Satisfying the ATB Requirement: Is Income Collection Necessary?

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In this article, the authors analyze LTR 202009002, the first spinoff ruling on a research and development business with no collection of income. They examine the R&D process and pre-commercialization income opportunities in the drug industry, consider other possible fact patterns, and speculate on future guidance.

In the past two years, the IRS has focused on the question whether the active trade or business (ATB) requirement for spinoffs under section 355 requires the collection of income, particularly in pharmaceutical and technology ventures. The issuance of LTR 202009002, in which the IRS concluded that the absence of income collection under the facts presented did not prevent the ATB requirement of section 355 from being satisfied, confirms that the IRS will rule favorably in at least some situations without the collection of income. A private letter ruling may not be relied on as precedent by other taxpayers, however, and in the absence of published guidance, the specific situations in which taxpayers can satisfy the ATB requirement without the collection of income remain unclear.

Although not entirely clear, it appears likely that LTR 202009002 involves a pharmaceutical or biotechnology company that develops and conducts clinical testing of new drugs. To better understand the IRS's conclusion in LTR 202009002, this article (1) reviews the history of the collection of income requirement and the IRS's recent statements on the topic; (2) provides background information on the research and development process, funding arrangements, and pre-commercialization income opportunities common to the pharmaceutical industry; (3) analyzes the facts of LTR 202009002 in greater detail; (4) considers other fact patterns in which the IRS might rule favorably; and (5) speculates on the form that future guidance may take.[1]

I. Collection of Income Requirement History

Generally, if a corporation distributes appreciated property to its shareholders, the corporation is subject to tax at both the corporate entity level and the shareholder level. The corporation must recognize gain as if the property were sold at its fair market value.[2] To the extent that a distribution is made from the corporation's earnings and profits, it is taxed to the shareholder as a dividend.[3] Section 355 offers a limited exception to this tax treatment by permitting a distributing corporation (Distributing) to distribute the stock of a controlled subsidiary (Controlled) without the recognition of gain to Distributing or to Distributing's shareholders if a number of statutory and non-statutory requirements are satisfied.

Among other requirements, for a distribution to qualify for nonrecognition treatment under section 355, both Distributing and Controlled must be engaged in the active conduct of a trade or business immediately after the distribution of Controlled stock by Distributing.[4] Each such trade

[1] We have not requested the background file from the IRS for LTR 202009002, which might provide additional information. This article solely analyzes the information contained in the private letter ruling itself.

[2] Section 311(b).

[3] Sections 301(c)(1) and 316.

[4] Section 355(b)(1).

or business must have been actively conducted throughout the five-year period ending on the date of the distribution.[5] The trade or business will be considered active if its conduct involves active and substantial management and operational functions performed by the corporation.[6] Activities performed by the corporation itself do not include activities performed by persons outside the corporation, including independent contractors, and thus those activities generally must be performed by employees of the corporation.[7]

The ATB requirement operates in tandem with the other requirements under section 355 as a means of limiting nonrecognition treatment to transactions that are separations of actively conducted corporate businesses. In *Rafferty*,[8] the First Circuit interpreted the ATB requirement to mean that "a corporation must engage in entrepreneurial endeavors of such a nature and to such an extent as to qualitatively distinguish its operations from mere investments. Moreover, there should be objective indicia of such corporate operations."[9] In finding that those indicia were not present, the First Circuit noted that the corporation paid neither salaries nor rent, and its only activity appeared to be collecting rent, paying taxes, and keeping separate books.

It would seem that a taxpayer could be engaged in entrepreneurial activities without the collection of income, particularly in a start-up venture. Nonetheless, reg. section 1.355-3(b)(2)(ii) provides:

> A corporation shall be treated as engaged in a trade or business immediately after the distribution if a specific group of activities are being carried on by the corporation for the purpose of earning income or profit, and the activities included in such group include every operation that forms a part of, or a step in, the process of earning income or profit. *Such group of activities ordinarily must include the collection of income and the payment of expenses.*[10] [Emphasis added.]

Over the years, taxpayers and their representatives generally came to believe that the IRS's position was that this regulation requires the collection of income to satisfy the ATB requirement.[11] That belief was supported by the potential implications of two revenue rulings from the 1950s.

In Rev. Rul. 57-464, 1957-2 C.B. 244, the IRS considered whether the separation of a manufacturing business from a group of real estate assets qualified for nonrecognition treatment under section 355. The real estate assets consisted of an old factory building used for storage, a duplex apartment rented to employees, a small office rented to a single tenant, and two houses (one of which had been occupied by a tenant for the past five years and one of which was occupied by the sister-in-law of the president of the corporation). The IRS ruled that the separation failed to satisfy the ATB requirement because, among other reasons, the net rental income was "negligible" and the rental activity was "incidental to the manufacturing business."

In Rev. Rul. 57-492, 1957-2 C.B. 247, the IRS ruled that an oil exploration and production operation that did not include any income-producing activity or any source of income until less than five years before its separation failed to satisfy the ATB requirement. The IRS noted that

[5] Section 355(b)(2).

[6] Reg. section 1.355-3(b)(2)(iii).

[7] *See id*. For purposes of the ATB requirement, all members of a corporation's separate affiliated group (SAG) (as defined in section 355(b)(3)(B)) are treated as one corporation, and therefore activities performed by employees of a member of a corporation's SAG are treated as performed by the corporation. Section 355(b)(3)(A). It also appears that business activities performed by employees of a non-SAG affiliate corporation may be attributed to a corporation for section 355 purposes under some circumstances. Rev. Rul. 79-394, 1979-2 C.B. 141, *amplified by* Rev. Rul. 80-181, 1980-2 C.B. 121 (Controlled engaged in active business even though it used employees of a sister subsidiary under a reimbursement arrangement). *See also* prop. reg. section 1.355-3(b)(2)(iii) (activities performed by a corporation include activities performed by employees of affiliates).

[8] *Rafferty v. Commissioner*, 452 F.2d 767 (1st Cir. 1971), *aff'g* 55 T.C. 490 (1970).

[9] *Id*. at 772. In finding that Controlled did not satisfy the ATB requirement, the First Circuit noted that Controlled's sole activity before the date of distribution was leasing real estate back to its parent for a fixed return, an activity that the First Circuit characterized as "almost indistinguishable from an investment in securities" and the type of "passive investment" that Congress intended to be excluded from nonrecognition treatment under section 355.

[10] Prop. reg. section 1.355-3(b)(2)(ii) contains the same language.

[11] Although it was generally believed that the IRS's position was that gross income is required to satisfy the ATB requirement, it appears that profit is not required. *See, e.g.*, Rev. Rul. 85-122, 1985-2 C.B. 118 (a ski resort that experienced significant losses for several years satisfied the ATB requirement).

"although substantial expenditures were made . . . nevertheless, section 355 of the Code contemplates that an active business ordinarily includes the collection of income as well as the payment of expenses."

Consistent with these two revenue rulings, taxpayers submitting a transactional ruling request under Rev. Proc. 2017-52, 2017-41 IRB 283, must submit a table showing the amount of gross income earned during each of the past five years for each ATB on which each of Distributing and Controlled are relying to satisfy the ATB requirement.[12] The IRS has recognized some circumstances under which a taxpayer can satisfy the ATB requirement without the collection of income for a short period. Some exceptional business interruptions (for example, drought, fire, financial distress, or seasonal downtime) are permitted if there is an intent to resume operation of the business as soon as practicable.[13] Beyond this limited exception, however, it appears that the IRS has historically taken the position that gross income is required to satisfy the ATB requirement, even if the business generates significant expenses. This has proven particularly problematic for businesses that may have several years of substantial R&D outlays that yield no revenue until a marketable product has been created.

II. IRS Reconsiders Its Position, Announces Study

On September 25, 2018, the IRS issued the following statement (the "September 2018 statement") indicating that it was willing to reconsider whether the ATB requirement could be satisfied without the collection of income[14]:

> The IRS has observed a significant rise in entrepreneurial ventures whose activities consist of research and development in lengthy phases. During these phases, the ventures often collect no income or negligible income but nonetheless incur significant financial expenditures and perform day-to-day operational and managerial functions that historically have evidenced an "active" business. For instance, a venture in the pharmaceutical or technology field might engage in research to develop new products with the purpose of earning income in the future from sales or licenses. The venture might even forgo current income opportunities to obtain increased future income by developing products on its own. The nature and duration of the research phases is often dictated by regulatory agencies, which require complex review processes that can span multiple years and cost millions of dollars.
>
> Due to the emergence of these ventures, the IRS and the Treasury Department are considering guidance to address whether a business can qualify as an ATB if entrepreneurial activities, as opposed to investment or other non-business activities, take place with the purpose of earning income in the future, but no income has yet been collected.

The September 2018 statement further indicated that pending completion of the study, the IRS would entertain requests for private letter rulings regarding the ATB qualification of corporations that have not collected income. The IRS encouraged taxpayers to request pre-submission conferences before submitting private letter ruling requests.

On March 21, 2019, the IRS followed up on the September 2018 statement by suspending Rev. Rul. 57-464 and Rev. Rul. 57-492 pending

[12] Rev. Proc. 2017-52, section 3.03(3)(b). *See also* Rev. Proc. 96-30, 1996-1 C.B. 696, App. C, section 4.03(2)(h), *modified and amplified by* Rev. Proc. 2003-48, 2003-2 C.B. 86, *obsoleted in part and superseded by* Rev. Proc. 2013-32, 2013-28 IRB 55, *superseded by* Rev. Proc. 2017-52 (requiring taxpayers to submit profit and loss statements for each of the five years preceding the distribution for each ATB; those statements had to show that each ATB had "gross receipts and operating expenses . . . representative of the active conduct of a trade or business for each of the past 5 years").

[13] *See, e.g.*, Rev. Rul. 82-219, 1982-2 C.B. 82 (one-year interruption because of unforeseen loss of only customer, and taxpayer took reasonable steps to restore income flow); Rev. Rul. 57-126, 1957-1 C.B. 123 (relative dormancy of citrus business for five years because of series of freezes where separate identity of citrus division was maintained). This issue may arise if a business is temporarily suspended as a result of the COVID-19 pandemic.

[14] "IRS Statement Regarding the Active Trade or Business Requirement for Section 355 Distributions" (Sept. 25, 2019).

completion of the study regarding collection of income.[15] The IRS suspended these rulings because the analysis underlying their conclusions "focuses, in significant part, on the lack of income generated by the activities under consideration. Consequently, these rulings could be interpreted as requiring income generation for a business to qualify as an ATB."

On May 6, 2019, the IRS issued a request for information regarding the ATB requirement for section 355 separations of entrepreneurial activities (the "May 2019 request").[16] The IRS stated it had been studying whether and to what extent corporations may use section 355 "to separate established businesses from newer entrepreneurial ventures that have not collected income but have engaged in substantial research and development (R&D) and other activities." The May 2019 request also said the IRS was "considering the extent to which section 355 could apply to a separation of two or more R&D segments of a stand-alone entrepreneurial venture from each other in a tax-free manner."

As in the September 2018 statement, the IRS specifically identified pharmaceutical and technology ventures as examples of ventures that collect little or no income during lengthy and expensive R&D phases. It requested information to help it identify the types of entrepreneurial ventures that should qualify as ATBs absent a five-year history of income collection. The IRS asked a series of questions to aid its analysis, focusing on several topics, including:

- how those R&D ventures are created and funded;
- what steps are necessary to obtain regulatory approval of products developed in the R&D phase of such ventures;
- what types of opportunities exist to collect income from those ventures before a marketable product is developed (and whether those opportunities increase if particular steps toward final regulatory approval are accomplished);
- in what situations might an R&D venture benefit from separating part of its activities; and
- what types of entrepreneurial ventures, in addition to R&D, might satisfy the ATB requirement in the absence of income collection.[17]

On May 17, 2019, the IRS issued LTR 201920008 (released February 15, 2020), a transactional ruling under Rev. Rul. 2017-52, which some practitioners viewed as indicating that the IRS was willing to rule that a taxpayer could have a qualifying ATB without the collection of income. However, the ruling states: "Following the Distribution, Distributing and Controlled will engage in the Continuing Relationships, including the provision of Services. Once Controlled ceases providing Services to Distributing, Controlled may not generate revenue, but it will continue to seek to generate future revenue through future Events." This suggests that Controlled did collect income from continuing transactions with Distributing.[18] Thus, it seems that this ruling is less relevant to whether the ATB requirement can be satisfied without the collection of income.

III. Pharmaceutical Industry

Given the IRS's focus on pharmaceutical ventures in the September 2018 statement and the May 2019 request, some background on the R&D process and funding arrangements common in the pharmaceutical and biotechnology industries is helpful in examining the fact patterns on which the IRS may be willing to issue private letter rulings in the section 355 context. As discussed later, in Section IV, although not entirely clear, it appears likely that LTR 202009002 involves a drug developer that is engaged in clinical testing to develop new drugs.

[15] Rev. Rul. 2019-9, 2019-14 IRB 925.

[16] "IRS Request for Information Regarding the Active Trade or Business Requirement for Section 355 Separations of Entrepreneurial Ventures" (May 6, 2019).

[17] *Id.*

[18] The regulations indicate that a trade or business that serves only other business functions of the same corporation and has no income from third parties can satisfy the ATB requirement. *See, e.g.*, reg. section 1.355-3(c), Example 9 (research department transferred to Controlled satisfies ATB requirement even if it furnishes its services solely to Distributing both before and after the distribution).

A. Development of New Drugs

Developing a new medicine is a long, complex, and expensive process, with risk of failure at each step. The Food and Drug Administration must approve a drug[19] before it is commercialized. Approval is based on demonstrable evidence of safety and efficacy, supported by data obtained from laboratory screening, preclinical (that is, animal) testing, and a sequence of rigorous clinical (that is, human) testing. Data from laboratory screening and preclinical testing are used to demonstrate that the investigational compounds are likely safe to test in human studies. Although hundreds of thousands of compounds may be initially screened, and thousands of new medicine candidates are further screened in the laboratory, only a few may eventually result in an FDA-approved medicine, after many years of testing and development. Laboratory screening and preclinical testing eliminate the vast majority of compounds before testing in humans. A May 2016 study estimated that of those compounds reaching the clinical trial phase, only 11.83 percent ultimately are approved by the FDA after an average of 10 to 15 years of development and an average of $1.4 billion in out-of-pocket costs for laboratory screening, preclinical testing, and clinical testing.[20]

During early preclinical development, the primary goal is to determine if the product is reasonably safe for initial use in humans and if it shows pharmacological activity that justifies further development. Key elements of pharmacological studies include pharmacodynamic analysis, which evaluates how the drug interacts with the body, and pharmacokinetic analysis, which determines which organs the drug affects and how long the drug stays in the body. These tests are usually performed in multiple species. The pharmacological activity of a biopharmaceutical is evaluated using in vitro and/or in vivo tests.[21] In vitro tests are used to demonstrate the affinity of the biopharmaceutical for the target, and in vivo studies are used to establish the potential biological activity in appropriate animal models. These studies provide information on the mechanism of the product and its potential for clinically relevant activity. Performing in vitro tests and in vivo animal tests usually is the first major step toward regulatory approval. Only 5 in every 5,000 compounds studied in preclinical testing progresses to clinical testing.[22]

When an investigational product is identified as a viable candidate for further development, the focus is on collecting the data necessary to establish that it will not expose humans to unreasonable risks when used in limited, early-stage clinical studies. Under FDA requirements, the drug developer — sometimes referred to as the sponsor (usually a pharmaceutical or biotechnology company) — must first submit data showing that the drug is biologically active and reasonably safe for use in initial, small-scale studies in humans.[23] An investigational product is approved for human testing through a request for a waiver called an investigational new drug application,[24] which is submitted to the FDA. If the FDA does not oppose the request for a waiver, the new drug can be studied in rigorously designed studies with ongoing oversight by the FDA.

Once cleared to begin human studies, the drug developer initiates a clinical development program that consists of a prescribed sequence of steps or phases. Each phase may consist of one or more individual clinical studies, each of which is described in a formal protocol. Before initiating each phase, the FDA often engages in extensive advisory discussions with the drug developer to ensure that the planned study designs align with the regulatory authority requirements and preferences.

[19] A drug is generally defined as an "article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man" and an "article (other than food) intended to affect the structure of and function of the body of man." 21 U.S.C. section 321(g).

[20] Joseph DiMassi, Henry G. Grabowski, and Ronald W. Hansen, "Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs," 47 *J. Health Econ.* 20, 20-33 (May 2016).

[21] In vitro tests are performed in a laboratory outside a living organism. In vivo tests are performed on a living organism.

[22] FDA, "The Beginnings: Laboratory and Animal Studies" (last accessed May 13, 2020).

[23] 21 C.F.R. section 312.23(a)(8).

[24] 21 C.F.R. section 312.3(b).

1. Phase 1.

Phase 1 studies,[25] sometimes called clinical pharmacology studies, represent the first introduction of a new drug into human subjects. The focus of these studies is on clinical safety. These studies enroll either patients with the disease or condition of interest, or normal healthy volunteers. These studies are designed to collect and analyze data on the metabolism and pharmacologic actions of the drug in humans. Phase 1 studies also assess side effects associated with increasing doses of the investigational product and, if possible, early evidence on efficacy. Phase 1 studies usually involve only a small number of subjects (usually between 20 and 80) and may be uncontrolled (that is, performed without a comparison against a control group) or self-controlled (that is, "crossover," in which patients are switched from the investigational product to some other product or placebo, thus serving as their own control group).

2. Phase 2.

Once phase 1 studies have demonstrated that the investigational product is safe in limited use, the next step is conducting phase 2 studies,[26] which are designed to test efficacy (that is, how the drug affects the disease or condition under study). These studies enroll patients with the disease or condition that the drug is intended to prevent, diagnose, or treat. Drug developers hope to identify the lowest dose that delivers an acceptable level of efficacy. Safety and efficacy are juxtaposed using what is called the therapeutic index. Phase 2 studies use a limited number of subjects (usually between 100 and 200) and are controlled, meaning that the investigational product is compared with a placebo and/or standard therapy.

3. Phase 3.

If the investigational product survives the early phase testing, it will be tested in phase 3 studies,[27] which are designed to model real-world use. These studies use a larger patient population (usually between hundreds and thousands) to assess safety and efficacy and to evaluate the overall benefit and risk for patients who best fit the profile of the intended patient population for the product. In some cases, selection criteria for test subjects may incorporate anticipated concomitant therapies and conditions that may be encountered in the patients to whom the drug is ultimately prescribed. Because the drug will be prescribed according to FDA-approved product labeling, which describes the disease or condition and intended patient population, these studies are designed to specifically support product claims, as represented in the label. Phase 3 studies provide the most compelling evidence of product safety and efficacy and are often referred to as pivotal studies.

Usually, once phase 3 studies have been completed, the drug developer submits all supporting data to the FDA in a dossier known as a new drug application (NDA). Occasionally, the FDA may request additional information to be considered, either in parallel with the dossier review or as a post-marketing commitment that requires the drug developer to more fully explore some aspects of the drug, usually in studies of long-term safety. These are called peri-approval and post-approval studies, respectively.[28] Once an investigational product has been approved by the FDA, the drug can be marketed to customers.

B. Funding, Pre-Commercialization Income

There are several ways in which a research enterprise can be established. It may be a start-up biotechnology company created to explore a promising new drug, device, vaccine, or technology. The enterprise may be formed by someone engaged in independent research (for example, a physician-entrepreneur) or by an academic (for example, a faculty member in a biochemistry department). Alternatively, the enterprise may have begun as a division of a global pharmaceutical corporation.

To fund these fledgling enterprises, there is a full spectrum of potential financial arrangements between the innovator biotechnology company and prospective investors. As discussed later,

[25] *See* 21 C.F.R. section 312.21(a).

[26] *See* 21 C.F.R. section 312.21(b).

[27] *See* 21 C.F.R. section 312.21(c).

[28] These are also referred to as phase 3B and phase 4 studies, respectively.

these range from contributions in exchange for ownership equity in the company to contractual arrangements, partnerships, and acquisitions. As the drug progresses along the development pathway, the potential for the innovator to attract investment funding and achieve commercialization increases. Thus, potential investors are likely more willing to invest as the chances for regulatory approval and subsequent commercial success increase. The further along the pathway, the more perceived value among investors.

The following are some of the potential funding arrangements.

1. Friends and family funding.

As with any start-up venture, seed money must be obtained to fund initial attempts to establish "proof-of-principle" (empirical evidence of the investigational product's potential therapeutic value and safety). Although R&D activities are costly, particularly once a product enters the clinical testing phase, laboratory screening and preclinical testing do not require as much funding, nor do they require as broad a base of knowledge of the drug development, review, and approval processes. Thus, initial funding may be obtained in part from contributions from friends and family in exchange for ownership equity in the drug developer's company.

2. Angel investor funding.

As funding requirements increase, there may be a need to seek more substantial investment. An angel investor (sometimes referred to as a private investor, seed investor, or angel funder) is usually a high-net-worth individual who provides financial backing for small start-ups or entrepreneurs, typically in exchange for ownership equity in the drug developer's company. An angel investor may provide a one-time investment to help the business get started, or may provide ongoing investments at critical development points.

3. Venture capital funding.

As the R&D for a new drug continues into the clinical testing phases, the costs to conduct the studies increase significantly. A 2016 study found that the average cost of a phase 1 study conducted in the United States ranged from $1.4 million to $6.6 million, including estimated site overhead and monitoring costs.[29] The average cost of a phase 2 study ranged from $7 million to $19.6 million, whereas the average cost of a phase 3 study ranged from $11.5 million to $52.9 million.[30] There can be multiple phase 1, phase 2, and phase 3 studies for a new drug.

These expenditures are beyond the capacity of most individual investors and require financing at a level that may be provided by venture capital firms in exchange for ownership equity in the drug developer company. Venture capital firms often hold the drug developer to very aggressive timelines to demonstrate positive results indicating that the new drug has potential commercial value, and these firms may insist on embedding themselves into the day-to-day management of the drug developer.

4. Arrangements with established market participants.

Another option for funding is for the drug developer to engage with an established pharmaceutical or biotechnology company. This option provides not only access to funding but also an opportunity to access R&D expertise and experience with the relevant regulatory agencies. Funding arrangements can take many forms, ranging from contractual arrangements to joint ventures to an outright acquisition of the start-up venture by the funding company. The funding company may agree to provide financial support and to pay a fee in exchange for a right of first refusal to acquire the new drug. The funding company may also pay a license fee in exchange for the right to access the drug developer's research data. This allows the funding company to perform due diligence to determine the extent to which it wants to invest in the new drug. The funding company may also make milestone payments to the drug developer as the new drug reaches critical development points. Alternatively, the funding company and the drug developer may enter into a revenue-sharing agreement once the new drug has been commercialized, with the funding company

[29] Aylin Sertkaya et al., "Key Cost Drivers of Pharmaceutical Clinical Trials in the United States," 13 *Clinical Trials* 117 (Apr. 2016) (first published Feb. 8, 2016).

[30] *Id.*

assuming primary responsibility for marketing the new drug to customers.

The amount of collaboration between the funding company and the drug developer in the drug development process varies. In some cases, the funding company enters into a contractual arrangement with the drug developer to allow it to participate in the operations of the drug developer. This may be desirable in that the funding company may add value in terms of the efficiency and advancement of the R&D process, given its experience and expertise. Although it is most common for the funding company to acquire the new drug from the drug developer, it may instead enter into a revenue-sharing agreement once the new drug has been commercialized. For example, the funding company may negotiate for a share of revenue from sales in a particular region (for example, the EU or Asia-Pacific) or after a particular period has elapsed (for example, three years after FDA approval). Another option would be a joint venture in which the two companies share the financial and operational responsibilities of the drug development process as well as a share of the revenue from product sales. In some circumstances, the funding company may simply acquire the drug developer's company.

5. Grants.

Drug developers may also obtain grants from federal agencies, including the National Institutes of Health, the National Institute of Mental Health, and the Defense Advanced Research Projects Agency. Nonprofit organizations (such as foundations), disease-specific advocacy groups, and pharmaceutical companies may also provide grants to drug developers. Agencies and organizations generally do not receive equity ownership or a portion of revenue from the sale of the new drug in exchange for the grants.

IV. LTR 202009002

In LTR 202009002, the IRS ruled that under the facts presented, the ATB requirement was satisfied, even though no income was collected. The private letter ruling involves a publicly traded Distributing, which is an Industry A company that seeks to create Items A. Typically, for Items A to be commercialized, they go through a four-step process. Each step is composed of subparts, with Step 2 consisting of four subparts: steps 2A, 2B, 2C, and 2D. Step 2C is composed of steps 2C1 and 2C2.

A. Historic Business With Collection of Income

Distributing's historic business (Business 1) consists of activities in Step 1 through Step 2C1, and relies on R&D to identify and create Products A. Products A are then tested and modified to create Items A for later testing and ultimate commercialization. Over the years, Distributing has created Items A and continues to create other Items A. Item 1, a type of Item A, has progressed through Business 1 from Step 1 through Step 2C1. At Step 2C1, Item 1 has been tested in a variety of possible conditions, and its development is typical of Distributing's Business 1 practice.

For over five years, Business 1 consistently generated income through contractual relationships with Industry AA companies from research-oriented contracts or certain licensing. For example, Distributing received income from agreements with several Industry AA companies, including Collaborator A. Distributing and Collaborator A are parties to the Collaborator Agreement, whereby Collaborator A received access to all of Distributing's Items A (except for Item 1), each of which was in Step 2C1 or earlier. In exchange, Distributing received "an upfront cash licensing fee and annual research and reimbursement of at least $*a* per year for at least *b* years."

The facts of the private letter ruling are redacted, so it is difficult to discern Distributing's industry and activities with certainty. However, based on the high-level description of the facts, it appears likely that Distributing is a drug developer engaged in clinical testing of new drugs. Products A could be biological compounds, while Items A could be new drugs (with Item 1 being a specific type of drug). Steps 1 through 3 might refer to phases 1 through 3 of the clinical testing process, as described in Section III.A, earlier, with Step 4 potentially being the filing and approval of an NDA. Under this hypothesis, it is unclear what the references to the subparts of Step 2 relate to in the clinical testing process. It is possible that the references to

subparts of Step 2 relate to different types of incremental phase 2 studies for a particular type of drug, given that the private letter ruling indicates that at Step 2C1, Item 1 has been tested in a variety of possible conditions.[31] This suggests that at a minimum, Item 1 has progressed beyond initial laboratory screening and preclinical testing and is in clinical testing at Step 2C1.

Assuming that Distributing is a drug developer and that Items A are new drug candidates, it would not be unusual for Distributing to collaborate on the development of a drug with an established pharmaceutical company at the clinical testing phase, which requires significant funding. Under the facts of the private letter ruling, it appears that Distributing receives licensing income and reimbursement of research costs from a collaborator in exchange for giving the collaborator access to Distributing's new drugs (other than Item 1) that have begun clinical testing. Potential collaborative scenarios are described in Section III.B, earlier.

B. Potential Income, but No Current Income

More than five years before the date of the proposed spinoff transaction, Distributing began conducting R&D, testing, and regulatory functions for Item 1, intending to develop Item 1 from Step 2C2 through Step 3 (Business 2).[32] Item 1 has not progressed beyond Step 2C2. Step 2D generally consists of duplicating tests performed in Step 2C2 but on a larger scale. After Step 3 but before Step 4, Business 2 will partner or collaborate with one or more Industry AA partners that have the experience, knowledge, and sales force to move Item 1 efficiently through the next steps. However, the ruling indicates that despite a progression to Step 4, Step 3 activities will still need to be conducted, and Business 2 will conduct those activities.

Given that Step 2D generally consists of duplicating tests performed in Step 2C2 but on a larger scale, Step 2C2 and Step 2D may be part of the same clinical testing phase, given the differences between phase 1, phase 2, and phase 3 studies. Assuming that Step 2 consists of phase 2 studies, it appears that preliminary evidence of the efficacy of Item 1 has been obtained and that Business 2 consists of finishing phase 2 studies and completing phase 3 studies. Assuming that Step 4 is the submission of the NDA, it appears that Distributing will partner with a pharmaceutical company to move Item 1 through the FDA review process and commercialization and that Business 2 will continue to perform any additional clinical testing required by the FDA before approval of the NDA.

Distributing has incurred significant salary and wage expense in connection with Business 2, but Business 2 has not yet generated income. However, the ruling then states the following regarding potential income for Business 2:

> Even though Business 2 has never generated income, Distributing believes that Business 2 had the ability to generate income since Date A through licensing of certain rights to Item 1 or partnering with Industry AA companies. Distributing represents that, based on the Items A that were included in the Collaborator Agreement, it believes that it could have entered into a partnership or collaboration agreement with Collaborator A for the development and commercialization of Item 1 similar to the Collaborator Agreement, and that Item 1 has greater potential and value. Distributing also represents that it is easier to obtain income from Items A the further they have progressed through the steps. Distributing submitted a list, provided to it by Investment Banker, of deals within the past five years, between parties unrelated to Distributing, involving licenses of other Items A in Step 2C with upfront cash payments by the licensee to the licensor. Distributing has stated that the listed Items A are similar and comparable to Item 1.

[31] Alternatively, Step 1 could refer to laboratory testing and preclinical research, Step 2 could refer to clinical research, Step 3 could refer to the submission and approval of an NDA, and Step 4 could refer to post-approval commercialization and sale.

[32] Before the commencement of Distributing's Business 2, described later, steps 2C2 through 4 (the remaining steps to bring Items A to commercialization) were performed by third-party Industry AA companies under license and collaboration agreements.

> However, Distributing has decided to forego immediate collection of income from Business 2 in favor of the prospect of collecting significantly greater income after Step 3 is completed with respect to Item 1. As indicated above, after Step 3 but before Item 1 is commercialized, Business 2 intends to partner or collaborate with Industry AA partners that have the experience, knowledge, and a salesforce to move Item 1 efficiently through to the next steps. Business 2 will then generate income at this step through receipts of royalties, milestone payments, or profit-splits.[33]

Given that the likelihood that a new drug will be commercialized dramatically increases as it progresses through the clinical testing phases, it is not surprising that the private letter ruling states that "it is easier to obtain income from Items A the further they have progressed through the steps." The development of a new drug is risky. Although a drug developer may earn license income and fees from collaborators during the clinical testing process, the opportunities to earn that income increase as the new drug progresses through clinical testing and produces more compelling evidence of safety and efficacy, and as it becomes less likely that a competitor will bring an equivalent or superior drug to market first.[34] By the time the NDA is submitted for a new drug, the drug developer can earn significantly more income because companies are willing to pay more money for rights to a product that is more likely to be commercialized and generate sales.

C. IRS Ruling

Distributing proposes to contribute Business 2 to a newly formed Controlled in exchange for all the stock of Controlled and the assumption by Controlled of all of Business 2's liabilities. Distributing will then distribute all the stock of Controlled pro rata to Distributing's shareholders. Distributing represents that except for the issue of whether the absence of income collection prevents Distributing's Business 2 from satisfying the ATB requirement, the proposed transaction qualifies for nonrecognition treatment under section 355.

The IRS ruled that based solely on the facts and information submitted and the representations made, the absence of income collection does not prevent Distributing's Business 2 from satisfying the ATB requirement. Although not explicitly stated, it appears that the following facts may have influenced the IRS's favorable ruling: (1) Although Business 2 has never generated income, Distributing believes it has the ability to generate income through licensing fees or by partnering with other companies, and (2) Distributing has decided to forgo immediate collection of income from Business 2 in favor of the prospect of collecting far more income.

In both the September 2018 statement and the May 2019 request, the IRS highlights similar fact patterns. The September 2018 statement notes that a "venture might . . . forgo current income opportunities to obtain increased future income by developing products on its own." The May 2019 request specifically requests information on the following topics:

> What types of opportunities exist to collect income from the results of research before any marketable product is developed? Do markets (or recognized communities of investors, joint venturers, or customers) exist with respect to these opportunities? If so, do these opportunities vary by industry? Do opportunities to collect income from these sources increase as a result of preliminary approval by a regulator or accomplishment of particular steps toward final regulatory approval? If so, do these opportunities vary by industry?

There are opportunities for drug developers to earn income from a prospective new drug while the drug is in the clinical testing phase and before it is approved by the FDA. As discussed earlier, a drug developer may earn fees and license income from collaborators in the

[33] Given the reference to "after Step 3 but before Item 1 is commercialized," it appears that the references to royalties, milestone payments, and profit splits are references to income earned before commercialization.

[34] There can be evidence of competitor status, for example, on publicly accessible websites, such as the National Library of Medicine online database of clinical studies registered with the FDA (ClinicalTrials.gov).

pharmaceutical industry in exchange for access to certain rights to the new drug. However, most drugs in the clinical testing process ultimately fail. As a new drug moves toward FDA approval, collaborators are willing to pay drug developers significantly more money in exchange for rights to a product that likely will be commercialized and earn significant sales revenue.

What remains ambiguous is whether a business must have the current ability to generate income in order to satisfy the ATB requirement. For example, it is unclear whether a business that engages in substantial R&D activities to generate income in the future but lacks the current ability to generate income would be treated as satisfying the ATB requirement, even though it would seem that the business is engaged in entrepreneurial activities. If the IRS were to require that a business have the current ability to generate income, it may be difficult for a business that engages only in the early stages of laboratory screening and preclinical testing for a new drug to satisfy the ATB requirement. It is also unclear whether a contractual arrangement for the sharing of expenses, or a joint venture, with the expectation of future profit-sharing would be sufficient. Further, given the risky nature of the pharmaceutical industry, a drug developer could incur significant expenditures without ever earning income, particularly if the new drug fails or if a competitor brings an equivalent or superior drug to market first.

Moreover, the question remains as to what qualifies as income for purposes of the ATB requirement. LTR 202009002 does not address whether a corporation can satisfy the ATB requirement if the only income it earns consists of nontaxable revenue, such as grants or similar funding. As indicated earlier, such funding is common in the pharmaceutical and biotechnology industries.

Finally, it is unclear whether the IRS would be willing to issue a favorable ruling for a business that has not generated any income and is not engaged in substantial R&D, but engages in other entrepreneurial activities and generates substantial expenditures. For example, it is unclear whether the IRS would issue a favorable ruling for a real estate development that has not yet reached completion. Although the IRS ruled in Rev. Rul. 57-492 that such a venture would not satisfy the ATB requirement, the withdrawal of that revenue ruling suggests that the IRS might consider taking a different position in the future.

V. What's Next?

The issuance of LTR 202009002 is helpful in that it confirms that the IRS will rule favorably in some situations without the collection of income. Every situation is fact-dependent, however, and it will be interesting to see in what other situations and industries the IRS rules favorably.

Unfortunately, because of the nature of the private letter ruling process, we will not see the IRS's analysis or reasoning in situations in which it refuses to rule favorably. Before submitting a request for a private letter ruling, taxpayers generally ask for a pre-submission conference with the IRS to discuss any significant legal issues concerning the proposed spinoff transaction. If, as a result of the conference, the IRS indicates that it is unwilling to issue a favorable ruling, the taxpayer usually decides not to submit the ruling request. In addition, after a taxpayer submits a ruling request, the IRS might refuse to rule favorably, usually causing the taxpayer to withdraw the ruling request. The IRS does not publicly disclose situations in which it refuses to rule favorably, nor does it publicly disclose its reasons for refusing to rule favorably. Further, after a taxpayer submits a ruling request, it might restructure a proposed transaction to address a concern expressed by the IRS. Because the IRS publishes only the final private letter ruling, the full contours of IRS deliberations are not publicly available.

Upon completion of the study described in its September 2018 statement, it is possible the IRS will issue guidance on satisfying the ATB requirement without income collection. Guidance could take various forms.

For example, the IRS and Treasury could promulgate proposed regulations expanding on what is meant by "ordinarily" in reg. section 1.355-3(b)(2)(ii). The proposed regulations could provide a list of factors that will be considered in determining whether a corporation meets the ATB requirement despite the absence of income collection. These factors might be drawn from the questions asked by the IRS in the September 2018

statement and the May 2019 request. The proposed regulations could include safe harbors or favorable presumptions for when a corporation meets the ATB requirement, despite the absence of income collection. The proposed regulations could also address whether the receipt of nontaxable revenue can qualify as collection of income.

Further, the proposed regulations could include examples of fact patterns in which the ATB requirement is satisfied in the absence of income collection and examples of situations in which the ATB requirement is not satisfied. The fact patterns could include a variety of industries, including pharmaceutical, technology, and perhaps others, such as real estate. Given that the regulatory milestones in the pharmaceutical industry are absent from the technology and real estate industries, it may be more difficult to determine when corporations in those industries should be treated as satisfying the ATB requirement.

Alternatively, the IRS could issue a revenue procedure requiring a taxpayer with an activity that has not yet generated income to provide certain information and make particular representations when seeking a private letter ruling.

In the absence of additional guidance, it will continue to be highly advisable to seek a pre-submission conference to ascertain IRS views on the taxpayer's facts before submitting a private letter ruling request. It is uncertain whether, in the absence of a private letter ruling, taxpayers could obtain sufficient comfort from a legal opinion. Substantial tax liability for Distributing and its shareholders may be at stake with respect to a given spinoff transaction, so taxpayers may be unwilling to rely solely on a legal opinion in a situation involving a business without income collection.

In any event, the IRS's willingness to favorably rule on an ATB without the collection of income is welcome and is consistent with the purpose of the ATB requirement — to permit the separation of actively conducted businesses. A business should be treated as actively conducted as long as it is engaged in meaningful entrepreneurial activity and not an investment activity, regardless of whether income has yet been collected. ■