BAYER’S NEXAVAR AND THE “WORKING” OF COMPULSORY LICENSING: MIND THE PATENT (INFORMATION) GAP!

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Patent Working and Compulsory Licensing

Section 146 of the Indian Patents Act mandates that every patentee discloses the extent to which she has commercially “worked” her patent. The rationale for this statutory mandate is that it helps evaluate if the patentee has satisfied the reasonable requirements of the public, and thereby fulfilled her part of the social bargain whilst securing a twenty year monopoly from the state. Should she fail in this important intellectual property “duty”, her patent is susceptible to a compulsory licence, wherein a third party can produce and sell a competing product expected to be more accessible and available to the general public.

Such a compulsory license was issued three years ago over Bayer’s patented anticancer drug Sorefanib Tosylate (sold as “Nexavar”) on the ground that it was exorbitantly priced at Rs 2.8 lakhs (about USD 4500 a month) and hardly available to 2% of the patient population. The license was issued in favour of Natco, an Indian generic company, which then sold the drug (as “Sorafenat”) at Rs 8,800 (about USD 150) a month.

While making its argument for a compulsory license over Bayer’s highly priced drug, Natco relied heavily on the patent “working” figures submitted by Bayer as part of its Form 27 declarations to the Indian Patent Office. These figures more than amply demonstrated that Bayer was hardly satisfying 2% of the patient population through its sales/disbursements of the drug. To this extent, Form 27 disclosures constitute an important edifice of the patent regime, and gauge the existence and extent to which a patentee translates a government secured monopoly into public benefit. But for a full and complete patent working disclosure, the compulsory licensing provisions will come to naught.

Defects in Bayer’s Form 27 Declarations

Unfortunately, the Form 27 declarations submitted by Bayer are incomplete in several particulars and raise several questions; questions that go to the heart of patent working and public interest. This report points to these various informational gaps and discrepancies, some of which are highlighted below:

1. Bayer did not file any Form 27 for the year 2008, despite its patent having been granted in April 2008.

2. Bayer submitted two separate Form 27s for the year 2009. However, till date, Bayer has refused to clarify as to which of the forms is the accurate one. Both forms contain significant inaccuracies/gaps.
3. It is not clear if Bayer submitted a Form 27 declaration for the year 2010. While our RTI request for such a form met with a negative response from the Indian Patent Office (indicating that no form had been filed), both the Controller as well as the IPAB refer to such a form in their respective decisions. It is to be noted that the figures mentioned by the IPO and the IPAB for the year 2010 include only “sample” and “support” packs. As such, there are no commercial sales/disbursements in this year. One wonders how the demand for the drug was met in that year. How did patients get their supplies? As with other queries, Bayer refused to answer this query, as also our query on what the terms “support” and “sample” pack meant and entailed. Were these packs distributed with conditions attached to ensure that they were not sold further by the recipients? Were they doled out to doctors in a bid to convert them to loyal customers?

4. Bayer’s per unit price for the drug in the Form 27 submissions is way below the figure quoted in the compulsory licensing decision. While the Form 27 data indicates that the per unit price is an average of Rs 96,000/-, the compulsory licensing decision indicates that the price is Rs 2.8 lakhs (approximately USD 4500) per month. Here again, Bayer refused to explain this discrepancy to us. It is also noteworthy that despite a compulsory licensing decision that was issued owing primarily to Bayer’s exorbitant price for the drug, it continues to sell in the open market at the same rate.

5. While Bayer discloses the various import and distribution figures for its patient assistance programme (PAP) programme in its Form 27 submissions, nowhere does it indicate the amount of revenues that it makes through this programme. This is an important figure to track, given that the PAP is not completely free, but has to be paid for partly by the patient.

Apart from queries seeking to clarify the various informational gaps/discrepancies in their Form 27 submissions, we also noted a very puzzling practice: Bayer routinely imports Nexavar well in excess of its needed supplies, year after year. Given that it sells an average of 1500-2200 drug units each year, one would expect it to import at numbers close to (or slightly higher) than this figure. However, it imports well in excess (up to 700% more!) of these sales figures year after year. Illustratively, it imported a whooping 11,536 units in the year 2012! And this is despite the fact that it had a leftover stock of 4644 from the previous year.

As to why it would import such disproportionate numbers year after year and presumably suffer losses is unclear. Needless to add, Bayer refused to answer our query on this front as well (our queries to Bayer are listed out in Annexure A and our email correspondence is annexed as Annexure B). This illogical import pattern and its possible nexus with potential tax avoidance strategies etc needs to be investigated.
BAYER’S NEXAVAR AND THE “WORKING” OF COMPULSORY LICENSING: MIND THE PATENT (INFORMATION) GAP!

From Faith Based to Fact Based IP: Government Apathy in Enforcement

At a broader policy level, our report suggests that one must take the business of numbers more seriously. In an ecosystem charged with emotional rhetoric, one needs more empirical data (“facts”) rather than “faith” in order to arrive at more optimal policy solutions.

Fortunately, the Indian patent regime contains potent provisions calling for such factual numbers, at least on the patent working front. Unfortunately, its implementation leaves much to be desired. Despite an earlier report by us (SpicyIP) in 2011 on the sheer impunity with which pharmaceutical patentees routinely ignored the patent working disclosure mandate (under section 146), the Indian government is yet to take any action. Further, our RTI application querying the government specifically on whether or not they had initiated any action against errant patentees met with a negative response. This, despite the fact that section 122 of the Patents Act clearly empowers the government to penalise errant patentees.

Our report is also meant to foster more transparency within the IP firmament, a mission that lies at the very core of SpicyIP’s mission.

Revocation of Bayer’s Patent?

India has a fairly potent compulsory licensing regime. Its invocation generally depends on whether or not the patentee has worked the patent adequately; and this hinges significantly on the numbers i.e., the sales/distribution figures for the drug in question.

If it turns out that even after two years of operation of the compulsory licence, the reasonable requirements of the public have still not been satisfied, the patent can be revoked under section 85 of the Indian Patents Act.

It is worrying that despite the issuance of a compulsory licence on the ground that Bayer was selling at an excessive price and catering to hardly 2% of the patient population, Bayer has not made any amends. Our personal investigations with pharmacies revealed that Bayer continues to dole out the drug at the earlier price (Rs 2,80,000 per month). Further, the more recent Form 27 submissions of Bayer appear to indicate that the 2% (percentage of patients having access to the drug, assuming that the number of patients that need the drug have largely remained the same) has not increased significantly since the time of issuance of the compulsory licence.

Of course, this 2% is bound to go higher, if one takes into account the sales figures of Natco and Cipla. Natco sells under a compulsory license, while Cipla has been selling “at risk”. Unfortunately, at present, these sales figures of Natco and Cipla are not publicly available.

However, even assuming Cipla and Natco are servicing a much higher number of the patient pool than Bayer (lets say, 50% of patients), as per the Bombay High Court decision, Bayer’s patent is susceptible to revocation, for the court had held that if
even a single patient does not have access to the drug, the reasonable requirements of the public cannot be said to be satisfied.

**Natco’s Failure to Comply with Compulsory Licensing Mandate:**

Despite a legal obligation to do so (under the terms of the compulsory licensing order issued by the IPO), Natco has failed to submit its sales figures to the Indian Patent Office. In response to our RTI application query, the IPO confirmed that even after three years of the compulsory license being issued, Natco is yet to submit any of its quarterly sales figures for sordafenib tosylate (sold as Sorefenat).

As for Cipla, it is under no legal obligation to submit or make available its sales figures. It is therefore imperative that the government put in place a mechanism to source this data with relative ease, so as to make for an effective invocation of the compulsory licensing and revocation provisions.

**Conclusion: Key Suggestions**

1. The government ought to immediately take action against errant patentees and licensees who fail to submit full and complete Form 27 information. It is worrying that even after evidence has been brought to their notice that patentees consistently and blatantly ignore this important statutory mandate, they have so far failed to take any action.

2. The IPO ought to initiate immediate action against Natco for failing to comply with the terms of the compulsory licensing order in terms of submitting its quarterly sales figures for their generic version of sordafenib tosylate (sold as Sorefanat).

3. The government ought to investigate the following:

   i) Why does Bayer routinely import exponentially higher volumes of Nexavar than is necessary for its routine disbursements/demand. What does it do with the excess stock year after year? Is there a tax evasion angle here?

   ii) How are Bayer’s “sample” and “support” packs ultimately disbursed. If they are “gifted” to doctors and then sold onwards by doctors to patients, does this not constitute a legal/ethical violation?

   iii) What percentage of the patient population today is able to access Sorefanib Tosylate from all suppliers put together (namely, Bayer, Natco and Cipla)?
This last bit of information is absolutely critical for determining whether or not the patient requirements are being adequately satisfied. Under the terms of the Bombay High Court order however, even a single patient not having access to the drug would render it susceptible to revocation.

4. In the future, government agencies, quasi judicial bodies (such as the IPO), and judicial bodies (such as the IPAB and courts) ought to ensure that there is consistency across usage of metrics in compulsory licensing and other decisions that turn on numbers. The Bayer vs. Natco CL decision is replete with inconsistent usage of metrics, such as “boxes” and “support packs” which find no mention in the Form 27 submissions by Bayer.
MAIN REPORT

I INTRODUCTION

A. The Patent “Working” Mandate and Form 27s

Section 146 of the Indian Patents Act mandates that every patentee discloses the extent to which she has commercially “worked” her patent. This has to be done through a declaration in a standard form titled “Form 27” (hence the phrase “Form 27” declaration/submission/mandate is used throughout this report).

The format for Form-27 is provided under the Second Schedule to the Patents Rules and requires patentees and their licensees to disclose the following particulars:

(a) Whether the patented invention has been worked on a commercial scale within India for the year in question;
(b) If the patented invention is not worked, the reasons for such non-working;
(c) If the patented invention is worked, the rights-holder must:
   i. specify the quantum and value of sales of the product covered by the patent in India for the relevant year in question;
   ii. specify the details of licences and sub-licences granted during the relevant year;
   iii. state whether the patented invention is manufactured within the territory of India in the relevant year; and
   iv. state whether the public requirement of the patented invention has been met either partly or adequately or to the fullest extent at a reasonable price for the relevant year;

The rationale for this statutory mandate is that it helps evaluate if the patentee has met the reasonable requirements of the public, and thereby fulfilled her part of the social bargain whilst securing a twenty year monopoly from the state. Should she fail in this important intellectual property “duty”, her patent is susceptible to a

1 Section 146(2) states in no uncertain terms that every patentee and every licensee (whether exclusive or otherwise) must disclose the extent to which the patented invention has been worked on a commercial scale in India. This mandate is again reiterated in Sub-rule (2) of Rule 131 of the Patents Rules which provides that working information shall be submitted in terms of the format set out under Form 27, within three months of the end of each year.
compulsory licence, wherein a third party can produce and sell a competing product expected to be more accessible and available to the general public.

B. **Bayer vs. Natco: India’s First Compulsory Licensing Decision**

India’s first (post TRIPS) compulsory licence was issued in 2012 in a landmark case concerning Bayer’s patented anticancer drug Sorafenib Tosylate (sold as “Nexavar”), on the ground that it was exorbitantly priced (Rs 2.8 lakhs a month or approximately USD 4500 per month) and hardly available to 2% of the patient population. The license was issued under section 84 of the Indian Patents Act in favour of Natco, an Indian generic company which then sold this drug (as Sorafenat) at Rs 8800 a month. The decision was upheld by the IPAB, the Bombay High Court and implicitly by the Supreme Court as well.

While making its argument for a compulsory licence over this highly priced drug, Natco relied heavily on the patent “working” figures submitted by Bayer as part of its Form 27 declarations to the Indian Patent Office. These figures more than amply demonstrated that Bayer was hardly satisfying 2% of the patient population through its sales/disbursements of the drug.

Form 27 disclosures constitute an important edifice of the patent regime and gauge the existence and extent to which a patentee translates a government secured monopoly into public benefit. Unfortunately, the Form 27 declarations submitted by Bayer are incomplete in several particulars and raise several questions - questions that go to the heart of the issue of patent working and public interest.

C. **From Faith Based to Fact Based IP: Government Apathy in Enforcement**

The various informational gaps/discrepancies in Bayer’s Form 27 submissions is particularly worrying, since these gaps remain even after a harsh adversarial process that resulted in the compulsory licensing dispute being dragged all the way to the Supreme Court.

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3 This section provides that a compulsory license may issue after three years of the date of grant of the patent, if the patentee: i) does not sell the patented invention at a reasonably affordable price; ii) does not satisfy the reasonable requirements of the public; or iii) has failed to work the patented invention in India.
7 The Supreme Court dismissed Bayer’s Special Leave Petition against the Bombay High Court order (which had upheld the orders of the IPAB and the Patent Office).
To be fair to Bayer however, these gaps must be seen against the backdrop of a lax regulatory regime, where, till date, the government has not taken any action against patentees who fail to comply with the Form 27 mandate to submit full and complete patent working information. This is despite the fact that such non compliance was widely known. In fact, as far back as 2010, we sourced information on patent working information submitted by large pharmaceutical companies to the IPO, and demonstrated widespread non compliance by them with this important statutory mandate.

We argue that it is critical that these provisions be enforced in their full rigour and patentees be compelled to comply. Further, the current structure/format of Form 27 is wanting in several respects. It needs to be made more comprehensive and tightly worded so as to elicit better compliance and foster a comprehensive disclosure regime that appropriately balances innovation imperatives against the larger public access to patent information.

At a broader policy level, we argue that one must take the business of numbers more seriously. In an ecosystem charged with emotional rhetoric, one needs more empirical data (“facts”) rather than “faith” in order to arrive at more optimal policy solutions.

D. Revocation of the Bayer patent?

India has a fairly potent compulsory licensing regime. Its invocation generally depends on whether or not the patentee has worked the patent adequately; and this hinges significantly on the numbers i.e. the sales/distribution figures for the drug in question.

If it turns out that even after two years of operation of the compulsory licence, the reasonable requirements of the public have still not been satisfied, the patent can be revoked under section 85 of the Indian Patents Act.

It is worrying that despite the issuance of a compulsory licence on the ground that Bayer was selling at an excessive price and catering to hardly 2% of the patient population, Bayer has not made any amends. Our personal investigations with pharmacies revealed that Bayer continues to dole out the drug at the earlier price (Rs 2,80,000 per month). Further, the more recent Form 27 submissions of Bayer appear

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8 In an RTI response, the government admitted to us that till date, not a single action has been initiated against any errant patentee in this regard.
9 In 2010, the SpicyIP team investigated the extent of compliance by transnational pharmaceutical companies (with the Form 27 mandate) and discovered that there was gross non-compliance by almost all the drug firms surveyed. See http://spicyip.com/2011/04/drug-firms-and-patent-working-extent-of.html.
10 Section 122 of the Patents Act empowers the government to penalise errant patentees; those that fail to comply with the section 146 mandate to submit full and complete patent working information.
to indicate that the 2% (percentage of patients having access to the drug) has not increased significantly since the time of issuance of the compulsory licence.\textsuperscript{12}

Of course, this 2% is bound to go higher if one takes into account the sales figures of Natco and Cipla. Natco sells under a compulsory license, while Cipla has been selling “at risk”.\textsuperscript{13} However, at present, these sales figures of Natco and Cipla are not publicly available.

Despite a legal obligation to do so, Natco has failed to submit its sales figures to the Indian patent office (IPO). In response to our RTI application query, the IPO confirmed that even after three years of the compulsory license being issued, Natco is yet to submit any of its quarterly sales figures for sorafenib tosylate (as mandated by the compulsory licensing order issued by the IPO in 2012). The IPO also confirmed that despite this breach by Natco of an important term of the compulsory licence, they have not initiated any action against Natco.\textsuperscript{14}

As for Cipla, it is under no legal obligation to submit or make available its sales figures. It is therefore imperative that the government put in place a mechanism to source this data with relative ease, so as to make for an effective invocation of the compulsory licensing and revocation provisions.

Lastly, we ask the question: does the available data make out a case for revoking Bayer’s patent over Nexavar. We argue that under the terms of the Bombay High Court decision, this patent is susceptible to revocation, for the court had held that if even a single patient does not have access to the drug, the reasonable requirements of the public cannot be said to be satisfied.\textsuperscript{15}

\textsuperscript{12} This is assuming that the number of patients that need the drug have largely remained the same.

\textsuperscript{13} It bears noting that at present Natco Pharma Ltd and Cipla Limited are also selling the drug. Natco does so under a compulsory licensing and available reports indicate that it began doing so from July 2012 (after the issuance of the compulsory license in March 2012). Cipla appears to have done an at-risk launch of the drug (sold as Soranib) in April 2010. It was sued immediately thereafter by Bayer and the matter was sent to an expedited trial (without an interim injunction phase) by Justice Bhat of the Delhi High Court. However, to this day, the trial has not effectively begun.

\textsuperscript{14} We first filed an RTI on Feb 10, 2014 seeking this information i.e. Natco’s submission of the quarterly sales figures. The government response indicated that Natco had not submitted any such figures to them. A repeat RTI on January 19, 2015 indicated the same. Furthermore, the government also confirmed that they are yet to initiate any action against Natco for this blatant contravention of an important licensing condition. We’ve uploaded all these RTI’s and the responses on the SpicyIP website. See <http://spicyip.com/wp-content/uploads/2015/04/natco-cl-rtis.pdf>

\textsuperscript{15} Bayer v. Union of India, W.P. Number 1323 of 2013, available at <http://bombayhighcourt.nic.in> (Last visited on April 12, 2015): “So far as luxury articles are concerned the meeting of adequate extent test would be completely different from the meeting of adequate extent test so far as medicines are concerned. In respect of medicines the adequate extent test has to be 100% i.e. to the fullest extent. Medicine has to be made available to every patient and this cannot be deprived/scarified at the altar of rights of patent holder. In fact this is the mandate of Parliament by providing for Compulsory Licensing. This would also be in accord with Doha Declaration 2001 which inter alia reiterates
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Therefore, even assuming Cipla and Natco are servicing a much higher number of the patient pool than Bayer (let’s say, 50% of patients), as per the Bombay High Court decision, Bayer’s patent is susceptible to revocation.

II. INFORMATIONAL GAPS IN BAYER’s FORM 27s

Our study of the various Form 27s submitted by Bayer over the years (collated in a tabular format in Section III below) highlights several discrepancies and informational gaps in the data submitted.16 Unfortunately, Bayer steadfastly refused to answer our questions and clarify the various discrepancies (see Annexure A containing a list of our queries and Annexure B containing our email exchanges with Bayer).

A. Key Highlights

While there are a number of informational gaps and discrepancies in the Form 27 data submitted by Bayer (as elaborated upon in various sections below), the following deserve highlighting:

1. No Form 27 was filed for the year 2008-09 by Bayer, despite the patent being granted to Bayer in March 2008.17

2. Bayer submitted two Form 27s for the year 2009.18 However, till date, Bayer has refused to clarify as to which of the forms is the accurate one. Both forms contain significant inaccuracies/gaps. While one of the forms quotes a per unit cost for the drug that is clearly wrong, the other does not bother to state the “value” of imports of the drug.19 In particular, the Controller of Patents specifically mentions in his order that these forms submitted by Bayer provide no “logical information about sales”.20

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18 In response to our RTI request asking for Bayer’s Form 27 submissions, the IPO (Indian Patent Office) sent us two separate Form 27 filings pertaining to the year 2009. This was documented in our earlier investigation of this issue. In 2010, we surveyed the extent of compliance of transnational pharmaceutical companies with the Form 27 mandate and discovered that there was gross non-compliance with this important statutory mandate. See <http://spicyip.com/2011/04/drug-firms-and-patent-working-extent-of.html>. Neither then (when we released the report) nor now (when we’ve queried them) has Bayer clarified this issue.
19 This is detailed out in the set of questions posed to Bayer in Annexure A of this report.
20 “It is noted that the Form-27 for 2009 filed by the Patentee does not provide any logical information about the sales.” See page 21 of the Controller’s order.
3. It is not clear if Bayer submitted a Form 27 declaration for the year 2010. While our RTI request for such a form met with a negative response from the Indian Patent Office (indicating that no form had been filed), both the Controller as well as the IPAB refer to such a form in their respective decisions. Bayer could have clarified this confusion but chose not to respond to our specific query on this i.e. whether or not it had actually submitted a Form 27 to the patent office or whether the figures for 2010 relied on by the IPO/IPAB for the compulsory licensing dispute were separately submitted by Bayer through an affidavit.

It is to be noted that the figures mentioned by the IPO and the IPAB for the year 2010 include only “sample” and “support” packs. As such, there are no commercial sales/disbursements in this year. One wonders how the demand for the drug was met in that year. How did patients get their supplies? As with other queries, Bayer refused to answer this query, as also our query on what the terms “support” and “sample” pack meant and entailed. Were these packs distributed with conditions attached to ensure that they were not sold further by the recipients? Were they doled out to doctors as sops?

4. Bayer’s per unit price for the drug in the Form 27 submissions is way below the figure quoted in the compulsory licensing decision. While the Form 27 data indicates that the per unit price is an average of Rs 96,000/-, the compulsory licensing decision indicates that the price is Rs 2.8 lakhs (or approximately USD 4500) per month. Further, our own personal investigations revealed that Bayer sells the drug at this price (Rs 2.8 lakhs in the market). Here again, Bayer refused to explain this discrepancy to us. It is also worrying that despite a compulsory licensing decision that issued owing primarily to Bayer’s exorbitant price for the drug, it continues to sell in the open market at the same rate.

21 See Bayer Corporation and Anr. v. Union of India, MIPR2010(1)242, ¶2.
22 Excerpt from the Controller’s Order [Natco v. Bayer CLA No. 1 of 2011] at p 21, 22: “ It is noted that the Form -27 for 2009 filed by the Patentee does not provide any logical information about the sales. Form 27 for the year 2010 discloses that the Patentee did not import any ‘sale pack’ but imported only 340 units [60 tablets pack] of ‘support pack’ and 340 units [60 tablets pack] of ‘sample pack’, both having an ‘invoice value’ of Rs. 10,045,692. It appears to me, from the Form-27 filed by the Patentee for the year 2009 and 2010, that only an insignificant quantum of the drug was made available by the Patentee to the public during these two years.”
Excerpt from the IPAB’s judgment [Natco v. Bayer OA/35/2012/PT/MUM] at paragraph 37: “In the year 2010, it is stated that no commercial sales packs were imported and only sample packs of Nexavar patient support packs were imported. Again, as far as the manufacture in India is concerned, it is stated as ‘NIL’. The number of Nexavar sales packs imported is stated to be NIL. The number of Nexavar patient support packs imported is stated to be 340 units and the number of Nexavar sample packs is stated to be 340 units. In the Form-27 for the year 2010, it is stated that the public requirement has been met to the fullest extent at reasonable price.”
23 However, this Form 27 figure is different only for the year 2013, where the per unit cost is stated to be Rs. 2,87,000.
Also, if the Form 27 data is true, and Bayer effectively sells in India at the same price at which it imports, it effectively means that it sells at a loss in India (since it is likely to have marketing and distribution costs in India). This needs to be investigated further.

5. While Bayer notes the existence of a patient assistance programme (PAP) in its various Form 27 submissions, nowhere does it indicate the amount of revenues that it makes through this programme. This is an important figure to track, given that part of the PAP is paid for by the patient. In the latest version of the programme, if the patient pays for 3 days supply of the drug, he/she gets the remaining 27 days for that month free. Further, even for the Patient Assistance Programme (PAP), Bayer continues to import well in excess of its requirement. See chart below (data taken from Table 1 in Section III):

<table>
<thead>
<tr>
<th>Year</th>
<th>PAP Imports</th>
<th>PAP Disbursements</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>340</td>
<td>N.A.</td>
</tr>
<tr>
<td>2011</td>
<td>1260</td>
<td>247</td>
</tr>
<tr>
<td>2012</td>
<td>10636</td>
<td>1011</td>
</tr>
<tr>
<td>2013</td>
<td>N.A.</td>
<td>1156</td>
</tr>
</tbody>
</table>

Bayer failed to respond to our questionnaire (see Annexure A) asking them to explain this anomaly. Further, it appears strange that there is such a low uptake for a near-free drug program, particularly when a significant set of patients have no access to Bayer’s regular drug sold at an exorbitant price in the market.

6. There is no clarity on what Bayer means by the term “sample packs”. Are these given to doctors/hospitals completely free of charge/encumbrances or is there a nominal/minimal charge? Also, are there conditions attached to such disbursements? Could a doctor sell it to a patient, although the recipient has received it from Bayer for free? Are sample packs tracked after they have been given away to recipients (doctors/hospitals etc.) to check whether they are put in use and/or whether conditions attached to them are fulfilled?

7. It is not clear what is meant by the phrase “support packs”, and as to how these are different from “sample” packs. Although the term is not used in the Form 27 submissions, it is sprinkled rather liberally in the decisions of the Controller and the IPAB, where both record the import of ‘support’ packs for
the year 2010. Further the same set of queries posed for sample packs applies here as well (are they given away for free, are they tracked, etc).

8. Decoding the precise nature of support packs, sample packs and the PAP is crucial to assessing the extent of disbursement of the drug. Bayer, in particular, relied on their non-commercial distribution of the drug to counter arguments that its high pricing made the drug inaccessible to majority of the patients who need it across the country.

B. Puzzling Practices:
Apart from queries seeking to clarify the various informational gaps/discrepancies in their Form 27 submissions, we also noted a very puzzling practice, described below. Here again, Bayer refused to respond.

The Form 27 figures indicate that Bayer routinely imports Nexavar well in excess of its needed supplies, year after year. Given that it sells an average of 1500-2200 drug units each year,24 one would expect it to import at numbers close to (or slightly higher) than this figure. However, it imports well in excess of these sales figures year after year. Illustratively, it imported a whooping 11,536 units in the year 2012!25 And this is despite the fact that it had a leftover stock of 4644 from the previous year.

As to why it would import such disproportionate numbers year after year and presumably suffer losses is unclear. Bayer once again refused to answer our query on this front as well (our queries to Bayer are listed out in Annexure A).

Moreover, 2012 also indicates a massive shift in the import pattern. In that year, only 7.8% of the drug imported was listed as ‘commercial’ whereas all the remaining was listed as imported for the purpose of the PAP. This is in contrast to 40.55% in 2011.26 And yet, in 2012, only 1011 packs of the total imported drugs were actually disbursed as part of the program. At best, this highlights a severe coordination problem. At worst, it could mean duplicitous import patterns. This illogical import practice and its nexus with potential tax avoidance strategies, etc., needs to be investigated.

C. Bayer’s Refusal to Answer our Queries
We are not sure what to make of Bayer’s refusal to answer our queries. Their latest excuse (that despite the Supreme Court disposing of the main matter, other litigations continue and therefore they are prevented from responding) does not

24 These were the average figures that we collated from the Form 27s filed for the years 2009-2013.
25 It went on to sell a total (Commercial + PAP) of only 2137 units that year.
26 As the Form 27 data for 2010 is not available, we cannot calculate the proportion of commercial imports or PAP imports to total imports. However, it is to be noted that the import quantum in 2010 for the PAP was merely 340. The 10636 figure for 2012 indicates a thirtyfold increase.
hold much water, as the queries relate to clarifying information that was to be made publicly available through a statutory mandate.\textsuperscript{27} We can only draw an adverse inference that it suits them to be opaque on this count. It is incumbent on the government and courts to force them to yield this information for the larger public benefit and for a better functioning of India’s patent regime.

D. Different Metrics/Figures: Form 27 vs IPO/IPAB Usage

It bears noting that the IPO and the IPAB appear to have relied on different metrics/figures/terms than that deployed in Form 27, making it difficult to ascertain the veracity of information submitted by Bayer.

Illustratively, the Controller and the IPAB use the term, “support packs”, “boxes” and “packs” when these terms find no resonance in Bayer’s official Form 27 filings. Working out corresponding figures has proved very troubling. We hope that in future, the Form 27 format and data is the one that will be used uniformly by all agencies and courts that rely on such data.

Illustratively, the Controller notes that Bayer sold 593 boxes of the drug in 2011.\textsuperscript{28} However there is no clarity in the Controller’s order on how many packs/tablets are present in each box.\textsuperscript{29} Given that the Controller goes on to note that the supply of boxes for that year would meet the requirements of only 200 patients, one assumes that the number of boxes (593) has been divided by the number of months (3 months) to arrive at this figure. Therefore one patient requires one box a month. If this is so, then each box should contain around 2 packs (120 tablets of 200 mg each).

However, there is some inconsistency when we compare this with the Form 27 data for this year (2011). The Form 27 data states that the total sales in 2011 were 1562 packs \([1178 \text{ (commercial)} + 137 \text{ (free sample)} + 247 \text{ (PAP)}]\), Given that the total number of boxes sold was “593” as per the Controller order, this would mean that there were 3 packs to a box and not 2 as we initially assumed. This is further complicated by the fact that the Controller records Natco’s argument that approximately “200” boxes were imported by Bayer in 2009,\textsuperscript{30} whereas the Form 27

\begin{itemize}
  \item They also claimed that they had a review petition pending before the Supreme Court. This review petition was dismissed on March 12, 2015.
  \item Excerpt from the Controller’s Order [\textit{Natco v. Bayer} CLA No. 1 of 2011] at p. 22: “The Patentee has submitted that they have sold about 593 boxes during the year 2011.”
  \item The Controller notes that the sales for 2011 were 593 boxes. The Form 27 data for 2011 states that the total sales in 2011 were 1562 packs \([1178 \text{ (commercial)} + 137 \text{ (free sample)} + 247 \text{ (PAP)}]\), Given that the total number of boxes sold was “593” as per the Controller order, this would mean that there were 3 packs to a box and not 2 as we initially assumed. This is further complicated by the fact that the Controller records Natco’s argument that approximately “200” boxes were imported by Bayer in 2009, whereas the Form 27
  \item It bears noting that the number of boxes (200) figure was not stated by the controller as his finding, but as Natco’s argument in its submissions to the Controller (See para 10 (a) of the Controller’s Order: page 13 of the order).
\end{itemize}
for that year records the import of 4665 packs. This would imply that there are 23.32 packs per box.

IV. BAYER’s FORM 27 SUBMISSIONS: COMPREHENSIVE DATA

The table below encapsulates the import, sales and revenue figures for the kidney/liver cancer drug, Nexavar based on Bayer’s Form 27 submissions till date (from the years 2009 up until 2013).

Table 1: Overview of the Form 27 filings

<table>
<thead>
<tr>
<th>I. YEAR</th>
<th>II. USAGE</th>
<th>III. IMPORT FIGURES</th>
<th>IV. SALE/DISBURSEMENT FIGURES</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Quantum</td>
<td>Value</td>
</tr>
<tr>
<td>2009</td>
<td>Commercial</td>
<td>4665</td>
<td>45,53,7</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>397531</td>
</tr>
<tr>
<td>2010</td>
<td>Commercial</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td></td>
<td>Samples</td>
<td>340</td>
<td>1,00,45</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>,69232</td>
</tr>
<tr>
<td>2011</td>
<td>Commercial</td>
<td>1030</td>
<td>9,91,92</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>,710</td>
</tr>
<tr>
<td></td>
<td>Samples</td>
<td>250</td>
<td>2,40,75</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>,900</td>
</tr>
</tbody>
</table>

31 As noted earlier, Bayer filed two forms for the same year and has not clarified till date as to which is the accurate form to be relied upon. The authors have used one of the two sets of numbers for reasons mentioned in point “iv” under “Notes on Tables and Data” that follow this table.

32 The Controller notes this value as the stated ‘invoice value’. At page 21, 22: “It is noted that the Form-27 for 2009 filed by the Patentee does not provide any logical information about the sales. Form 27 for the year 2010 discloses that the Patentee did not import any ‘sale pack’ but imported only 340 units [60 tablets pack] of ‘support pack’ and 340 units [60 tablets pack] of ‘sample pack’, both having an ‘invoice value’ of Rs. 10,045,692. It appears to me, from the Form-27 filed by the Patentee for the year 2009 and 2010, that only an insignificant quantum of the drug was made available by the Patentee to the public during these two years.” One is not sure whether this ought to be entered under “imports” or under “sales/disbursement”.

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## A. Notes on Tables and Data

The above figures were directly sourced from the ‘Statement on Working of the Patented Invention on Commercial Scale in India’ (Form 27) submitted by Bayer before the IPO. As per Section 146(2) and Rule 131(1) of the Indian Patents Act and Rules thereunder, all patentees and licensees are to compulsorily submit “working” information.

It bears noting that the IPO made the 2012 and 2013 working information available online. We, therefore, sourced this information directly from the IPO website. However, since it did not do so for previous years, (2008, 2009 and 2011), we had to procure the required information from the IPO through an application under India’s RTI Act.

As noted earlier, we received no Form 27 pertaining to the year 2010. However, both the IPO and the IPAB refer to a form in this year. We extracted the figures quoted by them for that year of working.

The various column headings used above are explained as under:

i) Column III contains the quantity and value of the drug imported to India.

ii) Column IV presents the actual sale of the drug in India.

iii) The per unit sales price of the drug arrived at by dividing the total value by the quantity sold/imported.

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As noted earlier, even for the year 2008-09, Bayer filed no Form 27, despite the patent being granted in March 2008.
iv) Bayer states in its Form 27 submissions (for 2011, ‘12 and ‘13) that each unit of imports/sales corresponds to the following: “Nexavar Tab 200mg 60 ST”. From this, we assume that each unit in the above table represents a pack containing 60 tablets and each tablet is of 200 mg strength. Given that each patient requires 800 mg each day (400 mg twice a day), he/she has to have 120 tablets in a month. Therefore a patient would need two packs (of 60 tablets each) a month.

v) The Patient Assistance Programme (PAP) and the various figures under this are assessed under a separate heading below.

vi) As noted earlier, Bayer filed two forms for 2009 and has not clarified till date as to which is the accurate form to be relied upon. The first form, dated 30th March, 2010 states that the quantum of imports was 4665 units and that the corresponding value of the imports was Rs. 1,78,302. This would imply a per unit value of Rs. 38! Clearly, this figure is grossly incorrect! The second filing, dated 31st March, 2010, is clearly not complete. It does not have any entry in the value column for imports. However, given that the per unit cost for both imports and sales are largely the same across all other years (for which Bayer filed Form 27s), one can assume that the Value of imports for 2009 would be Rs 45,53,73975 (calculated at a per unit cost of Rs 97,615/-).

B. Discrepancies in Figures from Form 27 vs Controller Decision

As noted earlier, the Controller of Patents and the IPAB use the term “boxes”, “bottles” and “packs” when these terms find no resonance in Bayer’s official Form 27 filings. Working out corresponding figures has proved very troubling and we hope that in future, the Form 27 format and data is the one that will be used uniformly by all agencies and courts that rely on such data.

The Controller notes that Bayer sold 593 boxes of the drug in 2011. However there is no clarity in the Controller’s order on how many packs/tablets are present in each box. Given that the Controller goes on to note that the supply of boxes for that year would meet the requirements of only 200 patients, one assumes that the number of boxes (593) has been divided by the number of months (3 months) to arrive at this figure. Therefore one patient requires one box a month. If this is so, then each box should contain around 2 packs (120 tablets of 200 mg each).

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34 This is the recommended standard dosage. See dosage recommendation for Nexavar: <http://www.nexavar.com/scripts/pages/en/home/hcc/dosing.php>
35 Also, the 2009 figures do not include any such qualification but merely mention the numerical figure. But we assume it refers to the specific tablets outlined in the latest set of Form 27s.
36 Excerpt from the Controller’s Order [Natco v. Bayer CLA No. 1 of 2011] at p. 22: “The Patentee has submitted that they have sold about 593 boxes during the year 2011.”
37 The Controller notes that the sales for 2011 were 593 boxes. The Form 27 data for 2011 states that the total sales in 2011 were 1562 (1178 (commercial) + 137 (free sample) + 247 (PAP)] which would imply that there are 3 packs to a box. The Controller records the import of ~200 boxes in 2009 whereas the form 27 for that year records the import of 4665 packs. This would imply that there are 23.32 packs per box.
However, there is some inconsistency when we compare this with the Form 27 data for this year (2011). The Form 27 data states that the total sales in 2011 were 1562 packs \([1178 \text{ (commercial)} + 137 \text{ (free sample)} + 247 \text{ (PAP)}]\). Given that the total number of boxes sold was “593” as per the Controller order, this would mean that there were 3 packs to a box and not 2 as we initially assumed. This is further complicated by the fact that the Controller records Natco’s argument that approximately “200” boxes were imported by Bayer in 2009,\(^{38}\) whereas the Form 27 for that year records the import of 4665 packs. This would imply that there are 23.32 packs per box. Bayer however refused to clarify this point and help us determine the exact number of packs per box.\(^{39}\)

C. Excessive Procurement of the Drug

<table>
<thead>
<tr>
<th>Year</th>
<th>Import</th>
<th>Sales/Disb</th>
<th>Left Over (Stock)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>None</td>
<td>None</td>
<td>N.A.</td>
</tr>
<tr>
<td>2009</td>
<td>4665</td>
<td>1679</td>
<td>2986</td>
</tr>
<tr>
<td>2010(^{41})</td>
<td>680</td>
<td>NA</td>
<td>3666</td>
</tr>
<tr>
<td>2011</td>
<td>2540</td>
<td>1562</td>
<td>4644</td>
</tr>
<tr>
<td>2012</td>
<td>11536</td>
<td>2137</td>
<td>14043</td>
</tr>
<tr>
<td>2013</td>
<td>100</td>
<td>2167</td>
<td>11976</td>
</tr>
</tbody>
</table>

This indicates that the total number of packs finally disbursed in India from the time of first sale in India is 7545 \((1679 + 1562 + 2137 + 2167 = 7545)\). The total number of leftover stock is however 11,976. This is a huge number indicating that Bayer has imported well in excess of their actual requirement. Bayer refused to respond to our query on this asking for an explanation on this illogical pattern of importing well in

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\(^{38}\) It bears noting that the number of boxes (200) figure was not stated by the controller as his finding, but as Natco’s argument in its submissions to the Controller (See para 10 (a) of the Controller’s Order: page 13 of the order).

\(^{39}\) It might well be the case that this number (593 BOXES) is a figure tallying with the annual year 2011 (Jan to December 2011). Whereas the Form 27 FOR 2011 only relates to the financial year (March 2011 to March 2012). Again, this could have been verified by Bayer. But they chose not do so.

\(^{40}\) Assuming that the quantities in the PAP columns indicate total quantity disbursed under that programme and not those/only those paid for.

\(^{41}\) The Controller and IPAB record that the Form 27 submitted by Bayer for the year 2010 mentions the import of 340 packs pursuant to the PAP and 340 sample packs. However, the quantity of the drug disbursed as a part of the PAP is unknown.
excess of its requirements year after year.

D. Analysis of PAP Programme:

Table 3: PAP Programme

<table>
<thead>
<tr>
<th>YEAR</th>
<th>PROGRAMME DETAILS</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>Not stated</td>
</tr>
<tr>
<td>2010</td>
<td>NA</td>
</tr>
<tr>
<td>2011*</td>
<td>“Under current Patient Assistance Programme (PAP), patient needs to purchase 1 cycle/month treatment (120 tab/per cycle/month), the patient gets 6 cycles/months (120 tab/per cycle/month) free treatment. In the alternative, patient may choose to purchase 2 cycles/months treatment (120 tab/per cycle/month), to get 10 cycles/months (120 tab/per cycle/month) free treatment.” (introduced in September 2011)</td>
</tr>
<tr>
<td>2012*</td>
<td>“Introduced in April, 2012, under modified PAP, patients need to purchase 3 days treatment (12 tab total/4 tabs per day), the patient gets 27 days treatment (108 tab total/4 tabs per day) free treatment.”</td>
</tr>
</tbody>
</table>

Note: *: As stated forth in two Form 27s (for 2011 and 2012 respectively)

It is to be noted that the information in relation to imports and sales (quantities and prices) for the PAP is available only for 2011 and 2012 and not for any earlier years. Also for the year 2013, it would appear that no packs were imported for the PAP scheme. However, there are PAP distributions shown for that year. Presumably, these distributions have been made from the leftovers (stock) of the previous year. Bayer refused to clarify this point.

In this regard, it bears noting that as with their regular commercial sales (and imports), Bayer appears to have imported PAP quantities well in excess of their actual disbursements in India, year after year, as documented below. Here again, Bayer refused to clarify this point when we raised it with them through our emails.

Table 4: Import and Sales figures for the PAP.

<table>
<thead>
<tr>
<th>I</th>
<th>II</th>
<th>III</th>
<th>IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>YEAR</td>
<td>IMPORT FIGURES</td>
<td>SALES/DISBURSEMENT FIGURES</td>
<td>PER UNIT PRICE (approx Rs.)</td>
</tr>
<tr>
<td></td>
<td>QUANTITY</td>
<td>VALUE</td>
<td>QUANTITY (UNITS)</td>
</tr>
</tbody>
</table>

14
**E. The PAP Figures: How Much is Paid For?**

What is not clear from the PAP table is how much of the PAP quantity is a “sale” and how much is a free disbursement. For each PAP scheme requires the patient to buy a fixed quantity first, before being able to avail of the free disbursements.

It also bears noting that over time, the amount of “paid” supplies required to be purchased in order to merit the free supplies decreased proportionately. When the scheme began in 2011, the payment was for only 1/6<sup>th</sup> of the total treatment time (2 of 12 months of treatment being paid, and 10 months being free) or 1/7<sup>th</sup> (1 of 7 months being paid, and 6 months being free). Later the quantum of pay in order to merit free supplies decreased in that one needed to pay for only 1/10<sup>th</sup> of the total treatment time (3/30, with a patient having to pay for only 3 days in order to merit treatment for all 30 days).

To illustrate this better, while in 2011 (scheme introduced in September 2011 as per the 2012 Form 27), one needed to pay Rs 2,80,000 (a month’s supply) in order to get 6 months supply free, whereas in 2012 (April 2012) when the scheme changed, if one paid Rs 2,80,000 (for an entire month), one would get 10 months free. This is a welcome trend and needs to be noted. However, as to whether this scheme was implemented successfully in practice and patients adequately benefited without going through a largely bureaucratic process that disincentivised them needs to be seen.

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### V CONCLUSION: KEY SUGGESTIONS

1. The government ought to immediately take action against errant patentees and licensees who fail to submit full and complete Form 27 information. It is worrying that even after evidence has been brought to their notice that patentees consistently and blatantly ignore this important statutory mandate, they have so far failed to take any action.

2. The IPO ought to initiate immediate action against Natco for failing to comply with the terms of the compulsory licensing order mandating the submission of its
quarterly sales figures for their generic version of sorafenib tosylate (sold as ‘Sorefanat’).

3. The government ought to investigate the following:

i) Why does Bayer routinely imports exponentially higher volumes of Nexavar than is necessary for its routine disbursements/demand? What does it do with the excess stock year after year? Is there a tax evasion angle here?

ii) How are Bayer’s “sample” and “support” packs ultimately disbursed? If they are “gifted” to doctors and then sold onwards by doctors to patients, does this not constitute a legal/ethical violation?

iii) What percentage of the patient population today is able to access Sorefanib Tosylate from all suppliers put together (namely, Bayer, Natco and Cipla)?

This last bit of information is absolutely critical to determining as to whether or not the patient requirements are being adequately satisfied. Under the terms of the Bombay High Court order however, even a single patient not having access to the drug would render it susceptible to revocation.

4. In the future, government agencies, quasi judicial bodies (such as the IPO), and judicial bodies (such as the IPAB and courts) ought to ensure that there is consistency across usage of metrics in compulsory licensing and other decisions that turn on numbers. The Bayer vs. Natco CL decision is replete with inconsistent usage of metrics, such as “boxes” and “support packs” which find no mention in the Form 27 submissions by Bayer.
ANNEXURE A

List of Questions to Bayer on their Form 27 submissions for Nexavar

We sent these questions to Bayer by way of email (see correspondence in Annexure B below). Despite reminders and follow ups, they steadfastly refused to answer these queries. Initially they cited the doctrine of sub-judice as an excuse. It bears noting that subjudice never stands in the way of a litigant clarifying publicly available information submitted as part of a statutory mandate. Rather it only seeks to prevent a litigant from subverting the course of justice by making comments intended to influence the course of a case.

In a later email, they later cited to other litigations in court around this drug. We can only draw an adverse inference from all of this and would urge the government to investigate these figures and numbers.

Questions to Bayer:

1. Patient and Drug Figures

How many tablets does a patient need to take per month? Is our calculation of 120 tablets (at 200mg per tablet and 4 tablets a day) accurate? How many tablets are there in each pack? In each unit? Is our calculation of 60 tablets per pack (as mentioned in the Form 27 fillings) accurate? The Form 27 for 2009 does not state the relevant unit for the information relating to quantum of imports and sales. It merely gives the number of 4665 without stating whether 4665 is the number of “packs” (with 2 packs being the requirement per patient per month). Could you please clarify this information?

How many packs/tablets are there in each “box”? Please see the use of the term “box” in the Controllers decision and our assumption (from the CG order numbers) that one box is meant to satisfy the requirements of one patient and contains 2 packs. Is this accurate? Also we are given to understand that this usage of the term “box” comes from your affidavit submitted to the IPO. Please confirm.

One possibility is that this number (593 boxes) pertains only to the annual year 2011 (Jan 2011 to Jan 2012). Whereas the Form 27 for 2011 relates to the period between March 2011 to March 2012. Please confirm.

Also, see the IPAB ruling extracted below:

“It is noted that the Form -27 for 2009 filed by the Patentee does not provide any logical information about the sales. Form 27 for the year 2010 discloses that the Patentee did not import any ‘sale pack’ but imported only 340 units [60 tablets pack]
of ‘support pack’ and 340 units [60 tablets pack] of ‘sample pack’, both having an ‘invoice value’ of Rs. 10,045,692.”

What does a “unit” (eg 340 units) entail? By the IPABs logic above, it would appear that each unit contains only 60 tablets and therefore is the same as “pack”. Therefore patients require 2 units or 2 packs in a month? Is this accurate? Also in all the Form 27 submissions, the numbers stated under each of the columns are for “packs” /“units” i.e. half a monthly requirement per patient? Please confirm.

2. Column Meanings

In your Form 27 submissions, what do the figures under the head ‘value’ reflect (i) under the import column and (ii) under the sales/disbursement column? In particular, please clarify:

i) In relation to the import column, does “value” refer to the proposed sale price or the price of the import? Is the price of import a notional value price or the actual price of the import?

ii) Also please clarify what the term “value” means in relation to the columns ‘PAP’ and ‘sample’. Is this the actual price of import or the notional value? Also is there any part of PAP or sample that is being sold? Or are all these being given out for free? In which case, is the commercial sale value reflected in the relevant column only a notional value on par with the sales of regular units sold (outside of PAP and sample)?

3. Sales Price Discrepancy

i) The per unit/sample price as tabulated above is less than 1 lakh (half monthly unit). Assuming a full monthly unit is taken (2 packs or units per patient per month), the per unit price would be under Rs 2 lakhs. However, this is still less than the selling price of Rs 2.8 crores as found in the Controller’s order (this figure was given by Natco and never contested by Bayer). Can you please help explain this discrepancy?

ii) What is the actual selling price of each pack/unit as of today? Was this the same rate as of the date of the Controllers’ order?

iii) As per our calculations, the per unit cost across the years is generally in the range of Rs 96,000. However, the per unit cost for imports in 2013 is stated to be Rs. 2,87,000. Why is there a sudden change in value of the drug (the unit remains the same as the previous year- 200mg 60 ST)?

4. PAP Queries

i) Does the number of packs listed under the head PAP reflect the total number of packs disbursed under the scheme including the initial sales made (where the patient has to pay for the first set of packs) and the later free units given out? OR
ii) Does the number of packs listed under the PAP category reflect only the free samples disbursed to patients? In which case, please confirm that the initial sales (packs that are required to be bought as part of the PAP) are included under the earlier commercial sales column?

iii) If the number of packs listed under PAP includes both initial sales and the free disbursements, please spell out exactly how many packs have been disbursed for free as part of the PAP program?

iv) If the number of packs listed under PAP includes both initial sales and the free disbursements, please confirm that the initial disbursements (to be paid for by the patient) are not already included under the earlier column “Commercial sales”. In which case, it would amount to double counting.

v) In the case of PAP disbursements (particularly the free units that are disbursed later), what does the ‘value’ column reflect? Is this only a statement of the worth of the goods on the market (and how much it might have been sold for) and not a reflection of revenue obtained from those packs (since there were no revenues)?

vi) In its Form 27 disclosure for 2012, Bayer explains that the ‘value’ of the number of units sold/disbursed in India for the PAP has been ‘derived at the rate of average selling price.’ Does this include only those PAP units that were given for free? Or even those that were sold (since a patient had to initially buy before he/she became eligible for free supplies in later months). Or are the “sold” units of the PAP program reflected in the “commercial sales” column?

vii) Please provide us details of the current PAP program (for the year 2014)? Is the scheme the same as that prevalent in 2013? How many units are required to be purchased initially?

viii) What was the exact PAP scheme in each of the years starting from 2009? Can you please provide elaborate details?

ix) Why did the imports under the PAP increase nearly fourfold in 2012 in the aftermath of the grant of the compulsory license? We note that you had 4644 units left over from the previous year, in particular, 1353 from those allocated for the PAP. If so, why was this additional quantity imported?

x) In 2011, the amount of imports under PAP was 1260, whereas the disbursements were only 247. Similarly in 2012, the amount of imports under the PAP was 10636 and the number of disbursements was only 1011.

xi) Why is there such a low uptake for a free drug program? It would greatly help if you could explain this and point us to factors that we may have overlooked.

5. Form 27 for 2010 and Lack of Commercial Sales?
BAYER’S NEXAVAR AND THE “WORKING” OF COMPULSORY LICENSING: MIND THE PATENT (INFORMATION) GAP!

i) Did Bayer sell the drug at all in 2010? We did not receive any Form 27 pertaining to the year 2010 in response to our RTI enquiry. However, a form appears to have been submitted, since both the Controller as well as the IPAB note these figures as appearing in the Form 27 submitted by Bayer for the year 2010. Were these figures ever submitted as part of Form 27 submissions to the patent office? Or were they only mentioned in an affidavit for the first time submitted to the IPO? If they were indeed submitted to the patent office as part of the Form 27 filing, would you please send us a copy of this Form as filed with the IPO? If this was not submitted to the IPO as part of your Form 27 filing obligation, but only submitted to the IPO during the course of the compulsory licensing dispute, would you please provide us with a copy of this submission and/or relevant details thereof?

ii) It is to be noted that the figures mentioned by the IPO and the IPAB for the year 2010 include only non-commercial imports. There are no figures for sales/disbursements. Does this mean that there were no sales of the drug in 2010? If this is the case, then would you please let us know as to how the demand for the drug that year was met? How did patients get their supplies?

6. Packs vs Boxes

The Controller notes that Bayer sold 593 boxes of the drug in 2011. However there is no clarity in the Controllers’ order on how many packs/tablets are present in each box. Given that the Controller goes on to note that the supply of boxes for that year would meet the requirements of only 200 patients, one assumes that the number of boxes (593) has been divided by the number of months (3 months) to arrive at this figure. Therefore one patient requires one box a month. And if this is so, then each box contains around 2 packs (120 tablets of 200 mg each).

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42 Excerpt from the Controller’s Order [Natco v. Bayer CLA No. 1 of 2011] at p 21, 22: “It is noted that the Form -27 for 2009 filed by the Patentee does not provide any logical information about the sales. Form 27 for the year 2010 discloses that the Patentee did not import any ‘sale pack’ but imported only 340 units [60 tablets pack] of ‘support pack’ and 340 units [60 tablets pack] of ‘sample pack’, both having an ‘invoice value’ of Rs. 10,045,692. It appears to me, from the Form -27 filed by the Patentee for the year 2009 and 2010, that only an insignificant quantum of the drug was made available by the Patentee to the public during these two years.”

Excerpt from the IPAB’s judgment [Natco v. Bayer OA/35/2012/PT/MUM] at paragraph 37: “In the year 2010, it is stated that no commercial sales packs were imported and only sample packs of Nexavar patient support packs were imported. Again, as far as the manufacture in India is concerned, it is stated as ‘NIL’. The number of Nexavar sales packs imported is stated to be NIL. The number of Nexavar patient support packs imported is stated to be 340 units and the number of Nexavar sample packs is stated to be 340 units. In the Form-27 for the year 2010, it is stated that the public requirement has been met to the fullest extent at reasonable price.”

43 Excerpt from the Controller’s Order [Natco v. Bayer CLA No. 1 of 2011] at p. 22: “The Patentee has submitted that they have sold about 593 boxes during the year 2011.”

44 The Controller notes that the sales for 2011 were 593 boxes. The Form 27 data for 2011 states that the total sales in 2011 were 1562 [1178 (commercial) + 137 (free sample) + 247 (PAP)] which would imply that there are 3 packs to a box. The Controller records the import of ~200 boxes in 2009 whereas the form 27 for that year records the import of 4665 packs. This would imply that there are 23.32 packs per box.
However, there is some inconsistency when we compare with the Form 27 data for this year (2011). The Form 27 data states that the total sales in 2011 were 1562 packs [1178 (commercial) + 137 (free sample) + 247 (PAP)]. Given that the total number of boxes sold was “593” as per the Controller order, this would mean that there were 3 packs to a box and not “2” as we initially assumed. This is further complicated by the fact that the Controller records the import of approximately “200” boxes in 2009 whereas the form 27 for that year records the import of 4665 packs. This would imply that there are 23.32 packs per box. Can you explain this? How many packs are there in a box?

7. Sample Packs

i) What are sample packs? What is their purpose?

ii) Are these sold or given away free?

iii) Are they given to hospitals and doctors for free?

iv) While they are given out as samples, are any conditions attached to them? Can the recipient sell it to a patient, although the recipient has received it from Bayer for free?

v) Can the recipient do what he/she chooses with the said samples and disburse it to any person of his/her choice?

vi) Are there records kept of disbursements of sample packs to show the numbers disursed, the persons/entities to which they are so disbursed and the conditions attached with the disbursements?

vii) Are sample packs tracked after they have been given away to recipients (doctors/hospitals etc) to check whether they are put in use and/or whether conditions attached to them are fulfilled?

viii) What is the “ST” in “Nexavar Tab 200mg 60 ST” is abbreviated for? Do we take this to mean “standard tablet” as opposed to QT (quick release tablet)?

8. Support Packs

i) What are ‘support packs’? The decision of the Controller and the IPAB both record the import of ‘support’ packs for the year 2010.45 How are they different from sample packs?

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45 Excerpt from the IPAB’s judgment [Natco v. Bayer OA/35/2012/PT/MUM] at paragraph 37: “In the year 2010, it is stated that no commercial sales packs were imported and only sample packs of Nexavar patient support packs were imported. Again, as far as the manufacture in India is concerned, it is stated as ‘NIL’. The number of Nexavar sales packs imported is stated to be NIL. The number of Nexavar patient support packs imported is stated to be 340 units and the number of Nexavar sample packs is stated to be 340 units. In the Form-27 for the year 2010, it is stated that the public requirement has been met to the fullest extent at reasonable price.”
BAYER’S NEXAVAR AND THE “WORKING” OF COMPULSORY LICENSING: MIND THE PATENT (INFORMATION) GAP!

Here again, please answer all the questions that we posed for sample packs, since the same questions apply for support packs as well. In particular, are support packs sold or given away for free?

9. Estimating Patient Numbers

Why do you suppose that 3 months was taken as an average usage period for kidney and liver cancer patients by the Controller? Was this based on your submission to the Controller or did he arrive at this figure himself. If the average usage of the drug is 6-8 months for liver cancer patients and 4-5 years for kidney cancer patient, then the average is clearly greater than only 3 months of treatment. This will significantly impact the assessment of whether Bayer was satisfying the reasonable requirements for the drug to the full extent. The difference is as below:

The Controller, using a 3 month figure, arrived at an annual requirement of the public for either 3*9000 = [27,000 boxes per annum on the Bayer figures] or 70,000 boxes per annum on the GLOBOCON figures. When calculated as against the annual supply [~600 boxes in 2011], this amounts to meeting only about about 2.2% of the patient’s needs. However, when the number of months of treatment is taken at a realistic amount [12 months in a year for kidney cancer patients and 5 months in a year for liver cancer patients] the annual supply meets only 0.9% of eligible patients in 2010 and 1.9% in 2011.

10. Other Figures/Data

Could you please let us know additional figures as outlined below:

i) The total number of units of Nexavar imported till date (from 2009-2014).

ii) The total units of Nexavar commercial sold (“commercial sales”) in India till date (from 2009 to 2014) and the revenues made from them?

iii) The total number of units disbursed as PAP (PAP disbursements). This should exclude the initial sales made (i.e. the patient purchasing the first few units so as to avail of the subsequent free units). These initial sales ought to be included in the “commercial” sales category in point number (ii) above.

iv) The total number of units disbursed as samples (sample disbursements).

v) The total number of units disbursed as support packs (support pack disbursements).

v) Any other units disbursed outside of the above heads i.e. “commercial” sales, “PAP” disbursements, “sample” disbursements and “support” disbursements.
vi) What is the current price at which you are selling Nexavar in India? Please indicate if you are offering any differential rates (to patients directly, to hospitals, any special rates for doctors, for the government etc)?
ANNEXURE B

Email Exchanges with Bayer (reproduced below):

Begin forwarded message:

Subject: Re: Urgent and Important: Questionnaire on Bayer and Nexavar
From: Shamnad <shamnad@gmail.com>
Date: 18 February 2015 10:22:01 am IST
Cc: Ashish Gawde <ashish.gawde@bayer.com>, Joerg Thomaier <joerg.thomaier@bayer.com>
To: Angel-Michael Evangelista <angel-michael.evangelista@bayerzyduspharma.com>

Thank you for your response Mr Evangelista,

Sorry to hear that you will not be providing these clarifications.

Warmest wishes,

Shamnad Basheer

On 18-Feb-2015, at 9:02 AM, Angel-Michael Evangelista wrote:

Dear Mr. Basheer,

Thank you for your e-mail. With reference to your queries, you may be aware that we have filed a review petition for the CL case, in the Supreme Court. Further, we have on-going litigations for other issues in various courts of the country.

Keeping this in mind, we are not in a position to address your questions specifically. As we have always reiterated, we are committed to making our innovative therapies accessible to patients. We have furnished all necessary information to the regulatory / legal authorities.

Thank you for your understanding.

Best Regards,

Angel Michael Evangelista
Subject: Re: Urgent and Important: Questionnaire on Bayer and Nexavar
From: Shamnad <shamnad@gmail.com>
Date: 10 February 2015 10:09:12 pm IST
Cc: Angel-Michael Evangelista <angel-michael.evangelista@bayerzyduspharma.com>, Ashish Gawde <ashish.gawde@bayer.com>, Dorian Immler <dorian.immler@bayer.com>
To: Joerg Thomaier <joerg.thomaier@bayer.com>

Thanks again Jorg,

If this can come sooner, nothing like it. But I appreciate that you need more time to put this together. If you can please send by end of the month, it would really help.

Thanks!

Shamnad

On 10-Feb-2015, at 9:59 PM, Joerg Thomaier wrote:

Dear Shamnad,

I have no precise idea how quick a compilation of answers can occur, but I assume after alignment next week we may be able to deliver the answers we are able to give by end of the month, e.g. around 27th of February.

Kind Regards,
Jörg

Dr. Jörg Thomaier
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D-40789 Monheim
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Web: http://www.bayer.com

Managing Directors: Joerg Thomaier | Michael Reinartz
Place of Business: Monheim am Rhein | Amtsgericht Düsseldorf, HRB 67604
Dear Jorg,

Thanks very much for the response. Of course I am more than happy to wait. Some indication of a timeline by when you can respond will be helpful.

Warmest wishes,

Shamnad

Prof (Dr.) Shamnad Basheer
Founder and Managing Trustee, IDIA
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On 10-Feb-2015, at 9:49 PM, Joerg Thomaier wrote:

Dear Shamnad,

We will have an internal discussion about it but we were only able to slot this for next week due to local holidays (Carneval) her in the German Headquarter Area. So please give us the opportunity to work out any kind of answer we may be able to give, so that the answers you get are precise and in accordance with any rules we have to obey. As we discussed in Delhi we need to align things here and there may be things we just can’t share for different reasons including Business secrecies, but please trust in me that we really try to give you answers as far as we can – as we discussed in Delhi.
Thank you very much for your patience.

Kind Regards,
Jörg

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Managing Directors: Joerg Thomaier | Michael Reinartz
Place of Business: Monheim am Rhein | Amtsgericht Düsseldorf, HRB 67604

On 05-Feb-2015, at 10:01 PM, Shamnad wrote:
Dear Dr Evangelista:

Hope this finds you well. Given that the Supreme Court has now disposed off the matter, would you please consider addressing our various queries seeking clarifications on your Form 27 submissions and related data pertaining to the Nexavar patent. I attach the latest version of our draft report, along with our specific queries to you at the end.

I am also taking the liberty of copying in Dr Thomaier whom I had the great pleasure of meeting at a conference in Delhi recently. I mentioned to him that although we may be ideologically at different ends of the IP spectrum, we share a common interest in moving IP away from faith based assertions to fact/data based analysis. This study by us on patent working is in that vein and I really hope that you will help us find the answers to make this report more complete and accurate.

Thank you very much!

Shamnad Basheer

<Report-final 1V.doc>
Dear Dr Evangelista:

Hope this finds you well. Given that the Supreme Court has now disposed off the matter, would you please consider addressing our various queries seeking clarifications on your Form 27 submissions and related data pertaining to the Nexavar patent. I attach the latest version of our draft report, along with our specific queries to you at the end.

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Thank you very much!

Shamnad Basheer

On 26-Sep-2014, at 8:56 AM, Angel-Michael Evangelista wrote:

Dear Mr. Basheer,

The Company does not wish to make any comment in this regard, since the Nexavar matter is sub-judice.

Best Regards,
Angel Michael Evangelista

From: Shamnad [mailto:shamnad@gmail.com] Sent: Wednesday, September 24, 2014 6:35 PM To: Angel-Michael Evangelista Subject: Re: Urgent and Important: Questionnaire on Bayer and Nexavar

Dear Dr Evangelista:
BAYER’S NEXAVAR AND THE “WORKING” OF COMPULSORY LICENSING: MIND THE PATENT (INFORMATION) GAP!

Please let me know if you have the below emails. A quick line in confirmation would be greatly appreciated. I attach the questionnaire again.

Thanks,

Shamnad Basheer

On 21-Sep-2014, at 5:32 AM, Shamnad wrote:

Dear Dr Evangelista:

Please consider this version of the questionnaire instead.

Thanks!

Shamnad Basheer

<Report and questions-final 1P.doc>

On 20-Sep-2014, at 9:39 PM, Shamnad wrote:

Dear Dr Evangelista:

I hope this finds you well.

The reason I write now is to solicit certain clarifications from Bayer on a study that we are currently doing. This study pertains to Bayers’ patented drug Nexavar and certain data points in relation to its sales in India and revenues etc.

I'd be very grateful if someone from your team could please respond to this questionnaire at your earliest convenience, preferably in two weeks time.

I have made the background as comprehensive as possible and included all the data points we now have at our end (taken from various submissions to the indian patent office) so that it is easy for you to contextualise and respond to the queries. I hope you can accommodate this request.

Thank you very much.

Warmest wishes,
BAYER’S NEXAVAR AND THE “WORKING” OF COMPULSORY LICENSING: MIND THE PATENT (INFORMATION) GAP!

Shamnad Basheer

<Report and questions-final 1P.doc>

Prof (Dr.) Shamnad Basheer
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