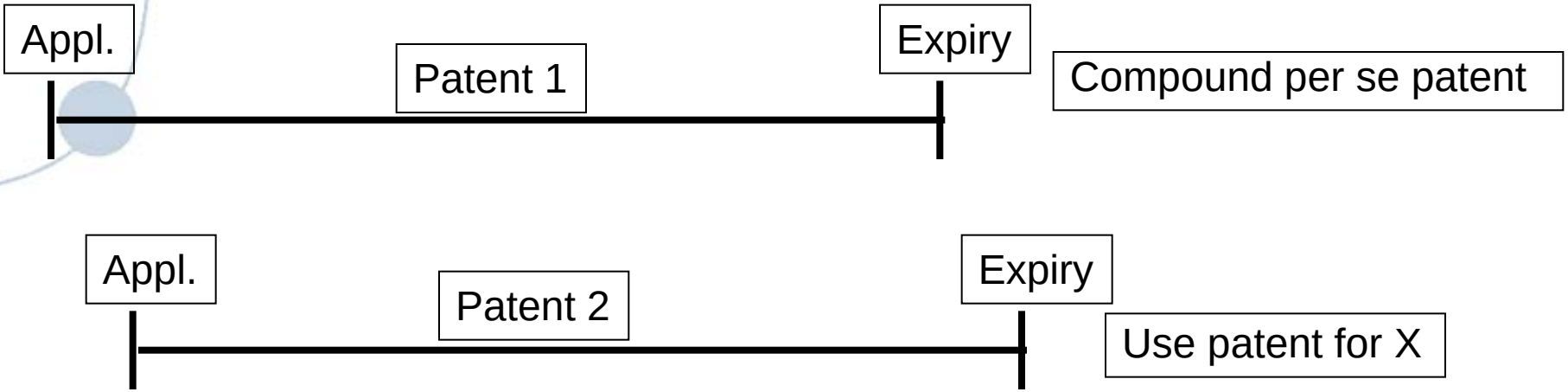
Yoshinobu Murofushi

Concerning the Handling of Drug Patents in Approval Reviews and NHI Price Listing of Prescription Generic Drugs under the Pharmaceutical Affairs Law

(1) Where the existence of a patent for the active ingredient of an original drug renders impossible the manufacture per se of the respective active ingredient, the generic drug shall not be approved.

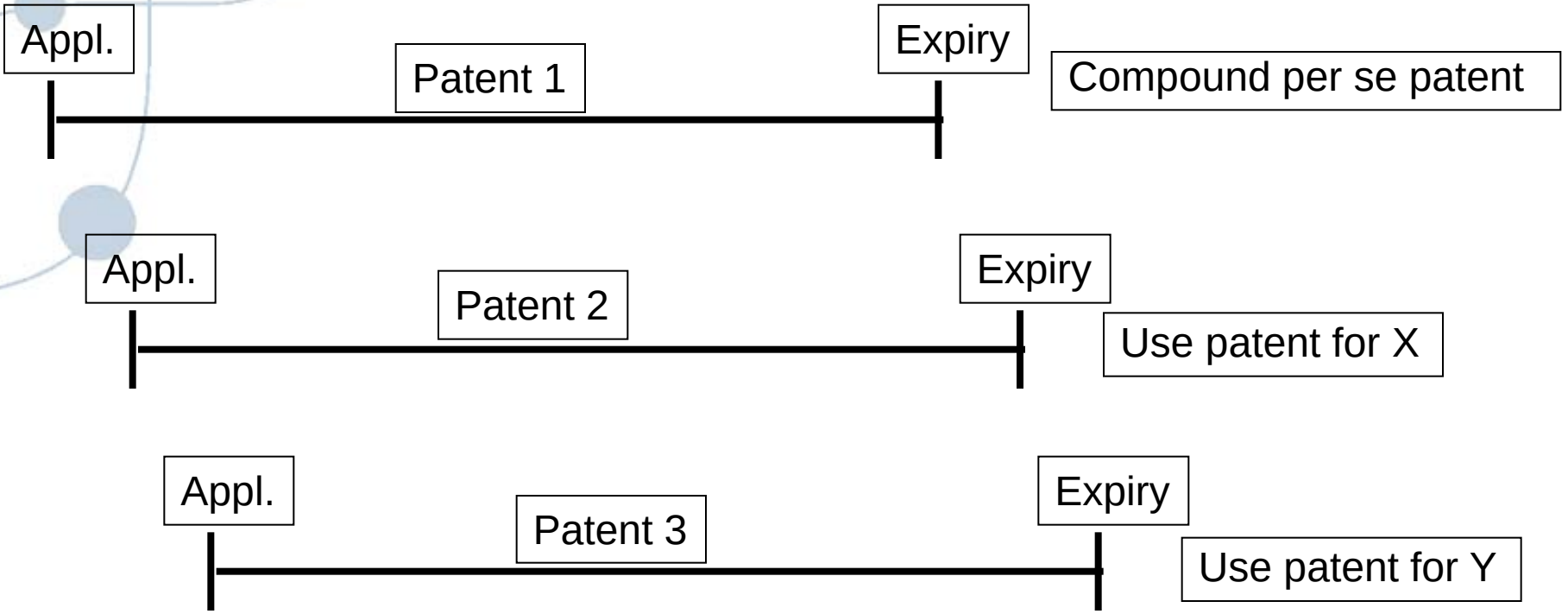
(2) Where a patent exists for certain indications and effects of an original drug, and the manufacture of a drug claiming the other indications and effects etc. is possible, the generic drug may be approved.

Case 1: Brand drug has an indication X



Any generics cannot enter into the market by the expiry of the use patent since the brand drug has one indication.

Case 2: Brand drug has indications X & Y



Generics with the indication of X must be approved at the expiry of the use patent for X.
Then, generics can obtain the additional indication of Y after the expiry of the use patent for Y via a partial change of the marketing approval.

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Three merits for entering into the market after the expiration of use patent for X

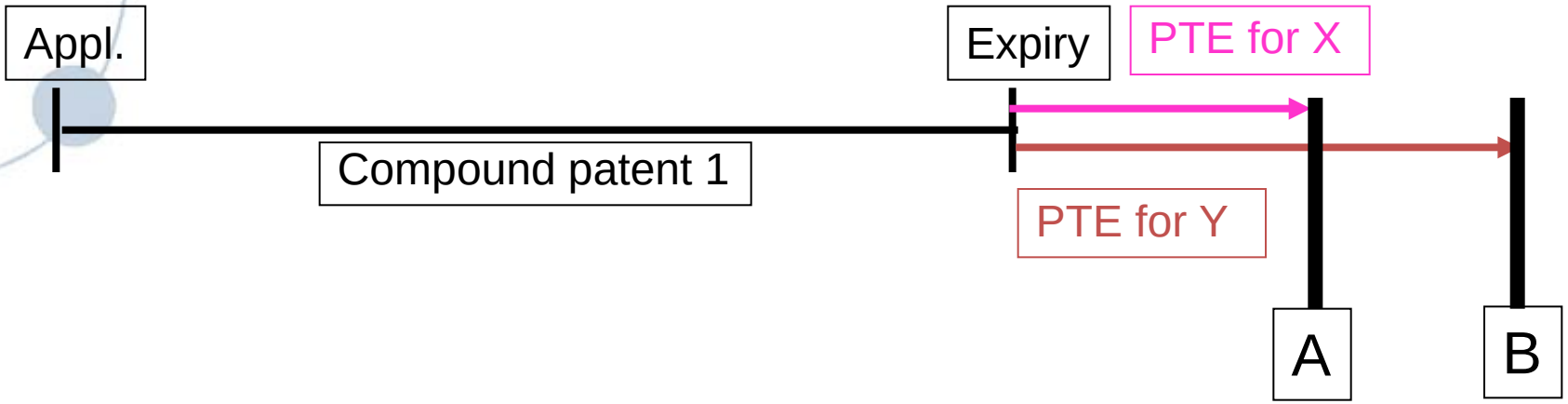
- Please note that generics can enjoy these merits even if the market size for the indication X is small.
- (1) Generics won't need to wait for getting the NHI price for the indication Y since they has obtained the NHI price already when the indication X was approved.
- Thus, generics can enter into the market with the product having the indication Y just after the expiry date of patent 3 without waiting for getting the NHI price. This may allow you to make a head start for at longest 6 months.

Three merits for entering into the market after the expiration of use patent for X

- (2) According to our government, even if a generic does not have the indication Y, the cost will be reimbursed if a doctor prescribes the generic for the said indication Y.
- (3) Earlier market entry may give a generic a higher NHI price. As you know, the revision of the NHI price takes place every two years.

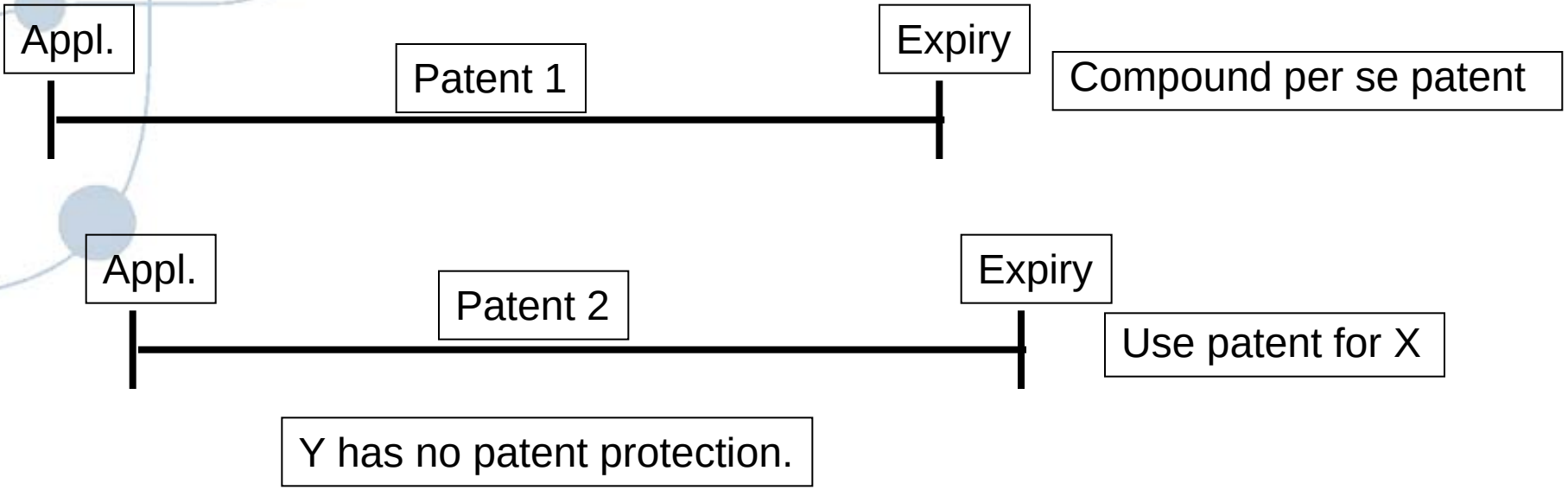
  Thus, in case a generic with only indication X is largely discounted, the NHI price for the second generics which enter into the market for the first time after the expiry of patent 3 may be rather lower.

Case 2': Brand drug has indications X & Y



Generics with the indication X must be approved at the expiry of the PTE for X (="A").
Then, generics can obtain the additional indication Y after the expiry of the PTE for Y ("B") via a partial change of the marketing approval.

Case 3: Brand drug has indications X & Y



If the brand drug obtains a subsequent indication Y which is not covered by any patents, generics with the indication Y must be approved at the expiry of the compound patent.
Then, generics can obtain the additional indication X after the expiry of the use patent for X via a partial change of the approval.
Thus, the patent life must be shortened due to the addition of non-patent protected indication Y.