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Importance of intellectual property generated by biomedical research at universities and academic hospitals

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Dear Dr. Heger,

Reviewers have now commented on your paper. You will see that they are advising that you revise your manuscript. If you are prepared to undertake the work required, I would be pleased to reconsider my decision.

For your guidance, reviewers' comments are appended below.

If you decide to revise the work, please submit a list of changes or a rebuttal against each point which is being raised when you resubmit your work.

Your revision is due by Dec 21, 2016.

To submit a revision, go to http://jctres.edmgr.com/ and log in as an Author. You will see a menu item call Submission Needing Revision. You will find your submission record there.

Yours sincerely

Yao Liu
Editorial Board Member
Journal of Clinical and Translational Research

Reviewers' comments:

Reviewer #1: This is a well-written paper on a very interesting topic. I applaud the authors' efforts to bring the matter of IP so insightful to the reader. Please find below some general comments and suggestions and some comments and suggestions to specific

sections/sentences in the manuscript.

General comments:

o Time line or diagram of process (from invention, to patent, publication, CE/FDA, and commercialization/licensing) would be nice, perhaps for different continents if it differs significantly.

o Section '2. The role of the technology transfer office' is quite detailed and could be shortened somewhat.

o Section '3. Academic researchers and IP: the pros and cons' could be moved up, directly after the Background, for nicer flow in the manuscript.

o An additional topic which may be added is the non-disclosure agreement (NDA) as this forms an important part of protecting intellectual property prior to the filing or acceptance of a patent application. It is important that researchers are aware of the strengths and weaknesses of NDAs.

o It may be very illustrative and educative to discuss a specific invention (specific solution for a specific problem, as discovered in the lab) and the claims that describe the invention (as broad as possible, taking into account the boundaries of the prior art), showing the potential value of a patented invention beyond its initially intended application (e.g. a preparation method).

o I would like to see more emphasis on the difference between the use and impact of patents in the pharmaceutical industry (often only one patent associated with a product, or patents protecting production methods) and the medical device industry (often multiple patents associated with one product). In the medical device industry, many unpatented, but published inventions made it to commercialized products, while this is much more difficult in pharmaceutical research/industry.

o The current emphasis is too strong on the perception that unpatented inventions do not make it to the bedside. Many unpatented, but published inventions made it to commercialized products. These inventions, however, do not give a compeditive edge. The main point of IP rights is that it ensures that the research investment put into the further development of the invention (clinical research, FDA approval, product development) is benefitting patent-holding party only, and not its competitors (who could copy the solution for a fraction of the costs once the product makes it to the market, if not IP-protected). Nonetheless, other aspects, like production methods, software and algorithms (kept as trade secret), and design can still provide a sufficient competitive advantage for commercialization.

o I would like to see more emphasis on that academic institutes can use an IP-oriented business model to generate income and facilitate further research. The problem for academic institutes is that holding IP rights is expensive (I believe 50k over 20 years) and may require laborious and costly legal support, which is often unaffordable for non-commercial institutes. Expensive clinical studies are not required for applying for IP rights to an invention, only for FDA approval. Hence, academic parties should try to file potentially commercializable IP before publication, to either start up a spin-off company to commercialize the invention, or to sell or licence the IP to a commercializing party, giving this party a competitive advantage. Most companies with a large researcch(&development) department often make a large part of their profit off of 'adjacency' IP that has been created in the process, which the company does not commercialize itself, but licences to another. To facilitate this, often an organ is in place which checks all outgoing publications for potentially protectable IP, like a KTO. This is a business model which should be adopted by academic institutes as well, as they can be considered large researcch(&development) departments. Turning inventions, before publishing in scientific journals, into IP rights could form a major stream of income for these institutes. However, in order to achieve this, academic institutes should invest more in IP and staff to ensure the valorization and protection of inventions and IP, such as knowledge transfer offices/ innovations departments and legal support.

Some specific comments on the section '1. From invention to patent filing':

"Important to note is that patents allow their owners to block others from using the invention without permission, but do not automatically provide them with the right to sell products that are based on their invention, as these products may fall under the claims of other issued patents." Patents allow their owners to block others from commercializing the invention without permission; academic research building on the patented work may still be done and published.

"A special type of invention that is frequently made at university hospitals and can also be patented is a not yet described use of an existing drug, even if the particular compound is already patented itself. Such a "second medical use patent" can be particularly attractive to the company already selling the drug." I may be mistaken, but I believe one cannot patent the use or application of an invention (i.e., one can patent a drug, but not a treatment). When an invention described in a patent needs to be tailored to fit a new application, then these specific features can be patented (if novel and inventive).

"Non-obviousness: an invention may be novel, but not considered to contain an inventive step." An important issue here is that the invention should not be constructed of a combination of knowns (e.g., combining the air-filled balls idea disclosed in the Donald Duck with knowledge from a document disclosing the use of helium to make a zeppelin fly, to salvage sunken ships faster).

"Industrial applicability: all inventions that can be industrially applied, that is they have some economic value, are eligible for patenting." Important here is that it is also beneficial over other known inventions. Otherwise, the patent has little value as competitors can easily

work around it.

"A patent claiming for instance a machine for perpetual motion, even if it could be proven to work, would not be automatically granted a patent as it does not (of itself) have an industrial application." Perhaps not the best example as this machine will most likely find industrial application. Maybe a better example is inventing a new type of production system and method that has no potential of becoming as efficient as currently known systems and methods.

"And even if someone did manufacture a time machine, it would lack novelty because H. G. Wells and many others already described it." Wells may have described it, but not in an enabling fashion. In a patent, the invented system, drug, and/or method should be described in an enabling way, so that others can build on to it. Hence, when someone would really invent a time machine, probably many patents will be filed in the process. Interestingly, whether the machine works or not, that is of less interest to a patent officer. However, when an invention is deemed to fail, or has no benefits over other known solutions, then it is very costly to maintain this IP. An examplary field where this may be apperant is cryonics.

"If time is not of the essence, there are two good reasons for postponing the filing of the application." The reason for postponing patenting an invention is that a patent is only valid for 20 years, so if one can wait, he should wait until he is ready to release the product to the market (or needs to make any of his progress public, such as for FDA-approval). Besides that, indeed, one can also add more data in the first year. This is mainly to further support the claims (claims can only be added or modified based on the text in the initial application I believe). By waiting with patenting, one also becomes more assured that the money spent on the patent will be worth it as he has more data supporting the use and benefits of the invention (or it prevents investing in a patent on an invention that doesn't work).

Reviewer #2:
In my discussions with academic investigators, I have frequently encountered a fundamental lack of knowledge and understanding what IP and patents are, why they need protection and how that can be achieved. Therefore, I find the present manuscript very useful. Nonetheless, I have a few comments for further improvement.
Main suggestions
1. The introduction section follows a logic I share only partly. In most developed countries, the main role of universities and academic hospitals (other than direct patient care) is training of the next generation and fundamental research. This can lead to discoveries that may lead to commercially successful and clinically useful products. In most countries, developing such products is explicitly not the primary task of academic institutions. That is why academic institutions increasingly consider transferring related IP to spin-off companies or immediately license it to commercial entities. Wouldn't that be an easier (and shorter) story line to set the scene for the subsequent sections?
2. I'm not sure that it is warranted to talk only about spin-off companies and similar semi-internal routes for development to commercialization; in many cases, the IP is licensed to a third party for that.
3. Section 1.1: In the Introduction you mention KTOs and Innovation Departments side by side, but in the rest of the manuscript you only talk about KTOs. Either both should be mentioned consistently or an overarching term should be used in the Introduction that can consistently be reused in the rest of the manuscript, for instance Technology Transfer Office (TTO).
4. P. 12, end of 2nd paragraph: Under many jurisdictions, the initial rights to IP developed by an employee belong (at least in part) to his/her institution, hence the strong role of the institutional TTO in the process. However, if the TTO decides not to file, typically all rights are returned to the inventors. I am aware of examples, where the inventors then have filed at their own cost and risk - and been successful (although in a minority of cases). This scenario may be worth mentioning.
5. The authors repeatedly (and rightly so) mention that filing patents per se can be costly, at least by academic standards. It may be worthwhile to give readers a rough idea what these costs are.
6. I found the description of the role of the TTO in section 2 correct but depicted a little too rosy. Many researchers consider TTOs to be a pain in the neck (see doi 10.1007/s00210-015-1106-5). Articles such as this may help researchers understanding why TTOs can be difficult to deal with but I recommend actively addressing this issue.
7. Section 3, 1st paragraph: While I share the impression that basic researchers may think less about IP, the authors may wish to add that basic research may similarly lead to IP as translational and clinical research. The development of PCR would be a fine example.
8. Section 3.2: The authors may wish to mention an ancillary benefit of filing. Several academic institutions, for instance for promotion or tenure decision, assign the same value to a filed patent as to a published original paper in a scientific journal. After all, it has undergone the same type of peer review.
9. In my experience, many researchers do not understand the fundamental difference between the inventor and the owner of a patent. This may be worth explaining.
10. To avoid over-enthusiastic researchers, it may be worth mentioning that the probability of leading to a commercially successful and clinically useful product is higher with protected IP than without but that even with a patent only a minority of inventions ever lead to commercial success. In my own and probably non-representative experience, one of my inventions led to a product with peak sales of 1.6 billion whereas the other eight never led to a product on the market.
Minor comments
11. P. 5, l. 42: No need to reintroduce the abbreviation "IP".
12. P. 6, l. 24-31: Generic companies in most cases do not need to repeat the most essential clinical studies. They just must show the pharmaceutical quality of their products and pharmacokinetic bioequivalence (biosimilars are a notable exception).
13. Sentence spanning p. 6-7: This is a very crucial sentence for the entire manuscript as it lays out the key criteria for patentability. It may be obvious to the authors, but it is not for many of their potential readers. Therefore, I strongly suggest to more clearly explain that

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19. P. 15, l. 42: The abbreviation CDA has not been introduced.
20. P. 16, l. 20: Do you mean "IP lawyers" or "patent lawyers"? The latter is a widely accepted term, the former is not.
21. In several places, the authors talk about "pre-seed and seed funding". I think I know what they mean but many researchers may be unfamiliar with these terms, making it worthy to explain them.
22. P. 19, l. 22: "exceptions are" probably should read "exceptions include" unless the authors are very certain that these are the only exceptions. See also p. 21 l. 27.

********Author response********

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Reviewer #1: This is a well-written paper on a very interesting topic. I applaud the authors' efforts to bring the matter of IP so insightful to the reader. Please find below some general comments and suggestions and some comments and suggestions to specific sections/sentences in the manuscript.

General comments:

o Time line or diagram of process (from invention, to patent, publication, CE/FDA, and commercialization/licensing) would be nice, perhaps for different continents if it differs significantly. Done (Figure 3).

o Section '2. The role of the technology transfer office' is quite detailed and could be shortened somewhat. We have slightly shortened this section, but not too much because in our experience the role of the KTO is not well known among researchers.

o Section '3. Academic researchers and IP: the pros and cons' could be moved up, directly after the Background, for nicer flow in the manuscript. Done.

o An additional topic which may be added is the non-disclosure agreement (NDA) as this forms an important part of protecting intellectual property prior to the filing or acceptance of a patent application. It is important that researchers are aware of the strengths and weaknesses of NDAs. Text on NDA added.

o It may be very illustrative and educative to discuss a specific invention (specific solution for a specific problem, as discovered in the lab) and the claims that describe the invention (as broad as possible, taking into account the boundaries of the prior art), showing the potential value of a patented invention beyond its initially intended application (e.g. a preparation method). We have included a brief anecdote in section 3.1:

As an example of a simple invention: back in 1989 at the Academic Medical Center in Amsterdam, two clinical virologists thought of a way to purify DNA from tissue material, which was based on the very simple discovery that DNA binds to glass beads at a certain pH and is released again at a different pH [2]. This method was patented and developed into DNA isolation kits, which have been used in molecular biological and biomedical research all over the world for more than 20 years now.

o I would like to see more emphasis on the difference between the use and impact of patents in the pharmaceutical industry (often only one patent associated with a product, or patents protecting production methods) and the medical device industry (often multiple patents associated with one product). In the medical device industry, many unpatented, but published inventions made it to commercialized products, while this is much more difficult in pharmaceutical research/industry. We have deliberately centered the paper on patented inventions (both medical

devices and pharmaceutical agents). We feel that such elaboration would dilute the central message. More importantly, this is an issue that will be solved by the KTO once an invention is brought under its attention through e.g., and IDF. Our paper serves mainly to get researchers at academic institutions to the KTO. We believe that the KTO will handle it accordingly from that point onward.

o The current emphasis is too strong on the perception that unpatented inventions do not make it to the bedside. Many unpatented, but published inventions made it to commercialized products. These inventions, however, do not give a competitive edge. The main point of IP rights is that it ensures that the research investment put into the further development of the invention (clinical research, FDA approval, product development) is benefitting patent-holding party only, and not its competitors (who could copy the solution for a fraction of the costs once the product makes it to the market, if not IP-protected). Nonetheless, other aspects, like production methods, software and algorithms (kept as trade secret), and design can still provide a sufficient competitive advantage for commercialization. This is an excellent point. However, we have focused on patented inventions. This point therefore falls outside of the scope.

o I would like to see more emphasis on that academic institutes can use an IP-oriented business model to generate income and facilitate further research. The problem for academic institutes is that holding IP rights is expensive (I believe 50k over 20 years) and may require laborious and costly legal support, which is often unaffordable for non-commercial institutes. Expensive clinical studies are not required for applying for IP rights to an invention, only for FDA approval. Hence, academic parties should try to file potentially commercializable IP before publication, to either start up a spin-off company to commercialize the invention, or to sell or licence the IP to a commercializing party, giving this party a competitive advantage. Most companies with a large research (& development) department often make a large part of their profit off of 'adjacency' IP that has been created in the process, which the company does not commercialize itself, but licences to another. To facilitate this, often an organ is in place which checks all outgoing publications for potentially protectable IP, like a KTO. This is a business model which should be adopted by academic institutes as well, as they can be considered large research (& development) departments. Turning inventions, before publishing in scientific journals, into IP rights could form a major stream of income for these institutes. However, in order to achieve this, academic institutes should invest more in IP and staff to ensure the valorization and protection of inventions and IP, such as knowledge transfer offices/ innovations departments and legal support. We believe that better screening will not de facto lead to better and commercially more viable inventions. Approximately one in every 100 inventions turns out profitable for the research institute, whereby the revenue from the invention is often mitigated by the research expenses. Such screening programs are also very elaborate (perhaps too elaborate) for research institutes such as academic hospitals. The yield therefore does not justify the means. Most companies (compared to institutes) have smaller R&D programs and therefore have the available infrastructure to invest in elaborate screening programs. We therefore chose not to address this issue too much.

Some specific comments on the section '1. From invention to patent filing':

"Important to note is that patents allow their owners to block others from using the invention without permission, but do not automatically provide them with the right to sell products that are based on their invention, as these products may fall under the claims of other issued patents." Patents allow their owners to block others from commercializing the invention without permission; academic research building on the patented work may still be done and published. Indeed, but this point requires some nuance in light of the definition of ‘commercializing.’ IP rights differ per country and it is therefore more suitable to use the term “use” in this context.

"A special type of invention that is frequently made at university hospitals and can also be patented is a not yet described use of an existing drug, even if the particular compound is already patented itself. Such a "second medical use patent" can be particularly attractive to the company already selling the drug." I may be mistaken, but I believe one cannot patent the use or application of an invention (i.e., one can patent a drug, but not a treatment). When an invention described in a patent needs to be tailored to fit a new application, then these specific features can be patented (if novel and inventive). We believe there is a misunderstanding here. A treatment method indeed cannot be patented in Europe, but that is not what we mean by “second medical use patent.”

"Non-obviousness: an invention may be novel, but not considered to contain an inventive step." An important issue here is that the invention should not be constructed of a combination of knowns (e.g., combining the air-filled balls idea disclosed in the Donald Duck with knowledge from a document disclosing the use of helium to make a zeppelin fly, to salvage sunken ships faster). We have decided to omit this part because it is too complex and falls outside of the scope of the review paper.

"Industrial applicability: all inventions that can be industrially applied, that is they have some economic value, are eligible for patenting." Important here is that it is also beneficial over other known inventions. Otherwise, the patent has little value as competitors can easily work around it. The aim to be more beneficial over other inventions is not a criterion per se. What is more important is the inventive step.

"A patent claiming for instance a machine for perpetual motion, even if it could be proven to work, would not be automatically granted a patent as it does not (of itself) have an industrial application." Perhaps not the best example as this machine will most likely find industrial application. Maybe a better example is inventing a new type of production system and method that has no potential of becoming as efficient as currently known systems and methods. This example has been omitted from the paper.

"And even if someone did manufacture a time machine, it would lack novelty because H. G. Wells and many others already described it." Wells may have described it, but not in an enabling fashion. In a patent, the invented system, drug, and/or method should be described in an enabling way, so that others can build on to it. Hence, when someone would really invent a time machine, probably many patents will be filed in the process. Interestingly, whether the machine works or not, that is of less interest to a patent officer. However, when an invention is deemed to fail, or has no benefits over other known solutions, then it is very costly to maintain this IP. An examplary field where this may be apperant is cryonics. As stated before, we have eliminated this section from the text.

"If time is not of the essence, there are two good reasons for postponing the filing of the application." The reason for postponing patenting an invention is that a patent is only valid for 20 years, so if one can wait, he should wait until he is ready to release the product to the market (or needs to make any of his progress public, such as for FDA-approval). Besides that, indeed, one can also add more data in the first year. This is mainly to further support the claims (claims can only be added or modified based on the text in the initial application I believe). By waiting with patenting, one also becomes more assured that the money spent on the patent will be worth it as he has more data supporting the use and benefits of the invention (or it prevents investing in a patent on an invention that doesn't work). This has been added.

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2. I'm not sure that it is warranted to talk only about spin-off companies and similar semi-internal routes for development to commercialization; in many cases, the IP is licensed to a third party for that. Thank you, we have addressed this on page 22 and section 5.

3. Section 1.1: In the Introduction you mention KTOs and Innovation Departments side by side, but in the rest of the manuscript you only talk about KTOs. Either both should be mentioned consistently or an overarching term should be used in the Introduction that can consistently be reused in the rest of the manuscript, for instance Technology Transfer Office (TTO). The terminology has been unified.

4. P. 12, end of 2nd paragraph: Under many jurisdictions, the initial rights to IP developed by an employee belong (at least in part) to his/her institution, hence the strong role of the institutional TTO in the process. However, if the TTO decides not to file, typically all rights are returned to the inventors. I am aware of examples, where the inventors then have filed at their own cost and risk - and been successful (although in a minority of cases). This scenario may be worth mentioning. This has been addressed in the last sentence of section 3.3.1.

5. The authors repeatedly (and rightly so) mention that filing patents per se can be costly, at least by academic standards. It may be worthwhile to give readers a rough idea what these costs are. Added in section 3.3.4.

6. I found the description of the role of the TTO in section 2 correct but depicted a little too rosy. Many researchers consider TTOs to be a pain in the neck (see doi 10.1007/s00210-015-1106-5). Articles such as this may help researchers understanding why TTOs can be difficult to deal with but I recommend actively addressing this issue. Good point, which we implemented in section 4.

7. Section 3, 1st paragraph: While I share the impression that basic researchers may think less about IP, the authors may wish to add that basic research may similarly lead to IP as translational and clinical research. The development of PCR would be a fine example. Added to section 2.

8. Section 3.2: The authors may wish to mention an ancillary benefit of filing. Several academic institutions, for instance for promotion or tenure decision, assign the same value to a filed patent as to a published original paper in a scientific journal. After all, it has undergone the same type of peer review. We have addressed your point in the 2nd paragraph of section 2.

9. In my experience, many researchers do not understand the fundamental difference between the inventor and the owner of a patent. This may be worth explaining. Addressed on page 14.

10. To avoid over-enthusiastic researchers, it may be worth mentioning that the probability of leading to a commercially successful and clinically useful product is higher with protected IP than without but that even with a patent only a minority of inventions ever lead to commercial success. In my own and probably non-representative experience, one of my inventions led to a product with peak sales of 1.6 billion whereas the other eight never led to a product on the market. Addressed at the end of section 4.

Minor comments

11. P. 5, l. 42: No need to reintroduce the abbreviation "IP". Modified.

12. P. 6, l. 24-31: Generic companies in most cases do not need to repeat the most essential clinical studies. They just must show the pharmaceutical quality of their products and pharmacokinetic bioequivalence (biosimilars are a notable exception). Thank you for pointing this out.

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18. P. 15, top line: Here the confusion between the term KTO in Europe and Innovation Department in the US comes to a climax as you tell us that KTOs have blossomed in the US. Please be internally consistent how you call the TTOs. See point 3.

19. P. 15, l. 42: The abbreviation CDA has not been introduced. This has been addressed on page 8, at the end of section 2 and on page 22.

20. P. 16, l. 20: Do you mean "IP lawyers" or "patent lawyers"? The latter is a widely accepted term, the former is not. Changed to contract lawyers.

21. In several places, the authors talk about "pre-seed and seed funding". I think I know what they mean but many researchers may be unfamiliar with these terms, making it worthy to explain them. The definitions are not always clear-cut, unfortunately, as the amounts vested in seed and pre-seed capital vary. We therefore chose not not specify the terms beyond what has been done in the text.

22. P. 19, l. 22: "exceptions are" probably should read "exceptions include" unless the authors are very certain that these are the only exceptions. See also p. 21 l. 27. Modified as suggested.

2nd editorial decision
Date: 24-May-2017

Ref.: Ms. No. JCTRes-D-16-00037R1
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Dear authors,

I am pleased to inform you that your manuscript has been accepted for publication in the Journal of Clinical and Translational Research.

You will receive the proofs of your article shortly, which we kindly ask you to thoroughly review for any errors.

Thank you for submitting your work to JCTR.

Kindest regards,

Yao Liu
Editorial Board Member
Journal of Clinical and Translational Research

Comments from the editors and reviewers:

Dear authors,

The editorial board of JCTR has carefully considered the comments from the reviewers and the revisions you implemented accordingly. We have decided that your manuscript is now acceptable for publication. Thank you for contributing this important paper to JCTR.

Kindest regards, also on behalf of the editorial board,

Yao Liu

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