リーガルフロンティア２１

プロジェクトベース

実務・英文契約書講座

第7回　パテントライセンス契約

2013 年 6 月 26 日（水）　午後7：00～9：00

会　場

〒101-0051　東京都千代田区神田神保町 3-10　神田第 3 アメレックスビル 7F
株式会社リーガルフロンティア２１
セミナールーム

テーマ	トピック	学習目標
⑦パテントライセンス契約 2013 年 6 月 26 日（水）	特許権、ライセンス、消極的効力、積極的効力、属地性、権利侵害、有効なクレーム、ロイヤルティ、パテントインデムニティ、職務発明、報奨・特許管理	典型的な英文のパテントライセンス契約書を素材にして、契約書の各条項の背後にある原理・原則を理解します。「ライセンス」とは何か、というような個々の規定の意味が検討対象となります。また、パテントライセンス契約書の別紙に記載される特許権の内容を、特許明細書等のリサーチする方法も学びます。

パテントライセンス契約

典型的な英文のパテントライセンス契約書

Oncle に掲載されている（公開されている）実際の書式を見て、

概要をつかむには「どこを見るか」
交渉でポイントとなるのは「どのような箇所か」

を確認する。

米国の特許実務（ライセンス契約実務）は、かなり「進んで」おり、英文契約書に書かれている内容を理解することが、当面の目標になる

学習目標

パテントライセンス契約書の別紙に記載される特許権の内容
特許明細書等のリサーチする方法

特許権

ライセンス

2. LICENSE GRANT

2.1 License to Fujisawa. Subject to the terms of Article 2 and the other terms and conditions of this Agreement, and except as provided in Section 3.8(a)(iii), DTI hereby grants and Fujisawa hereby accepts an exclusive (even as to DTI) license, with the right to sublicense as provided in Section 2.2, under the DTI Patents and DTI Know-How to make, have made, use, sell, offer to sell, have sold, export and import Licensed Products in the Field and in the Territory. It is expressly understood by Fujisawa that the exclusivity grant in this Section 2.1 is subject to the provisions of Section 3.8(a)(iii), which may have the effect of reducing the exclusivity in the Field for Licensed Products containing certain Back-up Compounds from all indications to only the Primary Indications.

2.2 Sublicenses. Fujisawa shall have the right to grant sublicenses at any time to a Third Party with respect to any rights conferred upon Fujisawa under this Agreement; provided, however, that (i) any such sublicense shall be subject in all respects to the restrictions, royalty and other payment obligations, reports, and other provisions contained in this Agreement, including but not limited to the obligations set forth in Article 3, (ii) Fujisawa shall notify DTI of the identity of such sublicensee promptly on execution of the sublicense; and (iii) subject to any confidentiality restrictions set forth in such sublicense agreements, Fujisawa shall forward to DTI a copy of any and all sublicense agreements promptly upon execution by the parties thereto.

2.3 Research License. Subject to the conditions and limitations set forth in this Agreement, Fujisawa hereby grants to DTI an exclusive (except as to Fujisawa), paid-up license, under the Fujisawa Technology to conduct research and development activities for the Phase I Trial with respect to Licensed Products pursuant to the Development Plan.

消極的効力

積極的効力

属地性

権利侵害

有効なクレーム

Valid Claim. "Valid Claim" means a claim of a patent application or an issued and unexpired patent that has not been held unpatentable, revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and that has not been admitted to be invalid or unenforceable through reissue, disclaimer or otherwise. If a claim of a

pending patent application has not issued as a claim of an issued patent within [*] years after the earliest priority date for such claim, such claim shall cease to be a Valid Claim unless and until such claim becomes an issued claim of an issued patent.

(Ono Agreement)

ロイヤルティ

Pitfalls in drafting royalty provisions in patent licences

Bio-Science Law Review

Vicky Clark

Principal, VC Legal

Drafting agreements is often described as more of an art than a science. There is certainly plenty of scope for creativity when drafting patent licences in the biotech field. The bottom line for the licensor is, however, that it receives its royalty. Given the risk of future disputes relating to royalties and the business impact that such disputes can have, it is essential to be aware of common pitfalls which may provide the licensee with the means of avoiding royalty payments.

There are at least two parties in any negotiation, each with a different perspective and different interests. This article is written from the perspective of the licensor. It examines some of the issues which may arise when negotiating royalty provisions and suggests ways in which to minimise the risk for the licensor of future disputes over royalty payments.

Definition of Licensed Products

Most patent licence agreements are drafted such that royalties are only payable in respect of 'Licensed Products' supplied by the licensee. Hence the way in which Licensed Products are defined has a fundamental impact on the royalties that will be payable to the licensor in due course. Where a product is at an advanced stage of development, it may be possible to specifically identify the product on which royalties will be payable (by use, for example, of the licensee's name or code for the product). Where a licence is granted at an early stage of development, and no commercial product as such yet exists, it is necessary to define the products on which royalties are due in a generic way.

It is not uncommon for licensees to insist that the generic definition of Licensed Products is explicitly linked to infringement of valid claims of the licensed patents (a Licensed Product, on which royalties are payable, would be one which infringes a valid claim of one of the licensed patents in the territory

in which it is supplied by the licensee). A definition of this kind raises plenty of scope for later disputes over royalty payments when a commercial product finally reaches the market.

Does the Product Infringe?

The question of whether a product infringes a patent is rarely straightforward. Cases of literal infringement are few and far between, particularly in relation to biotech patents. Even if a case appears at first glance to be one of literal infringement, the defendant can usually identify some ambiguity in the claims that are alleged to be infringed and this can be used as a basis to resist payment of royalties. The dispute between Celltech Chiroscience and Medimmune Inc, which is the subject of a recent Court of Appeal decision, is a case in point.

Celltech brought proceedings in the United Kingdom against Medimmune to recover royalties which Celltech claims are due to it under a licence granted to Medimmune in respect of Celltech's 'Adair patent'. The Adair patent covers certain humanised antibodies. Medimmune has developed a humanised antibody for the treatment of respiratory syncitial virus, which it sells under the trade name 'Synagis'.

Under the licence agreement between Celltech and Medimmune, royalties of 2 per cent of net receipts were payable on all antibodies which, but for the licence, would infringe a valid claim of the Adair patent. When Medimmune began to sell Synagis in the United States, Celltech sought to recover its royalty under the licence agreement. Medimmune refused to pay, claiming that the manufacture and sale of Synagis in the United States does not infringe the US version of the Adair patent.

Due to the dispute resolution provisions in the licence agreement, Celltech issued proceedings against Medimmune in the United Kingdom. The critical issue which the UK courts had to decide (by way of a preliminary issue) was whether the sale of Synagis in the United States infringes the US version of the Adair patent. This may sound a strange matter to be referred to the UK courts but the dispute resolution provisions in the agreement were clear and the UK courts are familiar with dealing with questions of foreign law.

Celltech were not able to present a straightforward case of infringement. The Adair patent relates to humanised antibodies which are part human and part mouse. In such antibodies, the mouse residues are called 'donor elements' and the human residues are called 'acceptor elements'. Celltech identified that in order to be effective, not only must the part of the antibody that binds to antigen (the complimentary determining regions or 'CDRs') be donor elements, but certain other residues must also be murine derived.

One of these non-CDR, murine-derived or donor elements is at the heart of the dispute between Celltech and Medimmune. Using the 'Kabat' numbering system, the US Adair patent specifies that the amino acid at position 23 must be a donor element. The amino acid at position 23 of the

Medimmune antibody is an acceptor (human derived) element. Celltech claims that, while there was no literal infringement of the Adair patent, Synergis infringes the Adair patent under the US 'doctrine of equivalents' as the residue used by Medimmune at position 23 is a conservative substitution3 for the amino acid specified in the Adair patent.

The doctrine of equivalents requires an analysis of the patent much like the purposive approach used by the UK courts. The analysis was complicated by defences relied upon by Medimmune, which would not have been available under English law, namely amendment estoppel and argument estoppel. Basically, the limitation in the US Adair patent relating to the nature of the residue at position 23 was introduced by Celltech during the prosecution of the US patent in order to overcome disclosures in a prior art document cited against the patent. As a result of the principles of amendment and argument estoppel which are available under US law, the UK court essentially held that the Adair patent had to be construed strictly and that Celltech could not rely on its equivalence argument. Hence despite the fact that the residue used by Medimmune in the Synergis antibody is a conservative substitution for the residue specified in the Adair patent, the UK court held (both at first instance and at the Court of Appeal) that Synergis does not infringe the US Adair patent and, consequently, that no royalties are payable by Medimmune on sales of the product in the United States.

Putting this in the context of the above discussion, Celltech might have reasonably assumed when Medimmune entered into the licence agreement that Medimmune accepted that its product infringed the Adair patent. Hence Celltech may have expected in due course to receive a royalty from Medimmune. In reality, Medimmune may have always known that it would ultimately contest infringement and resist paying royalties. By entering into the licence Medimmune could, however, have avoided distracting infringement claims at an early stage of product development.

This is not an unusual scenario. By entering into licence agreements, licensees can buy themselves valuable breathing space from infringement proceedings without making any significant commitment to the licensor. What is more, as and when the licensee makes it clear that it does not intend to pay royalties and alleges non-infringement, depending on how the licence is drafted, the licensor may be tied into the dispute resolution mechanism set out in the licence, rather than being able to choose the most appropriate forum to litigate the issue of infringement.

So how can the licensor avoid this 'infringement trap'? The licensor should try and obtain an express acknowledgement from the licensee in the licence agreement that royalties will be payable on the product under development by the licensee. This does not necessarily involve the licensee expressly acknowledging infringement (which can be a sensitive issue for many licensees) but could state that, irrespective of the issue of infringement, the licensee accepts that royalties will be due on product 'X' (defined as the product under development by the licensee).

An alternative is to uncouple the definition of Licensed Products from the issue of infringement. This would involve defining Licensed Products as any product the development, manufacture or supply of which utilises any of the 'licensed technology'. Licensed technology would be defined as the technology disclosed in the patents and, if appropriate, the know-how disclosed to the licensee. Know-how can often prove important in negotiating provisions of this nature, as where the licensee has obtained the benefit of confidential know-how, over and above the information disclosed in the licensed patents, the licensor has good justification for uncoupling the issue of royalties from patent infringement.

An argument often raised by the licensee in relation to infringement is that it is anti-competitive for royalties to be payable on any products which do not infringe a valid patent. The existence of valuable know-how can side-step this issue. In addition, there are good arguments to support the view that, when it comes to royalties, the European Commission will allow the parties to an agreement wide discretion in deciding the issue of compensation. In the situations to which this discussion relates, where infringement is arguable and the licensee has benefited from the licensed technology, so long as a patent is in force in the territory in which the product is supplied, it should not be anti-competitive for the parties to acknowledge in advance the issue of infringement.

Valid Claims

Linked to the issue of infringement is the provision, often sought by licensees, that royalties are only payable on products sold in territories in which a 'valid claim' exists. The requirement of validity provides the licensee with another potential get-out, as arguments can almost always be raised that a given patent or claim of a patent is invalid. Hence a licensee, seeking to avoid royalty payments, merely has to assert that the claims alleged to be infringed are not valid. The licensor invariably then has little choice but to invoke the dispute resolution mechanism in the licence agreement to resolve the dispute. Note that, as with infringement, this robs the licensor of the decision as to which is the most appropriate forum to decide the issue of validity.

To avoid this potential dispute, the licensor should not accept the natural meaning of 'valid claim'. Instead the licensor should seek to expressly define in the agreement a valid claim as one which is in force and which has not been held to be invalid by any patent office or court of competent jurisdiction. The licensor may also require that the decision of invalidity must not be final (i.e. a decision from which there is no appeal or which has not in fact been appealed). Using this approach, the licensee would be free to challenge the validity of any of the licensed patents in the normal way but would remain bound to pay royalties in respect of a patent until it was finally found to be invalid.

Other Considerations

If the licensee will not budge on the issues of infringement/validity of the claims, the licensor, being aware of the risk of future disputes, may seek to structure the compensation for the licence in ways

that do not rely entirely on royalty income. For example, the licensor could negotiate an initial lump sum licence fee and high milestone payments.

A minimum royalty provision can also help to alleviate the problem by ensuring that, irrespective of the issues of infringement and validity, the licensor will receive a fixed sum every quarter.

The licensor can also ensure that there are deterrents in the agreement against challenging infringement and/or validity. For example, the licensor could reserve the right to terminate the agreement if the licensee contests infringement or the validity of any of the claims of the licensed patents. This is entirely compatible with the provisions of the existing Technology Transfer Block Exemption and the proposed block exception that is due to replace it in May 2004. Without the licence in place, the licensor would then be free to sue the licensee for infringement in the most appropiate territory.

Royalty Stacking

Cambridge Antibody Technology ('CAT') announced recently that Abbott Laboratories, one of its major licensees, is contesting amounts due to CAT under the licence agreement between Abbot and CAT relating to Humira (Abbott's recently approved monoclonal antibody for the treatment of arthritis). From CAT's announcement it appears that royalty-stacking provisions are at the heart of the dispute between CAT and Abbot.

The concept of royalty stacking arises from the risk that multiple patents may affect a single product. Such a risk is said to be particularly high in the biotech field which is dominated by patent filings.

Take, for example, a gene therapy product. The most obvious patent to affect such a product is a patent that covers the DNA sequence for the gene. For an effective product, however, promoter sequences and an appropriate vector may be required. Each of these may also be covered by third-party patents. In addition, tools may have been used to develop the product. How was the DNA sequence identified? Were patented techniques used for this purpose? If so, do the patents relating to such techniques have reach-through claims that could affect the final gene therapy product?

Royalty stacking arises when, in order to take a product to market, the developer of the product takes licences from all of the owners of the patents which affect the final product. When the royalty payments are added together, the licensee may find itself with a non-profitable product. Hence it has become quite usual for licensees to insist on including anti-stacking provisions in licence agreements.

A typical anti-stacking provision states that the royalty rate payable to the licensor will be reduced if the licensee is obliged to enter into licences with third parties in relation to the product. It is not difficult to see how such a provision can lead to a disparity between the expectations of the licensor as to the royalty it will receive from the licensee and the actual royalty the licensee is contractually obliged to pay.

Notice

The first point to make is that to avoid such a disparity in expectations, the licensor should ensure that it is notified immediately if the licensee enters into a further licence that might affect the royalty received by the licensor. At least the licensor will then be able to avoid the sudden disappointment when the product comes to market and it finds that its royalty income is going to be far less than expected.

Control

Ideally, if the licensor accepts the concept of anti-stacking, it should retain some control over third-party licences entered into by the developer of the product. A scenario may arise in which the licensee believes that a third-party licence is required but the licensor disagrees. When the issue of infringement is ambiguous, the licensee may be keener to obtain the comfort of a licence than the licensor. As far as the licensee is concerned, the anti-stacking provisions will ensure that the money all comes out of the same pot, whereas the licensor is faced with a hit to its royalty income. One way to address this problem is to require the agreement of the parties to third-party licences and, in the absence of agreement, to refer the matter to an independent expert for determination as to whether a licence is required.

If the parties decide that a third-party licence is required, it is not unusual for the licensor that is affected by the anti-stacking provision to actually have conduct of the negotiations. That way the licensor can seek to minimise the impact of the third-party licence on its own royalty stream.

Floors

Another point to consider is putting a floor on the extent to which the royalty rate can be reduced in response to stacking. A royalty may start at, say, 5 per cent and be reduced in response to stacking but no lower than, say, 3 per cent. The licensor should also ensure that its own royalty rate is reduced only on condition that all other licensees accept similar anti-stacking provisions and the royalty rates of all licensees are reduced on a pro-rata basis in response to a third-party licence.

The minimum floor operates in a similar way to a minimum royalty which, as when dealing with the infringement and validity issues discussed above, can be a very useful tool to protect the income stream of the licensor in the event of disputes over stacking.

Research Tool Patents

Finally, it is not unreasonable for the licensor to make a distinction in relation to anti-stacking between research tool patents and product patents. The licensor may take the view that where the licensee has to enter into third-party licences in relation to patents which affect the actual product, anti-stacking measures may be appropriate. Where research tool patents are concerned, the licensor may feel that such patents are the responsibility of the licensee and should not affect the licensor's royalty in any way.

Combination Products

It is not unusual to see provisions in patent licenses dealing with 'combination products'. In the pharmaceutical field, a typical example of a combination product would be where an active ingredient is sold with some kind of mechanical device for administering it, such as an inhaler. The licence agreement may deal with such a product by stating that royalties will not be payable on the total value of the combination product. Hence an apportionment is required and royalties are only payable on the value attributable to the active ingredient, not the value attributable to the inhaler.

Unless provisions of this nature are carefully drafted, there is potential for future disputes as it is not always entirely clear where one product ends and another begins. Take, for example, a single pill or capsule that contains two actives. Is this one product or two? Consider also biotech products where the delivery device is not mechanical, such as an inhaler, but biological, such as a virus. Are the active and the virus two separate products?

It is possible that provisions relating to combination products could be invoked by the licensee in relation to biotech products to achieve anti-stacking by the back door. It is advisable, therefore, to ensure that any provisions relating to combination products set out examples of the type of scenarios that such provisions are intended to address. This ensures that in the future there can be no stretching of the interpretation of such clauses to cover situations that were never intended.

Conclusion

In view of the damage to the business of biotech companies that can be caused by royalty disputes, it is important for such companies to be aware of and to minimise the areas of ambiguity that can arise when drafting royalty provisions. It is, of course, impossible to avoid such disputes entirely, but it is possible to minimise the risks and to make such disputes as unattractive as possible to the licensee.

- Celltech Chiroscience Ltd v Medimmune Inc., [2003] EWCA Civ 1008.
- Each of the parties is entitled to call an expert in the foreign law in question (US patent law in this case) and the court then reaches its own conclusions based on the representations made to it.
- A conservative substitution is one in which an amino acid is replaced by another very similar amino acid, which substitution has little or no effect on the activity of the protein.
- Note that the case only resolved the issue of antibodies sold in the United States, not other jurisdictions. Celltech has issued separate proceedings against Medimmune in respect of sales of Synergis in Germany which Celltech claims infringe the German version of the Adair patent.
- Note that this is an entirely hypothetical consideration of the parties' positions and may or may not equate to the positions adopted by the parties. The author has no personal knowledge of the parties' intentions.

- In the Celltech case it may suit the company that all proceedings have to be brought in the UK courts but it is possible that due to procedural differences it would be advantageous to litigate the issue of infringement of foreign patents in the foreign jurisdiction in question.
- Hence the prevailing view that reach-through royalties are enforceable even though the product on which royalties are payable does not infringe the licensed patents.
- The position may be different in other jurisdictions and the US anti-trust laws may, for example, be stricter than the position adopted by the EU Commission on this point.
- Commission Regulation (EC) No. 240/96 of 31 January 1996 on the application of Article 85(3) of the Treaty to certain categories of technology transfer agreements, OJ 1996 L31, 9 February 1996, at 2 to 13.

パテントインデムニティ

職務発明

（資料２）

報奨・特許管理

（資料３）

（資料 1）

DEVELOPMENT AND LICENSE AGREEMENT

between

DISCOVERY THERAPEUTICS, INC.

and

FUJISAWA HEALTHCARE, INC.

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DEVELOPMENT AND LICENSE AGREEMENT

THIS DEVELOPMENT AND LICENSE AGREEMENT (the “Agreement"), dated as of July 29, 1999 (the “Effective Date"), is made by DISCOVERY THERAPEUTICS, INC., a Delaware corporation having a principal place of business at 2028 Dabney Road, Suite E-17, Richmond, VA 23230-3311, U.S.A. ("DTI"), and FUJISAWA HEALTHCARE, INC., a Delaware corporation having a principal place of business at Parkway North Center, Three Parkway North, Deerfield, Ill. 60015 ("Fujisawa"). DTI and Fujisawa are sometimes referred to herein individually as a “Party" and collectively as the “Parties."

WITNESSETH

WHEREAS, DTI owns certain patents, patent applications and know-how relating to DTI’s proprietary adenosine receptor agonist DTI 0009 and various other compounds;

WHEREAS, DTI has successfully advanced DTI 0009 through preclinical development and is about to or has commenced Phase I clinical trials;

WHEREAS, Fujisawa is a health care company with development and marketing activities in North America, and which desires to obtain additional potential drug products to sell in the United States and Canada for the treatment, through an injectable mode of administration, of paroxysomal supraventricular tachycardias ("PSVT") and atrial fibrillation and flutter ("AFIB/F") in humans, among other potential indications; and

WHEREAS, DTI wishes to license the rights, upon the terms and conditions contained in this Agreement, to Fujisawa in the United States and Canada to develop and commercialize pharmaceutical products containing DTI 0009 or Back-up Compounds (as hereinafter defined) for the treatment, through an injectable mode of administration, of all diseases in humans, including but not limited to PSVT and AFIB/F.

NOW, THEREFORE, in consideration of the above premises and covenants contained herein, the Parties agree as follows:

1. DEFINITIONS

1.1 “A1 Agonist Library" means all of the Al agonist compounds that are owned, licensed to or controlled by DTI and that are covered by one or more claims within the DTI Patents.

1.2 “Affiliate" means any entity that directly or indirectly Owns, is Owned by or is under common Ownership with, a Party to this Agreement. “Owns,"“Owned" or “Ownership" means direct or indirect possession of at least fifty percent (50%) of the outstanding voting securities of a corporation or a comparable equity interest in any other type of entity.

1.3 “Back-up Compound(s)" means any compound that Fujisawa selects from the A1 Agonist Library pursuant to Section 3.8, for use as provided in Section 3.8(b).

1.4 “Back-up Compound Notice Period" shall have the meaning ascribed to it in Section 3.8(a)(i).

1.5 “Compound" means the compound known as DTI 0009, which is further described in Exhibit A attached hereto.

1.6 “Data" shall mean any and all data, reports, and/or documentation (or analyses thereof) generated in connection with clinical trials, preclinical studies or other investigations of the Compound or any Back-up Compound.

1.7 “Development Plan" means the development plan, as may be amended, that is described in Section 3.4.

1.8 “Diligent Efforts" means the carrying out of obligations in a sustained manner consistent with the efforts a Party devotes to a product of similar market potential, profit potential or strategic value resulting from its own research efforts, based on conditions then prevailing. Diligent Efforts requires, at a minimum, that: (i) the Party promptly assigns responsibility for such obligations to specific employee(s) who are held accountable for progress and monitor such progress on an on-going basis, (ii) the Party sets and consistently seeks to achieve specific and meaningful objectives for carrying out such obligations, and (iii) the Party consistently makes and implements decisions and allocates resources designed to advance progress with respect to such objectives.

1.9 “DTI Data" shall have the meaning ascribed to it in Section 3.9.

1.10 “DTI Data Product" shall have the meaning ascribed to it in Section 5.6.

1.11 “DTI IND" shall have the meaning ascribed to it in Section 2.7(b).

1.12 “DTI Know-How" means any and all pre-clinical, clinical, technical, scientific, medical, sales and marketing information, data, knowledge, methods, inventions, materials, practices and trade secrets including, but without limitation, manufacturing processes and techniques, quality control information and procedures and pharmacological, toxicological and clinical test data and results, which is (i) owned by, controlled by, or licensed to DTI as of the Effective Date or is invented or developed by or licensed to DTI during the term of this Agreement (and available for sublicense to or otherwise able to be disclosed to Fujisawa), and (ii) necessary for, useful for or used in the manufacture, use, development, registration, formulation, sale, or marketing of a Licensed Product in the Field. DTI Know-How shall exclude the DTI Data, but shall include all Data generated by DTI in the conduct of the Phase I Trial and DTI’s Pre-Clinical Studies.

1.13 “DTI Patents" means any and all patents, patent applications or patents issuing from such applications, and all reissues, reexaminations, continuations, continuations-in-part, divisionals, extensions, or Supplemental Protection Certificates, which cover the manufacture, use, sale, offer for sale, importation or exportation of the Compound or Licensed Product in the Territory, which are owned by, controlled by or licensed to DTI either directly or indirectly, including specifically, but without limitation, U.S. Patent No. 5,310,731, and including any Jointly Owned Patents. The DTI Patents are set forth on Exhibit F, which shall be amended from time to time to include DTI Patents issued or filed from and after the Effective Date.

1.14 “DTI’s Pre-clinical Studies" shall have the meaning ascribed thereto in Section 7.1(x).

1.15 “DTI Target Dates" shall have the meaning ascribed to it in Section 3.4.

1.16 “Experimentation" shall mean the conduct of scientific experiments with respect to a compound in the Al Agonist Library, as evidenced by laboratory notebook entries regarding such experiments.

1.17 “FDA" means the United States Food and Drug Administration or its equivalent in Canada, or any successor entity thereto.

1.18 “Field" means the diagnosis, prevention and/or treatment of diseases, syndromes or conditions in humans, including but not limited to PSVT and AFIB/F.

1.19 “FTE" is an acronym that stands for Full Time Equivalent, which shall mean one or more researchers employed by DTI and possessing skills and experience necessary to carry out applicable tasks described in Section 2.7(a) with such time and effort to constitute one such researcher working the equivalent of a full year of effort on a full time basis (not less than 40 hours per week).

1.20 “Fujisawa Data" shall have the meaning ascribed to it in Section 3.9.

1.21 “Fujisawa Data Product" shall have the meaning ascribed to it in Section 5.5.

1.22 “Fujisawa Technology" means, to the extent necessary or useful to make, use or sell a Licensed Product, all patents and patent applications and information, trade secrets, data, inventions and know-how, owned by, controlled by, or licensed to Fujisawa (with the right to sublicense) provided that Fujisawa Technology shall only include such patents, patent applications, information, trade secrets, data (including the Fujisawa Data), inventions and know-how as were developed or owned by or licensed to Fujisawa: (a) from and after the date of this Agreement; and (b) solely in connection with the Compound and Back Up Compound. Fujisawa Technology shall not include the DTI Patents, DTI Know-How and any and all patents, patent applications, information, trade secrets, data, inventions and/or know how developed, owned or licensed by Fujisawa in connection with and/or relative to Fujisawa’s license arrangements with Medco Research, Inc. Fujisawa Technology shall not include trademarks for any Licensed Products, which shall be handled in accordance with Section 4.4.

1.23 “IND" means an investigational new drug application, as defined by the FDA in 21 CFR Part 312, or the equivalent application in Canada.

1.24 “Injectable Product" means a product that is formulated solely for intravenous, subcutaneous, intracoronary, intraarterial or intramuscular administration.

1.25 “Injectable Protocol" shall have the meaning ascribed to it in Section 2.7(b).

1.26 “Joint Management Committee" or “JMC" means the Committee described in Section 3.3.

1.27 “Jointly Owned Patents" shall be defined as set forth in Section 9.5.

1.28 “Licensed Product(s)" means an Injectable Product that contains as its active ingredient the Compound or a Back-up Compound.

1.29 “NDA" means a New Drug Application as defined by the FDA in 21 C.F.R. Part 314, or its equivalent in Canada.

1.30 “Net Sales" means gross amounts invoiced for the sale of the Licensed Product(s) in finished package form sold by Fujisawa or its sublicensees, less

(a) any and all normal and customary trade and quantity discounts, customary allowances actually granted to purchasers of the Licensed Product(s) for returns and recalled Licensed Product (whether in the form of either a credit or free replacements actually given in place of returned or recalled Licensed Product(s), allowances to end users (whether in the form of either a credit or free product) participating in Fujisawa Sponsored Trial Support, capitation, market share or stop loss agreements, or other compliance incentive programs,

Medicaid rebates given pursuant to agreement with U.S. Department of Health and Human Services and any other rebates given pursuant to government based rebate programs (including without limitation state and local rebate programs) whether currently in effect or which become effective during the term of this Agreement, administrative fees to managed health care organizations (including but not limited to Group Purchasing Organizations, HMO's etc.), chargeback and reporting rebates paid to wholesalers and other distributors;

(b) freight expenses for shipping finished product to such purchasers; and

(c) excise and value added taxes applicable to sales of the Licensed Products) in finished package form which Fujisawa has to pay or absorb on such sales.

No deductions shall be made for commissions paid to individuals whether they be with independent sales agencies or regularly employed by Fujisawa, and/or its sublicensee(s) and on its or their payroll, or for cost of collections. Licensed Products shall be considered "sold" when billed out or invoiced. Sale or transfer to an Affiliate or sublicensee for re-sale by such Affiliate or sublicensee shall not be considered a sale for the purpose of this provision, but the resale by such Affiliate or sublicensee to a Third Party shall be a sale for such purposes.

1.31 "Non-Injectable Product" means any product which is (i) not an Injectable Product, including, without limitation, those formulated for administration through the alimentary canal, including by mouth or for use in the mouth through sublingual absorption and/or absorption through submucosal or buccal tissue, and through transdermal administration, including absorption through rectal tissue and (ii) which contains as its active ingredient a Compound or a Back-up Compound.

1.32 "Non-Injectable Protocol" shall have the meaning ascribed to it in Section 2.7(b).

1.33 "Phase I Trial" means the Phase I clinical trial to be performed by DTI pursuant to the Protocol Number DTI 0009-001.

1.34 "Phase II Trial" means the first dose finding trial in patients.

1.35 "Phase III Trial" means the first controlled clinical trial after dose finding trials.

1.36 "Primary Indications" means PSVT and AFIB/F.

1.37 "PTO" means the United States Patent and Trademark Office.

1.38 "Regulatory Approval" means all approvals by the applicable regulatory agency in the relevant country of the Territory necessary to market and sell a Licensed Product.

1.39 "Remaining Compounds" shall have the meaning ascribed to it in Section 3.8(a)(ii).

1.40 "Territory" means the United States and its territories and possessions, and Canada.

1.41 "Third Party" means any entity other than DTI or Fujisawa.

2. LICENSE GRANT

2.1 License to Fujisawa. Subject to the terms of Article 2 and the other terms and conditions of this Agreement, and except as provided in Section 3.8(a)(iii), DTI hereby grants

and Fujisawa hereby accepts an exclusive (even as to DTI) license, with the right to sublicense as provided in Section 2.2, under the DTI Patents and DTI Know-How to make, have made, use, sell, offer to sell, have sold, export and import Licensed Products in the Field and in the Territory. It is expressly understood by Fujisawa that the exclusivity grant in this Section 2.1 is subject to the provisions of Section 3.8(a)(iii), which may have the effect of reducing the exclusivity in the Field for Licensed Products containing certain Back-up Compounds from all indications to only the Primary Indications.

2.2 Sublicenses. Fujisawa shall have the right to grant sublicenses at any time to a Third Party with respect to any rights conferred upon Fujisawa under this Agreement; provided, however, that (i) any such sublicense shall be subject in all respects to the restrictions, royalty and other payment obligations, reports, and other provisions contained in this Agreement, including but not limited to the obligations set forth in Article 3, (ii) Fujisawa shall notify DTI of the identity of such sublicensee promptly on execution of the sublicense; and (iii) subject to any confidentiality restrictions set forth in such sublicense agreements, Fujisawa shall forward to DTI a copy of any and all sublicense agreements promptly upon execution by the parties thereto.

2.3 Research License. Subject to the conditions and limitations set forth in this Agreement, Fujisawa hereby grants to DTI an exclusive (except as to Fujisawa), paid-up license, under the Fujisawa Technology to conduct research and development activities for the Phase I Trial with respect to Licensed Products pursuant to the Development Plan.

2.4 Retained Rights. Subject to Section 2.5, DTI retains any and all rights under the DTI Patents and DTI Know-How not expressly licensed to Fujisawa under this Agreement, specifically including, but without limitation, any and all rights to make, have made, use, sell, have sold, export or import (i) compounds covered by one or more claims in the DTI Patents other than the Compound and any Back-up Compound selected pursuant to Section 3.8 for any use, (ii) any Non-Injectable Products and (iii) Licensed Products outside of the Territory.

2.5 DTI Restrictive Covenant. DTI covenants that during the term of this Agreement it shall not, license (in whole or in part), conduct, fund, develop or participate in, directly or indirectly through one or more Third Parties, the research, development, distribution or commercialization in the Territory of any Injectable Products to treat the Primary Indications. DTI further covenants that it shall not, during the term of this Agreement, license (in whole or in part), conduct, fund, develop or participate in, directly or indirectly through one or more Third Parties, the research, development, distribution or commercialization in the Territory of any Licensed Products in the Field, subject to the terms of Section 3.8(a)(iii) and the last sentence of Section 2.1 DTI shall be further restricted in its development and commercialization efforts as set forth in Section 3.8(a)(i). The provisions of this Section 2.5 shall not apply to the extent that DTI obtains from Fujisawa the right to develop and commercialize a Licensed Product in the Field in the Territory, whether pursuant to Section 3.5(b), 3.6, 4.2(a), or Article 11.

2.6 Fujisawa Restrictive Covenant. Fujisawa covenants that it shall not use or practice the DTI Patents or DTI Know-How to make, offer to sell, have made, use, sell, have sold, export or import Licensed Products in the United States for any uses except as expressly granted in Section 2.1.

2.7 Disclosure of DTI Know-How.

(a) Upon signing the Agreement, and subject to the obligations of confidentiality set forth in this Agreement, DTI shall disclose to Fujisawa and provide copies of all documentation of DTI Know-How, including, but not limited to, all of DTI's data regarding its Al Agonist Library and the DTI IND. Except as provided in Section 3.8(a)(iv), DTI shall also promptly provide to Fujisawa a copy of any additional or new documents covering the DTI Know-How

that may come into DTI's possession after the Effective Date, including, in (a) particular any Data generated in connection with the Phase I Trial. In addition, DTI shall make available to Fujisawa, upon reasonable notice and during normal business hours, the reasonable assistance of DTI's employees who are knowledgeable about the DTI Know-How and DTI Patents in order to facilitate Fujisawa's efforts to develop and commercialize Licensed Products. DTI shall provide the assistance of at least one (1) FTE for a period of 1 year from the Effective Date, and thereafter at and for such times as Fujisawa may request. Fujisawa may, at its option, request that DTI provide and DTI shall provide, upon such request, such additional FTEs. Fujisawa shall reimburse DTI for such assistance at a rate equivalent to * annually per FTE, payable in equal quarterly installments commencing ninety (90) days from the Effective Date, but may terminate its right to receive DTI's assistance at any time after the first anniversary of the Effective Date.

(b) The Parties acknowledge and agree that an IND was submitted by DTI to the FDA on July 12, 1999 covering both the Licensed Product and the Non-Injectable Product (the "DTI IND"). The Protocol Number for the Phase I Trial for the Licensed Product is DTI-0009-001 ("Injectable Protocol") and the Protocol Number for the Phase I Trial for the Non-Injectable Product is DTI-0009-002 ("Non-Injectable Protocol"). DTI will, at Fujisawa's expense, transfer to Fujisawa the DTI IND together with any and all regulatory files, reports, data, written information and related documentation associated with such submission and promptly notify FDA in writing of such transfer. DTI will make such transfer within thirty (30) days after the date DTI completes the Phase I Injectable Protocol for the Licensed Product or within 30 days after the date Fujisawa exercises its option under Section 3.5(a)(ii), whatever date is earlier; provided however, that if transfer is delayed due to actions, lack of action, or policies of FDA, then the period for transfer shall be extended by the length of the relevant delay. The Parties acknowledge and agree that if such transfer is delayed due to the actions, lack of action or policies of the FDA or DTI, then the "Critical Target Dates" (as hereinafter defined) or other obligations due from Fujisawa shall be extended by the length of the relevant delay. The Parties further acknowledge and agree that once the DTI IND is transferred to Fujisawa: (i) Fujisawa will notify the FDA that the DTI IND does not cover the Non-Injectable Product and/or the Non-Injectable Protocol; (ii) except as otherwise provided in this Agreement, Fujisawa will have no responsibility whatsoever with respect to the Non-Injectable Protocol; (iii) at the same time as such transfer, DTI shall submit its own IND for the Non-Injectable Protocol; and (iv) the Parties shall be entitled to cross reference the IND of the other party, once DTI's IND for the Non-Injectable Product, has been allowed by the FDA.

2.8 Distribution Through Third Parties. DTI grants Fujisawa the right to distribute Licensed Products through Third Party distributors in the Territory; provided, that Fujisawa shall use distributors with expertise and distribution capacity appropriate to the Licensed Product.

2.9 Exclusivity. For the purposes of this Article 2, the phrase "exclusive except as to" shall mean that the licensee and the licensor shall share the rights granted in the relevant license grant, and the phrase "exclusive even as to" shall mean that the grantor shall retain none of the rights granted in the relevant license grant. Rights that are sublicensed pursuant to this Article 2 shall be exclusive only to the extent the licensor holds exclusive rights.

3. PRODUCT DEVELOPMENT

3.1 General. DTI shall be responsible for conducting the Phase I Trial for the Compound for the Primary Indications. Fujisawa shall be responsible for all other aspects pertaining to the development of, and obtaining Regulatory Approval for, the Licensed Products in the Territory. Subject to Section 3.5(c), Fujisawa shall have the final decision-making authority with respect to all aspects of the development of the Licensed Products.

3.2 Engagement of Third Parties. In the course of performing its development obligations under this Agreement, either Party may engage Third Parties to perform certain development activities, provided that (i) the other Party is informed of the use and identity of Third Parties for the relevant activity, and (ii) each Party obtains contractual undertakings from such Third Parties (including in particular with respect to quality assurance, compliance with law, and confidentiality) as may be applicable to, and customary in the pharmaceutical industry for, the relevant activity to be performed by such Third Party.

3.3 Joint Management Committee. Promptly after the Effective Date, the Parties shall form a Joint Management Committee ("**JMC**") which shall consist of two (2) representatives of each Party with expertise in such disciplines as clinical, regulatory affairs, manufacturing or marketing. One of the Fujisawa representatives shall serve as the chairperson of the JMC. All decisions of the JMC shall be made by a majority vote of the representatives on the JMC; provided, that Fujisawa shall cast the decisive tie-breaking vote in the event that the JMC is unable to come to a decision on any matter, subject to Section 3.5(c). Either Party may bring additional non-voting representatives to the meetings of the JMC so long as such Party provides prior notice at the time Fujisawa is required to provide an agenda under this Section 3.3 to the other Party that it intends to bring such representatives. The JMC shall meet regularly (but in no event less than three times per year) at such times and at such locations as shall be mutually agreed by the Parties. The JMC shall review development activities of DTI and Fujisawa in accordance with the Development Plan including, but not limited to, the choice of contract research organization, consultants, Third Party contract manufacturers and assignment of development activities, the development of new formulations and other product changes, and communication with FDA and other Third Parties. At least 10 business days prior to each regularly scheduled meeting of the JMC, Fujisawa and DTI shall provide a written status report to the JMC concerning its progress with respect to the Development Plan and Fujisawa shall provide an agenda for the upcoming meeting. Promptly after each meeting of the JMC, the chairperson shall provide minutes of such meeting.

3.4 Development Plan. Attached to this Agreement as Exhibit B is a Development Plan setting forth (i) DTI's anticipated timeline for commencement and completion of the Phase I Trial (the "DTI Target Dates"); and (ii) Fujisawa's anticipated timeline for the development program for the Licensed Product for the treatment of the Primary Indications in the United States, including target dates for key clinical and regulatory events ("Critical Target Dates"). The Critical Target Dates shall include, without limitation, the date by which Fujisawa shall enroll the first patient in Phase II and III clinical trials for the Licensed Product for the treatment of the Primary Indications (the "Clinical Target Dates"), and the date of submission of applications for Regulatory Approval in the United States. Fujisawa anticipates the commercial launch date for each Licensed Product to be *from the date of Regulatory Approval for each such Licensed Product. The Development Plan may be amended from time to time in writing by the JMC, subject to Section 3.5(c). Any amended Development Plan shall be attached hereto at Exhibit B.

3.5 Diligence.

(a) Development Efforts.

(i) Fujisawa shall use Diligent Efforts to carry out development of the Licensed Product for the treatment of the Primary Indications in accordance with the Development Plan. If Fujisawa determines that it will be unable to meet any of the Critical Target Dates identified in the Development Plan within six (6) months after the date specified in such Development Plan, it shall notify the JMC within thirty (30) days of such determination. The JMC shall develop a revised Development Plan for the Licensed Product which shall include new Critical Target Dates, provided however, that DTI's JMC representatives must agree to the new Critical Target Dates. In the event DTI's voting representatives do not agree to the Critical Target Dates set forth in the revised Development Plan, then either Party may, at its

election, proceed under Section 3.5(c).

(ii) DTI shall use Diligent Efforts to carry out the Phase I Trial in accordance with the Development Plan. If DTI fails to, or expects that it will fail to, meet any DTI Target Date, by more than three (3) months, Fujisawa may, at its option, assume control of and complete the Phase I Trial. In such event, the Parties shall cooperate fully and take all necessary steps to obtain the necessary Regulatory Approvals to effectuate the transfer of the Phase I Trial.

(b) Extended Delay. Subject to Section 11.5, if Fujisawa (i) fails to meet any of the Clinical Target Dates then in effect for the Licensed Product for a given Primary Indication within 12 months after the relevant Clinical Target Date specified in the Development Plan for such Primary Indication, or (ii) fails to submit for Regulatory Approval of that Licensed Product for such Primary Indication in the United States within 18 months after the date specified for such submission in the Development Plan with respect to such Licensed Product, then DTI may terminate Fujisawa's rights under this Agreement with respect to such Licensed Product for such particular Primary Indication. In such event, Fujisawa shall promptly transfer to DTI all INDs or their Canadian equivalent and other relevant regulatory filings as it may hold with respect to that Licensed Product for the particular Primary Indication, and any information as Fujisawa may possess which is necessary or useful to gain Regulatory Approval for and to commercialize such Licensed Product in the Territory for such Primary Indication. Such transfer shall be without cost to DTI, provided however that DTI shall pay any governmental filing or transfer fees that may be required. Fujisawa also grants to DTI, effective only in the event its rights to such Licensed Product for such Primary Indication are terminated under this Section 3.5(b), an exclusive fully paid and royalty-free (subject to DTI's obligations under Section 5.5) license under the Fujisawa Technology to make, have made, use, import, export, offer for sale and sell such Licensed Product for such Primary Indication and, to the extent it has the right to do so, grant to DTI a sublicense under any Third Party licenses to which Fujisawa has rights, to the extent that such rights are necessary or useful to make, have made, use, import, export, offer for sale and sell the Licensed Product. DTI shall thereafter assume the cost of maintaining its proportionate share of such Third Party license and shall perform such obligations of Fujisawa under such license agreement as are applicable to the relevant Licensed Product. To the extent such Third Party license is no longer applicable or useful to Fujisawa, Fujisawa shall assign to DTI all of its rights and obligations thereunder, rather than grant a sublicense under, such license agreement. The JAM shall have no authority with respect to the development and commercialization of a Licensed Product as to which rights have reverted to DTI under this Section 3.5(b).

(c) Disputes Regarding Critical Target Dates. If the Parties are unable to reach agreement as to the Critical Target Dates in any proposed revision to the Development Plan, then either Party may submit the issue for binding arbitration pursuant to Section 13.4, provided that such arbitration shall be conducted before an expert or expert panel in the field of clinical drug development (rather than before a judge or an attorney). Such expert may be mutually agreed upon by the Parties, but if no such expert is agreed upon within ten (10) days after the written notice from one Party to the other, then each Party shall promptly select one expert, and those two experts shall select a third expert, which shall comprise the panel. Notwithstanding any provisions concerning duration of arbitration proceedings set forth in Section 13.4, the panel shall meet with the Parties within thirty (30) days of selection to examine such proposed revisions to the Development Plan and shall hear the views and proposals of each Party. Within ten (10) days thereafter, it shall render its binding decision by majority vote, as to whether the Critical Target Dates proposed in the revised Development Plan are reasonable under all of the circumstances. The Parties shall share equally in the cost of the expert or expert panel, including any fees and expenses payable to the experts. If the expert or expert panel determines that the proposed Critical Target Dates are not reasonable, then Fujisawa will be held to the Critical Target Dates set forth in the most recently approved Development Plan, subject to any modifications agreed to by DTI. If such Critical Target Dates have passed as of the date of the expert's or expert panel's decision, the panel shall set new Critical Target Dates, taking into consideration the views and

proposals presented by the Parties in the course of the proceedings conducted under this Section 3.5(c).

3.6 Abandoned Products. Subject to Section 11.5, if Fujisawa decides, at any time or from time to time, that it does not desire to commence or continue research, development or commercialization activities, including without limitation, conducting clinical development or seeking Regulatory Approval of a Licensed Product (for either of the Primary Indications or any other indications) or to sublicense any of the foregoing activities, it shall provide written notice to DTI within thirty (30) days of such decision. Upon receipt of such notice, DTI may, at its election, terminate Fujisawa's rights under this Agreement with respect to such Licensed Product for such indication. In such event, Fujisawa shall (i) promptly transfer to DTI all INDs and their Canadian equivalent (as applicable) and other relevant regulatory filings as it may hold with respect to such Licensed Product for such indication, and any and all written information as Fujisawa may possess which is useful to gain Regulatory Approval for and to commercialize such Licensed Product for such indication. Such transfer shall be without cost to DTI, provided however that DTI shall pay any governmental filing or transfer fees that may be required; (ii) grant to DTI an exclusive fully paid and royalty-free license under the Fujisawa Technology to make, have made, use, import, offer for sale and sell (subject to DTI's obligations under Section 5.5) such Licensed Product for such indication in the Territory, and (iii) to the extent it has the right to do so, grant to DTI a sublicense under any Third Party licenses to which Fujisawa has rights, to the extent that such rights are necessary or useful to make, have made, use, import, offer for sale and sell such Licensed Product for such indication in the Territory. DTI shall thereafter assume the cost of maintaining its proportionate share of such Third Party license and shall perform such obligations of Fujisawa under such license agreement as are applicable to the relevant Licensed Product. To the extent such Third Party license is no longer applicable or useful to Fujisawa, Fujisawa shall assign to DTI all of its rights and obligations thereunder, rather than grant a sublicense under, such license agreement. The JMC shall have no authority with respect to the development and commercialization of a Licensed Product as to which rights have reverted to DTI under this Section 3.6.

3.7 Clinical and Regulatory Matters.

(a) Clinical Trials. DTI shall be responsible for conducting the Phase I Trial for the Compound for the Primary Indications under the Injectable Protocol. Fujisawa shall be responsible for conducting, at its expense, all other non-clinical and clinical studies necessary to obtain Regulatory Approval of the Licensed Products in the Territory in accordance with the Development Plan. The Parties shall conduct all such clinical trials in accordance with the applicable laws and regulations of the country in which the data generated in such clinical trial will be used to support an application for Regulatory Approval of the relevant Licensed Product.

(b) Drug Approval Applications Fujisawa shall be responsible for preparing and submitting, at its expense, applications for Regulatory Approval of the Licensed Products in the Territory. Fujisawa will submit the drug approval applications in its own name and shall be responsible for obtaining Regulatory Approval in the Territory and shall use Diligent Efforts to pursue and obtain Regulatory Approval in the U.S.

(c) Reporting. The Parties shall keep each other reasonably informed as to the progress of the clinical trials for which each is responsible and drug approval applications and of any issues raised by the relevant regulatory agencies together with Fujisawa' proposed response. The Parties shall provide each other with such reports on a periodic basis but not less than every four (4) months at the regular meetings of the JMC. Each Party shall report to the other concerning its progress with respect to clinical trials and applications for Regulatory Approval, including providing the other with written notice as soon as it has completed enrollment and dosed the last patient in each Phase I, II and III clinical trial.

(d) Responsibility. Subject to each Party's right to cross reference the other's Data and regulatory filings under Section 3.9, any and all regulatory applications and approvals in the Territory, including without limitation the IND and NDA for each Licensed Product shall be held solely by Fujisawa; provided, however, DTI shall hold the DTI IND until such time as it completes the Phase I Trial, at which point it will transfer the DTI IND to Fujisawa as provided in Section 2.7 or 3.5(a)(ii). DTI shall be responsible for all regulatory matters associated with the DTI IND during such time as it is the holder of the DTI IND as provided above; provided, that Fujisawa shall be included in all meetings and/or discussions with the FDA. DTI shall give Fujisawa at least 48 hours advance notice prior to any such meeting or discussion. DTI shall provide Fujisawa within 72 hours after any such meeting or discussion any documentation or correspondence from or with the FDA. After DTI transfers the DTI IND to Fujisawa, Fujisawa shall have the exclusive responsibility for any and all regulatory matters for each Licensed Product in each country comprising the Territory, including without limitation contacts (written or oral) with the applicable regulatory agency and submission of any and all information and/or documents to such regulatory agency.

(e) Cooperation. DTI shall cooperate fully with Fujisawa in Fujisawa's performance of its obligations under this Section 3.7, including preparation for and participation with Fujisawa in responding to any correspondence or requests received by Fujisawa from such regulatory authorities to the extent DTI has relevant information or contributed to the regulatory submission that is the subject of such inquiry.

3.8 Back-up Compounds.

(a) Selection of Back-up Compounds.

(i) As required pursuant to Section 2.7, DTI will provide to Fujisawa on the Effective Date all of its data and DTI Know-How regarding its A1 Agonist Library. During the sixty (60) day period following the Effective Date (the "Back-up Compound Notice Period"), DTI covenants that it will not license (in whole or in part), conduct, fund, develop or participate directly or indirectly through, one or more Third Parties the research, development, distribution or commercialization in the Territory of any compound in the A1 Agonist Library for use as an Injectable Product for any indication in the Field (including without limitation PSVT and/or AFIB/F). During such Back-up Compound Notice Period, Fujisawa may, at its option, provide written notice to DTI designating up to three (3) compounds from the A1 Agonist Library as Back-up Compounds. If Fujisawa so designates any Back-up Compound(s) during the Back-up Compound Notice Period, DTI covenants that it will not license (in whole or in part), conduct, fund, develop or participate in directly or indirectly through, one or more Third Parties the research, development, distribution or commercialization in the Territory of such Back-up Compound(s) for use as an Injectable Product for any indication in the Field (including without limitation PSVT and/or AFIB/F).

(ii) If, after the expiration of the Back-up Compound Notice Period, Fujisawa does not make any such designation of Back-up Compounds, or designates less than three (3) Back-up Compounds, DTI may, subject to the restrictions in Section 2.5, license, conduct, fund, develop or participate in directly or indirectly through one or more Third Parties, the research, development, distribution or commercialization of any of the remaining compounds in the A1 Agonist Library (hereafter the "Remaining Compound(s)") for any indications other than the Primary Indications and in any formulation other than Injectable Products.

(iii) At any time after the expiration of the Back-up Compound Notice Period, and in the event Fujisawa has designated less than three (3) Back-up Compounds during the Back-up Compound Notice Period, Fujisawa may request in writing to designate any Remaining Compounds as Back-up Compounds; provided, that the total number of Back-up Compounds under this Agreement shall not exceed three (3). If Fujisawa makes such Back-up Compound designation with respect to a Remaining Compound for which DTI (or its sublicensee or contractee) has commenced Experimentation, then (A) Fujisawa covenants

that it will only develop and commercialize such Back-up Compound(s) as Licensed Products to treat the Primary Indications in the Territory and (B) the license grant to Fujisawa in Section 2.1 shall be restricted with respect to any Licensed Product containing such Back-up Compound such that DTI grants and Fujisawa accepts an exclusive (even as to DTI) license, with right to sublicense as provided in Section 2.2, under the DTI Patents and DTI Know-How to make, have made, sell, offer to sell, have sold, export and import Licensed Products containing the selected Back-up Compound to treat only the Primary Indications in the Territory. If, after the expiration of the Back-up Compound Notice Period, Fujisawa designates as a Back-up Compound any Remaining Compound for which DTI has not commenced Experimentation, then (A) Fujisawa may develop and commercialize such Back-up Compound as a Licensed Product in the Field pursuant to Section 3.8(b) and (B) the license grant to Fujisawa in Section 2.1 shall not be restricted to Primary Indications and the last sentence of Section 2.1 is not applicable in such event.

(iv) In the event that DTI plans to undertake development or commercialization of any Remaining Compound(s) with a Third Party, it shall first provide written notice to Fujisawa along with the DTI Know-How with respect to such Remaining Compound(s) as is reasonably necessary for Fujisawa to assess its potential, and shall evaluate in good faith any offer that Fujisawa makes to DTI with respect to Fujisawa's development and commercialization of such Remaining Compound(s). Notwithstanding DTI's disclosure obligation pursuant to Section 2.7 if DTI (or its sublicensee or contractee) has commenced Experimentation for any Remaining Compound, DTI shall not be required to provide Fujisawa with any additional DTI Know-How that DTI develops with respect to any such Remaining Compound(s), except for DTI Know-How that relates to the Primary Indications, in which case DTI shall be obligated to disclose promptly such DTI Know-How.

(b) Substitution of Back-up Compounds. If during its development of the Licensed Products, Fujisawa determines that the Compound that is the active ingredient in a Licensed Product then under development is not suitable for further development into a therapeutic product for use in humans, for safety, efficacy, or other reasons, Fujisawa may then substitute a Back-up Compound in place of the Compound. Such Back-up Compound shall then be considered a "Compound" for purposes of this Agreement. In such event, and where the substituted Compound was under development for the Primary Indications, the JMC shall discuss appropriate changes to the Development Plan to accommodate the changes in the pre-clinical, clinical and regulatory schedule necessitated by such substitution. If the Parties are unable to agree on such changes, Fujisawa shall be entitled to exercise its right to cast the decisive tie breaking vote with respect to all matters except for those subject to dispute resolution pursuant to Section 3.5(c).

3.9 Exchange of Information Between the Parties and Access to Data. Following the Effective Date and subject to the licenses set forth in this Agreement, each Party shall own all Data generated by such Party in the course of performing its obligations under this Agreement.

Fujisawa agrees to provide to DTI the right to access, inspect and copy any and all Data generated by or for Fujisawa under this Agreement (the "Fujisawa Data"). DTI agrees to provide to Fujisawa the right to access, inspect and copy any and all Data generated by or for DTI after the Effective Date in connection with its (or its sublicensees', to the extent such Data is made available to DTI to further provide to Fujisawa) development of the Compound and/or any Back-up Compounds as Non-Injectable Products or as Injectable Products outside the Territory (the "DTI Data"). The Parties acknowledge and agree that DTI Data does not include any Data generated in connection with the Phase I Trial, which such Data shall be part of the DTI Know How. Fujisawa hereby grants to DTI the right to use the Fujisawa Data and to refer to any submissions by Fujisawa for Regulatory Approval or any Master Files held by Fujisawa with respect to Licensed Products, in connection with any submissions for Regulatory Approval of the Non-Injectable Products and/or submissions for Regulatory Approval of the Injectable Products in countries outside of the Territory. In consideration of

such grant to DTI, DTI shall pay royalties to Fujisawa as specified in Section 5.5. DTI hereby grants Fujisawa the right to use the DTI Data and to refer to any submissions by DTI for Regulatory Approval or any Master Files held by DTI with respect to Non-Injectable Products, or Licensed Products outside the Territory, in connection with Fujisawa's submissions for Regulatory Approval of the Licensed Product in the Territory. In consideration for such grant to Fujisawa, Fujisawa shall pay royalties to DTI as specified in Section 5.6. Fujisawa's Data and DTI's Data shall be treated as "Information" pursuant to Section 10.

4. COMMERCIALIZATION

4.1 General. Fujisawa shall be responsible for commercializing the Licensed Products in the Territory and Fujisawa shall use Diligent Efforts to commercialize the License Products in the U.S. Fujisawa shall be solely and exclusively responsible for any and all matters regarding the commercialization of Licensed Products, including without limitation matters such as advertising, promotion and promotional materials, marketing, pricing, distribution and customer operations.

4.2 Failure to Launch.

(a) Subject to 4.2(b) and Section 11.5, if Fujisawa or its sublicensee does not launch a Licensed Product for treatment of each of the Primary Indications in the United States within nine (9) months after obtaining Regulatory Approval of such Licensed Product for such Primary Indication in the United States, or sooner notifies DTI that it will not launch such Licensed Product for such Primary Indication in the United States, Fujisawa's rights under this Agreement with respect to such Licensed Product for such Primary Indication and in the United States shall terminate upon the earlier of such notice or the 1 year anniversary of the grant of Regulatory Approval, and DTI shall be free to commercialize such Licensed Product for such Primary Indication in the Territory. In such event, Fujisawa shall promptly transfer to DTI all INDs, applications for Regulatory Approval and Regulatory Approvals, or their Canadian equivalents (as applicable) as it may hold with respect to such Licensed Product for such Primary Indication, and any written information as Fujisawa may possess which is useful to gain Regulatory Approval for and to commercialize such Licensed Product in the Territory for such Primary Indication. Such transfer shall be without cost to DTI, provided however that DTI shall pay any governmental filing or transfer fees that may be required.

(b) Upon the occurrence of the events in Section 4.2(a), Fujisawa shall also grant to DTI (i) an exclusive, fully-paid and royalty-free (subject to DTI's obligations under Section 5.5) license under the Fujisawa Technology to make, have made, use, import, export, offer for sale and sell such Licensed Product for such Primary Indication in the U.S., and (ii) to the extent it has the right to do so, a sublicense under any Third Party licenses to which Fujisawa has rights, to the extent that such rights are necessary or useful to make, have made, use, import, export, offer for sale and sell such Licensed Product for such Primary Indication. DTI shall thereafter assume the cost of maintaining its proportionate share of such Third Party license and shall perform such obligations of Fujisawa under such license agreement as are applicable to the relevant Licensed Products. To the extent such Third Party license is no longer applicable or useful to Fujisawa, Fujisawa shall assign to DTI all of its rights and obligations thereunder, rather than grant a sublicense under, such license agreement.

4.3 Distribution and Promotion.

(a) Pricing and Product Distribution. Fujisawa shall have the sole right to set prices for Licensed Products and shall obtain all pricing approvals as may be required. Fujisawa shall also be solely and exclusively responsible for distribution of the Licensed Products in the Territory.

(b) Advertising and Promotion. Fujisawa will prepare or have prepared, and have sole decision making authority over, any and all advertising and education materials for the Licensed Products in the Territory.

4.4 Trademarks. Fujisawa shall be responsible for developing, registering, maintaining and defending any and all trademarks for the Licensed Products, and shall own all such trademarks. Fujisawa shall, to the extent practicable in Fujisawa's sole discretion, market and sell the Licensed Products under a single trademark throughout the Territory. In the event that this Agreement is terminated in its entirety pursuant to Section 11.4, upon the request of DTI, the Parties shall negotiate in good faith the transfer or license and the consideration therefor of all Fujisawa trademarks with respect to the Licensed Products.

4.5 Exchange of Adverse Event Information.

(a) Within sixty (60) days of their respective submission, Fujisawa shall provide DTI with copies of that portion of the IND and NDA Annual Reports submitted by Fujisawa with the FDA and any other similar reports submitted with the applicable regulatory authority in Canada that address adverse event matters arising from the use of Licensed Products. Fujisawa shall provide DTI with copies of IND Safety Reports within three (3) days of their submission by Fujisawa to the FDA. Following Regulatory Approval for each Licensed Product in the United States (and Canada if applicable), Fujisawa shall provide DTI with copies of those Periodic Adverse Event Reports submitted by Fujisawa to the FDA or other applicable regulatory authority in Canada which relate to each Licensed Product. Such adverse event reports shall be provided by Fujisawa to DTI within thirty (30) days of their submission by Fujisawa to the FDA or such other regulatory authority.

(b) Fujisawa shall provide DTI with copies of 15-Day Alert Reports within three (3) days of their submission by Fujisawa to the FDA. Fujisawa shall report these expedited reports on FDA MedWatch forms. Fujisawa shall notify the contact person designated by DTI by fax at (804) 358-2451 or telephone at (804) 358-9468, as may be revised.

DTI shall be responsible for reporting to Fujisawa all serious adverse event reports occurring with each Licensed Product during the Phase I Injectable Protocol within three (3) days of receipt by DTI. Serious adverse events shall be designated using the current FDA definition of the term "serious". DTI shall provide Fujisawa with listings of all non-serious adverse events occurring with each Licensed Product during the Phase I Trial annually and at the completion of the study. Completion of a study shall be defined, for purposes of this Section 4.5(b) only, as that period of time one (1) week following Fujisawa's approval of the final study report.

After launch of the Licensed Products, DTI shall be responsible for reporting to Fujisawa all serious adverse events associated with the Licensed Products of which DTI becomes aware, whether within or outside the Territory, within twenty four (24) hours after DTI becomes aware of such serious adverse event. DTI shall notify Fujisawa of any non-serious adverse events associated with the Licensed Products within the Territory of which DTI becomes aware within ten (10) days of DTI becoming aware of the non-serious adverse event.

DTI shall report to Fujisawa all serious adverse events associated with the Non-Injectable Products during both clinical development and following launch of the Non-Injectable Products, both within and outside the Territory, within ten (10) days of DTI becoming aware of such serious adverse event.

DTI shall report both serious and non-serious adverse events on forms agreed upon by the Parties. DTI shall notify the contact person designated by Fujisawa by fax at (847) 317-1241 or telephone at (800) 727-7003, as may be revised.

4.6 Regulatory Actions; Product Recalls; Product Withdrawals. In the event (i) any government authority issues a request, directive or order that any Licensed Product be recalled or withdrawn; (ii) a court of competent jurisdiction orders such recall or withdrawal; or (iii) Fujisawa reasonably determines that any Licensed Product should be recalled or withdrawn for any reason, Fujisawa shall take all appropriate corrective actions requested by any such government authority. DTI shall fully cooperate with Fujisawa in connection with any such recall or withdrawal. In the event that such recall or withdrawal results from the breach of and/or failure to comply with any of DTI's obligations, representations and/or warranties under this Agreement, DTI shall be solely responsible for the expenses of such recall or withdrawal. In the event the recall or withdrawal results from any other reason, Fujisawa shall be responsible for the expenses of the recall or withdrawal. For purposes of this Agreement, the expenses of any such recall or withdrawal shall be all out of pocket expenses incurred by either Party relative to the notification, shipping, disposal and return of the recalled or withdrawn Licensed Product.

5. PAYMENTS AND ROYALTIES

5.1 License Fees. Fujisawa shall pay to DTI a nonrefundable, noncreditable license issue fee of * upon execution of this Agreement.

5.2 Development Costs. Within thirty (30) days of the Effective Date, Fujisawa shall pay to DTI the amount set forth on Exhibit C, which represents the actual development expenses incurred by DTI for the development of the Compound after January 1, 1999 and prior to the Effective Date. Fujisawa shall also reimburse DTI for the actual costs incurred by DTI in completing the Phase I Trial, a budget for which is attached as Exhibit E. Within thirty (30) days following the dosing of the last patient in the Phase I Trial, Fujisawa shall reimburse DTI for * of its estimated costs set forth in such budget. The remaining * (as may be adjusted up or down based upon actual costs as determined by JMC) shall be paid within thirty (30) days of the receipt by Fujisawa of a Final Clinical Study Report meeting the guidelines of the ICH (International Conference on Harmonization). Fujisawa shall be responsible for paying all additional development costs for the Licensed Product in accordance with the terms and conditions of this Agreement.

5.3 Milestones. Subject to the terms and conditions of this Agreement, Fujisawa shall pay to DTI the following noncreditable and nonrefundable amounts within thirty (30) days of the first achievement, by a Licensed Product in the United States, of the respective milestone event set forth below:

Milestone Event Payment

(1) Reissuance of U.S. Patent No. 5,310,731 *

(2) Completion of First Phase I Trial *

(3) Completion of First Phase II Trial for the Licensed Product *

(4) First Submission of a NDA for PSVT *

(5) First Submission of a NDA for AFIB/F *

(6) First Regulatory Approval of a Licensed Product for PSVT *

(7) First Regulatory Approval of a Licensed Product for AFIB/F *

Each milestone shall be paid only once; provided, however, that milestones need not be

achieved by the same Licensed Product (e.g., it may contain the Compound or a Back-up Compound, or it may be developed for PSVT rather than AFIB/F) in order to trigger a payment obligation under this Section 5.3. Milestones (1) - (3) above shall be deemed "achieved" as follows:

(a) Milestone (1) "Reissuance of U.S. Patent No. 5,310,731": Following Fujisawa's receipt of notice of the reissuance of U.S. Patent No. 5,310,731, Fujisawa shall have thirty (30) days within which to either (i) pay Milestone (1) and maintain this Agreement in full force and effect or (ii) terminate the Agreement in its entirety, in its sole discretion, pursuant to Section 11.4(c), in which case it shall not be responsible for paying Milestone (1) or any other milestone payment or any other monies under this Agreement.

(b) Milestone (2) "Completion of First Phase I Trial": Once the last patient in the first Phase I Trial has been dosed, DTI shall be deemed to have "completed" such trial, and Fujisawa shall pay Milestone (2) within sixty (60) days after the date upon which the last such patient was dosed. For purposes of clarity, it is understood that once the last patient is dosed, Fujisawa shall be responsible for making such milestone payment; however, in the event Fujisawa terminates this Agreement prior to such last patient being dosed, Fujisawa shall not owe Milestone (2), nor any other milestone or any other monies under this Agreement.

(c) Milestone (3) "Completion of First Phase II Trial": Within 30 days of the date upon which a "lock" is placed on the database for the first Phase II Trial for the Licensed Product (regardless of whether such trial involves PSVT or AFIB/F), Fujisawa will either (i) pay Milestone (3) and retain this Agreement in full force and effect, or (ii) provide notice that it elects to terminate the Agreement with respect to the particular Primary Indication tested; provided, that in the event of Completion (as hereinafter defined) of the first Phase II Trial for the remaining Primary Indication (or any other indication, if occurring earlier), Fujisawa shall either (i) pay Milestone (3) and retain this Agreement in full force and effect, or (ii) provide notice that it elects to terminate this Agreement with respect to such remaining Primary indication, subject to Section 11.5. For purposes of this Section 5.3(c), "Completion of first Phase II Trial" for such remaining Primary Indication (or other indication) shall mean occurrence of the 30/th/ day following the date upon which a "lock" is placed on the database for such Phase II Trial. In the event Fujisawa terminates this Agreement with respect to a particular Primary Indication, it will not owe such milestone payment, or any other milestone payment or other monies with respect to such terminated Primary Indication.

5.4 Earned Royalties. Fujisawa shall pay DTI a running annual royalty on aggregate, annual Net Sales of all Licensed Products in the Territory, according to the following marginal rates:

(a) For Net Sales of Licensed Products up to * of such annual Net Sales; and

(b) For the portion of Net Sales of Licensed Products in excess of * and not exceeding * of such annual Net Sales; and

(c) For the portion of Net Sales of Licensed Products in excess of * of such annual Net Sales.

5.5 Royalties to Fujisawa. If DTI (or its licensee or contractee) uses or relies upon any Fujisawa Data (as described in Section 3.9) that is contained in a Regulatory Approval application submitted by Fujisawa, in order to obtain Regulatory Approval for either a Licensed Product outside the Territory, any Non-Injectable Product or any product containing a compound from the Al Agonist Library (hereafter, a "Fujisawa Data Product"), DTI shall pay to Fujisawa a running royalty on annual Net Sales (as such term is defined pursuant to this Section 5.5) of such Fujisawa Data Product according to the following marginal rates:

(a) For Net Sales of such Fujisawa Data Product up to * of such annual Net Sales;

(b) For the portion of annual Net Sales of such Fujisawa Data Product in excess of * and not exceeding * of such annual Net Sales;

(c) For the portion of Net Sales of such Fujisawa Data Product in excess of * of such annual Net Sales;

provided, however, in no event shall the total royalty payments by DTI exceed * times the actual costs borne by Fujisawa for the study(ies) which generated the specific Data that is contained in Fujisawa's application for Regulatory Approval and which DTI (or its licensee or contractee) uses or relies upon to obtain Regulatory Approval for the particular Fujisawa Data Product. For purposes of this Section 5.5, the term "Net Sales" shall have the same meaning as provided in Section 1.28; provided, that (i) the word "Fujisawa" shall be replaced by the word "DTI" and (ii) the word "Licensed Product(s)" shall be replaced by the word "Fujisawa Data Product(s)".

5.6 Additional Royalties to DTI. In addition to the royalty owed on Licensed Products under Section 5.4, if Fujisawa (or its permitted sublicensee) uses or relies upon any DTI Data (as described in Section 3.9) that is contained in a Regulatory Approval application submitted by DTI, in order to obtain regulatory approval for a Licensed Product in the Territory (hereafter, a "DTI Data Product"), Fujisawa shall pay to DTI an additional running royalty, on annual Net Sales (as such term is defined pursuant to this Section 5.6) of such DTI Data Product according to the following marginal rates:

(a) For Net Sales of such DTI Data Product up to * of such annual Net Sales;

(b) For the portion of Net Sales of such DTI Data Product in excess of * and not exceeding * of such annual Net Sales;

(c) For the portion of Net Sales of such DTI Data Product in excess of * of such annual Net Sales;

provided, however, in no event shall the total royalty payments by Fujisawa exceed * times the actual costs borne by DTI for the study(ies) which generated the specific Data that is contained in DTI's application for Regulatory Approval and which Fujisawa (or its sublicensee) uses or relies upon to obtain Regulatory Approval for the particular DTI Data Product. For purposes of this Section 5.6, the term "Net Sales" shall have the same meaning as provided in Section 1.28; provided, that the word "Licensed Product(s)" shall be replaced by the word "DTI Data Product(s)". The Parties acknowledge and agree that Fujisawa shall not owe DTI any additional royalties under this Section 5.6 for any Data generated in the Phase I Trial.

5.7 Royalty Term. Fujisawa's obligation to pay royalties under Section 5.4 shall continue on a product-by-product basis (i) in the U.S. until five (5) years after the expiration, lapse or invalidation by a decision of a court or tribunal of competent jurisdiction from which no appeal is or can be taken of the last remaining DTI Patent (including any extension thereof) which contains a valid and unexpired claim covering the composition of matter or method of use of the relevant Licensed Product in the U.S. and (ii) in Canada until the fifth (5/th/) anniversary of the date of the first commercial sale of Licensed Product(s) in Canada (the "Royalty Term"). For purposes of this Agreement "valid and unexpired claim" shall mean a composition of matter or method of use claim or equivalent thereof, of an issued and unexpired DTI Patent (or corresponding patent application, provided that the original application containing such claim has not been pending for more than five years covering the relevant Licensed Product in such country, which (i) has not been revoked or held unenforceable or invalid by a decision of a court or other governmental agency of competent

jurisdiction, unappealable or unappealed within the time allowed for appeal; or (ii) has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue of disclaimer or otherwise.

5.8 Withholding Taxes. Any tax paid or required to be withheld by a Party on account of royalties payable to the other Party under this Agreement shall be deducted from the amount of royalties otherwise due. The withholding Party shall secure and send to the other Party written proof of any such taxes withheld and paid by the withholding Party or its sublicensees for the benefit of the other Party. The withholding Party shall reasonably assist the other Party in claiming exemption from such deductions or withholdings under any double taxation or similar agreement or treaty from time to time in force.

5.9 Blocked Currency. In each country where the local currency is blocked and cannot be removed from the country, at the election of the Party paying royalties, royalties accrued in that country shall be paid to the other Party in the country in local currency by deposit in a local bank designated by the other Party.

5.10 Royalty Payments and Reports. Beginning with the first commercial sale of a Licensed Product, royalties shall accrue on Fujisawa's fiscal quarter basis. The royalty-paying Party shall pay all amounts owed within forty-five (45) days following the end of the relevant calendar quarter. Each royalty payment shall be accompanied by a report summarizing the number, description, and aggregate sales of Licensed Products made and the royalty payable thereon according to Sections 5.4, 5.5, and 5.6 respectively, including a description of any offsets or credits deducted from such sales, on a product-by-product and country-by-country basis during the relevant three-month period. For any given royalty period, the royalty-paying Party shall pay the royalty at the rate specified in Section 5.4, 5.5, or 5.6 applicable to the then current year-to-date Net Sales level. Each statement provided at the end of the fourth quarter of each year shall contain a reconciliation of actual royalty payments made during that year and the amount actually owed for such year according to that year's Net Sales level, and the resulting amount, if any, shall be paid at the time of such fourth quarter statement, in accordance with the terms of this Section 5.10. The royalty-paying Party may credit any amounts paid in excess of the amount actually owed against future quarterly royalty payments.

5.11 Currency; Exchange Rate. Subject to Section 5.9, all amounts paid under this Agreement shall be paid in U.S. dollars to either Party by wire transfer to a financial institution to be designated by the Party to whom payment is owed. The royalty on sales by either Party or their respective sublicensee(s) of Licensed Products sold in a currency other than United States Dollars shall be converted into United States Dollars using the selling rate of exchange for the currency of the country from which the royalties are payable as published by the Wall Street Journal, New York, N.Y., U.S.A., for the last business day of the quarterly period for which the royalties are due.

5.12 Accounting. Each Party agrees to keep and maintain such records, using generally accepted accounting principles (GAAP) consistently applied, as it normally generates in the ordinary course of its business for a period of three (3) years showing the sale, use, and other disposition of products sold or otherwise disposed of under the license herein granted. Such records shall be kept in sufficient detail to enable the royalties payable hereunder by either Party to be determined. Each Party further agrees to permit its books and records to be examined by an independent certified public accountant selected by the other Party, at ordinary business hours with reasonable prior notice and not more than once per year, to the extent necessary to verify reports and payments provided for in this Agreement. Following completion of the Phase I Trial, Fujisawa may audit DTI's books with respect to any costs incurred by DTI and reimbursed by Fujisawa, including, without limitation, pre-clinical, and Phase I Trial expenses, and those incurred and reimbursed under Section 2.7, along with such Phase I Trial. No copies of either Party's records shall be copied or retained by such examiner. Such examination is to be made under appropriate confidentiality restrictions, at

the expense of the auditing Party, except in the event that the results of the audit reveal an underreporting of royalties due to the auditing Party of * or more in any year, then the audit costs shall be paid by the audited Party.

6. MANUFACTURING

6.1 General. DTI will be responsible for obtaining sufficient quantities of Licensed Products necessary for it to conduct the Phase I Trial. Fujisawa will be responsible for identifying a suitable manufacturer, developing commercial manufacturing processes and supplying subsequent clinical and commercial quantities of Licensed Products for distribution and sale in the Territory. DTI will cooperate with Fujisawa in connection with such third party manufacturer.

6.2 Quality Assurance. Fujisawa shall have day to day responsibility for commercial manufacturing and formulation issues related to product safety and regulatory compliance. All Licensed Products used in clinical and commercial supplies will be manufactured, tested, and released according to current cGMP's and all other applicable law and regulatory requirements of the country in which such Licensed Products are to be used or distributed and sold. Both parties will be responsible for maintaining its facilities and procedures, including those of Third Parties, in material compliance with cGMP's and applicable laws and regulatory requirements. The Parties will promptly notify each other in advance, if known, of any governmental regulatory inspections and, within twenty four (24) hours of any such inspection, shall provide the other Party with the results of any governmental regulatory inspections or other governmental regulatory action concerning the facilities or other manufacturing or formulation issues, copies of all Form FD 483's (or their non-U.S. equivalents) and compliance related documentation, including all actions taken by a Party in response thereto or as a result thereof. Any expenses incurred in improving compliance with applicable regulatory requirements or responding to Form FD 483's (or their non-U.S. equivalents) or other compliance-related documentation will be the full responsibility of Fujisawa.

7. REPRESENTATIONS AND WARRANTIES; DISCLAIMERS

7.1 Representations and Warranties.

(a) Each Party hereby represents and warrants to the other that this Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms, and that the execution, delivery and performance of this Agreement by such Party does not conflict with any agreement, instrument or understanding, oral or written, to which it is a Party or by which it is bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it. Each Party expressly represents and warrants that it has full right, power and authority to execute and deliver this Agreement and to perform their respective obligations contemplated hereby.

(b) DTI hereby represents and warrants to Fujisawa that:

(i) No consent of any Third Party is required for DTI to grant the exclusive license to Fujisawa under Section 2.1, to enter into this Agreement and/or to perform its obligations hereunder.

(ii) DTI owns, or controls (with the right to grant sublicenses consistent with those granted Fujisawa hereunder) the DTI Patents and DTI Know-How.

(iii) DTI has not, and during the term of the Agreement will not, grant any right to a Third Party under the DTI Patents and DTI Know-How in the Field that would conflict with any of the rights granted to Fujisawa under this Agreement.

(iv) DTI has not to its knowledge received any communication or claim from, or by any Third Party, nor is otherwise aware of, any issue relative to the validity, enforceability or infringement of any of the DTI Patents and/or that the practice of the inventions claimed in the DTI Patents and/or comprising the DTI Know-How infringe the rights of any Third Party.

(v) To the best of DTI's knowledge, there is no prior art that has not been cited by DTI to the PTO which would invalidate the DTI Patents. The DTI Patents have not been obtained through any misrepresentation that would affect or destroy the validity and/or enforceability of the DTI Patents.

(vi) There are no claims currently asserted or, to the best of DTI's knowledge, threatened by any Third Party involving, questioning and/or relative to: (i) Fujisawa's right to use and/or receive from DTI the exclusive license under this Agreement; and/or (ii) DTI's ability to enter into this Agreement and perform its obligations hereunder.

(vii) As of the Effective Date, it has not received any notices that the manufacture, use, sale or importation of the Compound or the Back-up Compounds infringe the intellectual property rights of any Third Party.

(viii) The U.S. Patent No. 5,310,731 is the subject of a reissue application to correct a defect with respect to certain claims in such U.S. Patent. Except with respect to this defect and to the best of DTI's knowledge, the DTI Patents are valid and enforceable, and there has been no lapse in any of rights provided by the DTI Patents.

(ix) DTI represents and warrants that to the best of its knowledge DTI has disclosed to Fujisawa all material information in DTI's possession or control concerning side effects, injury, toxicity or sensitivity reaction and incidents associated with the use of Licensed Products obtained from any non-clinical studies.

(x) DTI has conducted all pre-clinical studies for the Compound, the Back-up Compounds and the Licensed Products, if any (collectively "DTI's Pre-Clinical Studies") in substantial compliance with Good Laboratory Practices and all applicable Federal, state and local laws, rules, regulations and guidelines governing the conduct of pre-clinical studies. To the best of DTI's knowledge, neither DTI nor any of the investigators, institutions, laboratories, clinical research organizations or other individuals or entities participating in DTI's Pre-Clinical Studies have been or are"debarred" as such term is used in Section 335a of the United States Code. Any and all necessary financial disclosures have been obtained in accordance with 21 CFR Part 54, from the investigators and/or institutions participating in DTI's Clinical Studies, to the extent applicable.

7.2 Warranty Disclaimer. EXCEPT FOR THE REPRESENTATIONS AND WARRANTIES SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY OTHER REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED WITH RESPECT TO THE COMPOUND, THE BACK-UP COMPOUNDS OR THE LICENSED PRODUCTS. EXCEPT AS PROVIDED ABOVE, THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR THAT THE USE OF THE LICENSED PRODUCT(S) WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS, OR ANY OTHER EXPRESS OR IMPLIED WARRANTIES.

7.3 IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER FOR ANY INDIRECT, INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES, INCURRED BY EITHER PARTY AND ARISING FROM PERFORMANCE OR NONPERFORMANCE UNDER THIS AGREEMENT, WHETHER BASED ON AN ACTION IN CONTRACT OR TORT - OR BASED ON A WARRANTY.

8. INDEMNITY AND INSURANCE

8.1 Indemnification by Fujisawa. Fujisawa hereby agrees to indemnify, defend and hold harmless DTI and its agents and employees from and against any and all Third Party suits, claims, actions, demands, liabilities, expenses and/or loss, including reasonable attorneys' fees and costs (such Third Party suits, claims, actions, demands, liabilities, expenses and/or loss, including reasonable attorneys' fees and costs shall be referred to herein as "Losses") resulting from (a) Fujisawa's breach of any of its obligations, agreements, covenants, representations and/or warranties hereunder; (b) any use of DTI's Data (except where such Data is either fraudulent or otherwise does not meet the requirements of applicable rules, regulations and/or law) and/or (c) the manufacture, use, handling, storage, sale or other disposition of Licensed Products by Fujisawa, its agents, representatives, consultants or sublicensees except to the extent such Losses result from (i) the negligence or wrongdoing of DTI, its agents, representatives, consultants or employees, or (ii) from the actions or inactions of DTI, its agents, representatives, consultants or employees for which DTI is obligated to indemnify Fujisawa pursuant to Section 8.2.

8.2 Indemnification by DTI. DTI hereby agrees to indemnify, defend and hold harmless Fujisawa and its agents and employees from and against any and all Losses resulting from (a) DTI's breach of any of its obligations, agreements, covenants, representations and warranties hereunder; (b) any use of Fujisawa's Data (except where such Data is either fraudulent or otherwise does not meet the requirements of applicable rules, regulations and/or law); and/or (c) any use of Data generated by or on behalf of DTI in the Phase I Trial which is either fraudulent or otherwise does not meet the requirements of applicable rules, regulations and/or law; except to the extent such Losses result from (i) the negligence or wrongdoing of Fujisawa, its agents, representatives, consultants or employees, or (ii) the actions or inactions of Fujisawa, its agents, representatives, consultants or employees for which Fujisawa is obligated to indemnify DTI pursuant to Section 8.1.

8.3 Indemnification Procedure. If a Party (in this context, the "Indemnified Party" seeks indemnification under the applicable provision of this Section 8, the Indemnified Party shall promptly notify the other Party (in this context, the "Indemnifying Party") of its claim for indemnification ("Indemnified Claim"), but in no event more than ten (10) business days after the Indemnified Party has been served with legal process or otherwise received notice of the commencement of any action by a third party; provided, however, that the right of the Indemnified Party to indemnification shall be reduced in the event of its failure to give timely notice only to the extent the Indemnifying Party is prejudiced thereby. The Indemnified Party shall defend the Indemnified Claim. The Indemnified Party may retain separate co-counsel at its sole cost and expense and participate in the defense of the Indemnified Claim. The Indemnified Party shall fully cooperate with the Indemnifying Party's defense of any Indemnified Claim, including without limitation providing any and all required knowledge and documents and access to its employees.

8.4 Insurance. In addition to the foregoing, both Parties shall obtain appropriate insurance in accordance with standard commercial practices to cover their respective indemnities granted in Sections 8.1 and 8.2. Each Party agrees to provide evidence of such coverage if requested by the other Party.

9. PROTECTION OF PATENTS; CLAIMS OF INFRINGEMENT

9.1 Ownership of Intellectual Property. Each Party shall solely own inventions made within and outside of the United States by that Party's employees or agents or consultants in the course of performing any work under this Agreement. Inventions made jointly by employees, agents or consultants of DTI and Fujisawa shall be owned jointly by DTI and Fujisawa, with each party retaining an undivided one-half interest in such jointly-developed inventions pursuant to Section 9.5. The law of ownership of inventions of the United States

shall apply to any patents filed or issued outside the United States claiming inventions of the Parties. For all inventions under this Section 9.1, the Parties shall provide reasonable assistance to each other in perfecting title to such inventions.

9.2 Infringement of DTI Patents.

(a) Each Party shall promptly notify the other in writing of any alleged or threatened infringement of any DTI Patents in the U.S. Both Parties shall use their commercially reasonable efforts in cooperating with each other to terminate such infringement.

(b) Subject to Section 9.2(e), Fujisawa shall have the first right to bring and control any action or proceeding with respect to infringement of a DTI Patent in the U.S., to the extent such infringement involves a product which is an Injectable Product that is competitive with a Licensed Product, at its own expense and by counsel of its own choice. DTI shall have the right, at its own expense, to be represented in any such action involving a DTI Patent. If Fujisawa fails to bring an action or proceeding with respect to such infringement within: (b) (i) ninety (90) days following the notice of alleged infringement or (ii) ten (10) days before the time limit, if any, set forth in the appropriate laws and regulations for the filing of such actions, whichever comes first, it shall notify DTI and DTI shall have the right to bring and control any such action at its own expense and by counsel of its own choice, subject to Section 9.2(e). Prior to providing such notification to DTI, Fujisawa shall take any action (or cause to be taken any action) necessary to reasonably ensure that the rights of DTI under any such action are not prejudiced, including but not limited to filing a responsive pleading or obtaining an extension of time to do so. Fujisawa shall have the right, at its own expense, to be represented in any such action by counsel of its own choice.

(c) DTI (or its licensee) shall have the first right to bring and control any action or proceeding with respect to infringement of a DTI Patent in the U.S., to the extent such infringement involves a product which is a Non-Injectable Product, or is an Injectable Product, but is not competitive with a Licensed Product, at its own expense and by counsel of its own choice. Fujisawa shall have the right, at its own expense, to be represented in any such action by counsel of its own choice, where such action involves an Injectable Product. If DTI (or its licensee) determines not to pursue an infringement action under this Section 9.2, it shall promptly notify Fujisawa, and Fujisawa shall have the right to bring and control any such action at its own expense and by counsel of its own choice, subject to Section 9.2(e). Prior to providing such notification to Fujisawa, DTI shall take any action (or cause to be taken any action) necessary to reasonably ensure that the rights of Fujisawa under any such action are not prejudiced, including but not limited to filing a responsive pleading or obtaining an extension of time to do so. Fujisawa may elect, but shall not be obligated, to bring, at its own expense, any such action DTI (or its sublicensee) elects not to bring. DTI (and its sublicensee) shall have the right, at its own expense, to be represented in any such action involving a DTI Patent which Fujisawa brings under this Section 9.2(c).

(d) In the event a Party brings an infringement action against a Third Party, the other Party shall cooperate fully, including, where necessary, joining the action as a Party plaintiff. Neither Party shall have the right to settle any patent infringement litigation under this Section 9.2 without the prior written consent of such other Party. If there is no agreement between the Parties as to any proposed settlement, then the dispute shall be resolved pursuant to Article 13.

(e) Any recovery realized as a result of such litigation, after reimbursement of any litigation expenses for Fujisawa and DTI, shall belong to the Party bringing the litigation; provided, however, if Fujisawa recovers damages as a result of such litigation that are attributable to lost sales of Licensed Products, such amounts shall be treated as if they were Net Sales and Fujisawa shall pay to DTI the royalties due under Section 5.4 as if such amounts were Net Sales of such Licensed Products.

9.3 Defense and Settlement of Third Party Claims of Patent Infringement.

(a) General. If a Third Party asserts against Fujisawa or DTI that a patent, trademark or other intangible right owned by it is infringed by the manufacture, use or sale of any Licensed Product manufactured or sold in the Territory by Fujisawa or its sublicensee, each Party will promptly notify the other in writing and Fujisawa shall be solely responsible for (a) defending such action, subject to the requirements of this Section 9.3, and subject to Section 9.3(b) Fujisawa shall pay any and all costs, expenses (including attorneys' fees and costs) fees, license fees, payments, royalties and expenses in connection with such defense and/or settlement.

(b) Royalty Offset. Fujisawa may credit against the royalty payments owed to DTI under Section 5.4 for sales of Licensed Products * of all of its costs, expenses, fees (including attorneys' fees and costs), license fees, payments, royalties and any other amounts expended to defend or settle such action and/or obtain a license; provided, that the maximum amount of credit that Fujisawa may apply against such royalty payments in any given quarter shall not exceed * of the royalty payment owed in such quarter (the "*"). Any amounts in excess of the * Threshold for any prior quarter may be credited against subsequent quarterly royalty payments owed to DTI, subject to the * Threshold limitation for any such subsequent quarter, until the total amount has been credited.

(c) Settlement with a Third Party. The entity that controls the defense of a given claim with respect to a Licensed Product shall also have the right to control settlement of such claim; provided, however, that no settlement shall be entered into without the prior written consent of the other Party. If there is no agreement between the Parties as to any proposed settlement, then the dispute shall be resolved pursuant to Article 13.

9.4 Prosecution and Maintenance of DTI Patents. DTI shall be responsible for obtaining the re-issuance of U.S. Patent No. 5,310,731 and maintaining all DTI Patents. DTI shall keep Fujisawa informed as to the status of the reissuance and shall promptly provide copies of any and all documentation and correspondence to and from the PTO. Fujisawa shall reimburse DTI for all of its reasonable expenses incurred after the Effective Date for prosecuting and maintaining the DTI Patents (other than costs in connection with the reissuance) in the United States until such time as DTI commercializes a Non-Injectable Product in the United States, at which point Fujisawa shall be responsible for reimbursing DTI for *of its expenses for maintaining DTI Patents. DTI shall notify Fujisawa if it intends to abandon any DTI Patent or other patent covering the Licensed Product at least sixty (60) days prior to any relevant deadline. Fujisawa shall have the right, at its own expense and under its own name, to file and assume prosecution and maintenance of any patent or patent application abandoned by DTI, and all rights under such abandoned DTI Patent or other patent shall revert or be assigned by DTI to Fujisawa.

9.5 Prosecution and Maintenance of Joint Patents. For all patents claiming jointly owned inventions ("Jointly Owned Patents"), the Parties shall work together to develop a reasonable patent strategy appropriate for the technology at issue. DTI shall have the first right, but not the obligation, to prosecute and maintain any Jointly Owned Patents. DTI shall permit Fujisawa to review and comment on any documents filed with the relevant patent authorities in the Territory with respect to any Jointly Owned Patents. Fujisawa shall reimburse DTI for fifty percent (50%) of its expenses in prosecuting and maintaining Jointly Owned Patents in the Territory; provided, however, that Fujisawa may elect to forego its ownership interest in such Jointly Owned Patent application during the sixty (60) day period following the filing of such application, in which case it shall not reimburse DTI and shall assign over its interest. If DTI elects not to prosecute a Jointly Owned Patent, or to abandon any Jointly Owned Patent, it shall provide sixty (60) days written notice to Fujisawa prior to any relevant deadline and Fujisawa shall have the right, but not the obligation, to prosecute and maintain such patent at Fujisawa's expense, and under its own name. DTI shall have the right to grant licenses under any Jointly Owned Patents to any Third Party without the

consent of Fujisawa, subject to the license in Section 2.1. Fujisawa shall have the right to grant licenses under any Jointly Owned Patents (i) to any Third Party to make, have made, use, import, export, offer for sale and sell Licensed Products without the consent of DTI, but only so long as this Agreement is in effect, and only in connection with a sublicense permitted under Section 2.2 and (ii) to any Third Party for any other use, without the consent of DTI.

10. CONFIDENTIALITY

10.1 Information. Each Party shall keep all information received from the other Party (the “Information") confidential and shall not disclose nor use the Information without the other Party’s written consent except to the extent contemplated by this Agreement. This restriction shall not, however, prevent disclosure of the Information if and to the extent that disclosure is required by law, provided that the disclosing Party informs the other Party without delay of any such requirement, in order to allow such other Party to object to such disclosure and to seek an appropriate protective order or similar protection prior to disclosure.

10.2 Exceptions. The above obligations shall not apply or shall cease to apply to Information which:

(a) is now, or hereafter becomes, through no act or failure to act on the part of the receiving Party, generally known or available to the public;

(b) is known by the receiving Party at the time of receiving such information, as evidenced by its written records;

(c) is hereafter furnished to the receiving Party by a third party, as a matter of right and without restriction on disclosure;

(d) is independently developed by the receiving Party without any breach of this Section 10 as is evidenced by written records; or

(e) is the subject of a written permission to disclose provided by the disclosing Party.

10.3 Permitted Disclosures. Information may be disclosed for the purpose of filing, prosecuting and maintaining the DTI Patents, for obtaining Regulatory Approvals, and to employees, agents, consultants, Third Party contract manufacturer, sublicensees or suppliers of the recipient Party, but only to the extent required to accomplish the purposes of this Agreement and only if such individuals are required by law, contract or otherwise not to use or disclose such information except as permitted by this Agreement. Each Party will use at least the same standard of care as it uses to protect proprietary or confidential information of its own to ensure that such employees, agents, consultants, sublicensees or suppliers do not disclose or make any unauthorized use of the Information.

10.4 Disclosure of Agreement; Press Releases. Except as required by law, neither DTI nor Fujisawa shall release to any Third Party or publish in any way any non-public information with respect to the terms of this Agreement without the prior written consent of the other; provided; however that either Party may disclose the terms of this Agreement to the extent required to comply with applicable laws, including without limitation the rules and regulations promulgated by the Securities and Exchange Commission. Notwithstanding any other provision of this Agreement, each Party may disclose the terms of this Agreement to lenders, investment bankers, financial advisors and other financial institutions of its choice solely for purposes of financing the business operations of such Party, or to potential investors in or acquirors of such Party either (i) upon the written consent of the other Party or (ii) if the disclosing Party obtains a signed confidentiality agreement with such intended

recipient with respect to such information, upon terms substantially similar to those contained in this Section. Notwithstanding the foregoing, promptly following execution of this Agreement the Parties will issue mutually agreed upon press release(s). Any future press releases or other public disclosures cannot be made by one Party without the prior written consent of the other Party, with the understanding that Fujisawa will have sole decision making authority to the extent any such press release covers the Licensed Product, except to the extent required by law and except when the information has already been publicly disclosed in a prior press release or filing required under the Securities and Exchange Act.

11. TERM AND TERMINATION

11.1 Term. This Agreement shall commence on the Effective Date and expire at the end of the Royalty Term under Section 5.7. Upon the expiration (but not the earlier termination) of the Royalty Term, the licenses granted hereunder to Fujisawa shall convert to non-exclusive, fully paid and royalty-free licenses.

11.2 Early Termination for Material Breach. If either Party commits a material breach of this Agreement and such breach is not cured within ninety (90) days after written notice thereof by the non-breaching Party, or if such breach is incapable of cure during the applicable notice period, the breaching Party fails to make good faith efforts to cure such breach, the non-breaching Party may terminate this Agreement upon expiration of the notice period. Notwithstanding the foregoing, any termination by DTI under this Section 11.2 for a material breach by Fujisawa shall only be effective as to the particular Licensed Product at issue, and for the particular indication for which it was under development or being sold, except for material breach of Sections 2.1, 2.6, 3.8(a)(iii), 3.9, 5.3, 5.4, 5.6, and 10.1, in which case the entire Agreement may be terminated by DTI.

11.3 Termination for Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by DTI to Fujisawa are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "Intellectual Property" as defined under Section 101(56) of the Bankruptcy Code. The Parties agree that Fujisawa, as a licensee of such rights and licenses, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code. The parties further agree that, in the event that any proceeding shall be instituted by or against DTI seeking to adjudicate it as bankrupt or insolvent, or seeking liquidation, winding up, reorganization, arrangement, adjustment, protection, relief or composition of it or its debts under any law relating to bankruptcy, insolvency or reorganization or relief of debtors, or seeking an entry of an order for relief or the appointment of a receiver, trustee or other similar official for it or any substantial part of its property or it shall take any action to authorize any of the foregoing actions (each a "Proceeding"), Fujisawa shall have the right to retain and enforce its rights under this Agreement to the full extent under applicable law, including without limitation, any rights under Section 365(n) of the Bankruptcy Code.

11.4 Early Termination by Fujisawa.

(a) Termination for Safety. Subject to Section 11.6, Fujisawa may terminate this Agreement in whole or in part (i.e., with respect to a particular Licensed Product and/or indication) at any time upon thirty (30) days prior written notice if: Fujisawa determines that there are safety concerns regarding the Licensed Products such that no Licensed Product could reasonably be developed that would meet Fujisawa's standards for product safety, so long as such determination is made in good faith and that Fujisawa applies the same standards to evaluate the safety of Licensed Products as it typically and customarily would apply for the safety evaluation of other products, including products derived from its own research and development efforts, at similar stages of development. In the event Fujisawa terminates under this Section 11.4(a), it would not owe any milestone payment that became due during the thirty (30) day notice period, or any other monies hereunder with respect to

the terminated Licensed Product and/or indication, except for Milestone (2) under Section 5.3(b) in accordance with the terms thereof, where such termination occurred after the dosing of the last patient in the Phase I Trial.

(b) Termination for Other Scientific Reasons. Subject to Section 11.6, Fujisawa may terminate this Agreement in whole or in part (i.e., with respect to a particular Licensed Product and/or indication) upon ninety (90) days prior written notice if: it determines not to continue further research and development for reasons concerning efficacy, dosing regimen or formulation, so long as such determination is made in good faith and that Fujisawa applies the same standards to evaluate such factors with respect to Licensed Products as it typically and customarily would apply for the similar evaluation of other products, including products derived from its own research and development efforts, at similar stages of development. In the event Fujisawa terminates under this Section 11.4(b), it would not owe any milestone payment that became due during the ninety (90) day notice period, or any other monies hereunder with respect to the terminated Licensed Product and/or indication, except for Milestone (2) under Section 5.3(b) in accordance with the terms thereof, where such termination occurred after the dosing of the last patient in the Phase I Trial.

(c) Termination for Non-Issuance of Valid DTI Patent. Fujisawa may terminate this Agreement in its entirety for non-issuance of the DTI Patent pursuant to Section 5.3(a).

(d) Termination for Other Patent Issues. Fujisawa may terminate this Agreement in its entirety upon thirty (30) days prior written notice if it determines in good faith after receiving an opinion of outside patent counsel, that the manufacture, use, distribution or sale of any of the Licensed Products would likely infringe any patent that issues in the United States and/or Canada after the Effective Date.

(e) Termination for Convenience. After two (2) years from the Effective Date, Fujisawa may at its sole discretion elect to terminate this Agreement in its entirety for any reason at any time upon thirty (30) days prior written notice. In the event Fujisawa terminates under this Section 11.4(e), it would not owe any milestone payment that became due during the thirty (30) day notice period or any other monies hereunder, except for Milestone (2) under Section 5.3(b) in accordance with the terms thereof, where such termination occurred after the dosing of the last patient in the Phase I Trial.

(f) Obligations During Termination Notice Period. If Fujisawa terminates this Agreement pursuant to Section 11.4(a), (b) or (c), it shall not be obligated, during the applicable termination notice period in Section 11.4 (a), (b) or (c), to perform its obligations under Sections 3.5, 3.7, 4.1 and 4.2 of this Agreement.

11.5 Termination of Entire Agreement. Notwithstanding Section 3.5(b), 3.6, 4.2(a), 5.3(c), 11.4(a), or 11.4(b), in the event Fujisawa's rights to both Primary Indications are terminated (i) by DTI pursuant to Section 3.5(b), 4.2(a) or 11.2 or (ii) by Fujisawa pursuant to Section 3.6, 5.3(c) or 11.4(a) or 11.4(b), and in the further event that Fujisawa has not commenced development with respect to the Licensed Product for any other indication in the Field at the time of such termination, then DTI shall also have the right to terminate this Agreement in its entirety, in which case Fujisawa's rights, to the extent they exist, to make, have made, use, sell, offer for sale, import and export Licensed Products for all other indications in the Field shall terminate and Section 11.7 shall apply.

11.6 Effect of Partial Termination. In the event there is any termination under this Agreement (including without limitation any termination provided for under Section 3.5(b), 3.6, 4.2(a), 5.3(c), 11.2, 11.4(a) or 11.4(b), where such termination is only effective as to a particular Licensed Product and/or certain indication for such Licensed Product, the Parties acknowledge and agree that with respect to any other Licensed Product and/or indication licensed at such time to Fujisawa under this Agreement, the terms and conditions of this

Agreement shall remain in full force and effect, subject to Section 11.5.

11.7 Effect of Early Termination.

(a) In the event Fujisawa terminates this Agreement pursuant to Section 11.4(a) or 11.4(b) and the Phase I Trial is not concluded as of the effective date of such termination, Fujisawa shall be obligated to reimburse DTI under Section 5.2 only for the costs of such Phase I Trial incurred up to the effective date of such termination; provided, however, that Fujisawa shall nonetheless reimburse DTI for all costs owed to a Third Party which could not be canceled by DTI and reasonably incurred by DTI through the completion of the Phase I Trial. DTI shall use reasonable commercial efforts to negotiate a cancellation of such costs.

(b) In the event that Fujisawa terminates this Agreement pursuant to Section 11.4(a), (b), (c), (d) or (e), or either Party terminates for material breach under Section 11.2, the following shall apply:

(i) all licenses to Fujisawa with respect to Licensed Products shall terminate (or, where partially terminated, the Licensed Product and/or indication at issue);

(ii) except in the event Fujisawa terminates for DTI's material breach under Section 11.2, Fujisawa hereby grants to DTI a royalty-free (Except for those royalties provided in Section 5.5), non-exclusive license under the Fujisawa Technology to make, have made, use, sell, have sold, export and import Licensed Products worldwide, in the Field (or, where partially terminated, the Licensed Product and/or indication at issue);

(iii) Fujisawa and DTI shall cooperate to ensure that the development and commercialization of Licensed Products in the Territory continues with a minimum of delay resulting from the transfer of rights back to DTI. Fujisawa shall promptly transfer to DTI at DTI's written request all Fujisawa Technology and assign all INDs, applications for Regulatory Approval and Regulatory Approvals, or their Canadian equivalents (as applicable) as it may hold with respect to such Licensed Product(s) in the Territory, and any information as Fujisawa may possess which is useful to gain Regulatory Approval for and to commercialize such Licensed Product(s) in such country. In the event such assignment is not permitted by law, Fujisawa will cooperate in the cancellation of such government approval, clearance, registration or permit standing in its name and the reissuance of such government approval, clearance, registration or permit to DTI or its designee. Such transfer shall be without cost to DTI, provided however that DTI shall pay any governmental filing or transfer fees that may be required;

(iv) to the extent it has the right to do so, Fujisawa shall grant to DTI a sublicense under any Third Party licenses to which Fujisawa has rights, to the extent that such rights are necessary or useful to make, have made, use, import, offer for sale and sell such Licensed Product. DTI shall thereafter assume the cost of maintaining its proportionate share of such sublicenses and shall perform such obligations of Fujisawa under such license agreement as are applicable to the relevant Licensed Product. To the extent such Third Party license is no longer applicable or useful to Fujisawa, Fujisawa shall assign to DTI all of its rights and obligations, rather than grant a sublicense under, such license agreement; and

(v) Fujisawa shall take all such other reasonable actions and execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights hereunder.

Notwithstanding the foregoing, it is expressly understood and agreed that the foregoing provisions regarding license terminations, transfer of data, assignment of regulatory filings and the like shall only be effective as to the particular Licensed Product at issue, and for the particular indication for which it was under development or being sold, where this Agreement

is terminated in part as provided for in this Agreement.

(c) At the time of any early termination, if Fujisawa has already commenced manufacturing of the Licensed Product as to which its rights have been terminated. Fujisawa shall continue to provide for manufacture of the Licensed Products to the extent necessary to meet expected market demand, from the effective date of such termination until such time as DTI is able to secure an alternative commercial manufacturing source, as requested by DTI; provided, that Fujisawa shall in no event be required to continue to manufacture for more than eighteen (18) months after the effective date of such termination or in quantities in excess of those being produced at the time of such termination. As of the effective date of such termination, all Third Party manufacturing contracts for manufacture of Licensed Products shall be assigned to DTI, to the extent that Fujisawa has the right to do so, and DTI will assume any and all of Fujisawa's obligations under any of such contracts. Except in the event of Fujisawa's termination of this Agreement for DTI's material breach under Section 11.2, in addition, upon DTI's request, Fujisawa shall provide such technical assistance and know-how licenses on a royalty-free basis as may reasonably be requested to transfer such technology as is needed by DTI to commence or provide for commercial manufacture of Licensed Product. Fujisawa shall provide such technical assistance to DTI for a period of sixty (60) days following the effective date of termination. Fujisawa shall only be obligated to provide such assistance if it is promptly reimbursed for any and all out-of-pocket expenses incurred in rendering such assistance and at a reasonable hourly rate, mutually agreed to by the parties, for the work of the employees providing such assistance. In the event Fujisawa is unable to assign to DTI any such manufacturing contracts, then Fujisawa shall continue to have the Licensed Product manufactured for a period in no event to exceed eighteen (18) months from the effective date of termination so as to enable DTI to qualify a new Third Party contract manufacturer. If such Third Party is qualified prior to the end of such eighteen (18) month period, then Fujisawa's obligation to have the Licensed Product manufactured shall cease upon the date such Third Party is so qualified. Notwithstanding anything to the contrary contained in Section 8.1 or 8.2, during such period in which Fujisawa is continuing to have the Licensed Product manufactured after termination of this Agreement, DTI agrees to indemnify, defend and hold harmless, Fujisawa and its agents representatives, consultants and employees from and against any and all Losses resulting from the manufacture, use, handling, storage, sale or other disposition of Licensed Products by DTI, its agents representatives, consultants or employees, and/or the third party contract manufacturer, except to the extent such Losses result from the negligence or wrongdoing of Fujisawa, its agents representatives, consultants or employees (excluding any Third Party manufacturing the Licensed Product after the effective date of such termination) in accordance with Section 8.3. If any technology needed by DTI to commence or provide for commercial manufacture of Licensed Product is covered by one or more patents owned or controlled by Fujisawa, DTI shall receive a fully paid-up, royalty-free, non-exclusive worldwide license to practice any and all such patents for the purposes contemplated in this Section 11.7, with the right to grant sublicenses.

11.8 Accrued Obligations. Except where expressly provided for otherwise in this Agreement, termination of this Agreement shall not relieve the Parties hereto of any liability, including without limitation, any obligation to make payments hereunder, which accrued hereunder prior to the effective date of such termination, nor preclude any Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement nor prejudice any Party's right to obtain performance of any obligation. Upon termination, expiration or cancellation of this Agreement for any reason and subject to Sections 5.3(b), 11.4(a), 11.4(b) 11.4(e), Fujisawa shall not be required to make any milestone payments or royalty payments that may be due from and after the effective date of termination. The Parties further acknowledge and agree that notwithstanding anything to the contrary contained in this Agreement, any DTI patent infringement action brought by Fujisawa under Section 9.2 which is ongoing as of the time of such termination or expiration shall be transferred to DTI, upon DTI's request. In such event, Fujisawa shall have no responsibility with respect to the prosecution of any such action

pertaining to the infringement of the DTI Patents.

11.9 Surviving Obligations. Surviving any termination are:

(a) any cause of action or claim of Fujisawa or DTI, accrued or to accrue, because of any breach or default by the other Party;

(b) the provisions of Sections 3.9 (with respect to DTI's rights and subject to Section 5.5), 4.4, 5.5, 5.6, 5.12, 7.1, 7.2, 7.3, 8, 9.1, 9.5, 10, 11 and 14; and

(c) any accrued obligations under Section 11.8.

12. ASSIGNMENT

12.1 This Agreement and the rights, duties and obligations hereunder may not be assigned by either Party without the prior written consent of the other Party except to an Affiliate or in connection with a merger, consolidation or sale of all or substantially all of the assets or line of business of such Party to which this Agreement relates. This Agreement shall be binding upon and inure to the benefit of all successors and permitted assigns of the Parties.

13. DISPUTE RESOLUTION

13.1 Discussion. In the event of any dispute between the Parties regarding their respective rights or obligations under this Agreement, each Party agrees to discuss such matter in good faith in an effort to resolve the dispute without resort to formal dispute resolution procedures. At any time, either Party may call a meeting between a member of Fujisawa's Executive Committee and the Chief Executive Officer of DTI to attempt to resolve the dispute. Such meeting shall be held not later than ten (10) days after it is requested in writing by either

Party in New York, New York. If such dispute cannot be resolved through such procedures within fifteen (15) days of the date either Party requests a meeting of the officers designated above, then either Party may request an arbitration proceeding as provided in Section 13.2.

13.2 Alternative Dispute Resolution. Any dispute, controversy or claim arising out of or relating to the validity, construction, enforceability or performance of this Agreement, including disputes relating to an alleged breach or to termination of this Agreement and including any claim of inducement by fraud or otherwise, but excluding (i) any dispute, regarding the validity, enforceability, or infringement of any DTI Patent or trademark applicable to a Licensed Product and (ii) any dispute which is expressly prohibited herein from being resolved by this mechanism, shall be settled by binding Alternative Dispute Resolution ("ADR") by Mediation and Arbitration in the manner described below:

13.3 Mediation.

(a) Any such dispute, controversy or claim which would, but for this provision, be submitted to arbitration may upon the mutual written agreement of the Parties, before submission to arbitration, first be mediated through non-binding mediation in accordance with the Model Procedures for the Mediation of Business Disputes promulgated by the Center for Public Resources ("CPR") then in effect, except where those rules conflict with these provisions, in which case these provisions control. The mediation shall be conducted in the United States and shall be attended by a senior executive with authority to resolve the dispute from each of the operating companies that are Parties.

(b) Subject to Section 3.5(c), the mediator shall be appointed from the list of neutrals maintained by CPR.

(c) The Parties shall promptly confer in an effort to select a mediator by mutual agreement. In the absence of such an agreement, the mediator shall be selected from a list generated by CPR with each Party having the right to exercise challenges for cause and two peremptory challenges within 72 hours of receiving the CPR list, subject to Section 3.5(c).

(d) The mediator shall confer with the Parties to design procedures to conclude the mediation within no more than 30 days after initiation. Under no circumstances shall the commencement of arbitration under Section 13.4 be delayed more than 45 days by the mediation process specified herein.

(e) Each Party agrees to toll all applicable statutes of limitation during the mediation process and not to use the period or pendancy of the mediation to disadvantage the other Party procedurally or otherwise. No statements made by either side during the mediation may be used by the other during any subsequent arbitration.

(f) Each Party has the right to pursue provisional relief from any court, such as attachment, preliminary injunction, replevin, etc., to avoid irreparable harm, maintain the status quo, aid the arbitration or preserve the subject matter of the arbitration, even though mediation has not been commenced or completed.

13.4 Arbitration. Except as provided in paragraph (c) below and subject to Section 3.5(c), any dispute, controversy or claim arising out of or relating to the validity, construction, enforceability or performance of this Agreement which is not resolved by mediation, including disputes relating to alleged breach or to termination of this Agreement, other than disputes which are expressly prohibited under Section 13.2 from being resolved by this mechanism, shall be settled by binding Alternative Dispute Resolution ("ADR") in the manner described below:

(a) If a Party intends to begin an ADR to resolve a dispute, such Party shall provide written notice (the “ADR Request") to counsel for the other Party informing such other Party of such intention and the issues to be resolved. From the date of the ADR Request and until such time as any matter has been finally settled by ADR, the running of the time periods contained in Section 11.2 as to which Party must cure a breach of this Agreement shall be suspended as to the subject matter of the dispute.

(b) Within ten (10) business days after the receipt of the ADR Request, the other Party may, by written notice to the counsel for the Party initiating ADR, add additional issues to be resolved.

(c) Notwithstanding anything to the contrary contained herein, any dispute regarding the validity, enforceability, or infringement of any DTI Patent or trademark applicable to a Licensed Product shall be submitted to a court of competent jurisdiction in the country in which such patent or trademark right exists.

13.5 Procedure. The ADR shall be conducted pursuant to JAMS/ENDISPUTE Streamlined Arbitration Rules & Procedures or Comprehensive Arbitration Rules and Procedures (collectively, the “Rules"). Notwithstanding those rules, the following provisions shall apply to the ADR hereunder.

(a) Arbitrator. The arbitration shall be conducted by a single arbitrator knowledgeable about drug development ("the Arbitrator"). The Arbitrator shall be selected from a pool of retired independent federal judges to be presented to the Parties by JAMS/ENDISPUTE. Neither Party shall engage in ex parte contact with the arbitrator without first giving

reasonable advance written notice to the other Party and an opportunity to participate in such contact.

(b) Proceedings. The time periods set forth in the JAMS/ENDISPUTE rules shall be followed, unless a Party can demonstrate to the Arbitrator that the complexity of the issues or other reasons warrant the extension or shortening of one or more of the time tables. In such case, the panel may extend or shorten such time tables, but in no event shall the time tables being extended so that the ADR proceeding extends more than 12 months from its beginning to the Award. In regard to such time tables, that Parties (i) acknowledge that the issues that may arise in any dispute involving this Agreement may involve a number of complex matters and (ii) confirm their intention that each Party will have the opportunity to conduct reasonable discovery with respect to all material issues involved in a dispute within the framework provided above. The Parties will exchange information as required under current Rule 15 of the JAMS/ENDISPUTE Comprehensive Arbitration Rules and Procedures except that (i) in addition to exchanging the names of all experts who may be called to testify or whose report may be introduced at the ADR hearing, the Parties shall also provide, simultaneously with the names of all such experts, a copy of any report(s) (including all backup) prepared by the experts, and (ii) notwithstanding anything in Rule 15 to the contrary, and unless the Parties otherwise agree or the Arbitrator decides upon application of a Party that additional depositions are warranted, each Party shall be entitled to conduct one deposition of each of the opposing Party's experts and, in addition, shall be entitled to conduct two depositions of the opposing Party or of individuals under the control of the opposing Party. The Arbitrator shall not award punitive damages to either Party and the Parties shall be deemed to have waived any right to such damages. The Arbitrator shall, in rendering its decision, apply the substantive law of the State of Delaware, without regard to its conflict of laws provisions, except that the interpretation of and enforcement of this Section shall be governed by the Federal Arbitration Act. The Arbitrator shall apply the Federal Rules of Evidence to the hearing. The proceeding shall take place in the United States. The fees of the Arbitrators and JAMS/ENDISPUTE shall be paid by the losing Party, which shall be designated by the Arbitrator. If the Arbitrator is unable to designate a losing Party, it shall so state and the fees shall be split equally between the Parties.

(c) Award. The Arbitrator is empowered to award any remedy allowed by law, including money damages, prejudgment interest and attorneys' fee, and to grant final, complete, interim, or interlocutory relief, including injunctive relief but excluding punitive damages.

(d) Confidentiality. The ADR proceeding shall be confidential and the Panel shall issue appropriate protective orders to safeguard each Party's confidential Information. Except as required by law, no Party shall make (or instruct the Panel to make) any public announcement with respect to the proceedings or decision of the Panel without prior written consent of each other Party. The existence of any dispute submitted to ADR, and the award, shall be kept in confidence by the Parties and the Panel, except as required in connection with the enforcement of such award or as otherwise required by applicable law or upon the written request to the Arbitrator with notice to the other Party.

14. GENERAL

14.1 Notices. All notices under this Agreement shall be deemed to have been fully given when done in writing and faxed to the other Party, deposited in the United States mail, registered or certified, or sent by express courier (receipt confirmed) and addressed as follows:

To DTI: 2028 Dabney Road, Suite E-17
Richmond, VA 23230-3311
Fax No.: (804) 358-2451

Attention: Chief Executive Officer

With a copy to: Cooley Godward LLP
5 Palo Alto Square
3000 El Camino Real
Palo Alto, CA 94306
Fax No.: (650) 857-0663
Attention: Barbara A. Kosacz, Esq.

To Fujisawa: Fujisawa Healthcare, Inc.
Parkway North Center
Three Parkway North
Deerfield, ILL 60015-2548
Fax No.: (847) 317-7288
Attention: Chief Executive Officer

With a copy to: General Counsel

Either Party may change its address upon written notice to the other Party.

14.2 Retained Rights. Subject to Sections 2.5 and 3.8, nothing in this Agreement shall limit in any respect the right of either Party to conduct research and development and to market products using such Party's technology other than as herein expressly provided. Furthermore, nothing in this Agreement shall be construed to provide any license, implied or express, under any patent controlled by a Party, except to the extent expressly granted with respect to Licensed Products that are the subject of continuing development and commercialization pursuant to this Agreement.

14.3 Consents Not Unreasonably Withheld or Delayed. Whenever provision is made in this Agreement for either Party to secure the consent or approval of the other, that consent or approval shall not unreasonably be withheld or delayed, and whenever in this Agreement provision is made for one Party to object to or disapprove a matter, such objection or disapproval shall not unreasonably be exercised, even when not so expressly stated.

14.4 Force Majeure. Neither Party shall lose any rights hereunder or be liable to the other Party for damages or losses on account of failure of performance by the defaulting Party if the failure is occasioned by government action, war, fire, explosion, flood, strike, lockout, embargo, act of God, failure to supply by Third Party contract manufacturer or any other similar cause beyond the control of the defaulting Party, provided that the Party claiming force majeure has exerted all reasonable efforts to avoid or remedy such force majeure and has given the other Party prompt notice describing such event, the effect thereof and the actions being taken to avoid or remedy such force majeure; provided, however, that in no event shall a Party be required to settle any labor dispute or disturbance.

14.5 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

14.6 No Trademark Rights. Except as otherwise provided herein, no right, express or implied, is granted by the Agreement to use in any manner any name or any trade name or trademark of the other Party in connection with the performance of this Agreement.

14.7 Waiver. Except as specifically provided for herein, the waiver from time to time by either of the Parties of any of their rights or their failure to exercise any remedy shall not operate or be construed as a continuing waiver of same or any other of such Party's rights or remedies provided in this Agreement.

14.8 Independent Contractors. The status of the Parties under this Agreement shall be that of independent contractors. Neither Party shall have the right to enter into any agreements on behalf of the other Party, nor shall it represent to any person that it has any such right or authority. Nothing in this Agreement shall be construed as establishing a partnership, agency or joint venture relationship between the Parties.

14.9 Entire Agreement. This Agreement and the Exhibits attached hereto embodies the entire understanding between the Parties relating to the subject matter hereof and supersedes all prior understandings and agreements, whether written or oral. None of the terms of this Agreement can be amended or waived except by an instrument in writing executed by authorized representatives of each Party.

14.10 Governing Law. This Agreement shall be governed by the laws of the State of Delaware, without regard to conflict of laws principles.

14.11 Severability. Any of the provisions of this Agreement which are determined to be invalid or unenforceable in any jurisdiction shall be ineffective to the extent of such invalidity or unenforceability in such jurisdiction, without rendering invalid or unenforceable the remaining provisions hereof or affecting the validity or enforceability of any of the terms of this Agreement in any other jurisdiction.

14.12 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement in duplicate originals by their duly authorized officers or representatives.

Discovery Therapeutics, Inc.	**Fujisawa Healthcare, Inc.**
By: /s/ Donald A. McAfee	By: /s/ Noboru Maeda
----------	----------
Name: Donald A. McAfee	Name: Noboru Maeda
Title: President and	Title: Chief Executive Officer
Chief Executive Officer	

EXHIBIT A

COMPOUND*

EXHIBIT B

DEVELOPMENT PLAN

*

EXHIBIT C

DEVELOPMENT EXPENSES

SUMMARY OF DTI EXPENDITURES JANUARY - JULY, 1999

Drug Substance Manufacturing (*) *

Drug Substance Characterization (*) *

Drug Product Manufacturing (PDC) *

Regulatory (Quintiles) *

Plasma Assay (PPD) *

Toxicology (Covance) *

DTI Internal Effort 1Q99 *

DTI Internal Effort 2Q99 *

DTI Internal Effort July *

Grand Total Expenditures Due in accordance with Section 5.2 of the Development and License Agreement *

EXHIBIT D

[Intentionally omitted]

EXHIBIT E

PHASE I TRIAL BUDGET

Activity Vendor Cost ---------- ---------- ----------

Clinical Site Expenses * *

Data Management * *

Randomization * *

Medical Monitor * *

Plasma Assay * *

Bulk Drug Stability * *

Drug Product Stability * *

Drug Product Storage * *

Regulatory * *

DTI Internal FTE and Misc. *

DTI Travel to Clinical Site * *

Total *

Estimated Amount due from Fujisawa per Section 5.2 of Development and License Agreement *

Assumptions: % of total supporting Licensed Products studies *

EXHIBIT F

U.S. PATENT NO: 5,310,731

Issued May 10, 1994

（資料2）

AGREEMENT
ON
HANDLING OF INDUSTRIAL PROPERTY RIGHTS

THIS AGREEMENT made and entered into this 1 day of January， 2007 by and between ******* Technology Corp. （hereinafter "*******"） and ******* Design France S.A.S (hereinafter the "Subsidiary") with regard to applications for patent, utility model and design patent concerning inventions made by employees of the Subsidiary and handling of patents, utility models and design patents issuing thereon as well as administration and management of such industrial property rights.

WITNESSETH:

In consideration of the promises and covenants set forth below and of other valuable considerations, the parties hereby agree as follows:

ARTICLE 1 – DEFINITIONS

1.1 The term "Invention" shall mean any idea, invention, process, apparatus and/or design of a useful article made, discovered, developed or conceived as to which ******* and/or the Subsidiary shall obtain or otherwise be entitled to receive from Inventor employees, rights to file a Patent Application and/or proprietary rights to the Patent issuing thereon.

1.2 The term "Inventor" shall mean any person who have made, discovered, developed or conceived any idea, invention, process, apparatus and/or design of a useful article.

1.3 The term "Patent Application" shall mean any application for patent, utility model and/or design patent.

1.4 The term "Patent" shall mean the grant of a property right to the inventor, who is/are employee(s) of Subsidiary, issued by patent granting authority of any country (e.g. the National Institute of Industrial Property (INPI)).

1.5 The term "Technical Assistance" shall mean transfer of any technical information,

technical guidance or technical training.

1.6 The term "Subcontract of Work" shall mean any work such as research and development, designing, manufacture, engineering performed by a party as a subcontractor for another party.

1.7 The term "Home Country" shall mean the country in which the principal office of the Subsidiary is located.

1.8 The term "Other Countries" shall mean any countries other than the Home Country.

ARTICLE 2 – PARTY TO OWN PATENT

2.1 Any Invention made or developed solely by an employee of the Subsidiary and not jointly with any employee of ******* shall be handled as follows:

2.1.1 Any Patent Application in the Home Country shall be filed solely by the Subsidiary, and any Patent issuing thereon shall be owned solely by the Subsidiary.

2.1.2 Which of the parties will file any Patent Application in any of the Other Countries and which of parties will own any Patent issuing thereon shall be discussed in good faith and mutually agreed by ******* and the Subsidiary prior to such Patent Application.

2.1.3 Notwithstanding the preceding paragraphs 2.1.1 and 2.1.2, *******, after providing the Subsidiary with appropriate compensation, may solely file any Patent Application worldwide and any Patent issuing thereon can be owned solely by *******.

2.2 Notwithstanding the provisions of paragraphs 2.1, any Invention made or developed solely by any employee of the Subsidiary and not jointly with any employee of ******* in connection with any business pertaining to any Technical Assistance provided by ******* to the Subsidiary or any Subcontract of Work provided by the Subsidiary for ******* shall be handled as follows:

2.2.1 Any Patent Application in the Home Country shall be filed solely by

*******, and any Patent issuing thereon shall be owned solely by *******.

2.2.2 Any Patent Application in any of the Other Countries shall be filed solely by *******, and any Patent issuing thereon shall be owned solely by *******.

2.3 Any invention made or developed by any employee of the Subsidiary jointly with any employee of ******* in connection with any business pertaining to any Technical Assistance provided from ******* to the Subsidiary or any Subcontract of Work provided by the Subsidiary for ******* shall be handled as follows:

2.3.1 Any Patent Application in the Home Country shall be filed solely by *******, and any Patent issuing thereon shall be owned solely by *******.

2.3.2 Any Patent Application in any of the Other Countries shall be filed solely by *******, and any Patent issuing thereon shall be owned solely by *******.

2.4 Any Invention made or developed solely by an employee of the Subsidiary and not jointly with any employee of ******* shall be handled as follows:

2.4.1 Any Patent Application in the Home Country shall be filed solely by the Subsidiary, and any Patent issuing thereon shall be owned solely by the Subsidiary.

2.4.2 Which of the parties will file any Patent Application in any of the Other Countries and which of parties will own any Patent issuing thereon shall be discussed in good faith and mutually agreed by ******* and the Subsidiary prior to such Patent Application.

2.4.3 Notwithstanding the preceding paragraphs 2.3.1 and 2.3.2, *******, after providing the Subsidiary with appropriate compensation, may solely file any Patent Application worldwide and any Patent issuing thereon can be owned solely by *******.

2.5 Any invention made or developed by any employee of the Subsidiary jointly with any

employee of ******* which is not relating to Technical Assistance provided by ******* to the Subsidiary nor any Subcontract of Work provided by the Subsidiary for ******* shall be handled as follows:

2.5.1 Any Patent Application in the Home Country shall be filed jointly by parties, and any Patent issuing thereon shall be owned jointly by the parties.

2.5.2 Which of the parties will file any Patent Application in any of the Other Countries and which of parties will own any Patent issuing thereon shall be discussed in good faith and mutually agreed by ******* and the Subsidiary prior to such Patent Application.

2.5.3 Notwithstanding the preceding paragraphs 2.4.1 and 2.4.2, *******, after providing the Subsidiary with appropriate compensation, may solely file any Patent Application worldwide and any Patent issuing thereon can be owned solely by *******.

ARTICLE 3 – PROCEDURES FOR PATENT PROSECUTION AND MANAGEMENT

3.1 Notwithstanding the provisions of paragraphs 2.1.3, 2.2.1 and 2.3.1, the Subsidiary will undertake and be responsible for the following: the determination as to whether to file a Patent Application; prosecution of a Patent; and maintenance and management of a Patent and other related procedures insofar as they relate to any Patent in the Home Country.

3.2 Regardless of whether or not it is based on a Patent Application in the Home Country, ******* will undertake and be responsible for the following: the determination as to whether to file a Patent Application; prosecution of a Patent; and maintenance and management of a Patent and other related procedures insofar as they relate to any Patent in any of the Other Countries.

3.3 The Subsidiary shall fully cooperate with ******* with respect to the documentation of title transfer and other necessary matters concerning the Patent Application, prosecution of a Patent and other related procedures to be undertaken by ******* under paragraph 3.2 above.

3.4 The provisions of this Article shall apply mutatis mutandis to any Patent Application, prosecution of a Patent, maintenance and management of a Patent and other related procedures to be undertaken in any of the Other Countries pursuant to the result of negotiation between the parties under paragraph 2.1.2, depending on which of the parties hereto shall, upon negotiation, be designated to be the party to undertake and be responsible for a Patent Application and to own the Patent issuing thereon.

3.5 The Subsidiary shall undertake and be responsible for policing and enforcement of any Patent it owns; provided, however, that in the event the Subsidiary intends to send a letter of warning, notice of its Patents or file an infringement suit against any suspect infringer, it shall first notify ******* in writing of such intent and shall not proceed with such action without the prior written consent of *******.

ARTICLE 4 – BEARING OF EXPENSES

4.1 Any costs and expenses of a Patent Application, prosecution, maintenance and management of a Patent and other related procedures to be undertaken in the Home Country shall be for the account of the Subsidiary, provided, however, that in the event ******* owns the Patent issuing thereon in Home Country under paragraphs 2.1.3, 2.2.1 and 2.3.1 or ******* is, upon negotiation between the parties, designated as the party to undertake a Patent Application and to own the Patent issuing thereon in Home Country pursuant to the result of negotiation under paragraph 2.1.2, ******* shall bear any such cost and expenses.

4.2 Any costs and expenses of Patent Application, prosecution of Patent, maintenance and management of Patent and other related procedures to be undertaken in any of the Other Countries shall be for the account of *******; provided, however, that in the event the Subsidiary is, upon negotiation between the parties, designated as the party to undertake a Patent Application and to own the Patent issuing thereon in any of the Other Countries pursuant to the result of negotiation under paragraph 2.1.2, the Subsidiary shall bear any such costs and expenses.

4.3 The Subsidiary shall request ******* a budget for the costs and expenses under Article 4, excluding the costs and expenses which ******* is not obligated to pay, prior to the each half year period (i.e. prior to April and October) and obtain an approval from *******.

4.4 Subsidiary shall manage the costs and expenses within the budget approved by ******* under 4.3.1 above. If Subsidiary foreseen that actual expense and costs would exceed the budget, Subsidiary shall consult to ******* about the issue as soon as Subsidiary find the fact.

ARTICLE 5 – GRANT OF PATENT LICENSE

5.1 ******* shall have a royalty-free license to use any Patent owned by the Subsidiary in the Home Country.

5.2 The Subsidiary shall have a royalty-free license to use any Patent owned by ******* in Home Country and any of the Other Countries.

5.3 Notwithstanding the provisions of paragraphs 5.1 and 5.2, use by ******* or the Subsidiary, as the case may be, of any Patent issuing under paragraph 2.1.2, in any of the other Countries shall be negotiated in good faith between the parties.

ARTICLE 6 – LICENSING TO THIRD PARTIES

6.1 In the event the Subsidiary intends to grant a license to any third party under any Patent owned by the Subsidiary in the Home Country, the Subsidiary will first consult with ******* thereon.

6.2 In the event any Patent owned by the Subsidiary in the Home Country is reciprocally requested by any third party to be included in subject patents under a cross-licensing agreement between ******* and such third party, ******* shall have the right to license such Patent to such third party, provided that license under such third party's subject patents will be granted to the Subsidiary under the cross-licensing agreement.

6.3 Licensing to any third party of any Patent referred to in paragraph 2.1.2 which is owned by ******* or the Subsidiary, as the case may be, in any of the other Countries shall be first negotiated in good faith between the parties hereto. Notwithstanding the preceding sentence, in the event any Patent owned by the Subsidiary in the Other Country is reciprocally requested by any third party to be included in subject patents under a cross-licensing agreement between ******* and such third party, ******* shall have the right to license such Patent to such third party, provided that license

under such third party's subject patents will be granted to the Subsidiary under the cross-licensing agreement.

ARTICLE 7 – ALLOCATION OF LICENSING PROCEEDS

Allocation of any proceeds arising from licensing to any third party of any Patent owned by ******* or the Subsidiary, as the case may be, covered by this Agreement shall be determined by good faith negotiation between the parties hereto, taking into account the respective parties degree of contribution to the subject Invention in order for the allocation to reflect properly the degree of contribution.

ARTICLE 8 – REMUNERATION TO INVENTORS

8.1 The Subsidiary will remunerate the Inventor of a Patent owned solely by the Subsidiary in the Home Country under paragraph 2.1.1 for the patented Invention in accordance with the Subsidiary's internal rules concerning Inventor remuneration.

8.2 The Subsidiary will remunerate the Inventor of a Patent owned solely by ******* in the Home Country under paragraphs 2.1.3 and 2.2.1 for the patented Invention in accordance with the Subsidiary's internal rules concerning Inventor remuneration. ******* shall bear any such remuneration costs and expenses.

8.3 In the event any Patent referred to in the preceding paragraph issues on an Invention jointly made or developed between any of *******'s employees and any of the Subsidiary's employees under paragraph 2.3.1, the parties hereto will each remunerate their respective employees for such patented Invention in accordance with their respective internal Inventor remuneration rules. ******* shall bear any such remuneration costs and expenses.

ARTICLE 9 – PATENT MANAGEMENT

9.1 The Subsidiary shall, for the purpose of fully effectuating the matters set forth in this Agreement, maintain an office of Patent management or a patent committee and designate a person responsible for the business of such management.

9.2 For the purpose of fully effectuating the management system set out in the preceding paragraph, the Subsidiary shall establish and implement corporate rules concerning, inter alia the following matters.

9.2.1 administration regarding inventorship, including, inter alia, transfer of title to Inventions, recording and reporting;

9.2.2 lodging of report on Inventions;

9.2.3 assessment of Inventions;

9.2.4 determination as to whether to file a Patent Application;

9.2.5 procedures for prosecution, acquisition, maintenance and management of Patents; and

9.2.6 Inventor remunerations, as may be necessary.

ARTICLE 10 – REPORTS, NOTICES, etc

10.1 Whenever filing of a Patent Application in the Home Country under paragraph 3.1 is completed, the Subsidiary shall, without delay after the filing of each Patent Application, transmit to ******* a full set of copies of the Patent Application specification, drawings and other filling documents thereof.

10.2 In the event ******* determines not to file a particular Patent Application of an Invention in one or more of the Other Countries pursuant to paragraph 3.2, it shall without delay notice the Subsidiary of such determination.

10.3 ******* or the Subsidiary, as the case may be, shall without delay notify the other party when it shall have obtained any Patent issuing on a Patent Application under the provisions of Article 3.

10.4 The Subsidiary, as the case may be, shall first notify ******* in writing when it intends to withdraw or abandon any Invention, Patent Application or Patent under the provisions of Article 3, and shall not withdraw or abandon any such Invention, Patent Application or Patent without the prior written consent of the other party.

ARTICLE 11 – TERM

The term of this Agreement shall be for a period of two (2) years from the date of execution hereof; provided, however, that in the absence of any notice of refusal to renew from either of the parties to the other party within one (1) month prior to the expiration of the term or any renewed term thereafter, as the case may be, this Agreement will automatically be renewed for successive periods of one (1) year each upon the same terms and conditions.

ARTICLE 12 – RELATIONS TO PREVIOUS AGREEMENTS

The parties hereto agree that any previous promises. covenants or agreements between the parties hereto in respect of Patents (hereinafter "Previous Agreements") are hereby superseded as of the date of execution hereof .

ARTICLE 13 – GOOD FAITH NEGOTIATION

The parties hereto shall in good faith negotiate to solve any differences or discrepancies arising from or in connection with interpretation or performance hereof and any matters not specifically set forth herein.

ARTICLE 14 – EXPORT CONTROL

14.1 Each party hereto represents and warrants that it shall not use any products, software and/or technology provided by the other, or any other products, software and/or technology manufactured or developed by using them (collectively hereinafter called, "Products"), for the purposes of disturbing international peace and security, including (i) the design, development, production, stockpiling or use of weapons of mass destruction such as nuclear, chemical or biological weapons or missiles, (ii) the other military activities, or (iii) any use supporting these activities.

14.2 Each party also represents and warrants that it shall not sell, export, dispose of, license, rent, transfer, disclose or otherwise provide the Products to any third party, whether

directly or indirectly, with knowledge or reason to know that the third party or any other party will engage in the activities described above.

14.3 Furthermore, each party represents and warrants that it shall not directly or indirectly, export, re-export, transship or otherwise transfer the Products in violation of any applicable export control laws or regulations promulgated and administered by the governments of the countries asserting jurisdiction over the parties or their transactions.

ARTICLE 15 – SEVERABILITY

If any provision or provisions of this Agreement shall be held to be invalid, illegal, unenforceable or in conflict with the law of any jurisdiction, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.

ARTICLE 16 – GOVERNING LAW

This Agreement shall be governed by and construed in accordance with the laws of Japan.

IN WITNESS WHEREOF, the parties hereto have as of the year and date first written above executed this Agreement in duplicate, one copy of which shall be retained by each party.

(資料3)

********* TECHNOLOGY AMERICA, INC. PATENT ADMINISTRATION AND AWARD PROCEDURES**

1.0 PURPOSE

1.1. The purpose of these procedures is to establish methods to promote, develop, submit, and protect ******* Technology America, Inc.'s ("RTA" or the "Company") inventions that are patentable through the U.S. Patent and Trademark Office (the "USPTO").

i) **2.0 SCOPE**

2.1. These procedures describe the administration of patents and patent awards at RTA. All regular full-time and regular part-time employees are eligible for the benefits described in this procedure.

2.2. The intellectual property ownership rights of the Company and each RTA employee are governed by the terms set forth in the Intellectual Property section of the RTA Employment Agreement.

ii) **3.0 GENERAL PATENT INFORMATION**

iii) 3.1. Patent Definition

Patents are granted by the USPTO. Patents give their owners the right to exclude others for a predetermined period that starts with the issue date and expires 20 years after the date of filing the patent application. A patent must meet three standards:

1. Useful: The invention must perform some function or do something.
2. Novel: The invention must be unique.
3. Unobvious: The invention cannot be so obvious that its discovery would be apparent to a person with ordinary skill in the applicable field of study.

4.0 PATENT REVIEW PROCEDURES - Refer to Figure 1 for Patent Review Flow.

iv) 4.1. Technical Merit Evaluation

4.1.1. The first step in the patent review process is a determination of Technical Merit. In this step the Patent Review Committee (the "PRC") members will do an initial review of the invention and documentation as follows:

4.1.1.1 The inventor (an RTA employees) must complete the Technical Merit Disclosure form (Attachment 1). This form briefly outlines the invention.

4.1.1.2 The inventor must complete the Prior Art Search form (Attachment 2). This form outlines the patent searches performed to identify potential prior art related to the invention.

4.1.1.3 A patent search can be done by using the USPTO database or an approved patent search firm, such as NERAC or the local patent attorneys (a preliminary patent search). Any search firms with the exception of the USPTO are required to have a signed Non-Disclosure Form with RTA or attorney-client privilege with RTA to protect the Company's confidential information.

4.1.1.4 The completed forms are to be submitted to the PRC Chairman or his/her designate. The PRC may consider a submission before all required signatures are obtained on the above-referenced forms, but the signatures must be obtained before approval of the disclosure by the committee.

4.1.1.5 If the PRC Chairman determines that a disclosure is suitable for committee review, the inventor will be asked to attend a PRC meeting to present the disclosure and answer any related questions. The PRC Chairman may schedule regular (e.g., monthly) meetings or it may call a special meeting to consider a disclosure.

4.1.2. After an inventor's presentation, the PRC will vote on the disclosure. A simple majority of committee members at the meeting is required for the disclosure to be approved. If the PRC approves the disclosure, it will go on to the next step.

4.1.3. If the disclosure is not approved, the PRC may request that additional information be supplied or a more complete patent search be completed. If the PRC determines not to pursue the invention further, the PRC will inform the inventor(s).

4.1.4. The PRC Chairman will notify an inventor of the results of the PRC's vote on the inventor's disclosure using a suitable means such as e-mail.

v) 4.2. Documentation, Verification and Preparation

4.2.1. The Documentation, Verification, and Preparation step is the process of putting together the documentation that will go to the patent attorney to begin the filing process. After a disclosure has been approved by the PRC, the inventor must prepare the following information:

1) Abstract : A quick review of the invention.

2) Diagrams: Any diagrams that need to be included with the patent. These will typically make the foundation of the patent application in so far as the explanation of these diagrams will be the patent.

3) Background of the Invention: Describes the problem solved by the invention, as well as past solutions.

4) Brief Description of Drawings: A list of the drawings.

5) Description of the Preferred Embodiments: A detailed description of the invention and reasons why it is an improvement over any past solution. This typically is in the form of a description of the diagrams.

6) Claims: Describes the invention in the broadest terms reasonably possible. For example, if the invention was an IC, but the concept would also work with discrete ICs, the claims should be broad enough to include discrete IC's.

4.2.2. Once the documentation is complete, the inventor should contact the PRC Chairman to arrange a review. If the PRC Chairman, in consultation with legal

counsel, approves the documentation, it will be forwarded to a patent attorney, and the first award for completion of Technical Merit and Documentation shall be granted.

vi) 4.3. Application Preparation Step

4.3.1. During the application preparation, the patent attorney will prepare an official application based on the information provided by the inventor. This will typically be an iterative process between the inventor and the attorney.

4.3.2. The PRC Chairman will monitor the status of the application and will discuss issues with the inventor and attorney when needed. There may be deadlines that the inventor will have to meet in order to avoid delay fees and possible abandonment of the application.

4.3.3. Once this process is complete, the patent application will be ready for submission to the USPTO. The patent attorney will prepare all filing materials and final approval for filing will be made by the PRC Chairman.

4.3.4. Upon submission of the patent application to the patent office, the second award (for patent filing) shall be granted.

vii) 4.4. Patent Office Review

4.4.1. Once the patent application has been submitted to the USPTO, it will be reviewed by a patent examiner. The inventor may have to answer questions and provide clarifications during the review (typically referred to as Office Actions). The patent attorney will send all correspondence to the PRC Chairman.

4.4.2. The PRC Chairman will review the examiner requests and discuss these with the inventor and patent attorney as needed. There may be deadlines that the inventor will have to meet in order to avoid delay fees and possible abandonment of the application.

viii) 4.5. Patent Issued

4.5.1. The original letters patent and notification will be sent to the PRC Chairman.

4.5.2. The final patent award (for issuance) shall be granted.

ix) **5.0. PATENT AWARDS**

5.1. RTA's patent awards are as listed below. The awards are offered to inventors that are currently employed by RTA at the time that the award is granted by RTA. Expatriates who are no longer employed by RTA but are employed by another ******* company at the time of the award is granted will be ineligible to receive an award.

5.2. Other recognition awards such as plaques, certificates, etc. may be given to inventors at the discretion of the PRC and with the approval of Management. The awards stated and provided under these procedures are the sole consideration to be granted to employee/inventors and are in lieu of any claim for compensation for inventions under state or federal laws of the United States or of any other nation, including Japan. The Company may, in its sole discretion, provide additional recognition under circumstances that the company deems to be extraordinary.

5.3. The PRC and RTA Management retain the discretion to amend at any time the monetary values and award terms/criteria related to the RTA patents and the specific amount granted to any inventor hereunder.

x) 5.4. Technical Merit/Documentation Approved

PRC approves Technical Merit, and the documentation package is submitted to the attorneys to begin the application process. The PRC Chairman authorizes the patent attorney to begin drafting the application.

$500 per inventor, maximum of $1,500 per disclosure

xi) 5.5. Application Filed

The application is filed with the USPTO and RTA has received written confirmation from the patent attorney signifying this.

$750 per inventor, maximum of $2,250 per application

xii) 5.6. Patent Issued

The patent is issued by the USPTO and RTA has received written confirmation and the official letters patent from the patent attorney signifying this.

$1000 per inventor, maximum of $3,000 per patent

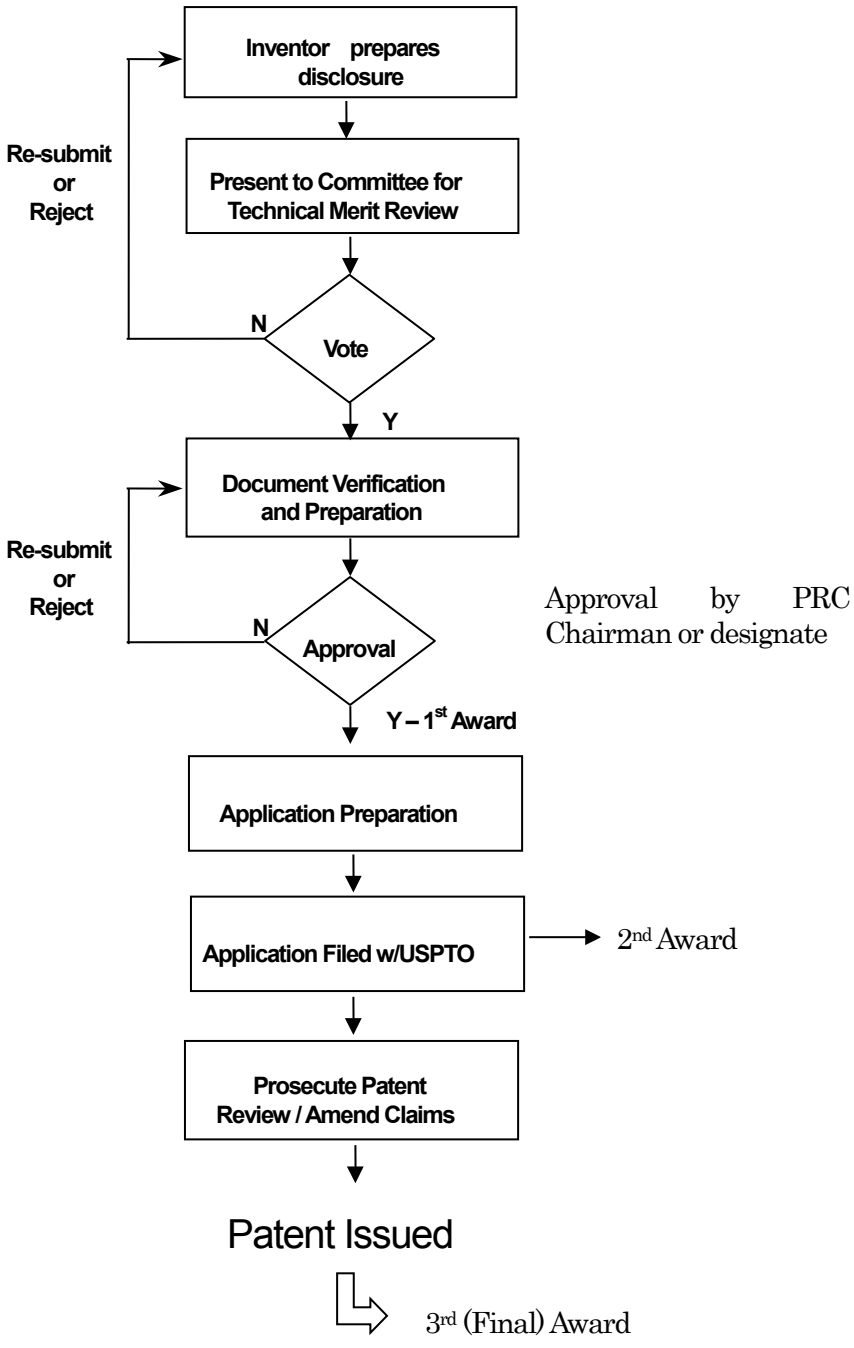
xiii) **6.0 Foreign Patent Application (outside of US) – To be determined in consultation with**

xiv) **IPG RT.**

xv) **7.0 LAB NOTEBOOKS AND DOCUMENTATION**

Lab notebooks are notations or written procedures documenting those steps taken to solve or investigate an idea. These notebooks are usually kept by engineers or technicians to record daily activities. RTA strongly recommends employees to maintain a lab notebook. Lab notebooks can serve as legal proof in patent proceedings as evidence of 'first to conceive' the invention. The lab notebook should be reviewed, signed, and dated periodically by a third party, such as the inventor's manager. Ideas may be submitted for patent consideration without a lab notebook and are not necessary to receive a patent.

Figure 1 - Patent Procedure Flow



Attachment # 1

TECHNICAL MERIT DISCLOSURE FORM

Date Received: _____
Disclosure Docket #: _____
Department: _____

---

1). Title of Invention:

Title goes here.

2). Inventor(s):

Inventor	Telephone	Supervisor
Name 1	800.555.1212	Supervisor Name
Name 2	800.555.1212	

xvi)

3). The Problem:

Change this text

4). Description of the Solution:

Change this text

a) How is the invention novel and unique?

Change this text

b) How is the invention not obvious?

Change this text

c) Is the Patent Search thorough and complete? (Form completed?)

Change this text

5). Business Considerations

a) How does the invention apply to RTA business, i.e., what are its practical aspects?

Change this text

b) Has the invention been described (e.g., in papers, presentations, specifications) to persons other than RTA / RTC employees? ____Yes ____No

If **YES**, then:

i) When was the invention described? _____

ii) Who was the invention described to? _____

iii) Was there a non-disclosure agreement when described? ___Yes ___No

Attachment # 1(cont.)

c) Has the invention been offered for sale (either directly or with a RTA / RTC product that would include the invention) to potential customers? ___Yes ___ No

If **YES**, then:

xvii)When did the offer for sale occur?_____

xviii) Was the invention complete when the offer was made? ___Yes ___No
(e.g., was or could the invention be built, simulated, known to work, etc.)

iii) Did the offer occur/originate in the U.S.? ___Yes ___No
(where:_____

6). Inventor(s) Signature:

(1)_____

(2)_____

(3)_____

First Name/M.I./Last Name Home Address Date

7). Witnesses:

Sign if read and understood. One must be the inventor's manager.

(1)_____

(2)_____

First Name/M.I./Last Name Home Address Date

Attachment # 2

PRIOR ART SEARCH

Disclosure Date: _____
Disclosure Docket #: _____

After performing the search for prior art, inventor does not feel prior art was discovered.
Inventor's Signature: _____
_____ Date:_____
Inventor's Signature: _____
_____ Date:_____
Inventor's Signature: _____
_____ Date:_____
After reviewing with the inventor, the manager does not feel prior art was discovered.
Manager's Signature: _____
_____ Date:_____

Was your search constrained by YEARS? _____ If so, to what years?_____

KEYWORD SEARCH / PRIOR ART SEARCH SUMMARY #1[(1)]:

_____

Patents found with key words: _____
Abstracts reviewed: _____
Full patents reviewed: _____

KEYWORD SEARCH / PRIOR ART SEARCH SUMMARY #2[(1)]:

_____

Patents found with key words: _____
Abstracts reviewed: _____
Full patents reviewed: _____

KEYWORD SEARCH / PRIOR ART SEARCH SUMMARY #3[(1)]:

_____

Patents found with key words: _____
Abstracts reviewed: _____
Full patents reviewed: _____

KEYWORD SEARCH / PRIOR ART SEARCH SUMMARY #4[1]:

Patents found with key words: _____
Abstracts reviewed: _____
Full patents reviewed: _____

Note 1 : Use format based on type of search used. Possible examples could be:
pencil IN TITLE and lead IN ALL_FIELDS and color IN ABSTRACT
pencil AND lead AND color

Attachment # 2 (cont.)

Please list all abstracts reviewed:

Patent # Author
Date

Please briefly summarize the patents found by the prior art search which are most closely related to your disclosure. Also, please comment how your disclosure differs from these patents.

Rev.	Summary of Changes	xix) Author and Date
A	Original Issue Replaces Mitsubishi Ver. E procedure	D.Zaterka 4/3/03
B	Changes to patent committee section responsibilities, format changes, elimination of some items from patent definition section. Replaced references to DEC-E with ******* or RTA.	D.Zaterka 7/23/03
C	Committee Chairman & Legal modified Ver. G Final Ver 1.0	11/17/03
D	Committee Chairman modified ver2.0	02/25/04