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NEW RULES UNDER THE INNOVATION LAW –
RULES FOR APPROVAL OF OUT-LICENSING ARRANGEMENTS

On May 7, 2017, the Israel Innovation Authority, the successor entity of the Office of the Chief Scientist (the “**IIA**”), published the long-awaited Rules for Granting Authorization for Use of Know-How Outside of Israel (the “**Licensing Rules**”). The Licensing Rules are practically identical to the Licensing Regulations that were scheduled to be enacted on December 8, 2014, but which were not then promulgated due to the dissolution of the government of the State of Israel. The Licensing Rules were published pursuant to Section 18 of Track 1 – R&D Fund (“**Track 1**”) recently published by the IIA pursuant to the Law for Encouragement of Research, Development and Technological Innovation in the Industry, 5744-1984 (the “**Innovation Law**”). In essence, the Licensing Rules now enable the approval of out-licensing arrangements and other arrangements for granting of an authorization to an entity outside of Israel to use know-how (“**Know-How**”) developed under research and development programs funded by the IIA. Subject to payment of a “License Fee” to the IIA, at a rate that will be determined by the IIA in accordance with the Licensing Rules, the IIA may now approve arrangements for the license of Know-How outside of Israel. This is a significant development for any company that has received IIA support (“**Grant Recipient**”) as it allows it to commercialize Know-How in a manner which was not previously available.

General Background – Restrictions on Transfer of Know-How

Prior to the enactment of the Licensing Rules, the Innovation Law had restricted the transfer out of Israel of Know-How, unless such transfer was permitted under Section 19B of the Innovation Law. While Section 19B(j) had provided general authorization for the Minister of Economy and Industry and Minister of Finance to regulate licensing transactions for the use of Know-How by an entity outside of Israel, no such regulations had been promulgated, thus effectively restricting the ability of Grant Recipients to enter into out-licensing transactions. This has been a problematic reality in light of the fact that licensing transactions are widespread in the high-tech industry, particularly in the pharma, medtech and life sciences industries.

In the absence of regulations, out-licensing transactions were only able to be approved either as: (i) an outright transfer of Know-How under Section 19B(b) of the Innovation Law, attracting the payment of the entire “transfer fee” as a condition to the transfer of the Know-How, or (ii) as a transfer of manufacturing rights under 19A(b) of the Innovation Law, in which case the Know-How remained in Israel and only the “manufacturing file” was permitted to be transferred abroad.

The Licensing Rules¹ introduce a mechanism for approval of out-licensing arrangements and set rules for determining the amounts payable to the IIA in connection with such licenses. The main advantage in the Licensing Rules is that in most cases payment to the IIA is required to be made from amounts actually received under the license, such that companies will no longer be required to pay the entire “transfer fee” upon receipt of the IIA’s approval for the transfer. As detailed further below, however, a material drawback of the Licensing Rules is that they do not provide a solution for a low-value licensing arrangements and indeed put the Grant Recipient “on the hook”, upon receipt of the Approval, for full repayment of the IIA grant amounts, which amounts may be quite high, even in cases in which the revenues from the license are low or lower than expected or calculated by the IIA.

The Licensing Rules

Approval of Out-Licensing Arrangements. Pursuant to the Licensing Rules, the Research Committee of the IIA (the “**Research Committee**”) is authorized to approve (the “**Approval**”) a transaction involving the grant of an authorization to use Know-How and any right deriving therefrom to an entity outside of Israel, including the transfer of such Know-How in any way other than the outright transfer of ownership rights in the Know-How (each such case, an “**Out-License**”). The Licensing Rules clarify that the grant of an exclusive license which completely expropriates the rights of the licensor to utilize the Know-How would be treated as an outright transfer of ownership, and not as an Out-License.

Transfer Payments. The Approval is subject to the payment of a “Transfer Fee”. The payment is required to be made in New Israeli Shekels, within three business days from the date any payment under the Out-License is received by the Grant Recipient.

1. Single Installment. In the event the transaction consideration is paid in one installment (which is rather unlikely in the licensing context), the “Transfer Fee” shall be equal to: (i) a percentage equal to the aggregate IIA grants received with respect to the Know-How being transferred divided by the aggregate monetary investments in the approved R&D program, up to a maximum percentage of 50% (the “**IIA Percentage**”) of the amount received; multiplied by (ii) the overall transaction consideration, as shall be determined by the Research Committee (the “**Overall Transaction Consideration**”)², as follows:

¹ On July 29, 2015, the Knesset enacted Amendment Number 7 to the Innovation Law (“**Amendment 7**”), by means of which the IIA was established instead of the existing Office of the Chief Scientist. The IIA was granted many far-reaching rights, including with respect to the actual creation of different tracks with different rules for the purposes of granting various types of benefits (the “**Tracks**”) all for the stated purposes of encouraging innovation, creating jobs in Israel and increasing productivity. Many sections of the Innovation Law, as well as relevant regulations, including the sections on the transfer of Know-How referred to above, were simply deleted and substituted by general guidelines, with the particulars of the guidelines to be published by the IIA on the internet. The IIA has indeed recently started publishing guidelines to the various Tracks, including Track 1, to which the IIA has appended the Licensing Rules in the form of an appendix. Track 1 with its appendices (not all of which have been published as of this date) has incorporated many of the deleted sections of the Innovation Law, as well as a number of the various cancelled regulations.

² Clearly this is a serious weakness in the Licensing Rules because the Research Committee will be called upon, in the case of licenses with multiple future payments of unknown amounts, to make some kind of determination of the overall total transaction consideration. It is not clear how such determinations will (or can) be made. Based

$$\frac{\text{Aggregate IIA grants received}}{\text{Aggregate monetary investments}} \times \text{Overall Transaction Consideration}$$

The Transfer Fee is subject to depreciation as set forth in the Innovation Law.

2. Multiple Installments. If the transaction consideration is paid in more than one installment (which is more typical in licensing transactions), the Grant Recipient shall be required to pay the IIA a percentage of any payment made to it under the Out-License, even if such installment exceeds the Overall Transaction Consideration, as follows:

(i) If the "Transfer Fee" (in accordance with the formula set forth in Section 1 above) is *higher* than the aggregate grant amounts plus interest (the "**Linked Grant Amount**"), the Grant Recipient shall be required to pay the IIA an amount equal to: (a) the IIA Percentage multiplied by (b) the amount of any payment made to the Grant Recipient under the Out-License (the "**Consideration**"), as follows:

$$\frac{\text{Aggregate IIA grants received}}{\text{Aggregate monetary investments}} \times \text{Consideration paid to the grant recipient in connection with a specific installment under the license}$$

(ii) If the "Transfer Fee" (in accordance with the formula set forth in Section 1 above) is *equal to or lower* than the Linked Grant Amounts, the payment to the IIA with respect to each installment shall be equal to: (i) the Linked Grant Amount divided by the Overall Transaction Consideration (the "**Minimal Percentage**"); multiplied by (ii) any payment of Consideration, as follows

$$\frac{\text{The Linked Grant Amount}}{\text{Overall Transaction Consideration}} \times \text{Consideration paid to the grant recipient in connection with a specific installment under the license}$$

Minimum Payment Amount. Notwithstanding the above, the aggregate *minimum* payment amount in connection with the Approval shall be equal to the Linked Grant Amount. In the event all Consideration under the license has been paid, but the payments to the IIA did not cover the Linked Grant Amount, the Grant Recipient shall be required to repay the remaining

on recent experience, presumably the determination will be outsourced to external "examiners" who are sub-contractors. This begs the question as to the criteria that will be used. One thing is certain: it will delay the approval process. Moreover, in certain cases, such as the out-licensing of pharmaceutical candidates, it is often simply not possible to estimate the value (since often the outcome is binary – worthless or a blockbuster), which is the reason why the parties prefer licenses to an outright transfers to begin with.

unpaid Linked Grant Amount within 14 days from the date the last payment under the Out-License has been received. In addition, if at any time the Research Committee determines that it is not likely that the Grant Recipient will be able to repay the Linked Grant Amount during the term of the Out-License, it may require that the Linked Grant Amount will be repaid immediately, provided that the Grant Recipient received a chance to present its claims prior to the effective date of such resolution.

As noted above, these minimum payment provisions are a material disadvantage of the Licensing Rules, and as a result many companies may avoid applying to the IIA for Approval for an Out-License, whether because the expected revenues from the Out-License are lower than the Linked Grant Amount or because they may turn out to be lower than calculated at the start. Indeed, the Licensing Rules may be most useful to biotech companies which enter into high-value joint development licenses with the big pharma companies, while the usefulness of the Licensing Rules for software or technology companies is questionable.

Maximum Payment Amount. The *maximum* amount payable to the IIA in connection with the Approval shall be limited to such amount as will be stated in yet-to-be published appendix to Track 1. If this appendix will mirror that which was stated in the previous regulations³, which were cancelled under Amendment 7, the maximum amount will be six times the Linked Grant Amount, *less*: (i) royalties paid; and (ii) any amounts paid to the IIA in connection with Approvals granted under the Licensing Rules. To date, Track 1 and the published appendices have to a great extent mirrored the pre-Amendment Innovation Law, and the regulations promulgated under it, but there is no assurance that the six-times ceiling amount will also be reinstated⁴.

If the payment amount under the formulas for calculation of the Transfer Fee is *lower* than the maximum ceiling amount, payment will be in accordance with the formulas, as detailed above.

Determination of the Overall Transaction Consideration. In the event there is a “special relationship” between the parties to the transaction, including related parties, business partners, family relatives or parties which have the same direct or indirect parent or joint holding rights in a third party, the Research Committee may determine the Overall Transaction Consideration on a basis of an external financial valuation obtained by it. The Research Committee may also rely on a financial valuation to determine the Overall Transaction Consideration if the transaction involves payment of non-monetary consideration, or if there is no maximum consideration amount, or if otherwise the consideration determined by the parties does not reflect the fair market consideration for such type of transaction⁵. The Research Committee is also authorized to determine that payments which the Grant Recipient

³ The former are known as the Regulations for Encouragement of Research and Development in Industry (Ceiling for Payments in connection with Transfer of Know-How Pursuant to Section 19B(b)(1) and (2)).

⁴ Under the prior regulations for the outright transfer of Know-How, there was also a three-times ceiling in cases where the recipient of the Know-How undertook to retain certain research and development personnel in Israel. There is no similar 3X ceiling with respect to the Licensing Rules.

⁵ The Licensing Rules imply that even where the transaction is on a fully arms’ length basis, the Research Committee may determine that the consideration does not reflect market price.

is expected to receive after more than seven years from the date of the Approval will not be taken into account.

Determination of the “Transfer Fee”. The Research Committee is authorized to determine, in its sole discretion and based on a professional opinion that certain of the payments included in the Overall Transaction Consideration will not be taken into account when determining the IIA Percentage or the Transfer Fee. Currently, there is no guidance on how the committee will determine which payments are to be excluded.

Termination or Amendment of License. At the request of the Grant Recipient, the Research Committee is authorized to update the Approval to also cover related grants approved following the grant of the Approval. In the event of termination or amendment of the Out-License there will be no refunds on payments already made to the IIA with respect to the Approval.

Corresponding In-Licensing. If in exchange for the Out-License the Grant Recipient receives a license to know-how developed outside of Israel, the Research Committee can authorize such transfer without payment of the Transfer Fee, provided that the new know-how being in-licensed is significant. In the event the “knowledge exchange” is approved, the original grant approval will be amended to include the new know-how and it will be deemed as an integral part of the Know-How, and will be subject to the restrictions of the Innovation Law and royalties obligations. The Grant Recipient is required to use the new know-how within four months, otherwise the Research Committee may terminate the Approval retroactively and treat the out-license as any out-license approved under the Regulations, including the requirement to pay the “Transfer Fee”.

Reports; Guarantees. Unless otherwise determined by the IIA, Grant Recipients receiving an Approval are required to submit annual reports signed by a CPA until the end of the term of the License. The chairman of the IIA may require appropriate security to guarantee full payments under the Approval.

Tax. This memorandum does not take into account the tax implications of any of the licensing arrangements discussed. Tax implication need to be separately considered.

Additional Information – Contact Details

Please direct any queries you may have regarding these matters to Barry Levenfeld (barry@arnon.co.il), Daniel Green (danielg@arnon.co.il) or Miriam Friedmann (miriamf@arnon.co.il).