FASB Emerging Issues Task Force

Issue No. 07-1

Title: Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property

Document: Issue Summary No. 1, Supplement No. 1 (including Working Group Report No. 2)*

Date prepared: May 30, 2007

FASB Staff: Bolash (ext. 358)/Beswick (ext. 453)

EITF Liaison: Matthew Schroeder

Date previously discussed: March 15, 2007

Previously distributed EITF materials: Issue Summary No. 1, dated February 26, 2007; Working Group Report No. 1 (distributed as Exhibit 07-1C to Issue Summary No. 1)

References:

FASB Statement No. 94, *Consolidation of All Majority-Owned Subsidiaries* (FAS 94)

FASB Statement No. 68, *Research and Development Arrangements* (FAS 68)

FASB Statement No. 131, *Disclosures about Segments of an Enterprise and Related Information* (FAS 131)

FASB Statement No. 154, *Accounting Changes and Error Corrections* (FAS 154)

FASB Interpretation No. 46 (revised December 2003), *Consolidation of Variable Interest Entities* (FIN 46R)

FASB Concepts Statement No. 5, *Recognition and Measurement in Financial Statements of Business Enterprises* (CON 5)

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* **The alternative views presented in this Issue Summary Supplement are for purposes of discussion by the EITF. No individual views are to be presumed to be acceptable or unacceptable applications of Generally Accepted Accounting Principles until the Task Force makes such a determination, exposes it for public comment, and it is ratified by the Board.**

APB Opinion No. 18, *The Equity Method of Accounting for Investments in Common Stock* (APB 18)

APB Opinion No. 22, *Disclosure of Accounting Policies* (APB 22)

AICPA Accounting Interpretation 2, *Investments in Partnerships and Ventures*, of APB Opinion No. 18 (AIN APB 18)

AICPA Statement of Position 78-9, *Accounting for Investments in Real Estate Joint Ventures* (SOP 78-9)

SEC Regulation S-X, Rule 4-08(g) (SEC Regulation S-X, Rule 4-08(g))

EITF Issue No. 88-18, "Sales of Future Revenues" (Issue 88-18)

EITF Issue No. 96-16, "Investor's Accounting for an Investee When the Investor Has a Majority of the Voting Interest but the Minority Shareholder or Shareholders Have Certain Approval or Veto Rights" (Issue 96-16)

EITF Issue No. 99-19, "Reporting Revenue Gross as a Principal versus Net as an Agent" (Issue 99-19)

EITF Issue No. 00-1, "Investor Balance Sheet and Income Statement Display under the Equity Method for Investments in Certain Partnerships and Other Ventures" (Issue 00-1)

EITF Issue No. 01-9, "Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)" (Issue 01-9)

EITF Issue No. 02-16, "Accounting by a Customer (Including a Reseller) for Certain Consideration Received from a Vendor" (Issue 02-16)

Previous Task Force Discussion

1. At the March 15, 2007 EITF meeting, the Task Force discussed Issue 1 including the Working Group's recommendation that a collaborative arrangement subject to the guidance in this Issue would be defined as an arrangement in which the parties share in the risks and rewards of the arrangement's operations from inception of the arrangement through its termination. The Task Force also discussed the Working Group's recommended indicators that could be used to identify a collaborative arrangement. The Working Group recommended that the indicators should not be considered individually presumptive or determinative; however, the relative strength of each indicator should be considered. The Task Force also observed that, in addition to the indicators proposed by the Working Group, there may be other indicators that could identify the existence of a collaborative arrangement.

2. The Task Force was not asked to reach a conclusion on Issue 1. The Task Force requested that the FASB staff modify and expand the indicators recommended by the Working Group to clarify the scope of the Issue and the example scenarios used to illustrate this Issue to consider additional fact patterns. The Task Force also requested that the staff discuss those revised indicators and illustrative scenarios with the Working Group.

3. The Task Force reached a tentative conclusion on Issue 2 that transactions with third parties (that is, revenue generated and costs incurred by participants in a collaborative arrangement) should be reported on the appropriate line item in each company's respective financial statement pursuant to the guidance in Issue 99-19. For example, a participant in a collaborative arrangement who is deemed to be the principal for a given transaction would record that transaction on a gross basis in its financial statements. In reaching that tentative conclusion, the Task Force elected not to pursue an accounting model that would be based on the equity method of accounting under APB 18.

4. The Task Force discussed Issue 3 but was not asked to reach a conclusion. The Task Force discussed the alternative views presented to address how sharing payments made to or received by a participant pursuant to a collaborative arrangement should be presented in the income statement but requested the FASB staff to explore an additional view for consideration. Under this additional view, all sharing payments would be recorded on a net basis within other

operating income or expense in the participant's statement of operations regardless of whether the related transactions are recorded gross or net under Issue 2. In addition, the Task Force discussed potential disclosures by participants to a collaborative arrangement under this view including summarized information for the results of the activities of the collaborative arrangement.

Working Group Report

5. In response to the Task Force discussion at the March meeting, the Working Group met on May 1, 2007 to discuss Issue 1 and Issue 3. The Working Group's recommendations on these issues are discussed below, and Working Group Report No. 2, is provided as Exhibit 07-1B.

Accounting Issues and Alternatives

6. To address the concerns raised by the Task Force at the March meeting, the FASB staff has revised the proposed definition of a collaborative arrangement in Issue 1 and provided additional fact patterns in Exhibit 07-1A (see also additional Scenarios 9 through 12). The revised definition of a Collaborative Arrangement is based on the May 1, 2007 Working Group meeting, as supplemented by the FASB staff based on additional research. The Working Group has also made a recommendation with respect to Issue 3.

Issue 1: How to determine whether an arrangement constitutes a Collaborative Arrangement within the scope of this Issue.

7. The Working Group recommends that whether an arrangement is a Collaborative Arrangement within the scope of Issue 07-1 is a matter of judgment that depends on the relevant facts and circumstances and that the indicators set forth below should be considered in that evaluation. A Collaborative Arrangement is a contractual arrangement with a similar economic substance to a joint venture but is not primarily conducted through a legal entity. If a Collaborative Arrangement were conducted through a legal entity in which the participants were

shareholders or other interest holders, the arrangement would be subject to FAS 94, APB 18, FIN 46(R), or other related literature.[1]

Indicators of a Collaborative Arrangement

8. The Working Group recommends that the presence of the following two indicators creates a rebuttable presumption that a Collaborative Arrangement exists. That is, if both indicators are present, then the participants should presume that the arrangement is a Collaborative Arrangement unless that presumption is overcome by careful analysis of the relevant facts and circumstances.

a. ***The parties are active participants to the arrangement.*** That is, the participants are not solely financial investors but, rather, they make significant contributions to directing and carrying out the joint operating activities. An arrangement involving a purely financial investor may be appropriately accounted for under Issue 88-18 or FAS 68, depending on the terms of the arrangement and the nature of the related activities.

b. ***The participants are exposed to significant risks and rewards that are dependent on the ultimate commercial success of the endeavor.***[2] An arrangement in which the partners are not exposed to variable outcomes dependent on the ultimate commercial success of the endeavor (for example, services being performed for fees paid in cash at fair market value rates, limitations on exposure to risk/reward, returns that are either guaranteed or limited by the arrangement), may indicate a contract subject to other authoritative literature.

   Terms of arrangements that indicate that participants to the arrangement are not exposed to significant risks and rewards dependent on the ultimate commercial success of the endeavor include the ability of a participant to exit the arrangement without cause and recover a significant portion or all of its cumulative economic participation to date; an allocation of initial profits to only one participant; and a limitation on the reward that accrues to a participant.

[1] A Collaborative Arrangement may include a legal entity in some portion of the arrangement for legal, tax, or regulatory purposes. Any consensus on this Issue does not affect the accounting for that legal entity under FAS 94, APB 18, FIN 46(R), or other related literature.

[2] For example, the "endeavor" in a biotechnology or pharmaceutical environment would be a drug candidate. In the entertainment industry, it would be a motion picture.

Many Collaborative Arrangements involve licenses of intellectual property, and consideration related to the license may be exchanged at the inception of the arrangement. Such an exchange does not necessarily indicate that the participants are not exposed to significant risks and rewards dependent on the ultimate commercial success of the endeavor.

The Working Group observes that the following two indicators may be present in a Collaborative Arrangement, but that they are neither presumptive nor determinative.

c. ***Through the arrangement the participants have a contractual or other legal right to own, access, or use the underlying intellectual property, for example, by holding the patent or a related license.*** The Working Group observed that most Collaborative Arrangements will relate to the development and commercialization of intellectual property, and the presence of intellectual property rights in an arrangement may indicate that the arrangement is a Collaborative Arrangement. However, there may also be arrangements that do not relate to intellectual property that may be Collaborative Arrangements.

d. ***There is a Steering Committee or other mechanism to provide participating rights[3] to the participants.*** The existence of a Steering Committee may indicate that an arrangement is a Collaborative Arrangement. Even when Steering Committees are present, however, one participant may have an overriding decision-making ability. In other words, a Steering Committee is present, but there may be a contractual mechanism whereby one party has the ability to resolve a deadlock, that is, to unilaterally determine the outcome of an issue. Such a provision would not necessarily prevent an arrangement from being considered a Collaborative Arrangement. The nature of the rights of the parties should be considered in evaluating the relative strength of this indicator.

The Working Group observed that the list of indicators above is not all-inclusive.

[3] Based on an analogy to participating rights as described in Issue 96-16, such rights allow a participant in an arrangement to effectively participate in decisions that occur as part of the ordinary course of the arrangement's activities and are significant factors in directing and carrying out the activities of the arrangement.

Evaluation of a Collaborative Arrangement

9. The Working Group recommends that participants to an arrangement should evaluate whether that arrangement is a Collaborative Arrangement at the inception of the arrangement based on the facts and circumstances present at that time. The initial determination of whether an arrangement is a Collaborative Arrangement should be reconsidered when any changes to the facts and circumstances alter either the roles of the participants in the arrangement (see indicator (a) above) or the participants' exposure to significant risks and rewards dependent on the ultimate commercial success of the endeavor (see indicator (b) above). The exercise of an option would be an example of a possible reconsideration event.

10. A Collaborative Arrangement can begin at any point in the lifecycle of the endeavor. As noted above, an arrangement should be evaluated at the inception of the arrangement and upon the occurrence of any reconsideration event. The lifecycle stage of the endeavor and the terms and conditions of the arrangement would both be factors to consider in the evaluation of the arrangement. In a Collaborative Arrangement, the participants financially participate in the endeavor through its eventual termination, although they need not be present at the inception of the endeavor.

11. The Working Group also discussed arrangements common in the pharmaceutical and biotechnology industries that the Working Group did not consider to be Collaborative Arrangements and used the characteristics of such arrangements to assist in identifying the indicators discussed above. Arrangements that the Working Group did not believe to be Collaborative Arrangements include services that are contracted at fair market value rates (for example, services performed by contract research organizations and contract sales organizations), contract manufacturing, some stand-alone royalty arrangements, passive revenue streams, and arrangements in which entities only receive incentives to increase sales. The Working Group believes that the relationship between the parties to these arrangements is typically more like that of a customer-service provider relationship, rather than the relationship found in a Collaborative Arrangement, and that these arrangements are within the scope of other existing GAAP.

12. The scope of this Issue is not intended to include arrangements for which the accounting is specifically addressed within the scope of other authoritative literature. To the extent that guidance in this Issue conflicts with other authoritative literature, the arrangement should be accounted for in accordance with the relevant provisions of that literature rather than the guidance in this Issue. In addition, this Issue does not address revenue recognition matters related to these arrangements (for example, determining the appropriate units of accounting; when the criteria for revenue recognition are met; or the appropriate revenue recognition convention for a given unit of accounting).

13. At the June 14, 2007 EITF meeting, the staff will ask the Task Force to affirm the recommendation of the Working Group.

Exhibit 07-1A includes several illustrations of arrangements found in the biotechnology and pharmaceutical and entertainment industries that demonstrate the application of these indicators in order to determine whether a Collaborative Arrangement exists.

Issue 2: How costs incurred and revenue generated on sales to third parties should be reported by the partners to a Collaborative Arrangement in each of their respective income statements.

14. The Task Force reached a tentative conclusion on Issue 2 at the March meeting that transactions with third parties (that is, revenue generated and costs incurred by participants in a collaborative arrangement) should be reported on the appropriate line item in each company's respective financial statement pursuant to the guidance in Issue 99-19. For example, a participant in a collaborative arrangement who is deemed to be the principal for a given transaction would record that transaction on a gross basis in its financial statements. In reaching that tentative conclusion, the Task Force elected not to pursue an accounting model that would be based on the equity method of accounting under APB 18.

Issue 3: How amounts owed to or due from other participants pursuant to a Collaborative Arrangement should be presented in the income statement.

15. In contrast to Issue 2, Issue 3 only addresses the income statement characterization of transactions between the participants in a Collaborative Arrangement and does not address the income statement characterization of transactions with third parties.

View A: All amounts either owed to or due from other participants in a Collaborative Arrangement should be recorded on a net basis within other operating expenses, regardless of whether the related transactions with third-parties are recorded gross or net.

16. Those holding this view believe that the amounts either owed to or due from other participants in a Collaborative Arrangement are not a component of the company's revenue generating operations and, thus, should not be included in revenues. For example, the payments received by a biotechnology firm will, in many periods, result from financial support by a large pharmaceutical firm for the research and development activities performed. It would be inappropriate to characterize these amounts as revenue, since the payments are intended to reduce the biotechnology firm's research and development expenditures. In addition, proponents of View A note that the pharmaceutical firm should also reflect its share of expenses from the net payments that it makes to the biotechnology firm, as these payments are akin to research and development and royalty expense incurred by the pharmaceutical firm. Proponents of this view also note that this presentation provides more information on the activities for which each participant is the principal, because the reporting of revenue and expenses will be unobstructed by the amounts owed to or due from other participants in a Collaborative Arrangement.

17. Opponents of this view believe that this presentation does not transparently report the continuing rate of the participants' underlying expenses and that it is a *de facto* equity method approach for the transactions between the participants in the arrangement. For example, the biotechnology firm's research and development expenses would be overstated because part of those expenses should be offset by the amounts due from the pharmaceutical firm in the arrangement. Because shared research and development expenses would be combined with profit sharing amounts under View A, the user would not be able to identify and analyze research and development at the biotechnology firm without additional information from the entity.

18. Opponents of View A also note that it is possible that this presentation could lead to a net credit in operating expenses, which could be misleading and confusing to users of the financial statements. For example, a net credit would result from the fact that the biotechnology firm does not show revenues relating to amounts due from the pharmaceutical firm under the Collaborative Arrangement. From the biotechnology firm's perspective, these amounts may relate to fees for research and development services or royalties that these entities would otherwise categorize as revenue.

View B: The classification of amounts due from or owed to other participants pursuant to a Collaborative Arrangement should be determined based on an accounting policy election.

19. The Working Group recommended that entities be permitted to report amounts owed to or due from other participants in a Collaborative Arrangement related to contractual expense reimbursements and other payments (for example, profit sharing payments) based on an accounting policy election. The accounting policy election must be reasonable, rational, and consistently applied. To the extent that an arrangement is within the scope of other authoritative literature regarding income statement characterization, the accounting policies for the arrangement should be based on the relevant provisions of that literature. Otherwise, the accounting policies should be based on the entity's determination of the income statement characterization that best reflects the nature of the arrangement and the entity's business operations.

20. Proponents of View B believe that this view addresses the concerns expressed by regulators and users with respect to the consistency and transparency of the accounting and presentation for Collaborative Arrangements. Current practice is diverse with respect to income statement presentation of Collaborative Arrangements. However, since there are many variations in the structure of Collaborative Arrangements, a consensus on one reporting model could lead entities to structure arrangements to get a favorable accounting presentation, or a presentation that is not consistent with the economics of the arrangement. View B, combined with transparent disclosure of the accounting policy, will represent an improvement over current practice, which

often has inadequate disclosure and the possibility for inconsistencies in the classifications of similar arrangements.

21. Because of the diverse nature of arrangements that could be considered Collaborative Arrangements and the diverse nature of the entities that may participate in Collaborative Arrangements, some proponents of View B believe that existing accounting literature was not sufficient to address these arrangements. View B permits entities the opportunity to adopt an accounting policy that reflects the nature of the arrangement and the entity's business operations.

22. Opponents of View B believe that in addition to transparency and consistency, the objective of a consensus on this Issue should be to improve comparability in financial reporting. View B does not achieve that objective. They believe that View B would perpetuate, and even possibly exacerbate, existing diversity in practice.

Issue 4: The disclosure of a Collaborative Arrangement in an entity's financial statements.

23. Regardless of the consensus reached under Issue 3, the resulting income statement presentation of amounts related to the Collaborative Arrangement represents an accounting policy that should be disclosed in accordance with APB 22. Issue 4 addresses the nature of the quantitative disclosure that should accompany the accounting policy disclosure.

View A: A company should disclose the income statement amounts attributable to amounts due to or from other participants to the Collaborative Arrangement in the footnotes to interim and annual financial statements. Individually significant Collaborative Arrangements should be disclosed separately.

24. Proponents of View A believe that the transparency of financial reporting for entities with Collaborative Arrangements subject to this consensus will be significantly improved through the quantitative disclosure of the impact of these arrangements. For example, depending on the consensus under Issue 3, an entity would disclose the amounts due to and owed from other

participants in the Collaborative Arrangement (Issue 3, View A) or the amounts due to and owed from other participants in the Collaborative Arrangement included in revenue, costs of sales, and research and development expenses. This information will provide users with information to allow them to understand the impact of these arrangements on a participant in a Collaborative Arrangement.

View B: A company should disclose summarized operating results for the activities of its Collaborative Arrangements and the income statement amounts attributable to amounts due to or from other participants in the Collaborative Arrangement in the footnotes to interim and annual financial statements. Individually significant Collaborative Arrangements should be disclosed separately.

25. Proponents of View B believe that Collaborative Arrangements have a unique and significant impact on the participants in a Collaborative Arrangement. As a result, quantitative financial information similar to that required by APB 18, paragraph 20(d), should be provided with respect to the activities of the Collaborative Arrangement. Such information would allow users of financial statements to better evaluate future prospects of the Collaborative Arrangement and its related impact on the reporting entity.

26. Opponents to View B believe that disclosure of information related to the activities of the Collaborative Arrangement could be misleading and not relevant to users of financial statements. Frequently, information about the Collaborative Arrangement is not prepared according to generally accepted accounting principles, but rather based on the contractual terms, which could be, for example, a non-financial measure.

27. Many opponents believe that such disclosure could cause competitive harm to the reporting entity. Such competitive harm would be disproportionately borne by smaller entities, as the arrangement is more likely to be significant to them than a larger entity. In addition, the disclosures proposed under View B could lead to disclosures that are not required under U.S. GAAP for similar items outside of Collaborative Arrangements. For example, many Collaborative Arrangements in the biotechnology and pharmaceutical industries relate to single

drug compounds. View B would effectively result in disclosing research and development expenses for this single product, which was specifically excluded from FAS 131 by the Board in response to constituents' concerns about competitive harm.[4]

Transition and Effective Date

28. The FASB staff believes that entities should recognize the consensus on this Issue as a change in accounting principle through retrospective application to all periods. If the Task Force reaches a consensus on View B for Issue 3, the FASB staff believes that entities can make a new accounting policy election upon adopting this consensus. If it is impracticable to apply the effects of a change in accounting principle retrospectively, disclosure should be made of both the reasons why reclassification was not made and the effect of the reclassification on the current period pursuant to the guidelines in paragraph 9 of FAS 154.

29. The consensus on this Issue shall be effective for annual periods beginning after December 15, 2007. The FASB staff believes that the application of this consensus may result in a significant change in accounting and financial reporting for certain entities that have not accounted for Collaborative Arrangements in a manner that is consistent with the consensus on this Issue.

30. Upon application of this consensus, the FASB staff believes that the following transitional disclosures should be made:

a. A description of the prior-period information that has been retrospectively adjusted, if any
b. The effect of the change on revenue and operating expenses (or other appropriate captions of changes in the applicable net assets or performance indicator), and on any other affected financial statement line item.

[4] FAS 131, paragraph 111.

Exhibit 07-1A

EXAMPLES ILLUSTRATING THE APPLICATION OF THE INDICATORS OF A COLLABORATIVE ARRANGEMENT IN THE EITF CONSENSUS ON ISSUE 1 OF ISSUE 07-1

The following examples illustrate the application of the indicators of a Collaborative Arrangement discussed in Issue 1. The application of the indicators depends on the relative facts and circumstances of the specific arrangement and requires significant judgment. The evaluations below reflect the application of the indicators to a given fact pattern based on the assumed facts; however, those judgments will vary in differing fact patterns.

Scenario 1

Big Pharma and Biotech agree to equally participate in the results of research and development activities for a drug candidate and in the commercialization activities if and when the drug candidate is approved for sale, pursuant to a joint development and marketing agreement (a 50 percent/50 percent arrangement). Assume further that Big Pharma and Biotech both agree to provide resources during the research and development and the commercialization activities. These activities are not conducted through a legal entity. A steering committee made up equally of representatives of Big Pharma and Biotech is established to jointly direct and approve the activities under the joint development and marketing agreement. If the parties are unable to reach a joint decision, the arrangement provides Big Pharma with an overriding decision-making ability. On a quarterly basis, Big Pharma and Biotech provide financial information about the research and development and the commercialization activities under the joint development and marketing agreement, and one participant is required to make a payment to the other participant for a proportionate share of the excess of the parties' combined operating results pursuant to their joint development and marketing agreement.

Evaluation: This arrangement is a Collaborative Arrangement. Both parties are active participants in the arrangement; are exposed to significant risks and rewards dependent on the ultimate success of the endeavor; and participate in making decisions regarding the arrangement.

Scenario 2

Big Pharma and Biotech agree to equally participate in the results of research and development activities for a drug candidate and in the commercialization activities if and when the drug candidate is approved for sale, pursuant to a joint development and marketing agreement (a 50 percent/50 percent arrangement). Assume further that Biotech is responsible for conducting research and development activities relating to the drug candidate, and Big Pharma is responsible for the commercialization activities if and when the drug candidate is approved for sale. These activities are not conducted through a legal entity. A steering committee made up equally of representatives of Big Pharma and Biotech is established to direct and approve the activities under the joint development and marketing agreement. If the parties are unable to reach a joint decision, the arrangement provides Big Pharma with an overriding decision-making ability. On a quarterly basis, Big Pharma and Biotech provide financial information about the research and development and the commercialization activities under the joint development and marketing agreement, and one participant is required to make a payment to the other participant for a proportionate share of the excess of the companies' combined operating results pursuant to their joint development and marketing agreement.

Evaluation: While each participant is solely responsible for different activities in this arrangement, this arrangement would be considered a Collaborative Arrangement. The participants will actively participate in the remainder of the project; they have established a mechanism for providing participating rights; and they are exposed to significant risks and rewards that are dependent on the ultimate commercial success of the endeavor.

Scenario 3

Biotech licenses intellectual property related to a drug candidate to Big Pharma, and Big Pharma contracts with Biotech to perform research and development on the drug candidate. Biotech is paid a specified rate per full-time employee assigned to the arrangement, and payments are not dependent on a successful development of a drug. The rate per full-time employee represents a fair market value rate and allows Biotech to earn a profit on these services. Big Pharma is responsible for directing and approving the activities of Biotech during the research and development phase.

During the research and development phase, Biotech has an option to buy into the arrangement to share expenses for the remaining research and development and the commercialization if and when the drug candidate is approved for sale. Biotech's purchase into the joint development and marketing agreement is in a form that surrenders the right to future license payments from the drug candidate from Big Pharma. If the option is excercised, Big Pharma is responsible for the commercialization of the drug candidate and pays Biotech a royalty on the product revenues of the drug candidate.

Evaluation: The arrangement should be evaluated based on the terms in place at the inception of the arrangement. At the inception of the arrangement in this Scenario, the arrangement would not be a Collaborative Arrangement because Biotech is not exposed to significant risks and rewards that are dependent on the ultimate commercial success of the endeavor.

An eventual exercise of Biotech's option would be a "reconsideration event" that would cause a reevaluation of whether the arrangement is a Collaborative Arrangement subject to the scope of Issue 07-1.

Scenario 4

Big Pharma out sources research and development and clinical trials on a drug candidate to an unrelated entity. The unrelated entity is paid a specified fair market rate per full-time employee assigned to the arrangement and payments are not dependent on a successful development of a drug. Big Pharma is responsible for directing and approving the activities of the unrelated entity during the research and development phase.

Evaluation: This arrangement is not a Collaborative Arrangement. Although both participants are active participants in the arrangement, the unrelated entity is not exposed to variability dependent on the ultimate commercial success of the effort because they are being compensated at market rates for services performed, and there is no mechanism to provide participating rights to the parties.

Scenario 5

Biotech provides a license for a drug candidate to Big Pharma. Big Pharma contracts with Biotech to perform research and development on the drug candidate and contract manufacturing. Biotech is paid a specified fair market rate per full-time employee assigned to the research and

development activities and payments for these activities are not dependent on a successful development of a drug. Biotech will be paid cost plus for any contract manufacturing that is performed if the drug candidate is successfully commercialized (also a fair market rate), as well as a royalty on the future sales of the product.

Evaluation: Although Biotech will be involved in the remainder of the project through the manufacturing arrangement and royalties, its fees are equivalent to fair market value. Additionally, it is not exposed to risks based on its pre-commercialization involvement in the effort. It also does not direct any of the joint operating activities and there is no mechanism for Biotech to have any participating rights in the effort. As a result, this arrangement is not a Collaborative Arrangement.

Scenario 6

Big Pharma hires Biotech to perform the research and development and the clinical trials for a drug candidate. Biotech has no contractual or other rights to the drug candidate. Biotech was not previously involved in the development of the drug candidate. Big Pharma directs the research and clinical trial activities. Biotech is paid a specified below fair market rate for its services that is not dependent on successful commercialization of the drug. However, Biotech still earns a profit on its services provided at this rate. If the drug is approved and successfully commercialized, Biotech will receive a royalty on future sales of the drug as compensation for providing services during the development phase.

Evaluation: Biotech's active participation in the arrangement and exposure to some risk through the fee and royalty terms of the arrangement creates a rebuttable presumption that the arrangement is a Collaborative Arrangement. However, the fact that Biotech still earns a profit on its services at the below market rate; that Biotech lacks a contractual or other legal rights to the underlying intellectual property; and that Biotech lacks participating rights overcome that presumption in this fact pattern. This arrangement is not a Collaborative Arrangement.

Scenario 7

Biotech completes pre-clinical research of a drug candidate independently. After Biotech receives approval to begin clinical trials, Biotech licenses the drug candidate to Big Pharma and the parties enter into an arrangement whereby they will equally participate in the results of the

remaining research and development activities for the drug candidate and in the commercialization, if and when the drug candidate is approved for sale, pursuant to a joint development and marketing agreement (a 50 percent/50 percent arrangement, before considering up-front license fees paid by Big Pharma to Biotech). Big Pharma and Biotech both agree to provide resources during the research and development and the commercialization activities. A steering committee made up equally of representatives of Big Pharma and Biotech is established to direct and approve the activities under the joint development and marketing agreement. On a quarterly basis, Big Pharma and Biotech provide financial information about the research and development and the commercialization activities under the joint development and marketing agreement, and one participant is required to make a payment to the other participant for a proportionate share of the excess of the companies' combined expenditures pursuant to their joint development and marketing agreement.

Evaluation: Although the arrangement did not start at the inception of the research effort, all indicators of a Collaborative Arrangement are present. Both parties are active participants in the arrangement; are exposed to significant risks and rewards dependent on the ultimate success of the endeavor; and participate in making decisions regarding the arrangement. Accordingly, this arrangement would be a Collaborative Arrangement from the inception of the arrangement. The fact that Biotech receives up-front license payments does not indicate that the arrangement is not a Collaborative Arrangement.

Scenario 8

Small Pharma has received approval to market its drug and hires Big Pharma to assist with the commercialization efforts, primarily to supplement Small Pharma's existing sales force in certain territories. Big Pharma receives a specified, below fair market fee for its services and will receive incentive compensation for meeting certain prescription sales targets in its territories.

Evaluation: This arrangement is not a Collaborative Arrangement. The fact that Big Pharma is receiving below fair market fees and incentive compensation may indicate that Big Pharma is exposed to variability dependent on the commercial success of the drug, but there is no mechanism for participating rights for each of the participants, and Big Pharma has no contractual or legal right to the underlying intellectual property.

Scenario 9

Small Pharma is in clinical trials for a drug candidate. Big Pharma enters into an arrangement with Small Pharma to fund 50 percent of the remaining development. Big Pharma and Small Pharma will both participate in the commercialization efforts and will share equally in revenues and marketing and distribution costs in the United States. When Big Pharma has received the amount that it contributed during the development effort plus an annual return of 15 percent, the arrangement will terminate, and Small Pharma can continue to market the drug as it sees fit with no further financial participation by Big Pharma.

Evaluation: This arrangement is not a Collaborative Arrangement because Big Pharma's return and the duration of its participation are limited by the terms of the arrangement. Big Pharma's rewards from participating in the arrangement are capped based on a financial term (the annual return of 15 percent on its investment in the development) and are not solely related to the commercial success of the endeavor. In addition, the time period over which Big Pharma participates in the endeavor is limited by the same financial term. Thus, Big Pharma does not participate in the endeavor through its eventual termination.

Scenario 10

Big Pharma and Biotech agree to participate in the results of research and development activities for a drug candidate and in the commercialization activities if and when the drug candidate is approved for sale, pursuant to a joint development and marketing agreement (a 50 percent/50 percent arrangement). Assume further that Biotech provides the resources for the research and development, and Big Pharma provides the resources for commercialization activities. A steering committee made up equally of representatives of Big Pharma and Biotech is established to direct and approve the activities under the joint development and marketing agreement. On a quarterly basis, Big Pharma and Biotech provide financial information about the research and development and the commercialization activities under the joint development and marketing agreement. Big Pharma must recover all funds contributed during the development effort prior to Biotech receiving its share of the commercialization proceeds. If the drug candidate does not generate enough revenue to enable Big Pharma to recover its contribution, then Biotech must repay Big Pharma from other resources.

Evaluation: This arrangement is not a Collaborative Arrangement because Biotech is obligated to repay Big Pharma regardless of the commercial success of the endeavor; therefore, Big Pharma is not exposed to risks and rewards that are dependent on the ultimate commercial success of the endeavor. Biotech should account for its participation in this arrangement as a financing pursuant to FAS 68.

Scenario 11

Big Pharma and Little Pharma agree to jointly participate in the results of the research and development activities for a drug candidate and in the commercialization activities if and when the drug candidate is approved for sale, pursuant to a joint development and marketing agreement. Assume further that Big Pharma and Little Pharma both agree to provide resources during the research and development and the commercialization activities. These activities are not conducted through a legal entity. A steering committee made up equally of representatives of Big Pharma and Little Pharma is established to jointly direct and approve the activities under the joint development and marketing agreement. If the parties are unable to reach a joint decision, the arrangement provides Big Pharma with an overriding decision-making ability. Little Pharma will be responsible for commercialization activities in the United States, and Big Pharma will be responsible for commercialization activities in Europe and Asia. Under the arrangement, they will share research and development costs incurred on a 50 percent/50 percent basis. Little Pharma will retain 65 percent of the net profits from commercialization activities in the United States, and Big Pharma will retain 70 percent of the net profits from commercialization activities in Europe and Asia. On a quarterly basis, Big Pharma and Little Pharma provide financial information about the research and development and the commercialization activities under the joint development and marketing agreement, and one participant is required to make a payment to the other participant for a proportionate share of the excess of the parties' combined operating results pursuant to their joint development and marketing agreement.

Evaluation: This arrangement is a Collaborative Arrangement. Both parties are active participants in the arrangement; are exposed to significant risks and rewards dependent on the ultimate success of the endeavor; and participate in making decisions regarding the arrangement.

Scenario 12

Studio A and Studio B agree to jointly participate in the production and distribution of a major motion picture. These activities are not conducted through a legal entity. Studio A will manage the day-to-day production activities and will be responsible for distribution in the United States, and Studio B will be responsible for distribution in Europe and Asia. Under the arrangement, they will share production costs incurred on a 50 percent/50 percent basis. Studio A will pay Studio B 50 percent of the net profits from U.S. distribution, and Studio B will pay Studio A 50 percent of the net profits from European and Asian distribution. The studios are responsible for all distribution costs in their respective locations. On a quarterly basis, Studio A and Studio B provide financial information about the production and distribution under the joint production and distribution agreement, and one participant is required to make a payment to the other participant for a proportionate share of the excess of the parties' combined operating results pursuant to the joint production and distribution agreement.

Evaluation: This arrangement is a Collaborative Arrangement. Both parties are active participants in the arrangement and are exposed to significant risks and rewards dependent on the ultimate success of the endeavor.

Exhibit 07-1B

FASB Emerging Issues Task Force

Issue No. 07-1

Title: Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property

Document: Working Group Report No. 2*

Date prepared: May 21, 2007

FASB Staff: Bolash (ext. 358)/Beswick (ext. 453)

EITF Liaison: Matthew Schroeder

Date previously discussed by Task Force: March 15, 2007

References:

FASB Statement No. 94, *Consolidation of All Majority-Owned Subsidiaries* (FAS 94)

FASB Statement No. 154, *Accounting Changes and Error Corrections* (FAS 154)

FASB Interpretation No. 46 (revised December 2003), *Consolidation of Variable Interest Entities* (FIN 46(R))

FASB Concepts Statement No. 5, *Recognition and Measurement in Financial Statements of Business Enterprises* (CON 5)

APB Opinion No. 18, *The Equity Method of Accounting for Investments in Common Stock* (APB 18)

AICPA Statement of Position 78-9, *Accounting for Investments in Real Estate Joint Ventures* (SOP 78-9)

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* **The alternative views presented in this Working Group Report are for purposes of discussion by the EITF. No individual views are to be presumed to be acceptable or unacceptable applications of Generally Accepted Accounting Principles until the Task Force makes such a determination, exposes it for public comment, and it is ratified by the Board.**

AICPA Accounting Interpretation 2, *Investments in Partnerships and Ventures*, of APB Opinion No. 18 (AIN APB 18)

SEC Regulation S-X, Rule 4-08(g) (SEC Regulation S-X, Rule 4-08(g))

EITF Issue No. 88-18, "Sales of Future Revenues" (Issue 88-18)

EITF Issue No. 96-16, "Investor's Accounting for an Investee When the Investor Has a Majority of the Voting Interest but the Minority Shareholder or Shareholders Have Certain Approval or Veto Rights" (Issue 96-16)

EITF Issue No. 99-19, "Reporting Revenue Gross as a Principal versus Net as an Agent" (Issue 99-19)

EITF Issue No. 00-1, "Investor Balance Sheet and Income Statement Display under the Equity Method for Investments in Certain Partnerships and Other Ventures" (Issue 00-1)

EITF Issue No. 01-9, "Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)" (Issue 01-9)

EITF Issue No. 02-16, "Accounting by a Customer (Including a Reseller) for Certain Consideration Received from a Vendor" (Issue 02-16)

Previous Task Force Discussion

1. At the March 15, 2007 EITF meeting, the Task Force discussed Issue 1 including the Working Group's recommendation that a collaborative arrangement subject to the guidance in this Issue would be defined as an arrangement in which the parties share in the risks and rewards of the arrangement's operations from the arrangement's inception through its termination. The Task Force also discussed the Working Group's recommendation for indicators that could be used to identify a collaborative arrangement. The Working Group recommended that the indicators should not be considered individually presumptive or determinative; however, the relative strength of each indicator should be considered. The Task Force also observed that, in addition to the indicators proposed by the Working Group, there may be other indicators that could identify the existence of a collaborative arrangement.

2. The Task Force was not asked to reach a tentative conclusion on Issue 1. The Task Force requested that the FASB staff modify and expand the indicators recommended by the Working Group to clarify the scope of the Issue and the example scenarios used to illustrate this Issue to consider additional fact patterns. The Task Force also requested that the staff discuss the revised indicators and illustrative scenarios with the Working Group.

3. The Task Force reached a tentative conclusion on Issue 2 that transactions with third parties (that is, revenue generated and costs incurred by participants in a collaborative arrangement) should be reported on the appropriate line item in each company's respective financial statement pursuant to the guidance in Issue 99-19. In reaching that tentative conclusion, the Task Force elected not to pursue an accounting model that would be based on the equity method of accounting under APB 18. For example, a participant in a collaborative arrangement who is deemed to be the principal for a given transaction would record that transaction on a gross basis in its financial statements.

4. The Task Force discussed Issue 3 but was not asked to reach a tentative conclusion. The Task Force discussed the alternative views presented to address how sharing payments made to or received by a participant pursuant to a collaborative arrangement should be presented in the income statement but requested the FASB staff to explore an additional view for consideration. Under this additional view, all sharing payments would be recorded on a net basis within other

operating income or expense in the participant's statement of operations regardless of whether the related transactions are recorded gross or net under Issue 2. In addition, the Task Force discussed potential disclosures by participants to a collaborative arrangement under this view including summarized information for the results of the activities of the collaborative arrangement.

Accounting Issues and Alternatives

5. To address the concerns raised by the Task Force at the March meeting, the FASB staff asked the Working Group to review Issue 1 and to modify and expand the indicators in order to clarify the scope of this Issue. In addition, the FASB staff asked the Working Group to review the example scenarios in Exhibit WG2 07-1A (including additional Scenarios 9 and 10) to "test" the definitions of a Collaborative Arrangement.

6. Based on the Task Force's discussion at the March meeting, the FASB staff removed two views (Views A and C to Issue 3 in Issue Summary No. 1) and added three new views for the Working Group's consideration—Views D', E, and F. The FASB staff also developed an additional fact pattern to illustrate the various views (Illustration 2 in Exhibit WG2 07-1B). The FASB staff asked the Working Group to (a) recommend the alternative views that should be presented to the Task Force at the June meeting and (b) develop a recommendation on Issue 3 for Task Force consideration.

7. The FASB staff also requested the Working Group's views on disclosures that should be included in the financial statements of entities that are participants in Collaborative Arrangements.

Issue 1: How to determine whether an arrangement constitutes a Collaborative Arrangement within the scope of this Issue.

8. To address the concerns raised by the Task Force at the March meeting, the FASB staff asked the Working Group to review Issue 1 and to modify and expand the indicators in order to

clarify the scope of this Issue. The FASB staff recommended that the Working Group consider the following:

a. Are there some indicators that are, in fact, presumptive or determinative? How should the existing and any additional indicators be weighted?

b. Is this meant to be an exhaustive list of indicators? If not, are you aware of other factors that should be considered for inclusion in this list? Alternatively, the Issue Summary and abstract could include a statement that there may be other indicators not listed. Should the following items be added as indicators?
   1. There are only a limited number of participants in the arrangements.
   2. The activities of the arrangement are not primarily conducted through a separate legal entity. However, the existence of a lower-level legal entity would not exclude an arrangement from being considered a Collaborative Arrangement.

c. Do the participants have to be involved in <u>both</u> development and commercialization? Could a participant join a Collaborative Arrangement after completion of development? Scenario 8 in Exhibit WG2 07-1A seems to indicate that participants must be in both stages. Should this point be clarified in the indicator included in paragraph 15(c) in Issue Summary No. 1?

d. Even when steering committees are present, one participant may have an overriding decision-making ability. In other words, in the event of a dispute on the steering committee, one participant may have the contractual ability to unilaterally determine the outcome. Would such terms in an arrangement impact your view of whether the Steering Committee indicator was present or whether the arrangement was a Collaborative Arrangement?

e. Should the Issue Summary (the basis for the discussion at the Task Force meetings) and any eventual abstract include examples of items that the Working Group does not

consider to be Collaborative Arrangements? For example, consider Working Group Report No. 1, included in Exhibit 07-1C of Issue Summary No. 1:

> The Working Group also discussed arrangements common in the pharmaceutical and biotechnology industries that the Working Group did not consider to be a Collaborative Arrangement and used the characteristics of such arrangements to assist in identifying indicators that a Collaborative Arrangement may exist. Arrangements that the Working Group did not believe to be Collaborative Arrangements include services that are contracted at fair market value rates (for example, contract research organizations and contract sales organizations), contract manufacturing, simple royalties, passive revenue streams, and entities that receive incentives to increase sales but do not collaborate in both the development and sale of the product. The Working Group believed that the relationship between the parties to these arrangements is typically more like that of a customer-service provider relationship, rather than the partner relationship found in Collaborative Arrangement, and that these arrangements are within the scope of other existing GAAP.

f. Should there be more examples of potentially conflicting existing GAAP? Issue 88-18 is specifically referenced. Should FAS 68 or any other literature be specifically mentioned in the Issue Summary and resulting abstract similar to the discussion in paragraph 16 of Issue Summary No. 1 (included in Exhibit WG2 07-1C)?

g. Should the consideration of options in evaluating whether an arrangement is a Collaborative Arrangement (see Scenario 3 in Exhibit WG2 07-1A) be included in the indicators or the body of the abstract, as opposed to being included in an illustration in an exhibit? Do you see options frequently in practice?

9. The Working Group developed the following recommendation with respect to Issue 1.

The Working Group recommends that whether an arrangement is a Collaborative Arrangement within the scope of Issue 07-1 is a matter of judgment that depends on the relevant facts and circumstances and that the indicators set forth below should be considered in that evaluation. A Collaborative Arrangement is a contractual arrangement with a similar economic substance to a joint venture but is not primarily conducted through a legal entity. If a Collaborative Arrangement were conducted through a legal

entity in which the participants were shareholders or other interest holders, the arrangement would be subject to FAS 94, APB 18, FIN 46(R), or other related literature.[1]

Indicators of a Collaborative Arrangement

The Working Group recommends that the presence of the following two indicators creates a rebuttable presumption that a Collaborative Arrangement exists. In other words, if one of these indicators is not present, the arrangement is not a Collaborative Arrangement. If both indicators are present, then the participants should presume that the arrangement is a Collaborative Arrangement unless the presumption is overcome by careful analysis of the relevant facts and circumstances.

a. ***The parties are active participants to the arrangement.*** That is, the participants are not solely financial investors but, rather, they make significant contributions to directing and carrying out the joint operating activities. An arrangement involving a purely financial investor may be appropriately accounted for under Issue 88-18 or FAS 68, depending on the terms of the arrangement.

b. ***The participants are exposed to significant risks and rewards that are dependent on the ultimate commercial success of the endeavor.***[2] An arrangement in which the partners are not exposed to variable outcomes dependent on the ultimate commercial success of the endeavor (for example, services being performed for fees paid in cash at fair market value rates, limitations on exposure to risk/reward, returns that are either guaranteed or limited by the arrangement), may indicate a contract subject to other authoritative literature.

Many Collaborative Arrangements involve licenses of intellectual property, and consideration related to the license may be exchanged at the inception of the arrangement. Such an exchange does not necessarily indicate that the participants are

[1] A Collaborative Arrangement may include a legal entity in some portion of the arrangement for legal, tax, or regulatory purposes. Any consensus on this Issue does not affect the accounting for that legal entity under FAS 94, APB 18, FIN 46(R), or other related literature.

[2] For example, the "endeavor" in a biotechnology or pharmaceutical environment would be a drug candidate. In the entertainment industry, it would be a motion picture.

not exposed to significant risks and rewards dependent on the ultimate commercial success of the endeavor.

The Working Group observes that the following two indicators may be present in a Collaborative Arrangement, but that they are neither presumptive nor determinative.

c. ***Through the arrangement the partners have a contractual or other legal right to own, access, or use the underlying intellectual property, for example, by holding the patent or a related license.*** The Working Group observed that most Collaborative Arrangements will relate to the development and commercialization of intellectual property, and the presence of intellectual property rights in an arrangement may indicate that the arrangement is a Collaborative Arrangement. However, there may also be arrangements that do not relate to intellectual property that may be Collaborative Arrangements.

d. ***There is a steering committee or other mechanism to provide participating rights[3] to the partners.*** The existence of a steering committee may indicate that an arrangement is a Collaborative Arrangement. Even when steering committees are present, however, one participant may have an overriding decision-making ability. In other words, although a steering committee is present, there may be a contractual mechanism whereby one party has the ability to resolve a deadlock, that is, to unilaterally determine the outcome. Such a provision would not necessarily prevent an arrangement from being considered a Collaborative Arrangement. The nature of the rights of the parties should be considered in evaluating the relative strength of this indicator.

The Working Group observed that the list of indicators above is not all-inclusive.

[3] Based on an analogy to participating rights as described in Issue 96-16, such rights allow a participant in an arrangement to effectively participate in decisions that occur as part of the ordinary course of the arrangement's activities and are significant factors in directing and carrying out the activities of the arrangement.

Evaluation of a Collaborative Arrangement

The Working Group recommends that participants to an arrangement should evaluate whether that arrangement is a Collaborative Arrangement at the inception of the arrangement based on the facts and circumstances present at that time. The initial determination of whether an arrangement is a Collaborative Arrangement should be reconsidered when any changes to the facts and circumstances alter either the roles of the participants in the arrangement (see indicator (a) above) or the participants' exposure to significant risks and rewards dependent on the ultimate commercial success of the endeavor (see indicator (b) above). The exercise of an option present in the initial arrangement would be an example of a possible reconsideration event.

A Collaborative Arrangement can begin at any point in the lifecycle of the endeavor. As noted above, an arrangement should be evaluated at the inception of the arrangement. The lifecycle stage of the endeavor and the terms and conditions of the arrangement would both be factors to consider in the evaluation of the arrangement. In a Collaborative Arrangement, the participants financially participate in the arrangement through its eventual termination, although they need not be present at the inception of the endeavor.

The Working Group also discussed arrangements common in the pharmaceutical and biotechnology industries that the Working Group did not consider to be Collaborative Arrangements and used the characteristics of such arrangements to assist in identifying the indicators discussed above. Arrangements that the Working Group did not believe to be Collaborative Arrangements included services that are contracted at fair market value rates (for example, services performed by contract research organizations and contract sales organizations), contract manufacturing, some stand-alone royalty arrangements, passive revenue streams, and arrangements in which entities only receive incentives to increase sales. The Working Group believes that the relationship between the parties to these arrangements is typically more like that of a customer-service provider relationship, rather than the relationship found in a Collaborative Arrangement, and that these arrangements are within the scope of other existing U.S. GAAP.

Exhibit WG2 07-1A includes several illustrations of arrangements found in the biotechnology and pharmaceutical industries that demonstrate the application of these indicators in order to determine whether a Collaborative Arrangement exists.

Issue 3: How amounts owed to or due from another participant pursuant to a Collaborative Arrangement should be presented in the income statement.

10. As noted above, the FASB staff removed Views A and C to Issue 3, and added three new views for consideration—Views D', E, and F—based on the Task Force's discussion at the March meeting. As a result, the FASB staff presented these five views, listed below, to the Working Group for its consideration. The FASB staff asked the Working Group to (a) develop a recommendation for the Task Force on Issue 3 and (b) recommend the alternative views that should be presented to the Task Force at the June meeting. The views recommended for presentation to the Task Force should be views frequently encountered in practice and with high technical merit.

11. The following views were presented to the Working Group for consideration:

View B: All amounts due from another participant pursuant to a Collaborative Arrangement should be reported as revenue and amounts owed to another participant should be presented as expenses.

View D: All amounts either owed to or due from another participant should be recorded either as revenue or as expense based on the nature of the respective amounts.

View D': All amounts either owed to or due from a partner should be recorded either as revenue or as expense <u>in single line items within total revenue and total operating expenses</u> based on the nature of the respective payments.

View E: All amounts either owed to or due from another participant in a Collaborative Arrangement should be recorded on a net basis within other operating expenses, regardless of whether the related third-party revenue and expense transactions are recorded gross or net under Issue 2.

View F: All amounts related to research and development activities should be recorded net within operating expenses, and all amounts related to commercialization activities should be recorded net within revenues.

12. The Working Group discussed whether Issue 3 should be divided into two issues—the classification of contractual reimbursements of specific direct and incremental costs and the classification of other payments made between the parties. Contractual reimbursements could include research and development, marketing, sales force effort, and manufacturing and distribution expenditures. Other payments could include profit sharing, royalties, or milestone payments.

13. With respect to contractual reimbursements, the Working Group explored a model based on the concepts in Issue 01-9 and Issue 02-16. Under that model, the recipient of a reimbursement of a specific, incremental, and identifiable cost would classify that amount according to one of the following:

a. On a gross basis (that is, the reimbursement would be classified as revenue, and the expense would be classified in the appropriate line)
b. On a net basis (that is, the reimbursement would reduce the related expense line item)
c. In a separate other operating income/expense line-item.

14. The Working Group initially favored classifying such reimbursements on a net basis. For example, a recipient of a reimbursement for a specific, incremental, and identifiable research and development cost would classify the payment as a reduction of research and development expenses in its income statement. After further considering this model and various alternative structures of Collaborative Arrangements, the Working Group determined that Collaborative

Arrangements with similar economic features but different structures would result in different financial reporting under the proposed model. The Working Group then concluded that it could not develop a single model for reporting amounts owed to or due from another participant in a Collaborative Arrangement.

15. As a result, the Working Group recommended that entities be permitted to report amounts owed to or due from another participant in a Collaborative Arrangement related to contractual expense reimbursements and other payments (for example, profit sharing payments) based on an accounting policy election. Participants in a Collaborative Arrangement should be required to disclose the pertinent terms of the Collaborative Arrangement, the amounts of and the accounting policies applied with respect to costs incurred and sales to third-parties, and the amounts owed to or due from another participant in a Collaborative Arrangement in annual and interim financial statements.

16. Some Working Group members suggested that participants in a Collaborative Arrangement should disclose summarized information about the results of the Collaborative Arrangement's operations, similar to the disclosure of summarized results of operations of an equity method investee required in APB 18, paragraph 20(d). Other Working Group members expressed concerns about providing such disclosure on the grounds that (a) the participants may not have access to the necessary information and (b) the information received from the other party would not be directly subject to the reporting entity's system of internal controls, so there also would be concerns with Section 404 requirements with respect to that information. The FASB staff will research those concerns with preparers and the PCAOB.

Exhibit WG2 07-1A

EXAMPLES ILLUSTRATING THE APPLICATION OF THE INDICATORS OF A COLLABORATIVE ARRANGEMENT IN THE EITF CONSENSUS ON ISSUE 1 OF ISSUE 07-1

The following examples illustrate the application of the indicators of a Collaborative Arrangement discussed in Issue 1. The application of the indicators depends on the relative facts and circumstances of the specific arrangement and requires significant judgment. The evaluations below reflect the indicators applied to a given fact pattern based on the assumed facts; however, those judgments will vary in differing fact patterns.

Scenario 1

Big Pharma and Biotech agree to equally participate in the results of research and development activities for a drug candidate and in the commercialization activities if and when the drug candidate is approved for sale, pursuant to a joint development and marketing agreement (a 50 percent/50 percent arrangement). Assume further that Big Pharma and Biotech both agree to provide resources during the research and development and the commercialization activities. These activities are not conducted through a legal entity. A steering committee made up equally of representatives of Big Pharma and Biotech is established to jointly direct and approve the activities under the joint development and marketing agreement. If the parties are unable to reach a joint decision, the arrangement provides Big Pharma with an overriding decision-making ability. On a quarterly basis, Big Pharma and Biotech provide financial information about the research and development and the commercialization activities under the joint development and marketing agreement, and one participant is required to make a payment to the other participant for a proportionate share of the excess of the parties' combined operating results pursuant to their joint development and marketing agreement.

Evaluation: This arrangement is a Collaborative Arrangement. Both parties are active participants in the arrangement; are exposed to significant risks and rewards dependent on the ultimate success of the endeavor; and participate in making decisions regarding the arrangement.

Scenario 2

Big Pharma and Biotech agree to equally participate in the results of research and development activities for a drug candidate and in the commercialization activities if and when the drug candidate is approved for sale, pursuant to a joint development and marketing agreement (a 50 percent/50 percent arrangement). Assume further that Biotech is responsible for conducting research and development activities relating to the drug candidate, and Big Pharma is responsible for the commercialization activities if and when the drug candidate is approved for sale. These activities are not conducted through a legal entity. A steering committee made up equally of representatives of Big Pharma and Biotech is established to direct and approve the activities under the joint development and marketing agreement. If the parties are unable to reach a joint decision, the arrangement provides Big Pharma with an overriding decision-making ability. On a quarterly basis, Big Pharma and Biotech provide financial information about the research and development and the commercialization activities under the joint development and marketing agreement, and one participant is required to make a payment to the other participant for a proportionate share of the excess of the companies' combined operating results pursuant to their joint development and marketing agreement.

Evaluation: While each participant is solely responsible for different activities in this arrangement, this arrangement would be considered a Collaborative Arrangement. The participants will actively participate in the remainder of the project; they have established a mechanism for providing participating rights; and they are exposed to significant risks and rewards that are dependent on the ultimate commercial success of the endeavor.

Scenario 3

Biotech licenses intellectual property related to a drug candidate to Big Pharma, and Big Pharma contracts with Biotech to perform research and development on the drug candidate. Biotech is paid a specified rate per full-time employee assigned to the arrangement, and payments are not dependent on a successful development of a drug. The rate per full-time employee represents a fair market value rate and allows Biotech to earn a profit on these services. Big Pharma is responsible for directing and approving the activities of Biotech during the research and development phase.

During the research and development phase, Biotech has an option to buy into the arrangement to share expenses for the remaining research and development and the commercialization if and when the drug candidate is approved for sale. Biotech's purchase into the joint development and marketing agreement is in a form that surrenders the right to future license payments from the drug candidate from Big Pharma. If the option is excercised, Big Pharma is responsible for the commercialization of the drug candidate and pays Biotech a royalty on the product revenues of the drug candidate.

Evaluation: The arrangement should be evaluated based on the terms in place at the inception of the arrangement. At the inception of the arrangement in this Scenario, the arrangement would not be a Collaborative Arrangement because Biotech is not exposed to significant risks and rewards that are dependent on the ultimate commercial success of the endeavor.

An eventual exercise of Biotech's option would be a "reconsideration event" that would cause a reevaluation of whether the arrangement is a Collaborative Arrangement subject to the scope of Issue 07-1.

Scenario 4

Big Pharma out sources research and development and clinical trials on a drug candidate to an unrelated entity. The unrelated entity is paid a specified fair market rate per full-time employee assigned to the arrangement and payments are not dependent on a successful development of a drug. Big Pharma is responsible for directing and approving the activities of the unrelated entity during the research and development phase.

Evaluation: This arrangement is not a Collaborative Arrangement. Although both participants are active participants in the arrangement, the unrelated entity is not exposed to variability dependent on the ultimate commercial success of the effort because they are being compensated at market rates for services performed, and there is no mechanism to provide participating rights to the parties.

Scenario 5

Biotech provides a license for a drug candidate to Big Pharma. Big Pharma contracts with Biotech to perform research and development on the drug candidate and contract manufacturing. Biotech is paid a specified fair market rate per full-time employee assigned to the research and

development activities and payments for these activities are not dependent on a successful development of a drug. Biotech will be paid cost plus for any contract manufacturing that is performed if the drug candidate is successfully commercialized (also a fair market rate), as well as a royalty on the future sales of the product.

Evaluation: Although Biotech will be involved in the remainder of the project through the manufacturing arrangement and royalties, its fees are equivalent to fair market value. Additionally, it is not exposed to risks based on its pre-commercialization involvement in the effort. It also does not direct any of the joint operating activities and there is no mechanism for Biotech to have any participating rights in the effort. As a result, this arrangement is not a Collaborative Arrangement.

Scenario 6

Big Pharma hires Biotech to perform the research and development and the clinical trials for a drug candidate. Biotech has no contractual or other rights to the drug candidate. Biotech was not previously involved in the development of the drug candidate. Big Pharma directs the research and clinical trial activities. Biotech is paid a specified below fair market rate for its services that is not dependent on successful commercialization of the drug. However, Biotech still earns a profit on its services provided at this rate. If the drug is approved and successfully commercialized, Biotech will receive a royalty on future sales of the drug as compensation for providing services during the development phase.

Evaluation: Biotech's active participation in the arrangement and exposure to some risk through the fee and royalty terms of the arrangement creates a rebuttable presumption that the arrangement is a Collaborative Arrangement. However, the fact that Biotech still earns a profit on its services at the below market rate; that Biotech lacks a contractual or other legal rights to the underlying intellectual property; and that Biotech lacks participating rights overcome that presumption in this fact pattern. This arrangement is not a Collaborative Arrangement.

Scenario 7

Biotech completes pre-clinical research of a drug candidate independently. After Biotech receives approval to begin clinical trials, Biotech licenses the drug candidate to Big Pharma and the parties enter into an arrangement whereby they will equally participate in the results of the

remaining research and development activities for the drug candidate and in the commercialization, if and when the drug candidate is approved for sale, pursuant to a joint development and marketing agreement (a 50 percent/50 percent arrangement, before considering up-front license fees paid by Big Pharma to Biotech). Big Pharma and Biotech both agree to provide resources during the research and development and the commercialization activities. A steering committee made up equally of representatives of Big Pharma and Biotech is established to direct and approve the activities under the joint development and marketing agreement. On a quarterly basis, Big Pharma and Biotech provide financial information about the research and development and the commercialization activities under the joint development and marketing agreement, and one participant is required to make a payment to the other participant for a proportionate share of the excess of the companies' combined expenditures pursuant to their joint development and marketing agreement.

Evaluation: Although the arrangement did not start at the inception of the research effort, all indicators of a Collaborative Arrangement are present. Both parties are active participants in the arrangement; are exposed to significant risks and rewards dependent on the ultimate success of the endeavor; and participate in making decisions regarding the arrangement. Accordingly, this arrangement would be a Collaborative Arrangement from the inception of the arrangement. The fact that Biotech receives up-front license payments does not indicate that the arrangement is not a Collaborative Arrangement.

Scenario 8

Small Pharma has received approval to market its drug and hires Big Pharma to assist with the commercialization efforts, primarily to supplement Small Pharma's existing sales force in certain territories. Big Pharma receives a specified, below fair market fee for its services and will receive incentive compensation for meeting certain prescription sales targets in its territories.

Evaluation: This arrangement is not a Collaborative Arrangement. The fact that Big Pharma is receiving below fair market fees and incentive compensation may indicate that Big Pharma is exposed to variability dependent on the commercial success of the drug, but there is no mechanism for participating rights for each of the participants, and Big Pharma has no contractual or legal right to the underlying intellectual property.

Scenario 9

Small Pharma is in clinical trials for a drug candidate. Big Pharma enters into an arrangement with Small Pharma to fund 50 percent of the remaining development. Big Pharma and Small Pharma will both participate in the commercialization efforts and will share equally in revenues and marketing and distribution costs in the United States. When Big Pharma has received the amount that it contributed during the development effort plus an annual return of 15 percent, the arrangement will terminate, and Small Pharma can continue to market the drug as it sees fit with no further financial participation by Big Pharma.

Evaluation: This arrangement is not a Collaborative Arrangement because Big Pharma's return and the duration of its participation are limited by the terms of the arrangement. Big Pharma's rewards from participating in the arrangement are capped based on a financial term (the annual return of 15 percent on its investment in the development) and are not solely related to the commercial success of the endeavor. In addition, the time period over which Big Pharma participates in the endeavor is limited by the same financial term. Thus, Big Pharma does not participate in the endeavor through its eventual termination.

Scenario 10

Big Pharma and Biotech agree to participate in the results of research and development activities for a drug candidate and in the commercialization activities if and when the drug candidate is approved for sale, pursuant to a joint development and marketing agreement (a 50 percent/50 percent arrangement). Assume further that Biotech provides the resources for the research and development, and Big Pharma provides the resources for commercialization activities. A steering committee made up equally of representatives of Big Pharma and Biotech is established to direct and approve the activities under the joint development and marketing agreement. On a quarterly basis, Big Pharma and Biotech provide financial information about the research and development and the commercialization activities under the joint development and marketing agreement. Big Pharma must recover all funds contributed during the development effort prior to Biotech receiving its share of the commercialization proceeds. If the drug candidate does not generate enough revenue to enable Big Pharma to recover its contribution, then Biotech must repay Big Pharma from other resources.

Evaluation: This arrangement is not a Collaborative Arrangement because Biotech is obligated to repay Big Pharma regardless of the commercial success of the endeavor; therefore, Big Pharma is not exposed to risks and rewards that are dependent on the ultimate commercial success of the endeavor. Biotech should account for its participation in this arrangement as a financing pursuant to FAS 68.