An easy guide to Australia's new patent law under the Intellectual Property Laws Amendment (Raising the Bar) Act 2012

Freehills

Patent Attorneys

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Introduction

The most significant amendment to Australia's patent legislation since enactment of the current *Patents Act 1990* (Cth) has now come into effect with the passing of the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* (Cth) into law.

This new law has far-reaching consequences for those seeking and enforcing patent rights in Australia, in effect establishing a class of new Act patents to which the higher validity standards required by the new law will apply, and old Act patents to which relatively lower validity standards established by the pre-amendment or old law will apply.

The changes brought about by the new law will also be felt in a procedural sense for patent applicants, patentees and opponents alike, with the commencement of new proceedings and the cancellation of others previously available under the old law.

Further, there will also be important consequences regarding exemption from infringement for patentees and alleged infringers with the codification of experimental use provisions, and a broadening of old law exemptions to cover acts done for seeking regulatory approval of any product for which approval is required for marketing.

In this guide we outline the key changes under the new law and our analysis. Given the complexity of the new law, our commentary is necessarily of a general nature and we strongly advise you to contact us should you require professional advice on any particular issue.

We trust that this document is of use to you.

Freehills Patent Attorneys

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Overview of Intellectual Property Laws Amendment (Raising the Bar) Act 2012

The *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* (Cth) (new law) constitutes the most extensive changes to Australian patent law and procedure as of the last 20 years. It is the result of a series of law reform proposals arising from numerous reviews of the Australian patent system over the last 10 years.

While the intention of the law is to encourage investment in Australian R&D, the reforms to Australia's IP system will impact on all users of the system, and all businesses conducting R&D in Australia.

The components of the new law that are most relevant to the Australian patent system have been contained in a series of schedules in the development of the Amendment Act as follows:

- **Schedule 1** – raising the quality of granted patents by increasing the threshold for patentability of inventions and requirements for a valid patent specification
- **Schedule 2** – providing for access to patented inventions for acts done in relation to obtaining experimental approval or experimental research
- **Schedule 3** – reducing delays in resolution of patent applications, thereby providing greater certainty for the public, and
- **Schedule 6** – simplifying the patent system by removing procedural hurdles and streamlining processes.

Many of the changes under schedules 1, 3 and 6 are technical and will involve complex interactions between the Amendment Act and regulations. Recognition that the legislation impacts patent applications pending at the time of enactment of the new law resulted in the changes under these schedules not coming into effect until 15 April 2013 (12 months after commencement).

The changes under Schedule 2 commenced on 15 April 2012.

Amendments relevant to validity

Written description and enablement, amendment

In brief

- The new law established under Schedule 1 increases the requirements for a valid patent specification by introducing a new written description and enablement ground.
- The law also limits the options available to patent applicants by precluding certain amendments.
- The effect of the law will most likely be to bring the Australian requirements regarding patent specifications into line with other patent systems, rather than to demand a higher or additional threshold to those applying in other jurisdictions.
- Therefore the outcome is likely to be that allowed Australian claims will bear more resemblance to foreign counterparts with respect to scope.
- The law applies to all patents/applications which are filed on or after 15 April 2013, or for which examination is requested after this date. It does not apply to patents/applications for which examination was requested prior to this date.

Written description and enablement

The new law in Schedule 1 requires that the patent specification must:

> disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the relevant art.

The language is taken directly from the corresponding provision in the United Kingdom legislation and it is quite clear that the intention is that this provision is to be interpreted in Australia as it has been in the UK. There is an expectation that to meet this requirement, the specification should enable the claimed invention to be produced across the full scope of each claim.

The best method of performance requirement remains.

Finally, under the new law, a similar enablement requirement also applies to provisional specifications. However, there remains no need to describe the best method in a provisional specification.

Amendment

Under the new law, applicants are not allowed to add new matter that goes beyond the **disclosure** contained in the specification at its filing date, except to correct a clerical error or obvious mistake. It follows that the relevant test as to whether amendments are allowable is no longer dependent on claim scope but rather on whether the amendment changes the description contained in the specification as filed.

Analysis

The provisions of Schedule 1 are quite dramatic in the sense that they establish a class of new Act patents to which the higher validity standards required by the new law will apply, and old Act patents to which relatively lower validity standards established by the pre-amendment or old law will apply. In doing so, these provisions have effectively swept aside case law for new Act patents that has been developed by the Australian courts over the last 100 years and brought in new grounds that have not yet been considered by the courts.

In more detail, old Act patents, (ie those patents or applications that had examination requested before 15 April 2013) will be assessed on the familiar written description ground that was well understood to merely require a patent specification to permit the skilled worker to produce **something** within each claim. Fair basis will also continue to apply, and these patents will not be revoked for lack of enablement.

Further, regarding amendment, the old law provides that the invention needs to be fully described at grant, but not necessarily earlier, allowing the applicant to correct an inadequate description of the best mode of the invention after filing, provided the amendment would not result in the specification claiming matter not disclosed in the specification as filed.

In contrast to the above, new Act cases will be assessed on grounds that have not yet been applied in the Australian courts. Although the intention is that these grounds are to be applied as they have been in the UK, we think it far from certain that the outcomes seen in Australian courts will be the same as in these jurisdictions.

In these circumstances, we think that to the extent that the Schedule 1 provisions introduce uncertainty as to the outcome of validity assessment on these grounds, that uncertainty is most likely to be seen before the Australian courts. Given the tendency of the Australian patent examiners to follow the prosecution of foreign counterpart applications in US and Europe, we think it likely that outcomes before the Australian Patent Office should be more certain—that is, if there is a problem in Europe on enablement for a given claim, one should reasonably expect the same problem to arise on that claim in Australia.

Obviousness

In brief

- The new law established under Schedule 1 increases the requirements for a patentable invention by expanding the prior art base and the common general knowledge relevant to testing obviousness.
- The effect of the law will most likely be to bring the Australian requirements regarding obviousness into line with other patent systems. It will not demand a higher or additional threshold to those applying in other jurisdictions.
- Therefore the outcome is likely to be that allowed Australian claims will bear more resemblance to foreign counterparts with respect to scope.
- The law applies to all patents/applications which are filed on or after 15 April 2013; or for which examination is requested after this date. It does not apply to patents/applications for which examination was requested prior to this date.

Expanded common general knowledge and expanded prior art base

The intention of the new law is to raise the inventive step standard by expanding the type of information that can be considered in a consideration of inventive step. According to the new law, inventive step is to be tested having regard to:

- common general knowledge (being that special subset of public knowledge known to the bulk of those skilled workers in the relevant field and accepted without question) as it existed inside or outside of Australia before the priority date of the relevant claim, considered separately or together with,
- one prior art document, or one or more prior art documents that the skilled person could be reasonably expected to have combined.

Analysis

Like the Schedule 1 provisions relevant to patent specifications discussed above, the provisions here will also establish a class of new Act patents to which the higher validity standards will apply, and old Act patents to which relatively lower validity standards established by the pre-amendment or 'old law' will apply.

In more detail, the common general knowledge relevant to old Act patents will remain limited to that as it existed in Australia prior to the relevant priority date. Further, the prior art base relevant to these patents will remain limited to that information that would have been 'ascertained, understood, and regarded as relevant' by the skilled worker.

The new law is expected to raise the bar to validity on the inventive step ground. Having said this, it is not crystal clear that the threshold is now at the same level as that set in the US, EP or other key jurisdictions. There are two important considerations.

First, the removal of the 'ascertained, understood and regarded as relevant' prior art carve out in the new law is not intended to result in all prior art information being axiomatically available for obviousness. We think that while a skilled person will be deemed to be aware of all publicly available prior art information, such information may still be excluded from obviousness considerations if it can be shown that the skilled person could not have appreciated its relevance.

Second, the requirement to assess the claimed invention in light of the common general knowledge is to remain. Even with the expanded prior art base, therefore, obviousness is unlikely to be found where it can be shown that the common general knowledge teaches away from the teaching of the prior art.

It seems reasonable to expect that Australian applicants will find obviousness more challenging, although having said this the Patent Office's practice of relying on the prosecution of corresponding US/European patent applications may result in there being limited real change in this regard.

We think that the real impact of the new law is likely to be felt far more keenly in opposition and revocation proceedings.

Usefulness

In brief

- The new law established under Schedule 1 increases the requirements for a patentable invention by requiring that an invention be useful.
- The law is expected to have limited application and in particular, an application to those patent claims that define inventions that are speculative with regard to possible use.
- The requirement is intended to bring Australian patent law into line with the requirements of US patent law.
- The law applies to all patents/applications which are filed on or after 15 April 2013; or for which examination is requested after this date. It does not apply to patents/applications for which examination was requested prior to this date.

The new law introduces a new requirement in respect of inventions of new Act patents to which the law applies. The new requirement is that that a claimed invention must be 'useful'. This requirement will not apply to patents or applications to which the old law applies, namely the old Act patents being those cases in which examination was requested before 15 April 2013.

According to the new law, an invention is to be taken not to be useful unless a **specific, substantial and credible use** for the claimed invention is disclosed

in the complete specification. Further, the disclosure in the complete specification must be sufficient for that **specific, substantial and credible use** to be appreciated by a person skilled in the relevant art.

It is clear that the relevant words are to be interpreted consistent with the US approach, and the relevant Australian legislative materials consider the following interpretations as appropriate:

- 'Specific' means a use specific to the subject matter claimed and can 'provide a well-defined and particular benefit to the public.'
- 'Substantial' means the claimed invention does not require further research to identify or reasonably confirm a 'real world use'. 'An application must show that an invention is useful to the public as disclosed in its current form, not that it prove useful at some future date after further research'.
- An asserted use will be 'credible' 'unless there is evidence that the invention is inoperative (ie does not operate to produce the results claimed by the patent application) or there is reason to doubt the objective truth of the statements in the specification.'

Analysis

It is important to note that the specific, substantial and credible use must be disclosed in the specification. According to the legislative materials this can take the form of an explicit disclosure, or if the skilled person could appreciate the use, with their background knowledge in the art and without undue burden then the disclosure need not be explicit.

In practice it is expected that this new law will not have a significant impact on the majority of patent applications and how they are drafted. The amendments will show their usefulness by eradicating the claiming of speculative inventions, thereby strengthening the requirement that patented inventions are useful.

While the new law does not apply to old Act patents, it is important to remember that inventions of both new and old Act patents are subject to the requirement that they have utility, ie that the claims actually achieve what is promised by the patentee in the specification. The Australian courts have been quite clear that where a single claimed embodiment does not meet this requirement, the relevant claim is likely invalid.

Amendments relevant to infringement

Obtaining regulatory approval

In brief

- Australia's patent law has been amended to provide that acts done solely for purposes connected with obtaining regulatory approval of a relevant product are to be exempted from patent infringement.
- The exemption applies to acts done in relation to agrochemicals, veterinarian medicines, medical devices, diagnostics and any other non-pharmaceutical subject matter for which there is a legally established regulatory approval regime.
- This amendment significantly broadens the narrow exemption applying pre-April 2012 that only applies to acts connected with obtaining regulatory approval of a pharmaceutical.
- The amended law applies to acts done on or after 15 April 2012 in relation to patents granted before, on or after this time.

The infringement exemption

According to section 119B, a person may undertake an act that would otherwise be an infringement of a patent claim:

> if the act is done solely for purposes connected with obtaining an approval required by a law…to exploit a product, method or process; or purposes connected with obtaining a similar approval under a law of another country or region.

Analysis

Prior to April 2012, there was no legislative provision that exempted acts done for obtaining regulatory approval of non-pharmaceutical subject matter from patent infringement. Section 119A applied (and will continue to apply) for exemption from patent infringement for those acts done solely for purposes in connection with obtaining regulatory approval of a pharmaceutical.

The concern with the pre-April 2012 law was that it put Australian manufacturers at a competitive disadvantage to those companies that have operations in other countries that allow 'springboarding' (ie undertaking infringing acts required for regulatory approval of a non pharmaceutical product before patent expiry), in the sense that the latter companies, in having a head start in obtaining regulatory approval, would then be able to launch products in Australia or elsewhere shortly after patent expiry and in advance of the Australian manufacturer.

The new law is not prescriptive of what acts would be considered to be exempted, although it is clear that the acts done must be in connection with a regulatory approval process required by law. This lack of prescription makes sense given that the new law is intended to cover current regulatory approval regimes, and those that may be established in the future. It also recognises that processes required under current regimes may change from time to time, necessitating particular acts at one time that were not required at another time.

Having said this, it is clear that the exemption will not apply to acts done in respect of a regulatory approval for a pharmaceutical, nor will it apply to acts done for experimental or research purposes, as these exemptions are dealt with under section 119A and section 119C of the legislation.

The phrase 'solely for purposes' is intended to exclude those acts done predominantly for a commercial purpose that might otherwise occur during the process of obtaining regulatory approval, including for example, stockpiling and export of the relevant product.

A party seeking regulatory approval of a generic product does not have to notify the patentee of his intention to undertake acts for obtaining regulatory approval of the generic product. What follows is that if the legislation establishing the relevant regulatory regime does not require the former to notify the patentee either, the patentee will not receive such notice. This is distinct from the outcome that applies to pharmaceutical patents whereby the party seeking regulatory approval must notify the patentee regarding his intentions to undertake acts that, but for the relevant exemption, would be an infringement of it.

Experimental use

In brief

- Australia's patent law has been amended to provide that acts done predominantly for the purposes of gaining new knowledge, or to test a principle or supposition regarding a patented invention are to be exempted from infringement.
- The exemption applies irrespective of whether the person undertaking the relevant act had in mind to later commercialise, for example, an improvement arising from the act, or whether that person was aware of the patent at the time the relevant act was undertaken.
- The amended law applies to acts done on or after 15 April 2012 in relation to patents granted before, on or after this time.

The infringement exemption for experimental use

According to section 119C, a person may undertake an act that would otherwise be an infringement of a patent claim 'if the act is done for experimental purposes relating to the subject matter of the invention'.

'Experimental purposes' is non-exhaustively defined as including:

- determining the properties of an invention
- determining the scope of a claim relating to the invention
- improving or modifying the invention
- determining the validity of the patent, or of a claim relating to the invention, and
- determining whether the patent for the invention would be, or has been infringed by the doing of an act.

Interestingly, an act that improves or modifies an invention is exempted from infringement, even if the improvement or modification is proposed for later commercialisation.

Further, section 119C requires that the experimental activities be 'related to' the subject matter of the invention. This achieves two outcomes:

1. that the exemption applies to experiments that include the claimed invention, so that the person undertaking the relevant work is not required to conduct patent searches before starting an experiment, and
2. that the exemption applies to experimentation on a patented invention, ie it does not cover experimentation using a patented invention. Importantly, it does not follow that infringement of a research tool patent is to be exempted merely because of section 119C.

Acts that remain outside the infringement exemption include those where the purpose is commercialisation. These include:

- 'market research' – testing the likely commercial demand for a product, and
- manufacture for the purpose of sale or use for commercial purposes.

Analysis

Prior to April 2012 there was no legislative provision that exempted acts done for experimental purposes relating to the subject matter of a claimed invention, and the common law that applied in the relevant circumstances was uncertain. In this context, this exemption is perhaps a welcome introduction into the Australian patent law. Having said this, the very language of the relevant provision, particularly in being inclusive with respect to the types of acts that might be within the exemption, seems unclear. We strongly recommend seeking professional advice as to whether the exemption is likely to apply in given circumstances.

Amendments relevant to procedure

Schedules 3 and 6 of the new law relate to new proceedings and cancellation of other proceedings with the objective of reducing delays in resolution of patent applications, and simplifying the patent system by removing procedural hurdles and streamlining processes.

The key changes relevant to examination, acceptance, opposition and re-examination practice are dealt with below.

Examination

Due Dates

Regulations to accompany these changes shorten the time frame for:

1. acceptance (allowance) due date has been shortened from 21 months to 12 months from receipt of a first examination, and
2. due date for requesting examination has been shortened from 6 months to 2 months from receipt of a direction from the Patent Office to request examination.

Item 1 applies to all applications where a request for examination is made on or after 15 April 2013. Item 2 applies to all directions issued on or after 15 April 2013.

Prior use and usefulness at examination

The prior art base in Australia includes information made publicly available through doing an act (prior use) or publication anywhere in the world.

Under the new law applicable to applications for which examination is requested on or after 15 April 2013, the examiner is able to consider all prior art information when assessing novelty, inventive step (for standard patent applications), and innovative step (for innovation patents).

For other applications, the examiner is not able to consider prior use or usefulness during examination.

The new law also expands the patentability requirements considered during examination to include consideration of whether a claimed invention is useful.

Modified examination

This specialised examination proceedings that considers prior art grounds only has been cancelled because it was not exclusively used. This means that for standard patents, ordinary examination is the only examination proceedings now available. This is consistent with the approach of most other patent offices.

Omnibus claims

Omnibus claims are claims that define the relevant subject matter by reference to description or figures or drawings contained in the patent specification.

Under the new law, claims cannot rely on reference to these things unless 'absolutely necessary to define the invention'.

Clearly there will be some debate regarding the circumstances in which the carve-out will apply. It seems that one example where it would apply is where a chemical composition can only be described with reference to a spectroscopic profile.

Omnibus claims are not, under the new law, considered as inherently unclear, so it seems that there will be good reason to persuade the examiner that these claims are 'absolutely necessary' as required by the relevant subject matter, particularly given the difficulty in invalidating these claims in revocation proceedings.

The relevant provision applies to applications for which examination is requested on or after 15 April 2013.

Acceptance

Standard of proof for acceptance

For applications for which examination is requested on or after 15 April 2013, the examiner is to apply the civil standard of proof to all grounds of invalidity considered during examination. This is a departure from earlier practice whereby the balance of probabilities standard is to apply to prior art grounds and the benefit of the doubt standard is to apply to specification and patentable subject matter requirements.

Therefore, the key change is that it will be for the applicant to persuade the examiner that it is more likely than not that the specification satisfies grounds including patentable subject matter, enablement, support, written description, and clarity of claims.

Interestingly, the expectation of the legislature is that in practice, this new law should not impose any requirement on the Patent Office to conduct further enquiries during examination than are currently undertaken. Given this, our expectation is that if there is to be any observable difference in obtaining allowance, this will most likely be seen in second and further examination reports where the Patent Office will exercise the balance of probabilities standard on non-prior art grounds. In the circumstances, this would point to the continuing importance of building a convincing case of likelihood of validity on all grounds in response to a first examination report.

Revocation of acceptance

The new law will give an examiner the discretionary power to revoke acceptance. The relevant provision does not specify the circumstance in which the power may be exercised for revocation. The intention appears to be that acceptance is to be revoked where an administrative error has resulted in acceptance of an application that should not have been accepted. However, there is nothing in the legislation that limits exercise of the power to this circumstance. A separate provision sets forth that a decision to revoke acceptance cannot be appealed to the Federal Court.

Postponement of acceptance

Prior to the new law it was possible to postpone acceptance leaving applicants with opportunity to take advantage of the more generous amendment opportunities that are available before acceptance. A particular circumstance where postponement of acceptance has been useful is in the recent Patent Office divisional case management practice where in attempting to avoid a two-month response due date, the applicant files claims allowed on the parent patent and files a postponement of acceptance to prevent allowance of those claims in the divisional. With this rule change, whereby the office has discretion as to whether to allow acceptance to be postponed, it should be more important to make sure that the claims for a divisional application have been settled during the two-month period available for requesting examination after a direction to request examination has issued.

Divisional applications and opposition

A range of amendments have been made to divisional application and opposition proceedings with the objective of resolving the delays in disputes before the Patent Office. The key amendments are as follows:

- cancellation of the opportunity to file divisional applications during an opposition – thereby preventing an applicant from effectively stepping around opposition proceedings once commenced,
- cancellation of the opportunity to convert a standard patent application to a divisional application of an earlier filed application during opposition proceedings – thereby preventing the applicant from avoiding earlier the application and other prior art by effectively amending the priority date of the claims,
- an option for the Patent Office to refuse a request by an applicant of an opposed application to withdraw the application. This may apply where the applicant does not also withdraw a divisional application of the opposed application, and
- introduction of two categories of opposition to be recognised, namely substantive (opposition to grant of patent or to patent term extension) and procedural (allowance of amendments and extensions of time).

Further changes to the regulations include the following:

For both substantive and procedural opposition

1. All documents are to be filed with the Patent Office, eliminating the current requirement for service by one party on another, and the opportunity for one party to object to late service of documents on another.
2. A higher threshold is to be met to obtain an extension of time for filing evidence.
3. It is not possible to file evidence if the time for doing so has expired and the time is not extended.
4. No mechanism is provided to request leave to submit further evidence, but the Patent Office may consult documents relevant to the opposition.
5. Opponents are required to file summaries of submissions 10 days prior to hearing, and applicants are required to do same within 5 days.

For substantive opposition

6. The due date for the opponent's evidence in reply is reduced from 3 months to 2 months.
7. The opponent must file any documents to be relied upon on filing of the Statement of Grounds and Particulars. The Patent Office may dismiss the opposition if documents are not filed.

For procedural opposition

8. The due date for commencing a procedural opposition by filing a Notice of Opposition is 2 months. This shortens the due date for an opposition to an amendment by 1 month, and extends the due date for an opposition to an extension of time by 1 month.
9. The due date for filing a Statement of Grounds & Particulars is shortened to 1 month from the filing of a Notice of Opposition.
10. The Patent Office has a discretion to direct, on a case-by-case basis the appropriate practice and procedures including directing evidential timeframes.

Most of the patent opposition changes apply to opposition proceedings commenced after 15 April 2013. The patent opposition changes apply to evidentiary periods and procedures commenced on or after 15 April 2013 for all existing opposition proceedings.

Re-examination

The new law changes the re-examination provisions so that the grounds of invalidity considered in the re-examination of a standard patent accord with the grounds considered during substantive examination. Specifically, grounds in addition to novelty and inventive step can be considered in re-examination including whether the claimed invention:

- is a manner of manufacture (ie patentable subject matter)
- is useful (ie having specific, substantial and credible utility, and meeting the promise of the invention)
- has been prior used
- is adequately described in and supported by the specification, and
- relates to human beings and/or processes for the generation of human beings.

In addition, the standard of proof in re-examination has been raised to the civil standard of balance of probabilities, (ie whether the Commissioner is satisfied that it is more likely than not that the relevant patent is valid on the relevant ground) which brings the standard of proof into line with that applied by the court.

Given that:

- re-examination proceeds without assessing if a new question of patentability is raised; and
- the likelihood of at least one claim being unpatentable is irrelevant to the proceeding, we expect that these proposed changes to re-examination should make re-examination a far more attractive option for attacking patents before the Patent Office.' This is particularly the case given that a petitioner who has been unsuccessful in re-examination proceedings will not later be estopped from attacking the patent in revocation proceedings before the court.

Finally, the new law provides that re-examination of patents granted under pre amendment old law will now be assessed on prior art and non prior art grounds as they existed under the old law.

Areas of Expertise

	Mining and Resources	Energy	Physics	Medical technologies	Analytical Instrumentation	Mechanical Engineering & Manufacturing	Consumer Products & Design	Building, Construction & Civil Engineering	Electronic & Electrical Engineering	Information & Communication Technologies	Chemical & Materials Engineering	Food, Beverage & FMCG	Biotechnology	Industrial Chemistry	Pharmaceuticals	Agribusiness & Agrochemicals
Partners																
James Cherry												●	●		●	●
Brett Connor	●	●		●				●			●			●		
John Dower		●			●	●	●		●	●						
Tom Gumley												●	●		●	●
Greg Noonan		●	●	●	●	●		●								
Special counsel																
Tracey Hendy	●			●		●	●	●				●				
Roger Henning	●	●				●			●	●						
Senior associates																
Karen Bentley												●	●		●	●
Sarah Couper													●			●
Daneta Crump	●	●		●		●	●	●								
Adam Denley													●		●	
Carl Harrap		●		●	●		●		●	●						
Stuart Irvine						●	●		●	●						
Rachel Montgomery	●	●	●		●	●										
Thor North			●	●	●		●		●	●						
Nicole Watling				●							●	●		●	●	
Professionals																
Rory Anderson	●							●			●			●		●
Alexandra Angelatos											●			●	●	
Carol Burnton													●		●	
Milena Dryza											●	●		●	●	●
Ronelle Geldenhuys					●	●		●	●	●						
Sarah Hennebry													●		●	●
Cassandra Horn					●		●									
Matthew Lay		●	●		●				●	●						
Emma Lees											●	●		●	●	●
Reginald Leones				●	●	●	●									
Jason Manakis			●	●		●	●									
Joe Mok			●						●	●						
Jonathan Schnapp				●	●				●	●						
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