Stay informed: Pharmaceutical and Life Sciences Industry Alert

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IPR&D acquired in a business combination – How many pieces?

Background

Pharmaceutical, medical technology and biotech companies continue to use mergers and acquisitions as a way to bolster their pipelines and improve efficiencies. In-process research and development (IPR&D) can be one of the most significant assets acquired in these deals. As such, recognition and measurement of IPR&D is an important consideration in the acquisition accounting.

Acquisitions in the pharmaceutical and life science industry often involve targets with marketed products and on-going research and development projects. A great deal of the transaction value may relate to the IPR&D; thus, it is crucial for both financial reporting and for communicating to the marketplace that the acquired IPR&D is accounted for properly.

IPR&D acquired in a business combination meets the definition of an asset under IFRS and US GAAP, and is recognized at fair value on the acquisition date. It is accounted for initially as an indefinite-lived intangible asset that is not subject to amortization. Asset identification is driven by general principles that require assets to be 'identifiable' and 'reliably measurable.' Each element of IPR&D that meets these criteria will be a separate 'unit of account' or accounting asset.

The unit of account for an IPR&D asset can have a significant impact on the accounting result as it determines the level at which fair value is measured upon initial recognition and the level at which impairment is tested in future periods. This alert explains how the requirements are typically applied in the pharmaceutical and life science industry and includes some illustrative examples. Other approaches may also be appropriate depending on the facts and circumstances of the transaction.

The observations and illustrative examples contained in this alert apply equally to companies under either IFRS or US GAAP, as the respective standards on business combinations (IFRS 3 & ASC 805) offer converged guidance on this topic.

Issue

The research activities of an acquired business generally are comprised of equipment and various intellectual property (IP). It is important to assess which are 'identifiable' under the accounting guidance; that is, which are separable or arising from contractual or legal rights. This assessment provides the basis for the IPR&D unit of account and may result in a more disaggregated breakdown than you would expect.

The compounds, formulations, biologics and, in some cases, delivery mechanisms in the industry are inherently unique. The contractual or legal rights, which are generally protected through patents, are the basis for premium cash inflows in the future.

These contractual or legal rights provide the starting point for 'identifiable' which is the first step when assessing unit of account. Patent protection and regulatory approvals are granted by national authorities; thus, a single compound or biologic may well have several distinct patents and regulatory approvals granted by different national or regional authorities. These rights often represent a separate intangible asset(s) at the date of acquisition and are not IPR&D. However, there may be both intangible assets and IPR&D related to a single compound.

An acquired IPR&D asset may therefore have a number of characteristics or different rights attached to it; the underlying chemical or biologic information, the method of production, the regulatory approvals and patent protection. These will vary depending on the stage of development and the nature of the product.

The next step is to consider whether an identifiable IPR&D asset should be recognized as a single unit of account, grouped with other identifiable IPR&D assets into a larger unit of account or disaggregated further. Separately identifiable rights arising from a single asset might need to be separated into individual units of account if the rights have distinctive characteristics. For example, if patent protection will expire significantly earlier in a major jurisdiction, such as Europe, then it might not be appropriate to aggregate the value of the European rights with rights elsewhere in the world. Furthermore, acquired idled projects or IPR&D that the acquirer does not intend to pursue at the acquisition date should be assessed from the perspective of a market participant to determine if individual projects represent a separate unit of account.

However, multiple assets that share similar characteristics are sometimes grouped into a single unit of account. This assessment requires significant judgment, as the characteristics of each asset need to be considered carefully.

The following table identifies several relevant characteristics for IPR&D assets and summarizes the separation / grouping considerations of each:

Characteristic	Consideration for separate assets or grouping
Nature of the asset	A tangible asset and an intangible asset are rarely combined into a single unit of account. A biologic is often a large complex molecule or combination of molecules, often produced using recombinant DNA. These may be produced using highly-customized equipment that does not have an alternative use. The close link between the tangible assets and intangible assets would not override the need for separate identification and recognition of tangible and intangible assets.

Characteristic	Consideration for separate assets or grouping
Useful life	Assets with different useful lives generally should not be grouped, as they must be amortized over different periods. Expected patent life should be considered when assessing whether IPR&D represents individual units of account. Differing levels and/or length of protection in individual jurisdictions would suggest that a drug has a different risk profile and potential for cash generation in each jurisdiction. Where material, the rights for each jurisdiction may be a separate unit of account.
Activities & costs	The nature of activities and costs underlying each activity of an IPR&D project are indicative of the asset(s) being created. This concept is particularly important when assessing the rights of a drug in multiple jurisdictions. Consideration should be given to • what activities generate costs, • when the costs are incurred, • what activities and risks remain for further development, • how the costs are managed during development, • whether the costs will be managed collectively in the future, and • whether the IPR&D project would be transferred by itself or with other separately identifiable assets. A similar cost and risk profile across jurisdictions may indicate that the rights can be combined in a single unit of account.
Development phase	The development phase of a project may indicate whether IP should be disaggregated. For example, a phase II drug is likely to have a global risk and cost profile. Economic and sales information for specific jurisdictions may only be available on a projected basis and might not be sufficiently reliable to support separate units of account by jurisdiction. These factors would tend to support a single unit of account. In contrast, a drug that has completed phase III and is on the verge of market approval in multiple jurisdictions may have reliable data to determine whether the rights in each jurisdiction are similar enough for aggregation or if they need to be separated.

The list above discusses each characteristic in the context of new drug development, though the characteristics identified and the concepts mentioned can also be applied to the IPR&D of delivery or enabling mechanisms. Regardless of the asset, this table highlights some of the key characteristics to consider but is not all-inclusive. All relevant facts and circumstances related to a specific acquisition need to be considered to determine an appropriate unit of account.

For additional discussion of factors used to assess the unit of account for IPR&D, refer to 'A Global Guide to Accounting for Business Combinations and Noncontrolling Interests' (PwC 2013) or the AICPA Accounting and Valuation Guide, 'Assets Acquired to be used in Research and Development Activities' (updated December 2013).

Illustrative examples

Example 1 – Rights to separate IP

Facts: PharmaCo, a pharmaceutical group, acquires GlobalDrug, a rival pharmaceutical business. GlobalDrug has incurred significant research costs in connection with two new drugs. Drug A is in phase III and PharmaCo expects that regulatory approval will be given within two years. Drug B is in phase II. Drug A's revenue-earning potential was one of the principal reasons why PharmaCo decided to acquire GlobalDrug.

Analysis: Each drug can be separately identified and the underlying IP is unique. The significant difference in phase of development suggests dissimilar cost and risk profiles between drugs. Therefore, each drug should be considered a separate unit of account. Further disaggregation might be appropriate and should be considered (see Example 2 below).

Example 2 – Rights in separate jurisdictions

Facts: PharmaCo, acquires NextGenBio, a small biotech firm. NextGenBio is developing a single compound that is expected to become a leading cancer medication. The project is in the early stage of development. If successful, NextGenBio plans to seek regulatory approval and to begin marketing of the medication in Canada, the USA and Europe.

Analysis: PharmaCo will likely recognize a single global asset for the drug. The early stage of development means that any risks related to a specific regulator or jurisdiction would not yet be well defined. In addition, the jurisdictions planned for initial release have similar regulatory requirements. Therefore the cost and risk profiles for the regulatory pathway should be similar. Separation of rights by jurisdiction would not appear to be required.

Alternative facts: Assume the same facts as above with the following changes: The project reached market approval in Canada, USA and Europe just prior to acquisition, and regulatory approval is currently being pursued in Japan and Brazil. The project has been scaled to allow for additional trials to meet the regulatory requirements in each future jurisdiction.

Analysis: It depends. Industry practice would suggest that PharmaCo may recognize at least two, and potentially up to five, separate assets: intangible assets representing the rights to the drug in each of the market-approved jurisdictions (or a single asset that includes rights for all market-approved jurisdictions if they can be aggregated as discussed above) and one IPR&D asset for the portion still being developed (or two if separated by jurisdiction). The late stage of development combined with the plan to scale trials to meet regulatory requirements may suggest that further disaggregation of the IP still being developed is warranted. However, the specific facts and circumstances would need to be assessed to determine if the cost and risk profiles would be different.

Regulator focus

Several regulators, including the SEC, have focused on this issue in recent periods, questioning whether IPR&D acquired in a business combination has been disaggregated appropriately. They are asking companies to provide explanations of how IPR&D assets were identified and justification for the limited disaggregation of IPR&D when few assets are separated.

Requested information by project (even if not identified as a separate unit of account by the entity) may include:

- The nature of the project
- The fair value of the project
  - How fair value was determined
  - Significant valuation assumptions used
- The level of completion at acquisition
- The anticipated completion date
- The estimated costs to complete
  - Nature of the costs
  - Timing of the costs

We expect this to continue be an area of focus.

Questions

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