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SUBMISSION TO THE PHARMACEUTICAL PATENTS REVIEW

RESPONSE TO DRAFT REPORT 30 April 2013

A. EXECUTIVE SUMMARY

Medicinal therapies are essential to the Australian healthcare system. The guarantee of market exclusivity provided by the Australian patent system is also fundamental to a viable healthcare system as it funds the significant investment that originator pharmaceutical companies make in medicinal therapies and thereby provide the framework essential to the launch of generic products. They are also fundamental to Australia's treaty obligations. While the initial research and development (R&D) is significant in itself, the investment made by originator pharmaceutical companies does not end at the R&D phase. Significant further investment is required to introduce products to market, educate healthcare providers and patients as well as undertake pharmacovigilance to ensure the safety of medicinal products.

The regulatory model for introducing generic products into the Australian market is quite different to that for originator products. Generic companies are able to take advantage of the significant investment made by originator companies, thereby enabling the introduction of generic products with minimal investment, and hence, at lower cost.

In this paper, in sections B and C, Sanofi provides background to the context in which originator and generic companies operate in Australia. Sanofi also specifically addresses a number of the Draft Recommendations made in the Draft Report. In each of sections D to H, Sanofi sets out the applicable Draft Recommendation, our understanding of that recommendation and issues raised by the adoption of the recommendation.
In summary, Sanofi’s position on the Draft Recommendations considered in this paper is as follows:

- **Draft Recommendation 5 (options 5.1 and 5.2):** Patent term extension (PTE) provisions in the *Patents Act* are provided in light of the regulatory environment for medicinal therapies in Australia. These provisions seek to restore the effective patent term for pharmaceutical patents eroded in light of the delay in exploitation of these patents due to Australian regulatory requirements. Sanofi does not agree that an “R&D subsidy” will substitute for the PTE provisions. Similarly, the later expiration of patents in Australia that results from PTEs arises directly from regulatory delays in Australia that result in the product being introduced later in Australia than in other jurisdictions. Sanofi submits that the Review Panel should focus on addressing these Australian regulatory delays.

- **Draft Recommendation 6.1:** There is little justification for seeking to limit PTEs to new compounds. The regulatory issues involved in introducing other medicinal therapies including new formulations and methods of treatment are every bit as complex and costly as those associated with introducing a new compound. Sanofi’s view is that PTEs should be available for all new medicinal therapies.

- **Draft Recommendation 8.2:** A transparency register is likely to introduce considerable uncertainty and a significant additional burden on originator companies and also the Therapeutic Goods Administration and afford little or no practical benefit for generic companies. Sanofi submits that the Review Panel ought recommend a system which requires generic companies to notify the patent owner of their earliest intention to bring products to market. This would ensure the earliest resolution of any controversy.

- **Draft Recommendation 6.4:** Sanofi considers that it is premature for the Review Panel to recommend amendments to section 117 of the *Patents Act 1990* (Cth) (the *Patents Act*) prior to the determination of the High Court in *Apotex v Sanofi-Aventis*.

- **Draft Recommendation 7.2:** Sanofi disagrees with the idea of an external patent oversight committee as it introduces a further layer of regulation, cost and ultimately, uncertainty.

Sanofi specifically does not comment on Draft Recommendation 6.4 in view of its involvement in proceedings that concern that very issue.
B. INTRODUCTION

Sanofi is a global and diversified healthcare company focused on discovering, developing and distributing therapeutic solutions directed to meeting patients’ needs in both traditional and emerging markets.

Sanofi is one of the leading healthcare companies in Australia, having operated here since 1994. In Australia, Sanofi operates four divisions focusing on Pharmaceuticals, Consumer Healthcare, Vaccines and Rare Disease. Sanofi is committed to improving the health and well-being of Australians through our diverse and extensive range of products that span the complete spectrum of wellness, treatment and prevention.

Within the Pharmaceuticals division, Sanofi provides medicinal therapies to Australian patients for the treatment of illnesses in several therapeutic areas including diabetes, osteoporosis, cardiovascular, oncology and general medicine.

Medicinal therapies are an essential part of Australia’s healthcare system. They provide health outcomes which could previously only have been provided by more expensive healthcare services. In monetary terms they provide significant benefits to the Australian Government in the way of reduced number and length of doctor visits and reduced number and length of hospital stays. In many cases they avoid the need for significantly more expensive interventions. New medicinal therapies extend these savings by replacing outmoded and less effective therapies. They also provide remedies in new therapeutic areas.

In general, the development of a medicinal therapy for the treatment of a given disease extends beyond the discovery of a new molecule. The greatest clinical benefits of a new molecular entity may not be realised until the molecule is formulated as a particular ester, salt, derivative or compound or until it is combined with another molecule. Similarly, it may be that significant clinical benefits can only be realised once such a molecule, compound, formulation or combination is administered in a particular manner or to treat a particular disease or disease process. All of these potential therapies must separately meet the particular regulatory standards set by the Therapeutic Goods Administration (TGA) to ensure the safety and efficacy of new medicines. This will invariably involve the conduct of new studies (including clinical trials) in order to demonstrate the safety and efficacy of the new therapy. For this reason, the term "medicinal therapy", as used throughout this paper, is not limited to
new molecules, but includes new compounds, new formulations, new combinations and new methods of use, each of which requires a separate development and regulatory effort by the sponsor.

C. THE ROLE OF ORIGINATOR AND GENERIC COMPANIES

Ensuring patient access to affordable and innovative medicinal therapies is critical to a well functioning health system and to community well-being. Both originator and generic companies have an important role to play in achieving this aim.

Originator (or research-based) companies such as Sanofi invest heavily in R&D to seek to identify new medicinal therapies including new therapeutic compounds, new formulations of compounds and new therapeutic uses (or indications) of compounds, all of which deliver significant health benefits to patients.

Bringing any new medicinal therapy to the Australian market involves significant expenditure even after the initial R&D phase including in the conduct of clinical trials, applications for regulatory approval, post approval sales and marketing, doctor and patient education and market surveillance and pharmacovigilance.

Revenue from the sale of medicinal therapies is essential to ensuring that the cycle of development of new medicinal therapies continues. Sanofi for example, re-invests in the order of 17% of sales revenue into its R&D program.

In recent years however, financial return on R&D investment in pharmaceutical innovation has declined, heading toward neutral or possibly even negative returns (see Annexure A). A continuing trend in this fashion will have disastrous consequences for future development of medicinal therapies. In this regard, it must be recognised that in many therapeutic areas, even today, there are no (or limited) treatment options. In this regard Sanofi refers to the editorial in Angewandte Chemie (Angew. Chemie Int. Ed. 2011, 50, 7452-53) (one of the leading chemistry journals in the world) which states as follows:

There still is a much higher unmet medical need than often perceived by the public. Today only about 300 of the estimated 6000 potential drug targets in the human genome are addressed by approved drugs. Although the impact of these drugs on public health is already remarkable, there remains a large number of diseases with limited or no treatment options,
most prominently in oncology (e.g., malignant melanoma, ovarian, pancreatic, and small-cell lung cancer), but also in cardiovascular (e.g., stroke, heart failure, atrial fibrillation) and neurodegenerative diseases (e.g., Alzheimer's, Parkinson's, multiple sclerosis), women's healthcare (e.g., endometriosis, myoma), and, on the rise again, infectious diseases (e.g., multiresistant bacteria, new flu viruses).

Strong patent rights are the only means of guaranteeing the period of market exclusivity that is required to provide the revenues necessary to sustain a program of continual R&D re-investment.

Revenues from new medicinal therapies are also required to support the educational and pharmacovigilance programs that are essential to ensuring the safety and efficacy of such therapies once on the market. Again, strong patent rights are the only means of guaranteeing the period of market exclusivity that is required to sustain expenditure on such programs.

Generic companies enter the market only once originator companies have undertaken the R&D, regulatory, educational and pharmacovigilance programs necessary to bring a new medicinal therapy to market. Indeed the regulatory model for bringing generic products to market limits the cost exposure of generic companies in establishing their products by requiring only such clinical studies as are necessary to establish that the generic medicine is (bio)equivalent to the research-based medicine. Under this model, the generic company is able to take advantage of the originator's R&D investment, regulatory approval, brand building, market education and pharmacovigilance to launch with minimal investment. The resulting lower cost base enables the generic company to offer its products at a significantly lower price (as compared to the originator's products) resulting in immediate and significant loss of market share to the originator product.

Therefore a viable and profitable originator sector supported by a period of market exclusivity guaranteed by strong patent rights is necessary for the existence of a viable and profitable generic sector.

Failure to provide an appropriate period of market exclusivity via strong patent rights will lead to fewer innovative medicinal therapies being brought to market. This will, in turn, result in poorer health outcomes for patients and a higher cost to the Australian Government of providing healthcare.
D. LENGTH OF PATENT TERM EXTENSION

Draft Recommendation 5 (Option 5.1): The current model of using the patents system to subsidise pharmaceutical R&D indirectly should be replaced with a direct subsidy. To this end, the Government should reduce extensions of term for pharmaceutical patents and use part of the associated savings to fund R&D directly. Some of this funding should be targeted to socially beneficial research for which patents provide inadequate incentives to conduct. Such areas include new antibiotics which, once developed, must be used as sparingly as possible to prevent the development of antibodies and pharmaceuticals to address rare diseases, pediatric illnesses and endemic health issues in low income countries.

This option could also include an annual review of the savings delivered through any reduction in the length of extensions of term to be used in allocating funding to the replacement R&D subsidies.

Draft Recommendation 5 (Option 5.2): The Government should change the current extension of term provisions such that patents receiving an extension of term in Australia will not expire later than the equivalent patents in major trading partners.

Potential ways of achieving this include:

1) Providing an extension expiring up to 5 years after the original patent term or upon the expiry of the equivalent patent extension in one of a list of other jurisdictions including the US and EU. This option ensures Australian extended patents would not expire later than equivalent patents elsewhere. If originators are unable to seek regulatory approval in Australia at the same time as elsewhere, this option would reduce the effective patent life.

2) Changing the method of calculating the length of extensions of term to provide an incentive to submit applications for regulatory approval in Australia earlier than is currently the practice. This could be similar to the US method. This option creates an incentive to seek regulatory approval in Australia as soon as possible, reducing delays in access to medicines for Australian health consumers. Under this system, one-to-one
compensation is still provided for the time taken to process applications for regulatory approval.

Draft Recommendations 5.1 and 5.2 concerning the operation of the PTE provisions of the *Patents Act* would, if implemented, each adversely affect the position of patentees as compared with the current provisions.

Sanofi respectfully submits that, in putting forward these draft recommendations, the Review Panel has fundamentally misunderstood the principle underlying the PTE system.

It is incorrect to state that the PTE system is used to “subsidise pharmaceutical R&D indirectly” (Draft Report, page 90). Rather, under the *Patents Act*, patentees are afforded a 20 year patent term as incentive to undertake the work and expense in seeking to discover and develop inventions. In return, a patentee is required to disclose its invention through the teaching of the patent specification, so as to give the world at large the benefits of that invention upon patent expiry. In relation to medicinal therapies, this has been a valuable benefit to the public in expanding the knowledge base of disease and available therapies thereby opening up new areas of research and the development of alternative therapies.

As discussed above in section B, and as noted in the Draft Report, the 20 year patent term provides a period of exclusivity which affords the patentee an opportunity to exploit the invention so as to “recoup the costs of developing and bringing new ideas to market” (Draft Report, page 3). This principle encompasses much more than R&D and is technology and industry neutral.

However, as demonstrated by Figure 2.2 of the Draft Report, the pharmaceutical industry is unique in that the commencement of the patent term does not typically coincide with the patentee’s ability to exploit the invention. Indeed, in light of the need for extensive clinical trials and the regulatory process required for obtaining marketing approval, there is often a significant delay before such exploitation can commence. This reduced period of market exclusivity is commonly referred to as the “effective patent life”.

Thus it can immediately be seen that by dint of the processes that are necessarily involved in bringing safe and efficacious medicinal therapies to market, the period of exclusivity enjoyed by owners of
pharmaceutical patents is considerably shorter than that enjoyed by patentees in all other fields of technology.

Viewed against this background it is apparent that the use of the phrase “patent term extension” is a misnomer. The PTE provisions do not in fact result in an extension to the patentee’s period of exclusivity. Rather, they seek to provide patentees of pharmaceutical patents with an “effective patent term” of 15 years (which is still 5 years shorter than the effective term afforded to patentees in other fields of endeavour).

Given this, the Review Panel’s approach in treating the PTE provisions as a sui generis right afforded to pharmaceutical patents under the Patents Act is fundamentally flawed. While it is true that the PTE provisions apply only to pharmaceutical patents, it is incorrect to characterise PTEs as an additional right provided under the Patents Act. In fact, they represent an attempt to restore the period of exclusivity for pharmaceutical patents to something akin to that which is afforded all other patentees. Indeed, in the United States, the corresponding PTE provisions are referred to, more accurately, by the phrase “patent term restoration”. In this context, there is no warrant for considering the economic merits of the PTE provisions in a standalone fashion as the Review Panel has done.

Further, as demonstrated by Figure 5.8 of the Draft Report, in the pharmaceutical sector more than 10% of patents achieve an effective patent term less than 10 years and almost half of all pharmaceutical patents do not achieve the expected effective patent term of 15 years. In these circumstances, Sanofi submits that consideration ought in fact be given to increasing PTE to ensure that a higher percentage of patentees are afforded the benefit of an “effective 15 year term”.

(a) Draft Recommendation 5 – option 5.1

The economic analysis relied on by the Review Panel to support this recommendation is fundamentally flawed.

First, the Review Panel suggests that providing an up-front R&D subsidy instead of a patent term extension will “achieve the same impact on an originator’s financial position” and, in fact, is “more efficient” in stimulating R&D investment in Australia (Draft Report, page 62). Leaving aside issues as to the calculation and allocation of subsidies for particular products, this proposal appears to be limited to addressing compensation for R&D expenditure and not to the very considerable other costs
incurred in bringing a new medicinal therapy to market in Australia. In this respect the Review Panel ignores its own acknowledgement that “[p]roviding a new pharmaceutical product to the Australian market involves considerable costs. Therefore, pharmaceutical companies require an appropriate return on the outlays associated with gaining regulatory approval and supplying the Australian market” (Draft Report, page 58).

A more serious issue is that the analysis underlying recommendation 5.1 simply misses the point of the PTE provisions. As discussed above, while the provisions undoubtedly provide an opportunity for patentees to earn revenues which recoup R&D expenditure, they are in fact provided to restore the patent exclusivity period to that akin to other technologies.

Second, it appears that the Review Panel proposes that the up-front subsidy be funded from “savings” which are said to flow from reductions in PBS expenditure achieved through earlier generic entry (Draft Report, page 72). Sanofi submits that on a proper analysis it is clear that such “savings” are illusory or, at best, grossly inflated.

These short term PBS “savings” will be offset by medium to long term increases in the cost of the health system. These increased costs arise as shorter effective patent terms for pharmaceutical patents have a marked impact on revenues from product sales in Australia, to the extent that it will be uneconomical to bring some medicinal therapies to Australia. As noted in section B above, this will lead to patients being denied access to the latest developments in medicinal therapy, leading almost invariably to increased cost in the public and private health systems through for example, increased number and length of doctor visits, increased number and length of hospital stays, and the need for significantly more expensive interventions.

The association between patient access to new and improved medical therapies and reduced health system costs has been demonstrated in numerous studies. For example, in a study published in 2004 in Disease Management the authors investigated the economic impact of providing patients with appropriate pharmaceutical therapy in treating four prevalent chronic conditions (asthma, diabetes, heart failure, and migraine) (Goldfarb et al. “Impact of Appropriate Pharmaceutical Therapy for Chronic Conditions on Direct Medical Costs and Workplace Productivity: A Review of the Literature” (2004) Volume 7, Number 1, 61 – 75). In this context “appropriate therapy” was considered to be that recommended by medical guidelines (or multiple clinical studies) as the most effective at treating/controlling the relevant condition. The authors of the study concluded that
appropriate pharmaceutical therapy led to improved patient health status, reducing utilisation of higher cost health care resources (and decreasing time lost from reduced workplace productivity).

Finally, it is apparent that recommendation 5.1 ignores Australia’s treaty obligations in that it is inconsistent with the Australia-United States Free Trade Agreement (AUSFTA) which requires Australia to provide PTE rights for pharmaceutical patents. Specifically, Article 17.9.8 requires Australia to make available an “adjustment” of the patent term to compensate the patent owner for “unreasonable curtailment of the effective patent term as a result of the marketing approval process”.

(b) Draft Recommendation 5 – option 5.2

As an alternative to the subsidy system, the Review Panel recommends that PTE in Australia be linked to patent expiry for equivalent patents in those countries deemed “major trading partners”.

This recommendation appears to be directed toward enabling generic companies to manufacture in Australia at the same time as such manufacture commences in jurisdictions with earlier patent expiry (Draft Report, page 90). Sanofi submits that there is no warrant for such an approach. The Review Panel has not referred to any evidence that demonstrates that Australian generic manufacturers have been adversely affected by the fact that some patents expire later in Australia. In any case, surely considerations as to generic manufacturers’ ability to compete in other markets ought play no role in determining the scope of rights under Australian PTE provisions, and certainly affords no justification for further reducing the effective patent term.

Further, there is no evidence whatsoever before the Review Panel as to the number of generics that manufacture in Australia (as opposed to off-shore) or as to the extent of a “head start”, if any, that overseas manufacturers have in bringing a product to market upon expiry of the patent in Australia.

Further, in considering the PTE system, the Review Panel must have regard to Australia’s obligations under Article 17.9.8 of the AUSFTA, which as noted above requires Australia to enact provisions for adjusting patent term to compensate patent owners for “curtailment of effective patent term as a result of the marketing approval process”. Clearly the reference to “marketing approval process” is a reference to the Australian approval process undertaken by the TGA. Thus, there can be no doubt that compliance with international treaty obligations requires the Australian legislation to provide a means of adjustment that is linked to the time course of the marketing approval process in Australia.
The PTE provisions that apply in the United States and Europe bear no relation to the effective term in Australia and in any case are not calculated by reference to the timing of obtaining regulatory approval from the relevant authority. The Review Panel’s recommendation is thus clearly inconsistent with Australia’s obligations under the AUSFTA.

The Draft Report notes that linking PTE in Australia to expiry in other jurisdictions may have the effect of reducing the effective patent life (Draft Recommendation 5, Option 5.2 (a)). This, it is suggested, will occur when originators are unable to seek regulatory approval in Australia at the same time as elsewhere. The Draft Report however fails to also acknowledge that a reduction in effective patent life will also result where although an application is made in Australia contemporaneously with applications in other relevant jurisdictions, the approval process of the TGA takes longer than that of its counterparts.

Sanofi submits that to the extent that it is considered desirable to have patent terms in the major jurisdictions co-terminus, focus should be directed to reforms in the TGA approval process. This may, for example, involve ensuring that originator pharmaceutical companies are able to rely solely on FDA or EMEA applications (or approval) for the purpose of registering medicines in Australia and/or that timing for approvals in Australia are more closely matched to that in other jurisdictions.

Sanofi requests that the Review Panel not proceed with Draft Recommendation 5 (Options 5.1 and 5.2) but instead consider whether PTE ought be extended to ensure that a greater number of pharmaceutical patents achieve a 15 year effective patent life.

E. SCOPE OF PATENT TERM EXTENSION

**Draft Recommendation 6.1:** The Government should maintain the current approach that allows extensions for drugs and formulations but not for methods of use and manufacture, which will continue to provide an incentive for the development and supply of active pharmaceutical ingredients and new formulations, without adding to the existing costs of medicines in Australia.

The Draft Report states that products based on new active ingredients and new formulations are “desirable, require considerable R&D and are prevented from entering the market until regulatory approval is given” (Draft Report, page 93). Sanofi endorses this finding and notes that new drug
formulations provide significant benefit to patients (and as discussed above, the entire health system) including for example through improved tolerance, better adherence to dosing regimens and improved therapeutic efficacy.

The Review Panel recommends that the government maintain the “current approach to PTEs that allows extensions for drugs and formulations” (Draft Recommendation 6.1). In this regard, Sanofi notes however that there is currently a great deal of uncertainty as to whether the “current approach” does in fact result in the grant of extensions for all new formulations. Indeed, the narrow approach taken by the Administrative Appeals Tribunal in Re LTS Lohmann Therapie Systeme AG & Schwarz Pharma Ltd v Commissioner of Patents (2010) 118 ALD 425 in refusing to grant a patent extension for a transdermal delivery system for administering rotigotine suggests that some new formulations may not fall within the scope of the current PTE provisions. Sanofi suggests that consideration be given to amending the Patents Act to address this issue.

Sanofi strongly disagrees with the Review Panel’s recommendation that extensions of term should not be permitted for methods of use. Indeed, the same criteria applied by the Review Panel to new formulations apply equally to new methods of use – such methods of use are “desirable, require considerable R&D and are prevented from entering the market until regulatory approval is given”. In this sense, as discussed above, a new method of use is most appropriately considered a new “medicinal therapy” in the same manner as a new molecular entity or formulation.

Specifically in relation to new methods of use (new indications), originator companies must engage in time consuming and expensive trials, including in most cases, human clinical trials in order to demonstrate the safety and efficacy of the use of the formulation in a particular disease or disease process. As is the case for novel compounds, there is no guarantee that such R&D will lead to a marketable product. As discussed above, failure to provide an appropriate period of market exclusivity via strong patent rights will lead to fewer innovative medicinal therapies being brought to market. This will, in turn, result in poorer health outcomes for patients and a higher cost to the Australian Government of providing healthcare.

Additionally, in circumstances where a particular indication has not been approved in Australia due to the lack of incentive to do so, there are additional public health risks. For example, in circumstances where a formulation cannot be used to treat a disease in Australia (but has been proven efficacious in other jurisdictions), there is the risk that a doctor will prescribe the formulation “off-
label” without the benefit of the safety and efficacy assessment ordinarily undertaken by the TGA for the Australian patient population, which in turn are embodied in prescribing conditions for Australian medical practitioners.

The Draft Report states that “no evidence has been provided to the panel that such inventions are subject to the same extent of cost, delay and risk as pharmaceutical products” (Draft Report, page 96).

An example is Sanofi’s anti-rheumatic product Arava which was originally indicated in Australia solely for the treatment of rheumatoid arthritis. In order to provide the data necessary to obtain regulatory approval to market the drug for a new indication, namely psoriatic arthritis, Sanofi conducted human clinical trials showing the safety and efficacy of Arava in the treatment of this condition which involved considerable time and expense.

In these circumstances, Sanofi submits that there is no warrant for excluding methods of use from the ambit of the PTE provisions.

For the reasons set above, the absence of PTEs over methods of use patents puts at risk Australian patients’ access to new and innovative medicinal therapies, available in other parts of the world where such extensions are granted.

**Sanofi requests that the Review Panel recommend reforms to the PTE regime to ensure that pharmaceutical patents claiming new formulations and new methods of use are eligible for an extension of term.**

F. TRANSPARENCY REGISTER

**Draft Recommendation 8.2:** A transparency register linking therapeutic goods registered with the TGA with related patents should be introduced.

The Pharmaceutical Background and Issues Paper identified concerns regarding the certificates required to be given under sections 26B and 26C of the *Therapeutic Goods Act 1989* (Cth) (the *Therapeutic Goods Act*).

Sections 26B-D of the *Therapeutic Goods Act* were enacted pursuant to article 17.10.4 of the AUSFTA which is as follows:
Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting the safety or efficacy information, to rely on evidence or information concerning the safety or efficacy of a product that was previously approved, such as evidence of prior marketing approval by the Party or in another territory:

(a) that Party shall provide measures in its marketing approval process to prevent those other persons from:

(i) marketing a product, where that product is claimed in a patent; or

(ii) marketing a product for an approved use, where that approved use is claimed in a patent,
during the terms of that patent, unless by consent or acquiescence of the patent owner; and

(b) if the Party permits a third person to request marketing approval to enter the marketing with:

(i) a product during the term of a patent identified as claiming the product; or

(ii) a product for an approved use, during the term of a patent identified as claiming that approved use,

the Party shall provide for the patent owner to be notified of such request and the identity of any such other person.

[emphasis added]

The question posed by the Review Panel was “are the laws on patent certificates appropriate?”.

The overwhelming response to that question in submissions filed with the Review Panel was “no”.

Generic manufacturers argued that they “unfairly bear the burden of determining which patents apply” in forming a view as to which certificate should be given under section 26B of the Therapeutic Goods Act (Draft Report, page 162).
On the other hand, originators expressed the view that s26B of the Therapeutic Goods Act did not properly implement article 17.10.4 of the AUSFTA which requires patent owners to be notified of an application for registration of a generic drug with the aim of encouraging early resolution of patent disputes (Draft Report, page 162). This failure results from the fact that generic manufacturers have adopted the position that a patent is invalid until a court holds otherwise such that they are entitled to provide a certificate under s26B(1)(a) and thereby avoid notifying the originator of an intention to launch a generic product. In light of this approach, and the fact that applications to the TGA are confidential, the first “notification” to an originator of launch of a generic product occurs when the product appears on the Australian Register of Therapeutic Goods (the ARTG). Originator companies must monitor the ARTG for such “notification”. Listing on the ARTG means that the launch of the generic product is imminent (in some cases, generic products are launched immediately upon ARTG registration, prior to PBS listing, so as to take advantage of what is referred to as “first mover advantage”).

Originator companies also raised concerns about the operation of sections 26C and 26D of the Therapeutic Goods Act in and noted the clear imbalance between the penalties for originators under these sections as compared with those that apply under s26B. The Review Panel’s proposed response to the concerns raised about the certification system is to leave the system untouched and instead to recommend the establishment of a “transparency register”. At the outset, Sanofi notes that although the Draft Report refers to a system in which generic manufacturers provide s26B certificates to the TGA and to the relevant patentee within a certain period of filing an application for inclusion on the ARTG (Draft Report, page 169), no recommendation to this effect is made in the Draft Report.

Sanofi is of the view that the establishment of a transparency register does not address any of the concerns raised by innovator companies about the operation of the certification system. It does however appear to be directed at reducing the “burden” placed on generic companies in determining “which patents apply”. Sanofi submits that the Review Panel’s attempt to address this supposed issue is misguided for at least the following reasons:

(a) the Draft Report states that a transparency register is consistent with the aims of the patent system “one of which is to publish IP rights information to enable competitors to determine their freedom to operate” (Draft Report, page 165). This is not and never has been one of the “aims” of the patent system. Rather, the patent system rewards patentees with a monopoly
right for a twenty year term in return for disclosure to the world at large of the invention in a manner sufficient to enable others to work and improve the invention upon patent expiry.

(b) as the Draft Report itself acknowledges, the transparency register is but one “limited” aspect of the Orange Book system (Draft Report, page 169). The Orange Book system in turn forms part of the broader scheme adopted in the United States under the Drug Price Competition Act and Patent Term Restoration Act of 1984 (commonly referred to as the “Hatch-Waxman Act”). That scheme operates to create balanced rights and responsibilities for both originators and generics. Importantly, the Review Panel in recommending the adoption of the transparency register fails to recognise the other elements of the Hatch-Waxman Act which in concert with the transparency register encourage resolution of patent disputes well before generic entry including:

- the certification requirements, one of which requires a statement for the basis upon which it is asserted that a patent is invalid, unenforceable or will not be infringed by marketing of the generic product to be provided to the originator;
- an automatic stay of 30 months applies to a generic application for approval if the originator commences infringement proceedings; and
- a period of market exclusivity for the filed generic application.

The Draft Report provides no basis for its failure to recommend the adoption of all elements of this system.

(c) the Draft Report states that the transparency register will enable competitors to “more easily identify which patents are relevant to their plans” (Draft Report, page 165). No evidence was however identified as to any great difficulty encountered by generics in identifying relevant patents. In fact, the Draft Report expressly notes the availability of numerous searching databases and services. Indeed, Sanofi submits that undertaking freedom to operate searches is a part of doing business for generics and commercial enterprises across all fields of endeavour. In no other such endeavours are patent holders required to assist competitors by identifying “relevant” patents.

Further no evidence was identified that the cost of undertaking these searches was prohibitive. In any case, the real cost is not in identifying “relevant” patents but in undertaking the legal analysis required to determine the risk of infringement of those patents. The transparency register does not assist in this regard at all. Still further, the transparency register does not
alleviate the need for generics to undertake patent searches as patents owned by other parties must still be identified (and assessed).

Another serious concern raised by this recommendation is that originators will be required to undertake assessments of their entire patent portfolios to determine what patents are “related” to the relevant ARTG registered product. Such determination will be made under the threat of loss of the right to enforce patents not entered on the register which are later adjudged (presumably by a court) to be “related”. Indeed, it appears that even an inadvertent omission would preclude the patentee from exercising the rights afforded to it under the Patents Act. Such a scheme would appear to be an appropriation of intellectual property rights on unjust terms which would be unconstitutional.

Further, it appears that the transparency register will be administered by the TGA. The imposition of such administrative and cost burdens on a government agency to make life “easier” for generic manufacturers is entirely inappropriate.

Indeed, it is puzzling that although the Review Panel acknowledges that the notification system contemplated under the AUSFTA has not been achieved with the current provisions of the Therapeutic Goods Act, it has not seen fit to address this issue. It is Sanofi’s view that a simple and efficient solution to this problem is for a generic applicant seeking to rely on data provided to the TGA by originators for the purposes of regulatory approval should be required to notify the originator immediately upon application for registration. This may be by way of the provision of a s26B certificate or some other form of notification. Such a system imposes no additional burden on generic manufacturers but achieves certainty in notifying originators of potential infringements at an early stage. Indeed while this option is raised by the Draft Report, no cogent reasons are provided for its dismissal. Such a system would be consistent with Australia’s obligations under the AUSFTA.

On the whole, Sanofi is concerned that the proposed transparency register appears to be a complex and incomplete answer to the issues raised by the Draft Report. Moreover, creating a transparency register appears to leave patentees exposed to a loss of valuable IP rights and creates administrative and cost burdens on a number of parties, without providing any real benefit to either the originator or generic pharmaceutical industries.

Sanofi requests that the Draft Report: (a) provide reasons as to why the preferred position of the Review Panel is not to require generic pharmaceutical companies to
notify originator pharmaceutical companies when relying on data provided to the TGA by the originator pharmaceutical companies; (b) reconsider any recommendation to create a transparency register and/or (c) provide reasons as to why those elements of the Hatch-Waxman Act which provide incentive to resolve patent disputes before generic entry should not be adopted in any system that includes a transparency register.

Sanofi also submits that the Review Panel ought consider amending the certification system to ensure that it meets the objectives of the AUSFTA discussed above.

G. AMENDMENTS TO CONTRIBUTORY INFRINGEMENT PROVISIONS

**Draft Recommendation 6.4:** Section 117 of the Patents Act should be amended to provide that the supply of a pharmaceutical product subject to a patent which is used for a non-patented indication will not amount to infringement where “reasonable steps” have been taken to ensure that the product will only be used in a non-infringing manner. Policy should impose a presumption that “reasonable steps” have been taken where the product has been labeled with indications which do not include any infringing indications.

The Draft Report suggests that the contributory infringement provisions of the Patents Act are presently unclear, and amending the provisions in the manner proposed would ensure certainty for both patentees and generic manufacturers (Draft Report, page 111).

The interpretation of section 117 of the Patents Act is a matter which may be considered by the High Court of Australia in May of this year in *Aptex Pty Ltd v Sanofi-Aventis Australia Pty Ltd & Ors* (Aptex Pty Ltd v. Sanofi-Aventis Australia Pty Ltd, High Court proceeding S 219/2012).

As Sanofi is a party in those proceedings it considers it inappropriate to comment on any aspect of the case. However, Sanofi suggests that it is premature for amendments to be made to section 117 of the Patents Act prior to determination of the case by the High Court.

Sanofi requests that the Draft Report not proceed to recommend that section 117 of the Patents Act be amended pending the decision by the High Court in *Aptex v Sanofi-Aventis*. 
H. OVERSIGHT OF IP AUSTRALIA GRANTS AND DECISIONS

Draft Recommendation 7.2: The Government should establish an external patent oversight committee that is tasked with reviewing grants and decisions issued by IP Australia and auditing the processes involved in making such decisions.

As a means for improving patent quality, the Draft Report broadly recommends the establishment of an external process for “auditing” the patent grants and decisions applied by IP Australia. The Draft Report envisages that a patent oversight committee could review patent grants and decisions by IP Australia, and play a role in shaping future patent law reforms and policies (Draft Report, page 125).

Sanofi is concerned by the level of generality at which this recommendation is expressed. For example, it is not clear how the external body is intended to operate, the scope of its authority or the persons who will comprise it. For example, would every IP Australia decision be “reviewed” and what would such a “review” entail? It is particularly difficult to comprehend how a committee might be established that would have comparable levels of expertise and training to the expert examiners at IP Australia.

The decisions of IP Australia are already the subject of review by the Administrative Appeals Tribunal, the Federal Court (and ultimately the High Court) and, the decision-making process is laid bare in the Australian Patent Office Manual of Practice and Procedure.

The establishment of a “patents oversight committee” would add a further layer of decision-making leading to increased complexity and cost without any demonstrated benefit.

Sanofi requests that the Draft Report clarify the nature of any proposed “external patent oversight committee” and estimate and justify the cost of such a committee to the Australian public.

Yours faithfully,

Laurence McAllister
Managing Director
Annexure A

An indication as to whether R&D efforts will be profitable can be obtained by comparing Internal Rate of Returns (IRR) to the Cost of Capital.

IRR is a measure which equates the cost of developing an investment and the expected benefits that the investment will deliver. In general, if the IRR on a project or investment is greater than the minimum required rate of return – the Cost of Capital – then the project is more likely to be profitable. Conversely, if the IRR on a project is lower than the cost of capital, then it is unlikely to be profitable.

IRR for Pharmaceutical R&D

A report compiled by Deloitte LLP and Thompson Reuters in January of this year entitled “Measuring the return from pharmaceutical innovation 2012 Is R&D earning its investment?” analysed the IRR for companies including Amgen, AstraZeneca, Bristol-Myers Squibb, Eli Lilly, GlaxoSmithKline, Johnson & Johnson, Merck & Co., Novartis, Pfizer, Roche, Sanofi, and Takeda.


A comparison of the static IRR results between 2010-2012 is shown in Figure 1 below. The Cohort IRR is the weighted average of IRR values for the aforementioned companies.
**Cost of Capital for the Pharmaceutical Sector**

The cost of capital for the pharmaceutical sector is most often cited at 7% - see, for example, [http://www.ibtimes.com/big-pharma-facing-patent-cliff-declining-rd-returns-919311](http://www.ibtimes.com/big-pharma-facing-patent-cliff-declining-rd-returns-919311).

An estimate of the Cost of Capital can also be obtained from [http://www.damodaran.com](http://www.damodaran.com). This website is maintained by Aswath Damodaran, Professor of Finance at the Stern School of Business at New York University.

The Cost of Capital is calculated for a particular sector as follows:

*The weighted average of the cost of equity and after-tax cost of debt, weighted by the market values of equity and debt:*

\[
\text{Cost of Capital} = \text{Cost of Equity} \left( \frac{E}{D+E} \right) + \text{After-tax Cost of Debt} \left( \frac{D}{D+E} \right)
\]
For the weights, we use cumulated market values for the entire sector.

The current reported Cost of Capital number for the pharmaceutical sector is 7.49%, as determined by averaging 223 companies. These values can be obtained from http://pages.stern.nyu.edu/~adamodar/New_Home_Page/datafile/wacc.html.htm.

Comparing R&D IRR and Cost of Capital

The following graph compares the Cohort R&D IRR to the Cost of Capital.

The graph clearly demonstrates, using the most recent Cost of Capital estimate, that the R&D IRR has fallen below the Cost of Capital. These results suggest that pharmaceutical R&D is on the cusp of being unprofitable, if not already unprofitable.