

BEFORE THE CONTROLLER OF PATENTS, DELHI

C.L. No. 1/2011

IN THE MATTER OF:

Natco Pharma Limited

... APPLICANT

VERSUS

Bayer Corporation

...RESPONDENT/PATENTEE

AFFIDAVIT

I, James Packard Love, aged 62 years, do hereby state on solemn affirmation the following:

1. I am the director of Knowledge Ecology International (KEI), a non-profit organization located in Washington, DC, United States of America. My work focuses on the impact of intellectual property protection on consumer interests, including in the areas of electronic commerce and access to medical technologies. I have also worked extensively on compulsory licensing policy issues, including the use thereof to address abuses of intellectual property.
2. I am the co-chair of the Trans-Atlantic Consumer Dialogue (TACD) Policy Committee on Intellectual Property Rights, and I have been an invited expert on intellectual property issues in meetings and consultations organized by the World Intellectual Property Organization (WIPO), the World Health Organization (WHO), the World Trade Organization (WTO), the United National Program on Development (UNDP), the United Nations Conference on Trade and Development (UNCTAD), the UN Human Rights Council, the Hague Conference on Private International Law, UNITAID, the World Bank and other multilateral and regional bodies. I have been an adviser to several national governments on intellectual property issues, including the Competition Commission in South Africa where I was the principle consultant to evaluate a complaint that the prices for AIDS medicines were excessive. I have extensive experience dealing with intellectual property rights, medicines and

pharmaceutical pricing, which is reported on my web page at <http://keionline.org/jamie> and reflected in my curriculum vitae, which is annexed hereto.

3. The facts deposed to in this affidavit are within my personal knowledge except where I indicate otherwise. To the extent that I rely on the information received from others, I believe that such information is true and correct. I respectfully submit that I am by my training and experience duly qualified to express the views and opinions that I express in this affidavit and to assess the repute, opinions and reliability of other persons to whom I refer.
4. I have been given to understand that Natco Pharma Ltd has filed a compulsory licence for the drug 'sorafenib' and I understand that Bayer Corporation, the patentee herein, holds the patent for the same. The relevant records in respect of the above matter being the application for compulsory licence, the documents attached thereto, have been made available to me. I understand that the price of sorafenib in India as sold by Bayer Corporation is Rs 2,80,000/- whereas Natco Pharma Ltd is proposing to manufacture and sell the same at Rs 8900/-.
5. In the light of the aforesaid documents, I have been asked to opine and comment on the following issues: What is meant by "reasonably affordable price" as contemplated by section 84(1) of the Patents Act? And, what is a reasonable royalty?

Reasonably Affordable Price

6. According to Section 84(1)(b) of the India Patent Act, any person may make an application to the Controller for a compulsory license on a patent, if "the patented invention is not available to the public at a reasonably affordable price."
7. In determining whether a price is "reasonably affordable," one can consider different standards for different types of goods. For a drug for cancer treatments, India should be guided by the standards set out in the 2001 World

Trade Organization (WTO) Declaration on the TRIPS agreement and public health, which I will refer to here simply as the “Doha Declaration.” Paragraph 4 of the Doha Declaration is an agreement among all of the WTO members, including India. It says:

4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

8. The Doha Declaration says “the TRIPS Agreement . . . should be interpreted and implemented in a manner . . . to promote access to medicines for all,” and WTO members have the right “to use, to the full, the provisions in the TRIPS agreement, which provided flexibility for this purpose.” This standard, “access to medicines for all” is also used in the 2008 World Health Assembly resolution WHA61.21, on World Health Organization's Global strategy and plan of action on public health, innovation and intellectual property (SIXTY-FIRST WORLD HEALTH ASSEMBLY WHA61.21, Agenda item 11.6, 24 May 2008), and in many other declarations and agreements involving intellectual property, including several bilateral and plurilateral trade agreements.
9. It is my understanding that sorafenib is used to treat kidney and liver cancer, and perhaps other types of cancer, and that its use is sometimes restricted by its high price, even in high-income countries, such as the United Kingdom. The high price for sorafenib is caused by legal barriers to competition, including in particular, patents that limit the ability of competitive manufacturers to make and distribute generic versions of sorafenib.

10. Under the Doha Declaration, governments have an obligation to grant compulsory licenses, when the prices are so high that “access to medicine for all” is not possible.
11. To determine if sorafenib is reasonably affordable in India, various issues and factors should be taken into account, including in particular, the incomes of patients, the availability of third party insurance or reimbursements, and the empirical evidence regarding access.
12. Before considering affordability in light of incomes, one should determine if patients benefit from third party insurance or reimbursements, provided by governments or the private sector, to pay for drugs. If such insurance or reimbursements exist, then the prices that would be affordable would be influenced by the ability of insurance schemes to pool risks. In such cases, one would consider the cost effectiveness of the drug, using such measures as the price per disability adjusted life year (DALY) or quality adjusted life year (QALY). As a general rule, many experts do not consider products cost effective unless they are priced at less than one year of average income for each DALY benefit, a view reported below in a report in the Bulletin of the World Health Organization on the cost-effectiveness of vaccines:

When considering the cost-effectiveness of different health interventions, researchers have assessed how much a given intervention will cost per year of healthy life that it will buy The World Bank has suggested that in any particular country, health interventions are cost-effective if they buy a year of healthy life for less than the national average per-capita gross domestic product (GDP). [“Less-used vaccines against major diseases are cost effective, researchers conclude,” Bulletin of the World Health Organization, 2000, 78(2).]

13. This approach is also taken by Ruth Lopert, Danielle L. Lang, Suzanne R. Hill and David Henry in a June 15, 2002 article in the Lancet (Vol. 359),

“Differential pricing of drugs: a role for cost-effectiveness analysis?” which discusses “a mechanism to derive cost-effective price thresholds for essential drugs in countries of variable wealth.”

14. The notion of using a benchmark such as “a year of per capita GDP per DALY saved” is a useful analytical tool, particularly in the sorafenib case for India where the prices by Bayer may exceed the benchmark by more than a hundred-fold (depending upon assumptions regarding the number of months one buys the drug and the expected average DALY benefit). However, even this benchmark is not the appropriate rule for a resource-constrained environment, where health care interventions by public sector reimbursement agencies have the opportunity and responsibility to buy products that are more cost effective than average national income per DALY saved. In the examples provided in the *Bulletin* article, health authorities were evaluating interventions that cost from \$20 to \$40 per DALY saved.
15. In resource-constrained environments, which are increasingly recognized to be a factor, the standard can be lower than one year of average income per DALY, even when reimbursement systems exist. A better approach is to examine the cost effectiveness of other products currently covered by third party reimbursements. With a budget constraint for the reimbursement agency, the cost effective price will be no more than the price that increases the total DALY benefits to the insured populations, and will certainly not be a price that decreases the total DALY benefits to the population covered by the reimbursements.
16. The discussion of cost-effectiveness is largely used to describe pricing to governments or insurance companies that pool risks.
17. I understand that as far as India is concerned, most people do not have government or private insurance or reimbursement for sorafenib.
18. In the absence of third party insurance or reimbursement schemes, one has to consider the impact of prices on access when resources are constrained by

household incomes, including those who have the lowest incomes, in order to address the need to implement intellectual property laws in “a manner . . . to promote access to medicine for all.”

19. If most people do not have insurance, then one begins by looking at a comparison of the price to the average incomes of people, and then considers the unequal distribution of incomes.
20. The World Bank estimates Gross National Income per capita of \$1330 in 2010. Using an exchange rate of 45.4549 in 2010, this is equivalent to Rs 60,455.
21. The Bayer price for sorafenib is Rs 280,000 for 120 200 mg tablets, the amount needed for 30 days. The annual cost of Bayer’s version of sorafenib is just over Rs 3.4 million, which is more than 50 times 2010 average incomes. Given the fact that a patient is required to continue to take the drug as long as the patient is able, and given the modest expected DALY benefits for doing so, the price of sorafenib in India would shatter both notions of cost-effectiveness for reimbursement agencies and be impossible to finance out of household incomes. This is hardly a close call.
22. In the absence of insurance, even if the product were priced just at one’s income, it would not be affordable. The average income is not the standard for affordability for a drug when there is no third party reimbursement. People who have cancer have to buy other drugs, to pay for medical services including doctor and hospital fees, and buy food, provide for shelter and clothing, and other living expenses. Thus, only a fraction of the household income will be available to pay for drugs. In the United States, the Internal Revenue Services allows taxpayers to deduct extraordinary medical expenses from taxable incomes. The standard in the United States is 7.5 percent of adjusted gross income, which is lower than the total income, because of other deductions in determining the adjusted gross income. The 7.5 percent used by the US IRS relates to all medical and dental services for the year, not simply the cost of a single drug. Note that in 2009, the World Bank reported that national outlays on health care were just 3.7 percent of India incomes. If the 3.7 percent of

average income figure were used as a standard, for just one drug, which would ignore all other health care expenditures, an affordable price in 2010 would have been approximately Rs 2,239 (using the World Bank income estimates), if the person's income was average. But average incomes are also not appropriate when most people do not have access to third party reimbursements.

23. Hundreds of millions of people living in India have incomes below the national average, and hundreds of millions of persons have incomes that are considered below the poverty line for India, which itself is a low income country. For these people, a reasonably affordable price would be lower than the average. If the policy objective is to provide access for medicine for all, this should be taken into account.
24. Yet another approach to consider whether or not the price for sorafenib is reasonably affordable is to look at the evidence regarding access in India. In such an analysis, one would look at the number of patients who would medically benefit from access to sorafenib, and compare that number to the number of patients that actually receive the product. Given the high prices currently charged for sorafenib, it is unlikely that the current number of patients receiving the drug covers many of the patients who would benefit from the product.
25. Bayer has reportedly defended its pricing of sorafenib on the grounds that patients have the opportunity to buy the drug from CIPLA, an Indian manufacturer of generic drugs. At the same time, Bayer is seeking damages and injunctions that would prevent CIPLA from selling sorafenib. Even if CIPLA continues to sell sorafenib, the price that CIPLA charges will not be low enough to overcome the pricing barriers for many cancer patients in India. Experience teaches us that competition between generic manufacturers will lead to lower prices than would obtain in the absence of such competition.
26. The standard set out in the Doha Declaration is "access to medicine for all." For that reason, the Controller has an obligation under the Doha Declaration to remove the barriers to generic competition so that the competition between

suppliers can dynamically lead to lower prices, therefore reducing if not eliminating the gaps in access that now exist.

Research and Development

27. In compulsory licensing disputes that involve both originators and generic manufacturers, the issue of the cost of research and development (R&D) is often raised to justify high drug prices and legal barriers to competition.

28. Bayer has declined to present evidence regarding its actual outlays on R&D for the development of sorafenib, but there is quite a bit of information about those R&D outlays on the public record. Beginning in 1994, Bayer entered into a drug development agreement with Onyx Pharmaceuticals. According to the Onyx 2002 10-K annual report filed with the US Securities and Exchange Commission:

Effective February 1994, we established a research and development collaboration agreement with Bayer to discover, develop and market compounds that inhibit the function, or modulate the activity, of the Ras signaling pathway or that appropriately modulate the activity of this pathway to treat cancer and other diseases. Bayer and we concluded collaborative research under this agreement in 1999, and based on this research, a development candidate, BAY 43-9006, was identified.

29. From 1994 to 1999, Onyx reports that Bayer provided Onyx with \$26.1 million for the Onyx work on the Ras signaling pathway.

30. Beginning in 2000, Onyx and Bayer began another collaboration, aimed at the clinical testing and development of BAY 43-9006 and other products that had been identified in their joint research program. BAY 43-9006 was later given the generic name sorafenib, and the brand name Nexavar.

31. On October 8, 2004, Bayer received an orphan drug designation for sorafenib/Nexavar for the treatment of renal cell carcinoma. Nexavar was

approved for marketing by the US FDA on December 20, 2005, for the orphan indication.

32. In addition to its research and development on sorafenib as a treatment for renal cell carcinoma, Bayer and Onyx explored a number of other uses for the drug, and also tested other compounds.
33. Governments also took an interest in sorafenib. The NIH's ClinicalTrials.gov database reports a February 2002 Phase II trial involving sorafenib that was sponsored and funded by the NIH, followed by dozens more trials funded by the NIH before the FDA approval for sorafenib in December 2005. Governments in other countries also may have funded research on sorafenib. From 2002 to December 2005, the ClinicalTrials.gov data reports 53 trials, including 35 with no industry funding, 3 with mixed funding, and 15 trials with only industry funding. The early role of the public sector was most important for Phase II trials, where 70 percent of the trials involving half of the enrolled patients were in trials that had no industry funding.
34. How much money did Bayer and Onyx spend prior to FDA approval? From 2000 through the end of 2005, Onyx Pharmaceuticals reported in their SEC 10-K reports that Onyx spent \$125 million, which was 50 percent of Bayer's outlays on the development of the drug. Combined with the \$26 million Onyx received from Bayer from 1994 to 1999, the SEC filings report a combined Bayer/Onyx outlay of \$275 million, which was spent to develop sorafenib as a treatment for several types of cancer, including but not limited to the approved indication for cancer of the kidney, and also for research on related products.
35. As noted, Bayer had received an FDA designation under the U.S. Orphan Drug Act in October 2004. The clinical trials that were related to the orphan indication, "treatment of renal cell carcinoma," were eligible for a 50 percent orphan drug tax credit, lowering the net cost of the investments to both Bayer and Onyx. There is no publicly available information on the amount of the tax credit received by Bayer or Onyx. The credit was available during the period of

the most extensive spending on clinical trials, and for the largest and most expensive trials that Bayer and Onyx undertook.

36. There are some additional issues worth noting or emphasizing regarding the reported expenditures on R&D. First of all, there is not much transparency for the specific claims. Onyx makes references to stock options given to consultants, building manufacturing capacity, and other items as part of its R&D costs, and hints that it was forced to take Bayer's invoices at face value, without really knowing if Bayer was padding its own expense reports, which Onyx was obligated to co-fund. We don't know how much of the outlays were for sorafenib as a treatment for kidney cancer, as opposed to more speculative uses that never panned out, or how much was spent on other drug candidates. We also do not know how much of the costs of the clinical trials were to support the pre-FDA approval expanded access programs, which were aimed at patients in high income countries who might soon be paying customers. Such programs are only marginally related to research and development of the drug, and may not be relevant to India, which did not benefit from the expanded access program.
37. As of February 12, 2012, there were 390 clinical trials registered with ClinicalTrials.gov. Of these, 9 percent were sponsored by Bayer alone, 20 percent were sponsored by Bayer and another party, 26 percent were sponsored or cosponsored by the US. National Institutes of Health (NIH), and 44 percent were sponsored by parties other than Bayer or the NIH.
38. While the outlays on research and development related to sorafenib were not trivial, the revenue from the sales were much larger. In 2006, its first year on the market, Onyx reported that Nexavar generated \$165 million in sales, an amount nearly equal to all joint outlays on R&D from 1994 to 2004. In 2007, Bayer reported Nexavar sales of \$371.7 million. By 2008, sales of Nexavar were reported at \$678 million, for a total of \$1.2 billion within three years of approval as an "orphan" drug.

39. Policy makers must consider a number of issues when addressing disputes over intellectual property rights on new drugs and vaccines. The cost of drug development is important, but it should not be raised selectively, only as an argument to defend high prices. If Bayer wants to raise the issue of R&D outlays, then it opens the door to look at the revenues and profits from the drug, and to ask if the spectacular sales figures were justified by the R&D outlays. Does Bayer want to be regulated like a public utility, on the basis of its costs, or does it want its products to be priced on the basis of the value they provide to society?
40. In the present case, Bayer is faced with a statute that says exclusive rights can be set aside when prices are not reasonably affordable. The fact that sales for sorafenib were far larger than R&D outlays is relevant, and undermines the rationale for the high prices. But the core issue of affordability can be evaluated on its own merits. Governments have all sorts of instruments to provide subsidies and rewards for new drug development. The U.S. Orphan Drug Tax Credit, the NIH research grants, and proposals for R&D innovation inducement prize funds are among the growing list of instruments to stimulate R&D that do not rely upon monopolies and high drug prices. A legislative requirement for affordable prices addresses the ethical issue of providing more equal access to life saving technologies, and it does not prevent policy makers from devising other ways to stimulate R&D.
41. Finally, there is a large body of evidence and argument that when faced with large disparities of incomes, it is both unethical and inefficient to tie R&D incentives to high drug prices, and a growing recognition that it is no longer defensible to implement drug development incentives that block access to life saving drugs for the majority of the world's population.

Reasonable Royalty

42. I am the author of the 2005 remuneration guidelines for non-voluntary use of a patent on medical technologies. The World Health Organization (WHO) and the United Nations Program on Development (UNDP) published the guidelines

jointly. (See Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies, UNPD and World Health Organization. Health Economics and Drugs, TCM Series No. 18.)

43. In the conclusion of the report, I wrote that, when making non-voluntary authorizations to use patents “Countries retain broad authority under the TRIPS Agreement to set royalties according to systems of their choosing. . . . Different countries may prefer different approaches to remuneration, based upon administrative capacity, resource constraints and policy objectives concerning access and innovation, among other factors.”
44. The flexible standards in the TRIPS Agreement regarding remuneration for compulsory licensing are evidenced by the variable ways that courts and governments around the world have chosen to set royalties for compulsory licenses.
45. In the present case, the Controller may want to consider three different approaches: The 2001 UNDP royalty guidelines; the 2005 Canadian royalty guidelines; and the 2005 WHO/UNDP tiered royalty method (TRM).
46. The 2001 UNPD royalty guidelines, which were proposed in the 2001 UNDP Human Development Report, are similar to the royalty guidelines earlier used by the Japan Patent Office. The base royalty rate is 4 percent of the price of the generic product. The 4 percent rate can be increased or decreased by 2 percent, depending upon such factors as the degree to which a medicine is particularly innovative and useful, which would be a rationale for increasing the rate, or the role of governments in paying for R&D, which would be a rationale for lowering the rate. In the case of patents on sorafenib, the product was considered innovative enough to be granted an initial priority review by the US FDA, has a relatively modest impact on life expectancy, and was significantly subsidized by a combination of tax credits for orphan drugs and NIH funding of clinical studies. Taken together, the base rate of 4 percent applied to the competitive price of the generic product would be a reasonable application of the methodology.

47. In 2005 Canada published royalty guidelines, in the context of legislation to authorize the manufacture of medicines under a compulsory license, for export to developing countries. The 2005 Canadian guidelines also used a 4 percent base royalty rate. The rate was adjusted, downwards, for countries that ranked lower than first on the UNDP Human Development Index (HDI).
48. The 2005 Canada royalty formula used the ratio of country rankings on the index. A base royalty of 4 percent was multiplied by this ratio: 1 plus the number of countries on the UNDP Human Development Index, minus the importing country rank on the index, divided by the number of countries on the index. India ranked 134 out of 187 countries on the 2011 UNDP Human Development Index. The calculation would be $.04 \times [(188-134)/187] = 1.15$ percent, applied to the generic price.
49. The 2005 UNDP/WHO report suggested a third way to calculate the royalties, the Tiered Royalty Method (TRM). The rationale for the TRM is fairly straightforward. You begin with an estimate of the average pharmaceutical royalty, which earlier PhRMA had estimated to be 4 percent of product sales. You then apply that percentage rate to the product's price in markets where pricing and access is considered acceptable, or to an appropriate proxy of the reasonable value of the product. That royalty payment, which is measured in money, rather than as a percent, is then adjusted by multiplying the ratio of relative per capita incomes.
50. I will illustrate the TRM by considering a stylized case of a drug that is priced at \$25,000 in county A, which has a per capita income of \$45,000, and country B, which is issuing a compulsory license, and which has a per capita income of \$1,500. The base royalty payment would be $\$25,000 \times .04 = \1000 . The \$1000 is supposed to represent the average royalty payment now paid to patent owners in Country A, based upon evidence presented to the United States Trade Representative (USTR) by PhRMA, the trade association. The base royalty of \$1000 would then be adjusted by the ratio of the income of Country B to County A, as follows: Royalty in Country B = $\$1000 \times (1500 / 45000) =$

\$33.33. The reason that \$33.33 is much lower than \$1000 is because incomes are much lower in Country B.

51. An additional adjustment can be made for cases where a country is facing an unusually high incidence of the disease. In the case of an epidemic, the adjustment would be based upon the relative income for patients needing treatment.
52. The challenge for the TRM in this case is to agree upon the proxy for the reasonable value of the sorafenib, where Bayer prices are considered excessive, even in high-income countries. Many high-income countries do not recommend reimbursements for sorafenib, or restrict access, because of its high price. For this reason, the high-income country price is not appropriate. To use the TRM, it would be necessary to substitute the price of a similar product, that is considered equivalent in terms of use or benefits, or to construct a synthetic proxy, such as one based upon one year of income per expected DALY saved.
53. Here it is worth noting that while it is fairly straightforward to measure incomes, there will be the issue of the appropriate income to use in India, when there are inadequate systems of insurance or reimbursements to pool risks. One could start with average incomes, and then consider the issue of the impact of the royalties for the many people that have lower than average incomes, to the extent that the royalty payment presents a barrier to access.
54. More controversial will be the measurement of the DALY benefits. To fully appreciate the complexity of the DALY measurements, one can review some of the documents published by NICE in the UK, evaluating the cost effectiveness of sorafenib. (See, for example: <http://www.nice.org.uk/guidance/index.jsp?action=article&o=41473>). Given the challenges in measuring its benefits, the TRM may not be the best choice for this drug. I will illustrate how the TRM might be applied in the case of the sorafenib, using stylized facts, to provide some perspective on the alternative methods. Suppose that each year of taking sorafenib was expected to have a benefit of .25 DALY, and the value of the DALY was the average income in India. The royalty amount for one year,

based upon 2010 incomes, would be equal to $\$1330 \times .25 \times .04 = \13.30 per year, or \$1.11 per package of 120 tablets.

55. For purposes of illustration, I will also make calculations for the TRM royalty on sorafenib in India, using the actual prices that Bayer charges in the United States for the Federal Supply Schedule, and in Sweden and Spain. In the United States, Bayer charges \$3,269 for 120 200 mg tablets, for products reimbursed via the federal supply schedule. In Sweden, Bayer charges 35286 SEK for 112 200 mg tablets. In Spain, Bayer charges 3603.63 EUR for 112 200 mg tablets. The calculations for TRM method royalties follow:

Reference Country	Price for one 200 mg tab	Royalty @ .04	GNI per capita in 2010	Ratio of India GNI per capita (\$1330) to reference country GNI per capita	TRM royalty in India, per tablet	TRM royalty in India, per year supply
USA FSS	\$27.24	\$1.09	\$47,390	.0281	\$.03	\$44.65
Spain	\$42.59	\$1.70	\$31,750	.0419	\$.07	\$104.18
Sweden	\$47.32	\$1.89	\$50,110	.0265	\$.05	\$73.35

56. Having presented the TRM calculations based upon the Bayer prices in the US, Spain and Sweden, I do not recommend them for this case, on the grounds that the Bayer prices for sorafenib are widely considered excessive, and indeed are so high that many governments and insurance agencies refuse to provide reimbursements because the drug is not cost effective at the Bayer prices. For this reason, the TRM would more appropriately be constructed using a proxy for the Bayer prices, including, possibly along the lines presented above.
57. While not necessarily relevant in this case, when the patented invention is only part of a product, such as the case for patents on one product in a multi-product fixed dose combination, or a new delivery mechanism for an older drug, courts and governments can apply the royalty to a fraction of the generic product sales,

to capture the fact that that the product is more than the patented invention(s). This adjustment, which may not be necessary in the case of sorafenib, would be to calculate a utilization factor, which is simply an estimate the fraction of the value of the product that is due to the patented invention.

Concluding Remarks

58. The central issue in this dispute concerns the evaluation of the price that Bayer has set in India for a drug to treat cancer. If the government determines that a price of Rs 280,430 per month for a cancer drug is reasonably affordable, then then law does not provide meaningful protection to people living in India, and it does not meet the standard adopted by the World Trade Organization in 2001 to implement intellectual property laws in a manner to promote access to medicine for all.

In witness whereof I have executed this affidavit on this 13 day of February 2012.



VERIFICAITON

I say that this affidavit has been drawn up under my instructions. All the statements made above are true and correct to the best of my knowledge and information and they are based on research and analysis performed by me. No part of this affidavit is false and nothing material has been concealed therefrom.

Verified at _____ on this _____ day of _____, 2012